



Risk Analysis:

Risk of Exporting Foot-and-Mouth Disease (FMD) in FMD-Susceptible Species from Argentina, South of the 42° Parallel (Patagonia South), to the United States

Evaluation of the FMD Status of Argentina, South of the 42° Parallel

Veterinary Services

National Center for Import and Export

Regionalization Evaluation Services

(June 2005)

TABLE OF CONTENTS

TABLE OF CONTENTS	2
LIST OF TABLES	3
LIST OF FIGURES	3
LIST OF ABBREVIATIONS	4
Executive Summary	6
Background	7
Objectives	8
Hazard identification	8
Risk analysis	8
Release assessment	8
Eleven factor analysis	9
1. The authority, organization, and infrastructure of the veterinary services organization in the region	9
2. Disease status-i.e., is the restricted disease agent known to exist in the region? ..	23
3. The status of adjacent regions with respect to the agent	25
4. The extent of an active disease control program, if any, if the agent is known to exist in the region	27
5. The vaccination status of the region	28
6. The degree to which the region is separated from adjacent regions of higher risk through physical or other barriers	28
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	31
8. Livestock demographics and marketing practices in the region	44
9. The type and extent of disease surveillance in the region	47
10. Diagnostic laboratory capacity	62
11. Policies and infrastructure for animal disease control in the region	67
Release Assessment – Summary of risk factors and mitigations considered	70
Likelihood of FMD introduction into the Argentina Patagonia South region	70
Likelihood of detection of FMD if reintroduced into the Argentina Patagonia South region	70
Release Assessment – Conclusion	71
Exposure Assessment	71
Consequence Assessment	72
Risk Estimation	75
References	77
Appendix 1: Epidemiologic characteristics of foot-and-mouth disease (FMD)	81

LIST OF TABLES

Table 1. Animal Health Personnel in the Patagonia South Region	16
Table 2. Human Resources at Strategic Control Posts in the Three Patagonia Sanitary Regions	32
Table 3. Airports with Sanitary Inspection in Patagonia South and North A and B.	38
Table 4. Total number of livestock producers and establishments and number of bovine and sheep livestock and establishments in Patagonia South in 2003.	44
Table 5. Number of pig and goat livestock and establishments in Patagonia South in 2003.	44
Table 6. Livestock figures used to construct sampling lists.	52
Table 7. Livestock figures used to construct sampling lists by province in Patagonia South.	53
Table 8. Sampled establishments, collected samples and results of the population sampling of Patagonia in 2001.....	54
Table 9. Sampled establishments, collected samples and results of the targeted sampling of Patagonia in 2001.....	55
Table 10. Number of samples required by the two-stage sampling design in 2002.	58
Table 11. Number of samples actually analyzed in each zone in 2002.	58
Table 12. Number of establishments with at least one positive animal of any species in Zone C	58
Table 13. Results of viral activity in sheep/goats for each sub-zone in Zone C.....	59
Table 14. Number of deer establishments and deer sampled in 2002.	59
Table 15. Sampling 2003. Number of premises sampled and collected and processed samples to determine viral activity by region.	61
Table 16. Number of ovine premises sampled and processed samples to determine viral activity in the Patagonia South and North B regions per province and their results.	62
Table 17. Number of diagnostic tests for FMD and VS serology 2003.	66
Table 18. Economic impacts of FMD adjusted from 1976 dollars to March 2001 dollars by Consumer Price Index.....	74

LIST OF FIGURES

Figure 1. Map of Argentina and List of Associated Provincial Acronyms	5
Figure 2: Map of the epidemiological zones of Patagonia	7
Figure 3. Map of SENASA Regional and Local Units.....	12
Figure 4. Functional Organization Chart of SENASA	15
Figure 5. Epidemiological zoning of Argentina for the purpose of serological sampling.....	50
Figure 6. Areas with and without vaccination	51
Figure 7. 2002 zoning map for serological sampling	56
Figure 8. 2002 further sub-zoning of Zone C in Map 2 above	57
Figure 9. Functional Organization Chart of SENASA Laboratory.....	64

LIST OF ABBREVIATIONS

APHIS:	Animal and Plant Health Inspection Service
BL2:	Biosafety level 2
BL3:	Biosafety level 3
CCFyC:	Quarantine, Borders and Certifications Unit
CFR:	United States Code of Federal Regulations
DILACOT:	Laboratories and Technical Control Office
DNFA:	National Agrifood Inspection Office
DNSA:	National Animal Health Office
DTA:	Animal Transport Document
EITB:	Enzyme-linked Immunoelctrotransfer 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
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 has officially requested the United States Department of Agriculture (USDA)/Animal Health and Plant Inspection Service (APHIS) to conduct an evaluation to recognize the Patagonia region of Argentina south of the 42° Parallel (Patagonia South) as free from foot-and-mouth disease (FMD). The last outbreak in Patagonia South occurred in October 1976. No new outbreaks have been reported since then. Due to the historic lack of FMD occurrence in Patagonia South, APHIS has decided to conduct a qualitative risk assessment to determine the FMD status of Argentina south of the 42° Parallel.

Argentina's Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA) has submitted information to support the request for recognition of FMD freedom. APHIS has evaluated the submission and has conducted a site visit to Argentina in December 2003 in order to substantiate the information reported in the documentation and add 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. The final analysis was based upon information obtained from the site visit, the information submitted in writing from Argentina and from published reports.

This document describes the animal health system in Patagonia South and the adjacent surveillance and buffer zones of Patagonia North B and North A, respectively. It identifies potential areas of risk, and discusses how this risk is mitigated. The following factors were considered of relevant importance in determining the FMD status of Patagonia South:

No new FMD outbreaks have occurred in Patagonia South since October 1976.

Surveillance programs in sheep and goat herds have not detected the presence of the FMD virus in the region under consideration. Neither was there evidence of viral activity in the cattle, sheep or goats in the surveillance zone, Patagonia North B, during or since the outbreaks in the rest of the country in 2001 and 2002.

No vaccination is carried out in Patagonia South, so any cattle or swine in that region exposed to the FMD virus would act as good sentinels of an outbreak.

APHIS considers the legal framework, animal health infrastructure, movement and border controls, diagnostic capabilities, surveillance programs and emergency response systems to be adequate to detect and control FMD outbreaks within the national boundaries of the region of consideration in Argentina, Patagonia South.

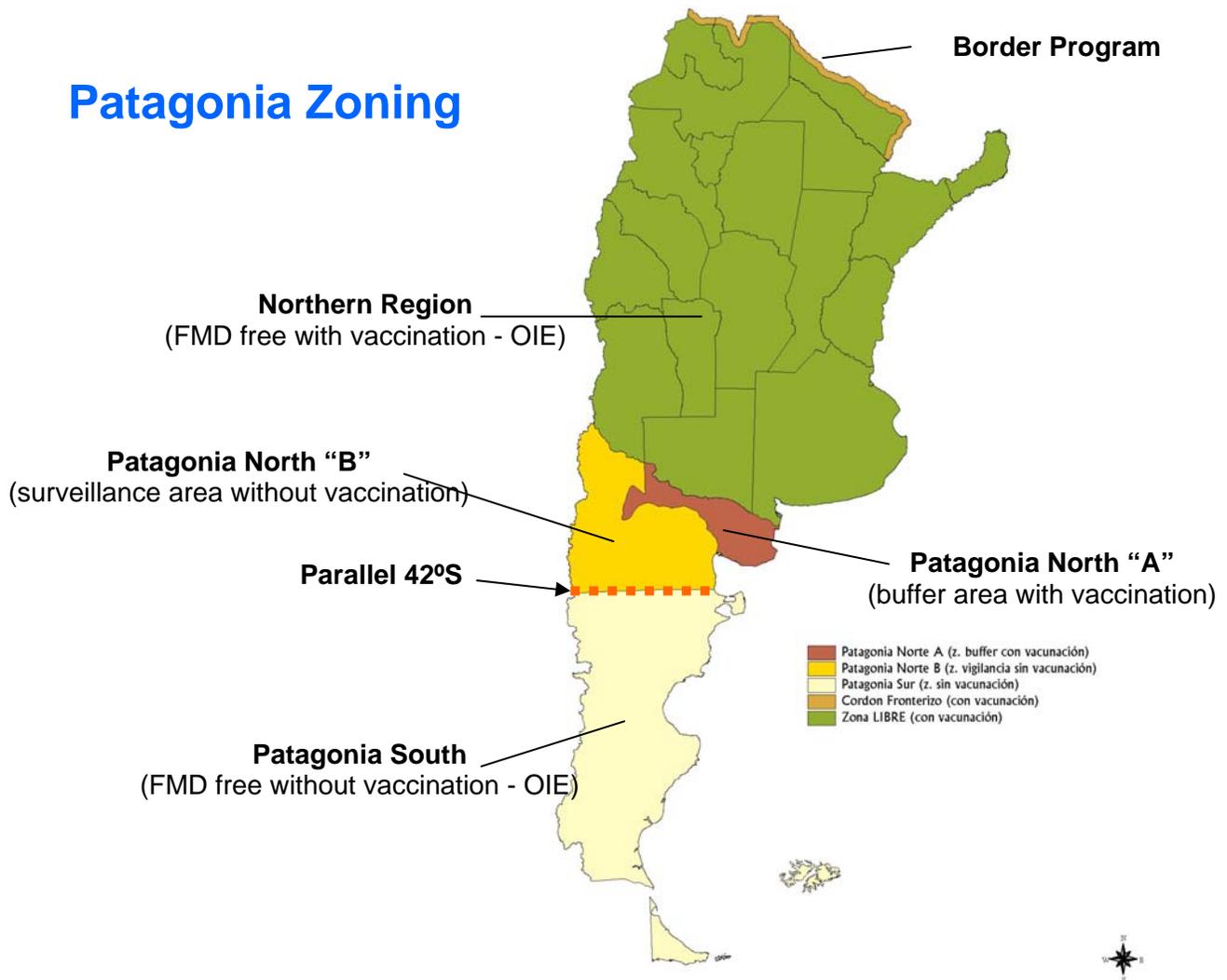
Although consequences of an FMD outbreak are severe, the likelihood of an outbreak occurring via exposure of the domestic livestock population to ovine meat or products imported from the Patagonia South region of Argentina is low.

Background

Argentina has officially requested that USDA/APHIS conduct an evaluation to recognize the Patagonia region of Argentina south of the 42° Parallel (Patagonia South) as free from foot-and-mouth disease. The last outbreak in Patagonia South occurred in October 1976. No new outbreaks have been reported since then. This is the first evaluation of the Patagonia South region in Argentina by the United States for FMD freedom.

Documentation was submitted by animal health officials of SENASA to support their request for FMD freedom. A site visit was also conducted 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 related to the animal health program in Argentina.

Figure 2: Map of the epidemiological zones of Patagonia



Objectives

This is an analysis of the risk of introducing FMD into the United States in FMD-susceptible species and related unprocessed products from Argentina, south of the 42° Parallel. The risk analysis is intended as a decision-making tool for APHIS Managers that will allow development of appropriate regulatory conditions with mitigations to address potential risks of disease introduction following any initiation of trade. It also constitutes an information source for APHIS stakeholders, providing justification for the conditions in the rule. The assessment focuses on the FMD status and control measures applicable to the Patagonia region of Argentina, south of the 42° Parallel.

Supporting data

The analysis is based on documentation provided by the Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA) [1-8], observations made by a joint Canadian Food Inspection Agency/APHIS site visit team [9-11], and published information [12-53]. SENASA, the full title of 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

The Animal and Plant Health Inspection Service (APHIS) has identified several World Organization for Animal Health (OIE) listed diseases [13] 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). One of these diseases that are recognized in APHIS regulations as such a hazard is foot-and-mouth disease. [54] In this regard, before opening trade in FMD-susceptible species and related products with a region or country that APHIS has not previously evaluated for FMD status, APHIS is obligated to conduct an import risk assessment to support rulemaking (9 CFR 92.2). [55]

The hazard identified is the foot-and-mouth disease 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 international recommended components for animal health import risk analysis.

Release assessment

For the purpose of this report, release assessment refers to the evaluation of the likelihood that FMD exists in the Patagonia region of Argentina south of the 42° Parallel and, if so, how likely would the disease be introduced into the United States through imports of FMD-susceptible

animals or their products from Argentina. The report includes an in-depth evaluation of the 11 factors [55] identified by APHIS in *Title 9, Code of Federal Regulations, Part 92.2 (9CFR 92.2)* as information to consider in assessing risk levels of free regions. Those factors are the following:

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,
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

Livestock systems in Patagonia South are mainly extensive (animals are grass-fed and range over vast areas of land with a minimum of labor or expense). The climate and the environment of Patagonia South are major factors which make the sheep industry the most prevailing livestock activity. This area contains almost 60% of the entire sheep population of Argentina. There were over 7 million sheep in 2003, and more than 72% of Argentina's best wool was produced in this region. Livestock density is less than one animal per hectare. Total sheep exports from the Patagonia South region surpassed 90% of the total of sheep exports from all of Argentina. Currently, Argentina is exporting 10,000 tons/year of sheep meat to the European Union (EU). Sheep production is highest in the province of Chubut, followed by Santa Cruz and then Tierra del Fuego. [1, 2]

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 which 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 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 wastes 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 to the EU or from farms approved to export to the EU or markets with equivalent requirements. [1-3]

SENASA is divided into several sections, four of which focus on animal health issues: (1) the National Animal Health Office (DNSA), (2) the National Agrifood Inspection Office (DNFA), (3) the Quarantine, Borders and Certification Unit (CCFyC), and (4) the Laboratories and Technical Control Office (DILACOT). These reflect organizational changes made in 2001 and 2002 [1, 2, 11] to address issues and problems identified during the FMD outbreak in 2001.

Prior to this 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 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.

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

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

Structure:

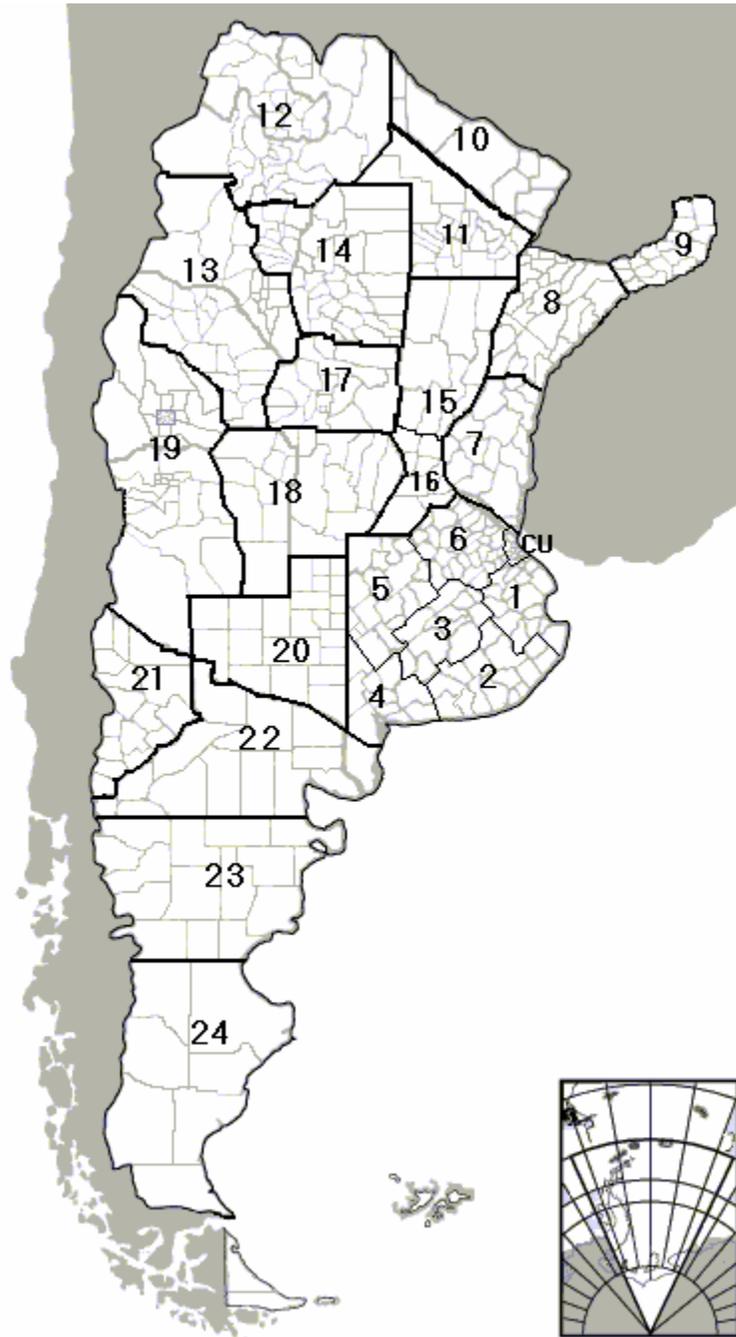
The reorganization was defined by Decree 394/2001. [2] In the new structure of SENASA, not only are the units no longer based on political borders, but also the chain of command has been changed to address issues that arose during the FMD outbreaks. The reorganization was intended to increase the efficiency 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, SENASA failed to report the FMD outbreak of 2000 for several months after it had been detected. [14]

Issues addressed also included centralization of command and control of the animal health programs. Apparently, 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, they had trouble focusing on animal health. Regarding the transparency issue, many of the reorganization elements addressed issues of internal monitoring, accountability, and compliance with national policies. The reorganization also addressed international standards, certification requirements, and an increased emphasis on border controls. [11]

In the reorganization, boundaries of regional units were redefined in order to assign personnel to them appropriate to the level of 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] Regions 21 and 22 on the map below make up Patagonia North A and B. Regions 23 and 24 make up Patagonia South. This is an evaluation of the FMD status of Patagonia South.

Figure 3. Map of SENASA Regional and Local Units



In addition, the reorganization involved the creation of several new units, including ones with a primary focus on compliance and one focused on auditing. In June 2003, the compliance unit contained 20 people. It was designed to operate outside of SENASA rules, giving it an element of independence.

In Animal Health, there are four main offices that report directly to the President of SENASA. These offices are as follows: [1]

- National Animal Health Office (DNSA)
- National Agrifood Inspection Office (DNFA)
- Quarantine, Borders and Certifications Unit (CCFyC)
- Laboratories and Technical Control Office (DILACOT)

The DNSA organization and structure is defined in SENASA Resolution No. 274/2002. [2] The DNSA is specifically responsible for 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 by the 316 local offices located throughout the country and supervised by 25 regional supervisors. The local offices are staffed by 237 veterinary medical personnel, 436 animal technicians, and 181 administrative employees. 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, and surveillance and assessment of the vaccination programs. [1]

The General Field Coordination Unit, which reports to the DNSA, implements its responsibilities through the local offices and regional supervisors mentioned in the previous paragraph. 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.
- 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.
- 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 jurisdiction and epidemiological surveillance actions.
- Supervision of compliance of legal regulations in force
- Organization and operation of local offices.
- Assessment of the field staff performance.
- Official representation of SENASA in their zone.

The DNFA 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 staff is comprised of 345 veterinary inspectors and 905 support staff. [2]

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]

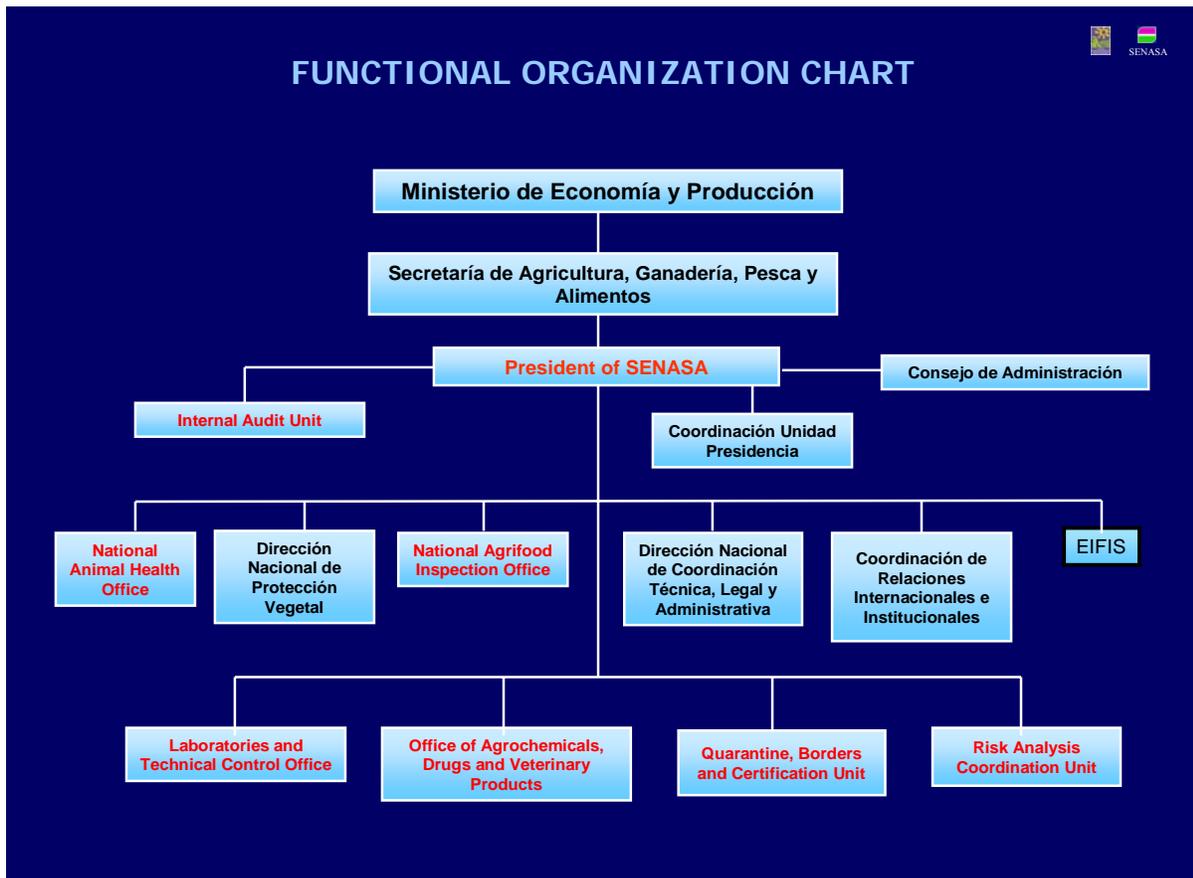
The DILACOT has two units – the Laboratory for Animal Products and Byproducts and the Laboratory for Plant Products and Byproducts. This office operates the National Reference Laboratory for food safety and animal and plant health. In addition, the DILACOT has regional laboratories and manages a network of laboratories accredited by SENASA. 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 of laboratories.
- Intervene in dispute resolution
- Confirm positive test results issued by the laboratories involved 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.
- Participate in reviewing regulations in its field of action and attend international meetings (e.g. Codex Alimentarius, MERCOSUR, OIE).

Additional support for the animal health system comes from a participatory structure based on 349 local animal health offices that were created in 1989 for the FMD Eradication Program, 10 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 NESS in accordance with the responsibilities and functions spelled out in the legal regulations in force. They work at the local, provincial and national levels and comply with established methodologies, procedures and operations. [2]

At the regional level, 23 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]

Figure 4. Functional Organization Chart of SENASA



Financial resources:

SENASA reported that its 2003 budget was 117 million pesos [11] (approximately \$39 million US 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.

Human resources:

In June 2003, SENASA reported a total of 3479 employees, including personnel who deal with plant issues. Of these 2558 are permanent staff members, of which 572 are veterinarians. Rules are in place for employees to address conflict of interest issues. For example, plant and field inspectors are not allowed to own or sell beef.

SENASA can expand its staff, when necessary, by hiring contract personnel, including veterinarians and animal health technicians. These are individuals who are employed on the basis of a standardized profile defined by SENASA for 4-month increments of time, and contracts are renewable. Permanent and contract veterinarians have the same authority.

In 2003, SENASA reported a complement of 921 contractors, of which 219 were contract veterinarians. This staff was expanded significantly during the time of the FMD outbreaks. Four thousand additional people were employed by SENASA during this period. [11]

SENASA can also broaden the scope of its activities through agreements with outside parties. For example, it has entered 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 all along the border by land or water. Border police also assist SENASA with enforcement of quarantines. They played a significant role in security during the FMD outbreak. Security forces that work at slaughter facilities also assist in the disease control program. [11] SENASA can call upon many border police and other security forces to help prevent entry of disease into Argentina.

The number of animal health officials and affiliates in the South Patagonia region is listed below:

Table 1. Animal Health Personnel in the Patagonia South Region

	Chubut	Santa Cruz	Tierra del Fuego	TOTAL
SENASA local offices	6	3	2	11
Commissions	26	4	-	30
SENASA veterinarians	7	3	2	12
SENASA technicians	12	6	2	20
SENASA administrative personnel	3	2	2	7
Provincial veterinarians	6	11	2	19
Private veterinarians	145	31	26	202

The DNFA in the Patagonia South region is comprised of 20 veterinary inspectors and 32 support staff. [2]

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 the license. National and provincial licensure is mandatory. [2]

The National Private Veterinary Physician Registry, created by SENASA Resolution No. 470/95, registers private veterinarians who take part in the NESS, notifying the local DNSA commission of any diseases that have similar clinical signs to FMD. SENASA Resolutions Nos. 234/96 and 422/03 incorporate Veterinary Physician Professional Associations and Councils into the NESS by use of the private registered veterinarians in their corresponding jurisdictions to monitor and

report suspect diseases. 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 eradication program, including verification that the veterinary license is up-to-date and in compliance with the scheduled training goals. This resolution is in the implementation stage.

Private veterinarians also perform pre-inspection examinations on bovines intended for export to the European Union. 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 SENASA veterinarians must comply with training requirements that are in-line with the main strategies in the FMD Eradication Plan. The goal of the Plan is to return to the health status of FMD-free with vaccination in the region north of the 42° Parallel and to promote measures to strengthen the national and continental structure of FMD epidemiological surveillance. 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 agents 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 the supervision of each one of the activities of the 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/WHO/FAO. 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 health 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.). A list of training activities for SENASA staff from 2001 – 2003 is listed in the November 2004 submission. [2]

Training for staff in the DNFA includes the following subjects: legislation in force (Decree No. 4238/68 and others), approval of establishments producing products intended for domestic consumption and export, HACCP, GMP, SSOP (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 are part of the organizations that are involved in the campaign against FMD and 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 No. 445/95 – Regional Patagonia Plan). [2]

Field offices and premises identification

SENASA has 25 regional offices representing 24 numbered regions and a twenty-fifth region (City of Buenos Aires) that is not numbered. Regional supervisors provide oversight for field offices. Field offices deal with local prevention and control measures, eradication, compliance, emergency actions, health actions (e.g., vaccination) and premises identification and movement controls and record-keeping. Many of these responsibilities are controlled through the registration of and assignment of a unique premises identification number (called a RENSPA number), which, in addition to other information on premises, is maintained in a national database. The team that visited Argentina in December 2003 visited regional and/or field offices in Viedma, Carmen de Patagones, and Choele Choel in Patagonia North A and in Río Grande and Río Gallegos in Patagonia South.

SENASA requires that all premises with agricultural animal production register with SENASA and obtain a RENSPA (Registro Nacional Sanitario de Productores Agropecuarios - National Sanitary Registry of Ag-producers) number. This is an alphanumeric identifier that encodes information about individual premises. The structure of the RENSPA number is such that it identifies the province, the municipality, the premises, and various aspects characterizing a particular premises, such as ownership, rental status, or shared occupancy. For example, if an individual owns more than one premises or if there are multiple producers using a single premises, the number code identifies this. Also, the number can also be coded to indicate whether a premises is rented, as well as the number of people participating in the ownership or rental. [1, 11]

XX	XXX	X	XXXXX	XX
Province	District	Internal Control #	Unique Farm # (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 does not report and there is a disease outbreak, 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.

In association with the RENSPA number, census information on all species on the premises, permit information showing animal movements, as well as other data are included in the database maintained by field officials. 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.

Compliance with the requirement to register premises is controlled by at least three mechanisms, and SENASA considers compliance with this requirement to be good for these reasons. [10, 11]

First, all premises with bovines must vaccinate for FMD. The vaccines are administered by personnel authorized, controlled, and audited by SENASA, which are contracted by the FMD foundations. In these areas, the premises must be registered in order for the cattle to be vaccinated. The official vaccinator counts the animals and updates the census. SENASA veterinarians visit premises for other purposes also. The veterinarian is expected to update a census of all animal species on the premises during his visit and report the information to the field office. Since FMD vaccines are administered twice yearly, census information on premises containing cattle can be updated twice yearly. If premises do not have cattle or are located in the non-vaccination zone, census information comes from a private veterinarian or through other official herd health practices.

Administration of FMD vaccines to any susceptible species does not occur in Patagonia South or Patagonia North B. Patagonia produces mainly sheep wool; therefore, epidemiological surveillance is carried out while performing wool industry-related tasks such as shearing, branding, pre-birth exams, and other husbandry activities. Also, other inspections related to FMD health verification such as serological sampling, dispatch of livestock, etc. and ectoparasite control are carried out throughout the year.

In Patagonia South, epidemiological surveillance is carried out jointly with endemic disease control programs against scabies and melofagosis. Resolution No. 445/94 "Patagonia Plan for the Control and Eradication of Scabies and other Endemic Diseases" is in force and lays down an executive structure (commissions, organizations, foundations, etc.) for sanitary projects. Due to its self-management and financing characteristics, the animal health work is adequately and more easily carried out. With these different animal health programs in place, a wide coverage of official inspections in sheep establishments over several years has been carried out with an annual average of more than 2,000 inspected establishments and over 1,500,000 sheep examined in the Province of Chubut alone. [2]

Second, premises must be registered in order to obtain a permit to move animals for commerce. The RENSPA number must appear on the permit. The Animal Transport Document (DTA) is required for all animal movements and must accompany the shipment. [1] Owners must apply for a permit within 30 days of movement for either beef or lamb and pay user fees associated with the movement.

Third, SENASA considers it likely that neighbors of unregistered premises with animal health problems will report the unregistered premises to the authorities.

The local office in Río Grande is one of 2 local offices in Tierra del Fuego. The 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 on 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 in 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 Grande Farmers' Association is a local non-governmental organization (NGO) that works with the provincial health commissions on matters of agricultural importance. It has no legal power, but is an industry group that works with the government on sanitary policy and supports the objectives of the agriculture industry.

The local office in Río Gallegos is one of 3 local offices in Santa Cruz province. The office basically has the same duties as the Río Grande local office plus has some staff that inspects baggage on the Argentina/Chile border at the Monte Aymond border post. Records of all farms showing ownership, number and types of animals, farm name and location, animal movements and RENSPA number are stored on a computer database. This database was demonstrated to the site visit team by one of the SENASA staff members. The software has the ability to search for data by any of the previously mentioned parameters. When shipping farm-to-farm, after animals are moved to the point of destination, the DTA must be turned in to the local SENASA office in the destination department within 15 days. That office notifies the local SENASA office of origin that the shipment has arrived. If the circle is not closed, no more DTAs for that RENSPA number can be issued.

The regional office of Viedma is located in Carmen de Patagones. The region has 11 local offices and 17 delegations (sub-local offices). There are 7 veterinarians working within this office. The local office of Carmen de Patagones is in the same building. This office manages all the data of the farms electronically and issues RENSPA numbers.

The local office in Choele Choel is under the jurisdiction of the Patagones Regional Office. It covers the border area between Patagonia North A and Patagonia North B along the Río Negro River. There are cattle owners on both sides of the river and some vaccination occurs south of the river along a water canal. The most common type of farm is 10-50 hectares and grows crops such as fruit, potatoes, and onions using irrigation.

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 is about \$3 million U.S. dollars, and the money is acquired through the collection of fees (50% from spraying fees and 50% 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 health regulations and FUNBAPA enforces them. The Chair of FUNBAPA is the President of SENASA. The advisory board consists of 11 members: 3 cattle/sheep farmers, 3 vegetable/fruit producers, 1 SENASA official, and 4 from the provincial governments. Technical and administrative audits are done for each of the programs by the SENASA national office or the SENASA local supervisors. Budget audits occur every year, and technical audits can occur every 6 months, depending on the program. Some past findings have been inadequate roads or lack of equipment, which are now being addressed.

Money and personnel are managed by FUNBAPA, rather than by the government. This allows for more efficient decision-making concerning budgetary matters and for better personnel management and movement (e.g. people that work well are promoted, while those that don't can be released more easily than if employed by the government). Potential employees for FUNBAPA must fill out an application and be interviewed. If they are hired, they will be trained in various technical duties including recognition of FMD clinical signs, self-defense techniques, use of fire extinguishers and application of first aid. The probationary period is 6 months. Employees receive training once a year in a refresher course that covers any new rules or regulations.

FUNBAPA is involved in a number of programs, most of which deal with fruits and vegetables. One such program is the Programa Barrera Zoofitosanitaria Patagonica (Patagonian Zoophytosanitary Barrier Program). Since 1993, FUNBAPA has been in charge of the Río Colorado (14 posts) and Río Negro (4 posts) barrier areas. In 2001, it took over 4 posts from SENASA and the provincial government in the Río Negro province on the border that separates the areas of vaccination from the areas with no vaccination. Then, in 2003, it took over the 3 posts along the 42° Parallel. Seven airports are also covered by FUNBAPA. There are a total of 177 FUNBAPA employees, and the organization feels it is adequately staffed. [10]

Movement controls within Argentina

A movement permit (DTA) is required when animals go to slaughter, go to market in Patagonia, cross provincial lines or are exported internationally and generally if an animal is moved from one farm to another. These permits are required in order to establish that the farm of origin is registered so that tracing can be conducted quickly. They record the identification numbers of both the premises of origin and the premises of destination. If a registered farm attempts to ship more animals than the census would predict and the discrepancy is noted when the permit application is being processed, then the shipment does not get a movement permit. The number and species of animal is recorded on the permit and then are subtracted from the RENSPA stock recorded for a particular farm.

Movements to slaughter within each sanitary region (intraregion) are carried out under the conditions established by SENASA Resolution No. 178/01. This resolution requires that these animals be accompanied by a DTA and the pertinent livestock Guia, have visible identification marks, and be transported in a vehicle approved by SENASA with a certificate accrediting washing and disinfection of the transport 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]

Movement of FMD-susceptible animals is limited in Patagonia South. The local SENASA office issues a DTA to keep track of all animal movements off a farm. Another movement permit, a provincial transit certificate (Guia), is issued by the Provincial Authority to validate ownership and identification of the animals. A SENASA official must inspect these animals on the farm of origin before movement and must verify official documents. When animals are shipped from farm-to-farm, the DTA must be returned within 15 days to the local office of destination and that office will contact the local office of origin of the shipment arrival. If animals are going to slaughter for domestic consumption, the veterinary inspection is limited to the ante-mortem 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 ante-mortem inspection at the slaughter facility. [10]

All vehicles carrying commercial shipments must also be registered with and approved by SENASA and issued a number. Former SENASA Resolution No. 809/81 establishes the mandatory washing and disinfection of all livestock vehicles, empty or with animals, 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 or B). There are automatic sprayers at all commercial entry points and handheld sprayers at others. Apparently, there is no charge for the DTA either. 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 really 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 program where the farmers must pay for the FMD vaccine and the Brucellosis vaccine. [10]

Swill feeding

SENASA Resolution No. 225/95 regulates housing and maintenance of pigs. This Resolution bans feeding pigs with raw viscera of any origin, kitchen garbage, hospital, clinic, or nursing

home garbage and garbage from national or international ports and airports. It does authorize 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.
- 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 trichinellosis or that constitute a risk because of inadequate sanitary-hygienic 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 infestations. 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 infrastructure to adequately monitor and control any incursion of FMD into the country. 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 9 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 reports. However, the observations made by APHIS during its 2004 visit to Patagonia and a 2005 site visit to the region north of the 42° Parallel revealed that many changes had been made in the veterinary infrastructure since that time. APHIS expressed confidence, based on its questions to and interactions with SENASA personnel, that reporting would not be delayed if an analogous event were to occur today.

2. Disease status-i.e., is the restricted disease agent known to exist in the region?

The Patagonia South region of Argentina has not recorded an outbreak of FMD since October 1976. This outbreak occurred in Chubut Province. The disease had originated from one lot of animals that had come from north of the 42° Parallel; the virus was type A. When the suspicion of FMD became known, SENASA implemented legal quarantine procedures, closure of streets and neighboring roads, installation of control and disinfection posts, epidemiological tracing and staff reinforcement. Animal movement restrictions and ring vaccination were carried out to stop

the spread of the disease. The species vaccinated included 4789 bovine, 8881 sheep, and 391 pigs. This was the only case when a stamping-out policy was not applied. [1, 2]

The last recorded outbreak in Santa Cruz Province occurred in Río Gallegos in 1971 (type O1). Pigs were exposed to the FMD virus by consuming infected beef with bone from the Province of Buenos Aires. Bovine, sheep and pigs were affected. A suspicious disease outbreak was reported to the authorities in Río Gallegos in some bovine animals on a small dairy farm near the city. The farm had 15 cattle and some pigs. The Local Commission began emergency response procedures which resulted in restricted movement of susceptible animals in the farm area, epidemiological tracing, installation of vehicle disinfection units, staff reinforcements and the on-site presence of the Chief of the FMD program. As a result of the epidemiological tracing, affected pigs in the farms located near the primary outbreak were detected. More preventative measures were taken including banning movement of susceptible animals, skins and products and by-products of animal origin and depopulation of farms in the area with susceptible species by stamping out. The carcasses were later buried in a pit that was built on the premises of the primary outbreak. In total, 2300 sheep, 48 cattle, 618 pigs, and 5 goats were slaughtered. [2, 10]

The last recorded outbreak in Tierra del Fuego occurred in December 1966 (type C). It was controlled using stamping out procedures and burial of the carcasses in early 1967. From the clinical and laboratory test results and epidemiological research, it was concluded that there was only one outbreak in cattle in only one establishment near Río Grande. Later studies showed that this virus was a new subtype C4 and was serologically related to isolated samples in Uruguay. The Police, the Navy and the YPF (Fiscal Oilfields) were all instrumental in preventing the spread of the outbreak. At first, 611 animals were slaughtered and then all pigs in a radius of 15 km of the outbreak were slaughtered. Animals were shot and buried. There were no secondary outbreaks. [1, 2]

During 2002, SENASA received 3 reports of suspect FMD cases in the Patagonia North A and B regions. FMD was ruled out in all cases. No such cases were reported in Patagonia South. [6]

The first case occurred in the Department of Pichi Mahuida, Province of Río Negro (Patagonia North A). Adult bovines had shown traumatic lesions in the tongue. No lesions were found in calves. The lesions were diagnosed as injuries caused by feeding on Pampas and salted grasses. This case was registered as a “notification.”

The second case took place in the Department of Bariloche, also in Río Negro (Patagonia North B). Two dead sheep were found at an establishment but with no clinical signs in the rest of the herd. A diagnosis of Maedi Visna/ Adenomatosis was made after necropsy. The animals came from other establishments with a history of the disease. This case was also registered as a “notification.”

The third case occurred in the Department of Patagones, Province of Buenos Aires (Patagonia North A). In this case, it was necessary to collect samples to confirm or rule out a vesicular disease since a diagnosis could not be determined by clinical signs alone. This case was registered as a “suspicion of vesicular disease.” The original report was filed by a private veterinarian that found oral lesions compatible with FMD in 14 bovines, from a total of 217,

during an inspection of a herd before transporting to a livestock auction. The animals did not show any other systemic signs. From that moment, the premises was placed under legal quarantine. The official veterinarian in charge collected epithelium and serum samples from the lot of affected cattle. Serology tests were done using ELISA 3ABC and EITB. All samples were negative. The epithelium samples were used to run virus isolation tests in BHK cell culture and suckling mice. These samples were also used for ELISA typing and PCR. All tests were negative. The diagnosis of FMD was ruled out with the results of the laboratory tests and follow-up of the diseases in the field. Infectious bovine rhinotracheitis (IBR) was diagnosed later by serology.

No reports of suspect vesicular diseases were made in 2003 or 2004 in the Patagonia regions.

Sheep are the predominant livestock in Patagonia South. Almost 60% of the sheep in Argentina reside in Patagonia. The livestock density is less than 1 animal per hectare. Due to the extensive husbandry practices and low animal density, contact between sheep and other species is negligible and between other sheep is low. Although every animal is not closely monitored due to husbandry practices, the low animal density, low number of animal movements off the farm, and the restrictive import policies into Patagonia reduce the risk of introduction of the FMD virus into the area and rapid spread of the disease before detection. In all cases of FMD outbreaks in Patagonia South the international community and trading partners of Argentina were immediately notified of the outbreaks after detection. [1, 2]

No vaccination is carried out in Patagonia South, 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 disease, the existence of suspect cases of this disease, or the 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 will be no indemnification for destroyed animals if the disease is not reported and the one who fails to report the disease as stated above will be fined.

Conclusions

The last FMD outbreak in the Patagonia South region of Argentina occurred in 1976. There is no evidence that there are any species infected with the FMD virus in Patagonia South.

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

Argentina is bordered by Paraguay in the north, Bolivia in the northwest, Uruguay and Brazil in the northeast and Chile in the west. Only Chile is considered by APHIS, Veterinary Services, to be FMD-free. [56]

Argentina recognizes FMD status for surrounding countries as classified by OIE. Chile is recognized as FMD-free without vaccination. Uruguay and Paraguay are considered FMD-free countries with vaccination. The states of Río Grande do Sul and Santa Catarina in Brazil,

bordering Argentina, are recognized as FMD-free regions with vaccination. Bolivia is not considered FMD-free. [2, 4]

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 2001, a program of joint actions and adaptation of strategies among the countries of the region was established within the action plan of the Hemispheric Program for the FMD Eradication (PHEFA). This program comprises of border work sub-projects, 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 Hemispheric Plan for FMD Control and Eradication 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 sanitary 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 agents 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. Recently, SENASA signed a letter of intent with SENASCSA (Paraguay 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.

Patagonia North B is a surveillance area which Argentina recognizes as free of FMD where vaccination is not practiced. The last FMD outbreak in this region occurred in 1994. There were

six outbreaks in the region. A stamping out policy was applied with a total of 565 cattle, 8286 sheep, 296 pigs, one goat and one camelid slaughtered (ill and contacts). [1, 2]

Patagonia North A is a buffer zone separated from Patagonia North B by the Negro River and from the rest of Argentina by the Colorado River. Vaccination is practiced in Patagonia North A. The last FMD outbreaks occurred in 2001 with seven outbreaks reported. 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, 2001 and July 23, 2001. The exposed population included 3268 cattle, 2690 sheep and 35 pigs. One hundred ninety-nine young cattle, less than 2 years old, were the only clinically ill animals. Initial attack rates varied from 0.3 to 12%. The average interdiction time of the establishments was 67 days.

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, 2001 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.

Conclusions

There is no evidence that FMD has been transported from surrounding countries or regions of Argentina north of the 42° Parallel into Patagonia South. All sides of Patagonia South are bordered by the ocean or areas free of FMD without vaccination according to OIE standards.

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

There is no active disease control program since no FMD outbreaks have occurred since 1976 in Patagonia South. [1] Some surveillance programs do exist, but passive surveillance and strong border and animal movement controls are the major defenses against an incursion of the disease into this area.

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

Conclusions

Argentina has a structured system of notification and official involvement to investigate any suspect FMD cases. An active surveillance program does exist, mainly in the buffer zones, to monitor viral activity in various FMD-susceptible species.

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 Patagonia North B. Administration of serum against FMD infection is not permitted in these regions. [1]

During the 1976 FMD outbreak in Chubut, cattle, sheep and pigs were vaccinated in the surrounding areas around the zone where the outbreak occurred. An initial dose was applied, and then the animals were revaccinated. Vaccination was discontinued after that since the emergency action plans had been set in place. [2]

Conclusions

No vaccination program is underway in Patagonia South or North B. In the absence of vaccination, it is likely that clinical signs 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 geographic description of the Argentine borders follows below: [4]

1. Chile (West and South)
2. Bolivia (North)
3. Paraguay (Northeast)
4. Brazil (Northeast and East)
5. Uruguay (East)

CHILE

Total length of the border: 4,591 km

Inland border: 4,591 km

- The Andean Range makes up a natural border.

BOLIVIA

Total length of the border: 765 km

River coastline border: 385 km

- Along the Pilcomayo River: 40 km (Province of Salta)
- Along the Grande de Tarija River: 120 km (Province of Salta)
- Along the Bermejo River: 125 km (Province of Salta)
- Along smaller rivers: 100 km (Provinces of Salta and Jujuy).

Inland border: 380 km

- The altitude along the border with Bolivia decreases from West to East (Average of 3000 m in the West and 400 m in the East). The climate and topography also change from more mountainous in the West to flatter lowlands towards the East.

PARAGUAY

Total length of border: 1,570 km

River coastline border: 1,570 km

- Along the Paraná River: 630 km (Provinces of Corrientes and Misiones)
- Along the Paraguay River: 290 km (Provinces of Formosa and Chaco)
- Along the Pilcomayo River: 300 km (Province of Formosa)

Inland border, deviated course of the Pilcomayo River: 350 km (La Estrella Lowlands, also known as the Pantalón System)

- The inland border lies to the West. The flat topography of the Province of Formosa continues into Paraguay with no natural barriers.
- The Pilcomayo River enters Argentina again to the East, in the town of Palmar, Salto.

BRAZIL

Total length of the border: 1,079 km

River coastline border: 1,021 km

- Along the Uruguay River: 695 km (Provinces of Misiones and Corrientes)
- Along the Pepirí-Guazú River: 134 km (Province of Misiones)
- Along the San Antonio River: 94 km (Province of Misiones)
- Along the Iguazú River: 129 km (Province of Misiones)

Inland border: 27 km (Bernardo de Irigoyen area)

- To the North, the border with Brazil runs along the Iguazú River and continues to the South along the Uruguay River.

URUGUAY

Total length of the border: 866 km

River coastline border: 866 km

- Along the Uruguay River: 491 km (Provinces of Corrientes and Entre Ríos)
- Along the De la Plata River: 375 km (Province of Buenos Aires)
- The border is clearly defined by the Uruguay River to the North and continues along the De la Plata River.

The Patagonia South 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. The geographic description of the South Patagonian borders follows below: [1, 2]

1. Chile (West and South)
2. Atlantic Ocean (South and East)
3. Province of Río Negro, Argentina (North)

The northern border runs along the 42° Parallel from the Atlantic Ocean to the Piltriquitrón Mountains. It then runs north along these mountains to the Serrucho Mountains, then west along the Villegas and Manso Rivers to the border of Chile.

The Cordillera of Los Andes forms a natural border between Patagonia South and Chile. It runs about 1900 km.

The Patagonia North B region is comprised of the Province of Neuquén (except for part of the Confluent department) and the area of the province of Río Negro that is south of the Negro River.

The Patagonia North A region is comprised of the Province of Río Negro north of the Negro River, part of the Confluent department of the Province of Neuquén, and the Patagones Department in the Province of Buenos Aires.

The Patagonia North A and B regions are bordered by constantly flowing rivers that make crossing difficult.

The area that runs along the 42° Parallel is sparsely populated with a population in the two main Departments along the Parallel having just over 3000 inhabitants altogether. National Route N° 258 in the west and National Route N° 3 in the east along the Atlantic Coast are the two main highways that enter Patagonia South at the Parallel. These routes are the principal roads used for extra-regional transit including commercial and tourist traffic. Other routes have lost their commercial importance because of the construction of Route N° 258 or are minor roads with only local traffic and not in good condition.

The climate is 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, other police authorities).

SENASA Resolution No. 9/2001, as amended by SENASA Resolutions Nos. 25/01 and 58/01, implements a sanitary barrier by law at the 42° Parallel in order to preserve the area south of the Parallel as a region free from FMD without vaccination. [2]

Conclusions

Most of the Argentine border is adequately protected by effective natural barriers to reduce the unrestricted flow of animals and animal products from areas of higher risk. In those areas where natural barriers do not exist, government control measures compensate. In fact, Argentina has set up a sanitary barrier by law that applies to the entire 42° Parallel to preserve the FMD-free status of the Patagonia South 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

Border controls are administered by the 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 enter the country legally by means of 45 authorized border stations which include terrestrial, maritime and fluvial ports and airports. International border crossings authorized by SENASA are listed below:

CHILE

- Jama Crossing (Province of Jujuy)
- Cristo Redentor Crossing (Province of Mendoza)
- 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)

BOLIVIA

- Salvador Maza Bridge (Province of Salta)
- Aguas Blancas Bridge (Province of Salta)
- Horacio Guzmán Bridge (La Quiaca, Province of Jujuy)

PARAGUAY

- San Ignacio Loyola Crossing (Fraternidad Portal, San Ignacio Loyola Bridge, and ferry, Clorinda, Province of Formosa)
- San Roque González de la Cruz Bridge (Posadas, Province of Misiones)
- Puerto Rico: this crossing is for cross-border traffic only (Province of Misiones)

BRAZIL

- Tancredo Neves Bridge (Port of Iguazú, Province of Misiones)
- Bernardo de Irigoyen Crossing (Province of Misiones)
- San Javier Bridge (Province of Misiones)
- Integración Bridge (Santo Tomé, Province of Corrientes)
- Port of Alvear (Province of Corrientes)
- Presidente A. Justo Bridge (Paso de los Libres, Province of Corrientes)

URUGUAY

- Salto Grande Bridge (Concordia, Province of Entre Ríos)
- José G. Artigas Bridge (Colón, Province of Entre Ríos)
- Libertador San Martín Bridge (Gualeduaychú, Province of Entre Ríos)
- Port of Buenos Aires (Ferrylineas and Buquebus)
- Jorge Newbery Airport (City of Buenos Aires)

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. (July 2003 submission) 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 number 394, 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 (e.g., 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 Patagonia South and North A and B are listed in Table 2.

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

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	1	1	3	72	17
Patagonia North B Terrestrial points - airports	1	2	3	4	82	--
Patagonia South Terrestrial points - airports	--	3	--	5	42	--
Totals	3	6	4	12	196	17

Commercial imports

SENASA Resolution No. 9/2001, as amended by SENASA Resolutions Nos. 25/01 and 58/01, implements a sanitary barrier by law at the 42° Parallel in order to preserve the area south of the Parallel as a region free from FMD without vaccination. [2]

SENASA does not allow the movement of FMD-susceptible animals to Patagonia South and North B regions from other regions of Argentina (including Patagonia North A), not even for slaughter (Resolution N° 1051/2002). [1, 2, 10] Imports from Patagonia North B to Patagonia South are allowed if import requirements are met. These requirements include:

- Two negative serological tests for FMD from FMD-susceptible species within an interval of 21 days, during which period the animals shall 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.
- FMD-susceptible animals must have remained in the source facilities for at least 90 days prior to dispatch application.
- Movement of animals to destination with official dispatch and previous notice.
- Animals shall 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.
- Animals shall be transported in sealed trucks and shall not move through zones where FMD vaccination is practiced.

Susceptible animals from FMD-free countries or zones where vaccination is not practiced, as recognized by OIE, are permitted to enter Patagonia South after approval. All sanitary requirements must be complied with by the foreign veterinary service, and then the animals are quarantined in Argentina before release.

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 N° 1354/94 defines the pre-importation procedures and controls 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 than Argentina into a FMD-free zone. 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 the Patagonia region include N° 58/01 and 1051/02. Resolution N° 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 SPS Agreement of the World Trade Organization (WTO) and the standards set by the OIE. Permits to import such products are required before the goods arrive in the country. The importer will be 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 N° 816/02. Import permits may be issued after an analysis of: [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
- Expected use of the product

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

1. Pre-importation authorization.
2. Verification of the health certificate issued by the country of origin.
3. Physical inspection, document control and verification of the identity of the imported products.
4. 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.
5. 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 pathology is found. Once the importer has this document, the imported goods may be collected.

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 carried out in all cases, without exemptions, if they are products under SENASA jurisdiction. Documents are checked, and products or animals are physically inspected and identified. All imports have to meet the requirements established by the responsible technical area as set by the standards of procedures in SENASA Resolution No. 816/02. Two inspection modes are used at borders: [2]

- Direct inspection – questioning, observation manual inspection of luggage and vehicles (e.g., trunks, rooms, cabins, boxes)
- 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 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 Airforce Police) that carry out sanitary supervision tasks at the border will be alerted to be more vigilant.

Shipping of animal-origin products to Patagonia must only be done from official establishments under SENASA control. They must be transported in authorized vehicles that have been sealed at the official point of origin and be accompanied by an official health certificate stating that the products being carried comply with the sanitary requirements for marketing in the Patagonia region. At the inspection posts, shipments 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.

Animals coming into Patagonia North A from the northern regions of Argentina must go straight to slaughter. The slaughter establishments must be approved by SENASA and previously assessed for biosecurity conditions and compliance with SENASA Resolutions Nos. 58/01 and 178/01. There are five slaughter facilities in this region. [2, 10]

Non-commercial traffic

The proportion of travelers, means of transportation and types of luggage inspected varies according to the borders at risk and parameters that make it possible to identify a risk profile 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 controls are carried out mainly at terrestrial posts and sea ports while indirect methods 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 on the borders with trained staff present all day long which interact with security forces, through cooperation agreements, to enforce sanitary regulations. It is not possible to estimate the amount and frequency of unauthorized crossings due to the condition of being illegal transit, but the measures explained above aim at minimizing the risk of introduction of animals or products of risk by informal methods. [2]

Property confiscation and transport infringements

The reports submitted by Argentina show the quantity of products condemned at terrestrial and aerial border posts under SENASA control in all of Argentina (2001, 2002) and in the Patagonia South, North A and North B regions (2001-2003). [1, 2] 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.

The Patagonia region was supplied by the central region, allowing fluid trade and supply channels of all kinds of products of animal origin when the country was considered one sanitary block in 1999/2000. With the new restrictions and prohibitions at the critical points of entry into

Patagonia during and after the 2001 FMD outbreak, there was a large initial economic impact resulting in a large number of confiscations, especially in Patagonia North A and B. With the economic crisis in 2002, confiscations decreased dramatically due to decrease in trade in the buffer and surveillance areas and a decrease in tourist traffic throughout the region.

Most offenders at border checkpoints are passengers that carry small quantities of products of animal origin as a souvenir or for personal or family use, or handcrafts which are forbidden.

Of the livestock transports that had infringements of laws or regulations in 2003, 72% were empty livestock transports that did not have a washing and disinfection certificate or had a certificate, but with hygiene deficiencies noted during visual inspection. These transports were not allowed to enter the Patagonia region until they corrected the sanitary deficiency in an authorized washing station.

Another 13% of livestock transports with infringements had deficiencies related to proper completion and filling out of the transport documents. This resulted in rejection of the shipment or no authorization to pass the checkpoint until the issuing official could be contacted.

Another 8% of these transports were stopped due to a lack of some identification on some of the animals. The transport was rejected and returned to the point of origin as condemned or an investigation was started to clear up the problem.

A lack of seals on the doors or badly placed seals was recorded in 2% of the cases. The contents were checked by border staff, and if no deficiencies were found, the transport was sealed again and authorized entry into the region. If a deficiency was found, the transport was rejected.

The remaining 6% of the infringements was due to expiration of the transport approval (approval is annual). In these cases, the infringement is recorded and then entry into the region is authorized.

Airports [10]

The site team visited several airports which act as control points mainly for tourist traffic. The Jorge Newberry Airport is in Buenos Aires and handles a significant level of traffic to Patagonia. Eighty percent of the flights are domestic and 20% 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 Patagonia South and North A and B. 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 quite thorough. SENASA is assisted in its activities by the aeronautical police. 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 had a separate line to scan baggage. All checked baggage from international flights is examined. About 90% of all luggage is scanned at the airport.

Passengers are provided with information on prohibited substances and required to fill out a customs declaration form if flying in on an international flight. Passengers carrying food products are given information on prohibited material regardless of destination. Any unauthorized cargo is confiscated. A new statement has been developed to accompany packages stating certain products are not being shipped in the packages or with a passenger. The proposed statement will be used for all airplane and bus travelers. One side will have the declaration statement and signature stating that no prohibited plant or animal products are being carried by the passenger and the other side will list the Resolutions involved and prohibited items. If undeclared prohibited items are found on inspection, there will be a review by SENASA 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 Newberry is subject to inspection by the Beagle patrol. A beagle dog is used to sniff for prohibited substances in baggage on the carts outside. One dog is brought over from Ezeiza airport for 10 days a month to inspect cargo. If there is luggage that is suspect, it is identified and 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 witnessed a beagle working who, in the process, detected a suspect package. The SENASA official labeled it so officials at the point of destination would investigate the package. The point of destination is the place to where the package is being shipped. 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 since the scanner was not operational, 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 Parallel 42° 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 the 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.

The Neuquén airport has a zoophytosanitary post operated to enforce Resolution N° 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 which come in from the north daily about 3 hours apart. Occasionally, charter flights fly in from Chile.

Three employees work at the airport for FUNBAPA. SENASA staff is not 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 check-in). A scanner capable of detecting organic material is used. Very few animal products are found; most are fruit. Most of the traffic is people from the area traveling to Buenos Aires, so most people are aware of the sanitary situation and know about 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. In 2002, about 148 kg of products were seized for various reasons (e.g. hidden products, no certificates, non-fumigated fruit, bone-in beef) at the Neuquén and Viedma airports.

There are some small, private airports in the Patagonia North A and B regions, but they aren't common. Long distances restrict travel as there are not a lot of places to refuel. These airports are not well-regulated, but if air control hears of something out of the ordinary, it reports the incident to FUNBAPA.

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. Saucos, 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. In this regard, 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 the 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. Sometimes 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 salary. [11]

Border patrol police on land, 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.

Border with Chile: As previously mentioned, Argentina is separated from most of Chile by the Andes Mountains. In addition, Argentina is working with Chile on joint surveillance and wants to implement a satellite surveillance system of people movement across the border (i.e. monitoring transport of prohibited materials/animals by people crossing the border). The responsibility includes aspects of disease prevention and animal movement. Much of the movement control focus is directed toward FMD. In this regard, since the OIE recognizes Chile as FMD-free without vaccination, SENASA does not consider Chile as a high-risk region.

Patagonia – International border

Patagonia South borders one country, Chile. The terrestrial border stations along this border are: [1]

1. Los Huemules in the Andes Mountains in Chubut Province
2. Cohayque in the Andes Mountains in Chubut Province
3. Intergación Austral (Monte Aymond) in the southern part of Santa Cruz Province

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 a few posts for inspection. When leaving Argentina to go through 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 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, 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 wasn't in operation at the time of the visit. Officials said that it would be in operation in a month from the time of the site visit.

The animal health status of Chile and Patagonia South is equivalent. Both areas are considered FMD and fruit fly free. Breeding stock is traded between these two regions. Commercial meat shipments are also allowed. However, passengers cannot bring meat over the borders. Contraband agricultural and food products confiscated from January to November 2003 amounted to 76 kg, 80% of which was fish products. Certain fresh plant products are also prohibited into the area.

A standard certificate for export/import must be presented by shippers at the border crossing. SENASA must have pre-notification 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, 7 days a week by Border Patrol officials. They check seals and documents, but do not open the seals to inspect cargo. The seals are inspected to ensure that they haven't 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. These products are put in a barrel and sprayed with methylene blue or povidine to render them inedible. They are then burned in large holes and covered with soil once the holes are filled.

Argentina and Chile conducted four exercises to coordinate border crossing activities. The results were very positive. The Foreign Services office organized these events. The countries share inspection responsibilities and leverage their personnel usage. Similar exercises have been conducted in northern Argentina with Uruguay and Brazil.

Patagonia – Internal borders [10]

Border posts from Patagonia North B to Patagonia South are situated along the 42° Parallel. They are the Arroyo Verde, Río Villegas, and El Maitén posts. [1]

The Arroyo Verde post is located on National Route N° 3 which is the main transportation route for commercial, tourist, and resident traffic along the Atlantic Coast. It is an obligatory route to the main cities of provincial political power, population centers, and tourism and commercial activities. These are areas with the highest population density and large commercial and economic interests.

The site review team visited the Arroyo Verde control post which has been in place since 1994. It deals mainly with zoosanitary traffic, but staff will also confiscate any discovered prohibited plant materials. Eight employees live at the post. There are no towns in the area. All vehicles going north to south are checked, except non-agricultural cargo trucks that have already been checked at a previous post and are sealed. The cabin of the truck is still checked in case the driver purchased something en route. All animal cargo trucks are checked, even if sealed. The seals are broken, the cargo checked and the vehicle is re-sealed. The old seal number and the new seal number are recorded on a stamp that is placed on the back of the health documents. Most animal products are bovine, chicken and fish. The seal must be broken by an official of either SENASA or the Food Safety Service. Unloading of cargo is monitored and the vehicle is re-sealed. Each destination must have its own PTR (restricted transit permit), so one truck may have multiple PTRs to drop shipments off at different locations.

For traffic going south to north, passenger cars are not inspected but buses are.

Land control posts between Patagonia North B 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 located in a trailer at present, but a small building is being built. It is only a zoosanitary post. There are six employees, with an additional three as needed, which staff the post 24 hours a day. They stop all traffic going into Patagonia North B and only cargo vehicles going north into Patagonia North A to check paperwork. Around 500 vehicles pass through this point daily. The previous month, November 2003, the post confiscated 5 kg of meat in a box being shipped to Patagonia North B on a passenger bus. Inspectors also 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.

Due to a lot of smuggling of bone-in meat to Neuquén, authorities wanted to protect the animals in the surrounding area with the FMD vaccine. A circular area around the city of Neuquén with 10 control posts was established and included as part of Patagonia North A. Roads in the area

are in the shape of a triangle with the border posts on the roads leaving the Confluent Department. This zoning was done in consultation with OIE. More than 18,000 vehicles cross the bridge daily between the cities of Neuquén and Cipolletti.

The area between the control posts separating Patagonia North A from North B is very inhospitable in the western region. 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. The police will stop anyone that seems to be trying 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
- Km 714

All control posts along the border are for zoosanitary inspection. Only some of them are for phytosanitary inspection. The site visit review team 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; a small amount goes south to Pedro Luro. Seventy percent of the traffic going into Patagonia goes through this control point. 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 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, do truck and cars get 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 (e.g. employees, space, electricity, equipment). There are three 8-hour shifts with a total of 48 people staffing the post. Agricultural inspectors number 10-11 during the day and 8 at night (less traffic). Officials can dispatch police for violations of trucks and autos. In some instances, confiscated products from this control post can be donated since the post is not within a controlled area yet; however, only the large confiscated shipments can be donated. Substances seized from personal vehicles are destroyed in front of the people so that the public knows the products are not just being stolen. Data are entered into a computer

about what animals/animal products and fruits are transported and for what purpose. All confiscated materials are recorded on paper records.

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 5 people. There is also a police car at all times just 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 10 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 (e.g. 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.

The post keeps paper records of all confiscated materials and other data. There is no computer or phone at this post, only a CB radio. Data are entered into a SENASA computer on a monthly basis.

Training of personnel

SENASA personnel conduct training of security and other forces working on border security. There is a manual of procedures that is applicable 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)
- 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 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 are trained after they are hired in various technical duties including recognition of FMD clinical signs, self-defense techniques, use of fire extinguishers and application of first aid. The probationary period is 6 months. Employees receive training once a year in a refresher course that covers any new rules or regulations.

Conclusions

APHIS considers Argentina, in the region under review (Patagonia South), to have adequate controls at ports of entry for legal commercial importation of FMD-susceptible species and livestock products. Argentina also has the legal framework, proper coverage of borders and adequate staffing to monitor the influx of animals and products via foot or passenger traffic from adjacent areas of higher risk.

8. Livestock demographics and marketing practices in the region

Livestock production systems in Patagonia South are mainly extensive on large farms carrying large numbers of sheep. The climate and the environment of Patagonia South are major factors that make the sheep industry the prevailing livestock activity. This area contains almost 60% of the entire sheep population of Argentina. There were over 7 million sheep in 2003 and more than 72% of Argentina's best wool was produced in this region. Prevailing breeds in the region are Merino and Corriedale. Average livestock density is 14 sheep per km² with Santa Cruz province having the lowest density at 9.5 sheep per km². Total sheep exports from the Patagonia South region surpassed 90% 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, 57]

Bovine production is secondary. Beef produced in Patagonia South is consumed locally. Matured and de-boned beef must be imported from outside to meet the consumption demands of the population in this region. Pigs are raised only for local consumption. Fresh pork meat (chilled and frozen) and pork sausages are not allowed into Patagonia South from other parts of Argentina. Livestock statistics are listed in Tables 4 and 5 below.

Table 4. Total number of livestock producers and establishments and number of bovine and sheep livestock and establishments in Patagonia South in 2003.

PROVINCE	Total No. of Establishments	Total No. of Producers	Establishments with Bovines	Total No. of Bovines	Establishments with Sheep	Total No. of Sheep
Chubut	4,095	4,323	1,733	188,347	3,116	4,633,518
Santa Cruz	1,567	1,567	119	46,798	771	2,333,526
Tierra del Fuego	87	78	75	30,815	50	520,403
TOTAL	5,749	5,968	1,927	265,960	3,937	7,487,447

Table 5. Number of pig and goat livestock and establishments in Patagonia South in 2003.

PROVINCE	Establishments with Pigs	Total No. of Pigs	Establishments with Goats	Total No. of Goats
Chubut	331	10,818	894	140,364

Santa Cruz	11	1,481	4	1,250
Tierra del Fuego	14	432	0	0
TOTAL	356	12,731	898	141,614

Each province has standards (provincial rural codes) for animal identification referent to the Registries of Marks and Signals. In addition, at a national level, Resolution No. 178/01 requires the identification of origin of animals to be moved to any destination. A clear, legible and identifiable mark or signal, in concordance with the design described in the DTA, shall be submitted.

For bovine species exported to the EU, there is a mandatory system called “Identification System for Bovine Cattle intended for Export,” created by SENASA Resolution No. 15/2003. All the farms registered in the “Registry of Rural Establishments Supplying Livestock for Slaughter for Export” use this system. It also applies to establishments registered to fatten bovines that are intended for slaughter for export. “Rural Establishments of Origin” are registered as premises that produce and raise cattle that eventually go to the Establishments for Slaughter for Export.

Movements of livestock within the Patagonia region are limited. There are no fairs or livestock concentration markets in Patagonia South. 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 South, 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 coldstore plants. Lambs are usually destined for export.

Animals are transported in special vehicles used for this purpose only. The vehicles must comply with SENASA Resolution No. 97/99 which requires approval of the vehicle by SENASA and SENASA Resolution No. 809/82 which prescribes hygiene and sanitation requirements.

To market or move animals, the farms must be registered and have a RENSPA number. Shipment of animals to any destination requires a DTA and a Guia that is issued by provincial authorities. The local SENASA offices keep a record of the movements of susceptible animals and report this information on a monthly basis to the statistics unit of DNSA, the Technical Management Unit and the CCFyC.

There are 19 slaughter plants approved by SENASA in the Patagonia region that comply with the regulations in force established by SENASA. All plants approved by SENASA are federally inspected. There are 3 plants approved for export of sheep meat to the European Union. 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 approved for export to the United States.

The procedures to approve plants for export are regulated by SAGPyA Resolution No. 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. Then the Bureau of Supervision of Products of Animal Origin has to carry out an assessment of the compliance of building, operative and documentary requirements, in accordance with a Procedures Initiative. Also, it must be verified 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:

- Capacity of pens at the export area.
- Daily slaughter numbers intended for export
- Slaughter capacity (animal/hour)
- Capacity of the maturation chambers, if pertinent
- Capacity of carcasses that can be introduced into chambers intended for “maturation,” complying with the following items in accordance with Decree No. 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 pre-determined 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, biosecurity control in all the slaughter facilities approved by SENASA are the following:

- Pens: animals are kept within pens and cannot go out of 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 solids, fats, liquids and chlorinates out 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 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 non-edible 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 non-edible by-products.

- Slaughter pathology wastes: Wastes are processed in digesters with pressurized steam or in melters to obtain by-products.

A slaughter facility 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. They must change into clothes that can only be worn in the main part of the facility and then shower and change back into their street clothes before going home. [10]

When a shipment arrives, the transport vehicles are washed and sanitized. The shipper must produce documents, such as the DTA and Guia, which have to be signed by the local official veterinarians or else the shipment is not unloaded. The local SENASA office that issued the DTA is contacted when the animals arrive.

A SENASA official inspects the flocks 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 post-mortem on 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 4 plant staff that examine the organs. No one is specifically assigned to inspect feet post-mortem. The inspectors look for parasites and inspect the head lymph nodes and other sites. All the feet and any condemned tongues and heads go directly into the digester. 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.

Conclusions

Large extensive sheep operations and export-approved slaughter facilities are likely to be the source of sheep meat and products exported to the United States from the Patagonia South region of Argentina. The livestock industry in Patagonia South appears to be well-organized, committed to the production of quality products and aware of necessary biosecurity precautions. APHIS concludes that the biosecurity measures and controls at major production facilities are effective in the prevention of FMD outbreaks. 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 to consider commercial sheep operations as a likely source for introducing FMD into the United States.

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

Patagonia South (i.e., the area of interest under consideration in this risk assessment south of the 42° Parallel) does not conduct its own sampling surveillance designed specifically for Patagonia. Surveillance activities in the Patagonia Region¹ are conducted only under the national

¹ The Patagonia Region consists of three areas: Patagonia South, Patagonia North B and Patagonia North A.

surveillance design and include both passive and active surveillance. Serological sampling in Patagonia is carried out mostly in Patagonia North A and Patagonia North B under Argentina's two-stage national serological sampling design put forth in 2001 to assess the foot-and-mouth situation in the national territory after the July 2000 epidemic.

While valid statistical inferences can be made about the presence or absence of disease in Patagonia from data collected under the national surveillance plan, the statistical confidence associated with such inferences may not be the same as that of the entire country. Confidence levels about Patagonia may be less than the confidence level under the national plan. In order to compensate for any possible loss in statistical confidence associated with inferential statements made specifically about Patagonia, additional sampling was conducted in Patagonia South in 2002-2003 to identify and measure viral activity in specific targeted areas of Patagonia. Additional sampling conducted in Patagonia included samplings of pigs, sheep, goats, farm deer and wild biungulates, and should compensate for any statistical confidence lost. In addition, the historical absence of disease, and the fact that in the absence of vaccination in Patagonia, clinical signs can be detected quickly, should give further evidence for the continued absence of viral activities in Patagonia South.

Overall, over 30% of all serological samplings in Argentina in 2002-2003 were conducted in the Patagonia Region. No animals sampled in Patagonia South ever tested positive and no viral activities were found in this area. Accordingly, the only two issues associated with conclusions based on serological sampling are the validity of the sampling procedures and the adequacy of the sampling coverage. APHIS believes that the sampling design under which sampling is conducted is both valid and efficient and the sampling coverage is adequate.

Serological Sampling in Argentina as a Whole

In July 2000, just after Argentina was recognized by the OIE in May 2000 as an FMD-free country without vaccination, a foot-and-mouth disease outbreak occurred and spread to 15 of the 18 provinces located to the north of the Río Negro and the Province of Neuquén (see Figure 5). The region south of these borders, including Patagonia South, remained free from FMD. Shortly after the outbreak, Argentina began a nationwide serological sampling in conjunction with a strong passive surveillance aimed at monitoring the disease and assessing its status throughout the national territory.

Since the July 2000 epidemic, serological sampling in Argentina has been conducted on a yearly basis starting in 2001 with a frequency of at least once a year. Their sampling approach is a standard two-stage stratified random sampling whereby the country is first divided into strata and where herds are selected at the first stage and animals within herds are selected at the second stage of sampling. This sampling design, explained in more detail below, allows for standard operating procedures of random sampling to be followed. In addition, more targeted sampling is conducted to target high risk areas, populations and herds such as those that had introduced animals from the northern regions of the country during the period when sanitary barriers had been lifted (Page 29 of the November 2004 submission entitled "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”). Serological sampling has been an integral part of the country’s FMD Eradication Plan aimed at removing the FMD virus from its national territory. SENASA maintains that after the July 2000 epidemic the primary reason for all of its epidemiological surveillance, both passive and active, has always been to search for the disease. SENASA’s main goal in conducting repeated countrywide serological samplings was to monitor the disease over time and to measure the progress of its FMD-Eradication Plan.

In general, serological sampling in the national territory of Argentina is conducted for the following main reasons:

- i. To estimate the prevalence of FMD in the areas where there had been disease outbreaks.
- ii. To detect the presence of infection in the areas where there had been no registries of clinical cases of FMD or where its occurrence was sporadic.
- iii. To detect viral activity (or infection), and
- iv. To estimate levels of population immunity given by vaccination against FMD where vaccination was practiced.

Two-stage sampling design

The Republic of Argentina has a surface of 2,780,199 km², 270,000 establishments with a population of 52.5 million bovines and 13.8 million sheep. For the purpose of sampling, the country is divided into zones and sub-zones with different geographical, productive and epidemiological characteristics with respect to the disease historical behavior and to the vaccination implementation (see Figure 4 below).

All serological samplings in Argentina have been conducted according to a two-stage statistical sampling plan that APHIS considers to be both valid and efficient². This sampling design (e.g., sample size and sampling regions and sub-regions, etc.) allows the estimation of the prevalence in the areas where there had been disease outbreaks at the desired level of statistical confidence (typically 95%) and the detection of the presence of infection in the areas where there had been no outbreaks. The design is flexible enough to permit necessary changes and adjustments to target high-risk areas based on epidemiological and other relevant considerations at the time of sampling and the goals that are set. For example, in 2003, with more than a year without clinical cases, sampling was redirected to detect the presence of infection in all the regions of the country and to estimate the immunity level of those areas where vaccination is practiced.

² The design of all serological samplings and the analysis of their results in Argentina are carried out by the Epidemiology Advising Commission and the Virology Advising Council, of the National Bureau of Animal Health of the Bureau of Epidemiology.

Muestreo Aftosa 2003-Zonificación

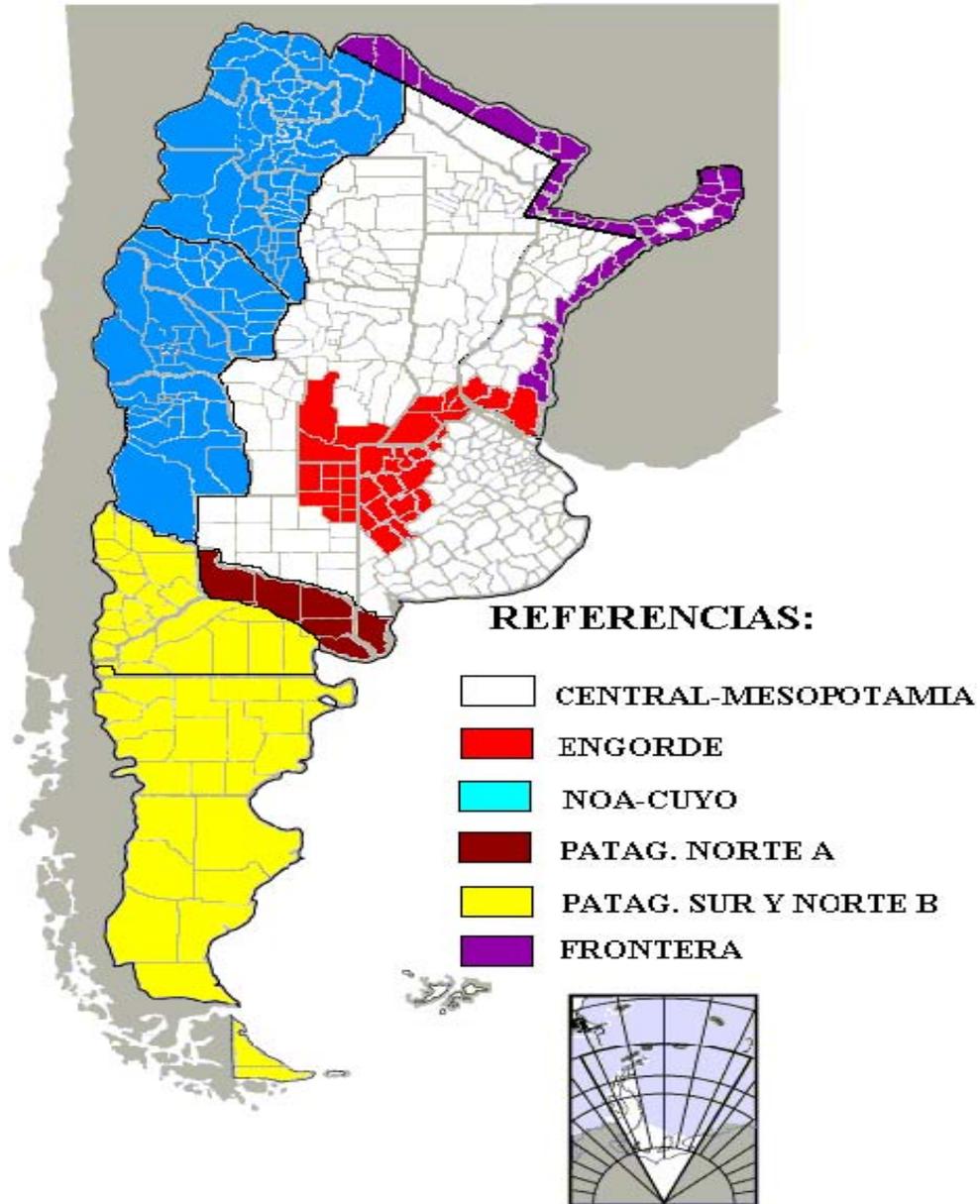
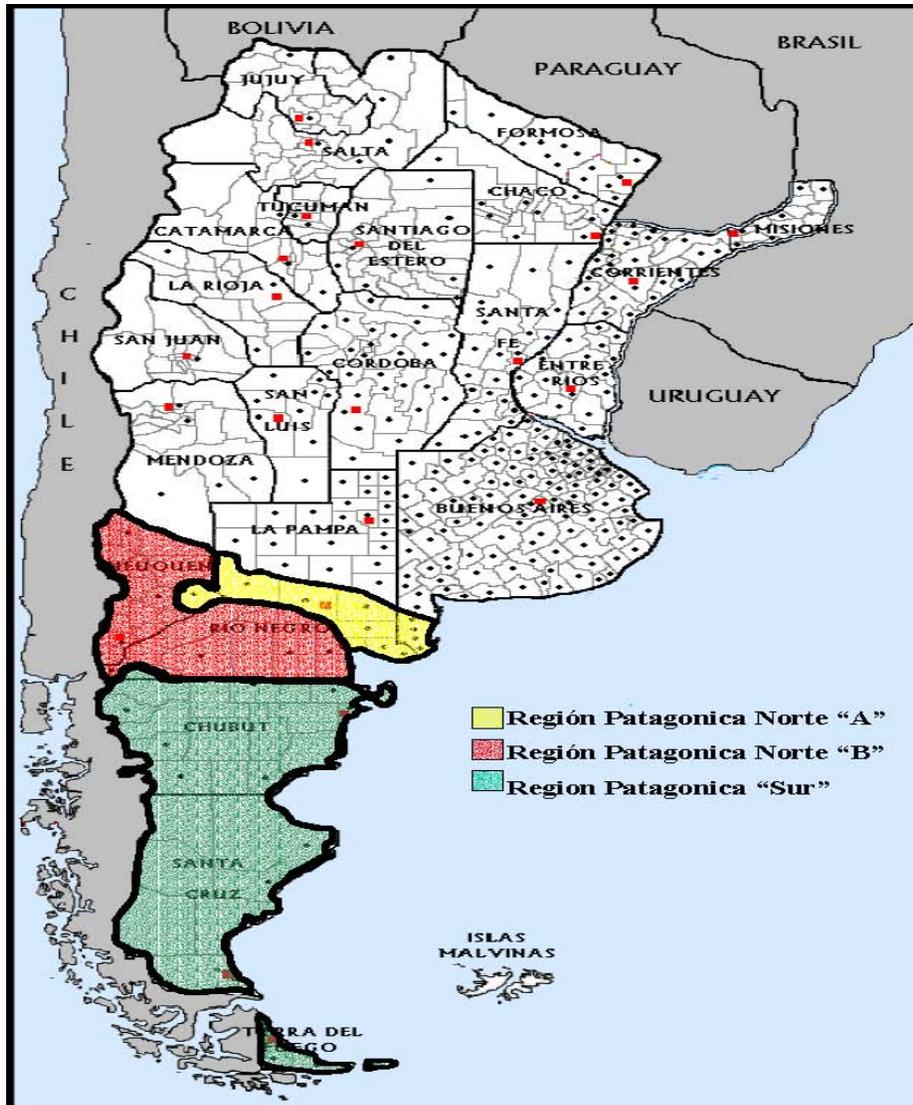


Figure 5. Epidemiological zoning of Argentina for the purpose of serological sampling



Geographical extension and animal demography of the areas with and without vaccination

- Area of Systematic Vaccin
- Area of Systematic Vaccin of surveillance
- Area without Vaccination -
- Free area without Vaccinal recognized by OIE

Figure 6. Areas with and without vaccination

Determining sampling sizes

As mentioned above, serological sampling in Argentina is conducted in two stages. The country is divided into zones and sub-zones according to several factors such as livestock production system and movement of animals, geographic characteristics and weather and climate conditions. In the first stage of sampling in each zone or sub-zone, herds (establishments) are selected at random from a list of herds according to the following standard statistical formula (See, for example, Cannon 2000): [53]

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

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 Number of infected herds in the population.
- N_h Total number of herds in the population

The second stage of sampling consists of sampling of animals from within a selected herd according to the following standard formula [53]

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

Where

- n_{w-h} Number of animals to be sampled from each of the n_h selected herds.
- γ_{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.
- N_{w-h} Average number of animals within a herd, i.e., average herd size.

The list of herds, as well as all livestock census data in Argentina, are compiled and updated by the Sanitary National Registry of Agricultural and Livestock Producers (RENSPA). Tables 6 and 7 list some of the demographic information and livestock figures used to construct sampling lists in Patagonia and elsewhere.

Table 6. Livestock figures used to construct sampling lists.

Province	Flocks/Herds	Total Bovine	Total Sheep	Total Swine	Total Goats
01 - BUENOS AIRES	61742	21050731	1194435	532465	9620
03 - CORDOBA	29444	6508375	98619	444343	45089
07 - ENTRE RIOS	39572	4697308	358300	42155	3277
10 - LA PAMPA	9351	3342981	128724	95093	25377
20 - SANTA FE	30252	6968040	55738	695451	47635

02 - CATAMARCA	3690	154575	11388	3159	54695
09 - JUJUY	4032	88918	473463	6518	106126
11 - LA RIOJA	3092	278874	8209	26658	142781
16 - SALTA	3037	447933	46725	34830	70899
21 - SANTIAGO DEL ESTERO	9394	1179385	99813	134939	278428
23 - TUCUMAN	6013	125361	7009	14102	7609
04 - CORRIENTES	10047	4480962	1540590	18956	5314
05 - CHACO	10911	1640889	284351	59811	129262
08 - FORMOSA	8945	1565381	60619	83805	155562
13 - MISIONES	26252	315442	6792	68619	2646
12 - MENDOZA	894	137378	8680	4529	192020
17 - SAN JUAN	733	30727	0	2811	30639
18 - SAN LUIS	5747	1523289	43225	21327	38940
14 - NEUQUEN	3757	133758	194007	6039	568500
15 - RIO NEGRO	5306	697501	1728045	7668	176353
06 - CHUBUT	4095	188347	4633518	10818	140364
19 - SANTA CRUZ	1567	46798	2333526	1481	1250
22 - TIERRA DEL FUEGO	87	30815	520403	432	0
Total	276306	55556155	10982250	2314096	2231136

Table 7. Livestock figures used to construct sampling lists by province in Patagonia South.

	Chubut	Santa Cruz	Tierra Del Fuego	Total
Total N° of Establishments	4,095	1,567	87	5,749
Total N° of Producers	4,323	1,567	78	5,968
Establishments with Bovines	1,733	119	75	1,927
Total N° of Bovines	188,347	46,798	30,815	265,960
Establishments with Sheep	3,116	771	50	3,937
Total N° of Sheep	4,633,518	2,333,526	520,403	7,487,447
Establishments with Pigs	331	11	14	356
Total N° of Pigs	10,818	1,481	432	12,731
Establishments with Goats	894	4	0	898
Total N° of Goats	140,364	1,250	0	141,614

Serological Sampling Activities in Patagonia

Serological sampling activities have been conducted in the entire Patagonia Region since the July 2000 FMD outbreak. The primary focus of this evaluation is serological sampling in Patagonia South. However, because Patagonia does not have its own independent serological sampling design, any discussion of serological sampling in Patagonia must necessarily be given in the context of serological sampling at the national level.

Serological Sampling in 2001 in Patagonia

After the reintroduction of FMD in the country in 2000, two serological surveys were carried out in 2001 in the Patagonia Region to verify the FMD free status of the region. The first survey was a population sampling approach conducted in accordance with the national two-stage statistical design; the second was a sampling targeting the establishments that had introduced animals from the northern regions of the country during the period when sanitary barriers had been lifted when the country was recognized free from FMD without vaccination by the OIE in May 2000. [6]

The species sampled in these two surveys were bovines and sheep. In the case of bovines, the test used was ELISA 3ABC-EITB, and for sheep VIAA-IDGA and ELISA in liquid phase³. An establishment was considered to be positive if at least one animal of any species was positive.

The tables 8 and 9 below show the collected samples and the results of these two serological studies. [2] Table 9 has information specific to Patagonia South.

Table 8. Sampled establishments, collected samples and results of the population sampling of Patagonia in 2001.

Region	Sampled Establishment	Sampled Animals	Establishments with Positive Serology	Seropositive Animals
Patagonia North B	251	5019	1	2
Patagonia South	256	6177	0	0
TOTAL	507	11196	1	2

³According to the supplier of the diagnosis kits, it was reported that the characteristics of the serological tests are the following:
ELISA 3ABC (PANAFTOSA): Sensitivity: between 99.8 and 100% (infected animals without/with vaccination, respectively.) Specificity: between 95.2 and 99.05 % (according to whether it has been vaccinated or not, and the number of vaccines received)
ELISA 3 ABC (CEVAN): Sensitivity: 100 %; Specificity: 99.5%
EITB (PANAFTOSA): Sensitivity: 99.8 to 100% (animals without/with vaccination, respectively); Specificity: 99.68 to 100% (according to whether it has been vaccinated or not, and the number of vaccines received)
VIAA-IDGA: Sensitivity: 70 %; Specificity: 99 %

Table 9. Sampled establishments, collected samples and results of the targeted sampling of Patagonia in 2001.

Province	Number of Establishments	Number of Sampled Animals	Establishments with Positive Serology	Seropositive Animals
Chubut	26	1171	0	0
Neuquén	32	1014	7	11
Río Negro	5	559	0	0
Santa Cruz	6	471	0	0
Tierra Del Fuego	1	87	0	0
TOTAL	70	3302	7	11

Additional studies were carried out in the establishments where animals reacting to the tests have been found. These studies included new samplings of susceptible animals, with EPF (esophagus-pharyngeal fluid) sample collection for isolation and PCR of positives. In all the cases the tests were negative, discarding the presence of infection. Additional samples, corresponding to a joint study with the Livestock and Farming Service of Chile (SAG), were collected from bovines and pigs in the Province of Tierra del Fuego. [8]

In addition, 30 pigs were sampled in Patagonia South in a serological survey carried out jointly with the Livestock and Agricultural Service (SAG) of Chile in Tierra del Fuego but independently from the country's national serological sampling plan.

Serological Sampling in 2002 in Patagonia

A series of four sero-epidemiological studies were carried out nationwide in 2002, the first of which was implemented at a national level while the others were more targeted. These studies were not specific for Patagonia South but were conducted as part of the active surveillance tasks performed in Argentina as a whole after the reappearance of the disease. We briefly discuss three of the four studies below and their results that are relevant to the two areas of interest, namely, Patagonia South and Patagonia North B where vaccination was not practiced. The four studies are: [2]

- Study 1. Bovine, ovine and goat sampling - Autumn 2002 (March-May)
- Study 2. Farm deer sampling - June and October 2002
- Study 3. Wild biungulates sampling in Patagonia- May-July 2002
- Study 4. Goat sampling in Mendoza - September, October 2002

The first one was implemented at a national level, while the others responded to more targeted areas in Patagonia. The first three are discussed in more detail below.

2002 Study 1. Viral Activity - Bovine, ovine and goat sampling

This study was conducted at the national level in March through May of 2002 according to the two-stage national sampling plan. In this study, the country was divided into three zones: A, B and C (see Figure 6). These were distinguished by differences in epidemiological characteristics relating to occurrence of clinical cases of the disease and the implementation of vaccination against the FMD virus.



Figure 7. 2002 zoning map for serological sampling

The three zones were further divided into smaller sub-zones⁴ in order to define areas that were as homogenous as possible in terms of the production, geography and management practices. Homogeneity was assessed according to the following parameters: (1) animal density, (2) composition of the bovine population (relationship heifer/cow), (3) animal movement (inflow and outflow), (4) geographical and political-administrative characteristics, and (5) vaccination campaigns operational capacity (in A and B zones only). The five sub-zones are (see Figure 7):

1. Sub-zone C1: Province of Neuquén.
2. Sub-zone C2: Province of Río Negro (except for the vaccination area)
3. Sub-zone C3: Province of Chubut.
4. Sub-zone C4: Province of Santa Cruz.
5. Sub-zone C5: Province of Tierra del Fuego.

⁴ A sub-zone may comprise a whole province, a group of provinces or an area formed by parts of different provinces.

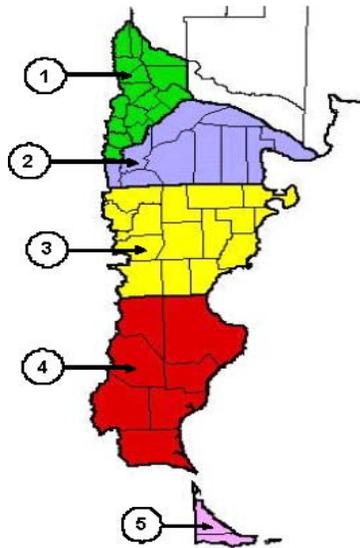


Figure 8. 2002 further sub-zoning of Zone C in Map 2 above

We shall confine our discussion of serological samplings in 2002 below to those conducted in Zone C only since this zone contains the area of interest in this risk analysis, namely, Patagonia South.

The purpose for serological sampling in this zone was to ascertain the absence of antibodies to non-structural protein (NSP) of the FMD virus in sheep and bovines in the Patagonia Region. Recall that Zone C has 300,000 bovines and 9,000,000 sheep, representing 1% and 65% of the total bovine and sheep populations, respectively, in the country. The disease was not detected in this zone during the 2000-2001 epidemics, and vaccination against FMD virus is not practiced.

The species sampled in this study were bovines, sheep and goats. Bovines were classified into two categories according to their age - Category 1: from 6 to 12 months of age; and Category 2: from 12 to 24 months of age. Sheep and goats, not vaccinated, of any age were sampled.

The sample size was determined in accordance with the two-stage national sampling design assuming a herd prevalence of 2% in Zone C; within-herd prevalence of 10%; and a level of statistical confidence of 95%. However, due to the different livestock characteristics in different sub-zones with respect to the proportion of susceptible species in Zone C, the design was slightly modified in each sub-zone. For example, in sub-zones C3, C4 and C5 (Provinces of Chubut, Santa Cruz and Tierra del Fuego), only ovine were sampled⁵; 152 premises were required to be sampled and 28 sheep from each premise, with a total of 4,256 samples by sub-zone.

In Neuquén and Río Negro Provinces (sub-zones C1 and C2), bovine species represent 33% and ovine species represent 67% of the entire livestock population in Zone C. Both species were

⁵ In these provinces the bovine species represents 3% of the entire susceptible livestock (sheep and bovines) in Zone C. Therefore, it was not considered as significant for the purposes of the sampling and only ovine samples were requested.

sampled with 152 premises by sub-zone, with 28 bovine samples and 28 ovine samples taken from each premises. A total of 4,256 samples were taken for each species. A total of 21,280 samples were requested by the sampling design for all of Zone C.

Table 10 reports the total number of establishments and animals required by the serological design to be sampled in this study. The number in parentheses represents the proportion of sampling in Zone C out of all sampling conducted nationwide in 2002.

Table 10. Number of samples required by the two-stage sampling design in 2002.

(Numbers in parentheses represent the proportions of sampling in Zone C out of sampling conducted nationwide in 2002.)

Zone	Establishments	Bovines	Sheep/Goats	TOTAL
A	2800	25200	14000	39200
B	984	19680	0	19680
C	760 (or 16.73%)	8512 (or 15.94%)	21280 (or 60.3%)	29792 (or 33.6%)
TOTAL	4543	53392	35280	88672

Only 78% or (69,017/88,672) of the samples required by the design was analyzed. There were various reasons for this, including sample collection difficulties in the field and laboratory samples that could not be processed because of identification and/or preservation problems. Table 11 gives the total number of actually analyzed samples, i.e., the effective sample size, by zone in Zone C. Here too, the number in parentheses represents the proportion of analyzed samples in Zone C out of all sampling nationwide conducted in 2002.

Table 11. Number of samples actually analyzed in each zone in 2002.

(Numbers in parentheses represent the proportions of analyzed samples in Zone C out of all sampling nationwide in 2002)

Zone	Bovines	Sheep/Goats	Total
A	21671	9171	30842
B	14893	0	14893
C	5292 (or 12.64%)	17990 (or 66.24%)	23282 (or 33.73%)
TOTAL	41856	27161	69017

Table 12 shows the results of serological sampling in Zone C in 2002 for each sub-zone.

Table 12. Number of establishments with at least one positive animal of any species in Zone C .

Sub-zone	Positives/total	Prevalence %	IC 95%
Province of Neuquén	4/118	3.4	0.1-6.7
Province of Río Negro (except for the vaccination area)	5/259	1.9	0.2-3.6

Province of Chubut	0/151	0.0	
Province of Santa Cruz	0/151	0.0	
Province of Tierra del Fuego	0/30	0.0	
TOTAL	9/709	1.3	0.5-2.1

Establishments with positive results were sampled further to determine if there was viral circulation. It has to be underlined that animals in this zone are not vaccinated; therefore, bovines are highly susceptible to the disease. Nevertheless, no clinical cases were detected during the 2000/2001 epidemic. In addition, no viral activity was detected in sheep in this zone. [2]

Table 13 reports the results of testing demonstrating that there was no viral activity in sheep/goats tested in this study in Zone C.

Table 13. Results of viral activity in sheep/goats for each sub-zone in Zone C.

Sub-zone	Positives/total	Prevalence %
Province of Neuquén	0/1138	0
Province of Río Negro (except for the vaccination area)	0/3971	0
Province of Chubut	0/4271	0
Province of Santa Cruz	0/4349	0
Province of Tierra del Fuego	0/4261	0

2002 Study 2. Serological Sampling of Farm Deer

A serological sampling of commercial deer farms was carried out during the months of June and October 2002 in order to ascertain the absence of FMD virus in commercial deer farms in Argentina. Four provinces were randomly chosen; a total of 15 farm deer establishments were randomly selected from them; and a total of 478 deer serum samples were collected as shown in Table 14.

Table 14. Number of deer establishments and deer sampled in 2002.

Province	N° of establishments	N° of samples
Buenos Aires	5	180
La Pampa	4	124
Neuquén	5	145
Río Negro	1	29
Total	15	478

These deer establishments were considered to be separate populations of deer since they were managed independently of one another and from other types of production. The sampling of at least 29 samples from each establishment allows a 95% statistical level of confidence to detect at least one positive case if the prevalence of infected animals were 10% or higher⁶.

All of the samples tested negative for antibodies to structural (ELISA in liquid phase) and nonstructural proteins (VIAA-IDGA) of the FMD virus.

2002 Study 3. Monitoring of wild biungulates in areas without vaccination

In 2002, a serological survey in wild biungulates in areas without vaccination was carried out with the aim of verifying the role of these species in the FMD epidemiological behavior in these areas and to ascertain the absence of FMD virus in wild susceptible species of the areas without vaccination. It was performed in game reserves in Patagonia.

The big game reserves in Patagonia are located in the Provinces of Neuquén and Chubut. There are no hunting areas approved in the other Patagonian regions. A total of 32 hunter-kill serum samples were obtained for the study. These consisted of 27 red deer captured in 9 big game reserves in the Province of Neuquén and 5 guanacos in an establishment in the Province of Chubut⁷.

As the animals are not vaccinated, a positive result to any of the tests would indicate that an animal has been in contact with the FMD virus. Here too, all the analyzed samples were negative to both tests.

Serological Sampling in 2003 in Patagonia

Serological sampling in 2003 was implemented countrywide in a similar manner to the way it was conducted in 2002. Here too, the country was divided into zones according to the following parameters: (1) animal density, (2) composition of the bovine population (relationship heifer/cow), (3) geographical and politic-administrative characteristics, (4) operating capacity of the vaccination campaigns, (5) risk areas (zones bordering with countries with FMD), and (6) surveillance zones (of free areas). That resulted in six zones as follows: [2]

Zone 1:	Central-Mesopotamia
Zone 2:	Fattening
Zone 3:	NOA-Cuyo
Zone 4:	North A Patagonia
Zone 5:	South and North B Patagonia
Zone 6:	Border

⁶ Considering that the population of sampled is not vaccinated and the high contact rate among individuals within a deer establishment and the behavior of the FMD in general in non immunized populations, the 10% design prevalence is conservative.

⁷ Red deer, wild boar and the guanaco are among the wild species of varying susceptibility to the FMD virus which are hunted in the different Patagonia game reserves.

Only ovine were sampled in Patagonia South and North B. However, bovines were sampled in Patagonia North A.

Slightly different sampling approaches were used in each zone. For example, in determining the minimum sample size required for sampling in Patagonia North A, a 1% herd prevalence, a 15% within-herd prevalence and a 95% statistical confidence were assumed. Bovines were categorized in three age categories: 6 to 12 months (Category 1), 12 to 24 months (Category 2), and more than 24 months (Category 3) in Patagonia North A.

In Patagonia South and North B, a 1% herd prevalence, a 10% within-herd prevalence and a 95% statistical confidence were assumed. Also, only sheep were sampled in these regions since sheep is the predominant species in these two areas. Accordingly, it was estimated that 459 premises should be selected and 10 sheep of any age from each one should be sampled, for a total of 4,590 samples.

Serological tests measured antibodies to non-structural proteins of the FMD virus in bovines and structural proteins in sheep. In bovines, the ELISA 3ABC-EITB test was used. The ELISA in liquid phase (ELISA lph) test was used to detect antibodies to structural proteins of FMD virus for O1 Campos and A 2001 types in sheep. The sampling approach by region is described in Table 15.

Table 15. Sampling 2003. Number of premises sampled and collected and processed samples to determine viral activity by region.

Zone	Number of Establishment Sampled	Number of Bovine Samples	Number of Ovine Samples	Number of Animals Samples
Central-Mesopotamia	417	4,140	0	4,140
Fattening	309	2,847	0	2,847
Border	419	4,287	0	4,287
NOA-Cuyo	348	3,371	0	3,371
Patagonia North A	321	3,161	0	3,161
Patagonia South and North B	486	0	4,951	4,951
TOTAL	2,300	17,806	4951	22,757

Table 16 shows the ovine samples collected and their results for the Patagonia South and North B regions, per province.

Table 16. Number of ovine premises sampled and processed samples to determine viral activity in the Patagonia South and North B regions per province and their results.

Zone	Province	Establishment	Serums	Positive Serums
Patagonia North B	Neuquen	18	180	0
	Rio Negro	86	840	0
	Chubut	214	2235	0
Patagonia South	Santa Cruz	140	1390	0
	Tierra Del Fuego	28	276	0
TOTAL		486	4921	0

If an establishment was found to have at least one positive animal, additional serological sampling was conducted in collecting up to 60 animals per establishment. If an animal resulted positive to this additional sampling, collection of Esophagus Pharyngeal liquid 1 was performed in two opportunities. For all of Argentina, out of the 2,300 premises that were sampled, 92 had at least one positive animal and were investigated further⁸. However, no positives were found in Patagonia South or Patagonia North B. That is, all 4,921 samples from 486 establishments were negative to the ELISA test in liquid phase. Similar results were obtained in 2002 when 17,990 sheep sampled collected in the same region tested negative (Table 6 above).

Conclusions

APHIS believes that the sampling design under which serological sampling is conducted in Patagonia is both valid and efficient and the sampling coverage is adequate. APHIS also believes that the serological sampling that has been conducted in Patagonia both under the national serological sampling plan, which will continue in the future, and the additional targeted sampling of pigs, sheep, goats, farm deer and wild biungulates since the July 2000 outbreak is adequate to detect disease and/or identify and measure viral activity in the area. Furthermore, the historical absence of disease in the region, quick detection of clinical signs should disease be introduced in the absence of vaccination, and the fact that 30% of all serological samplings in Argentina in 2002-2003 were conducted in the Patagonia Region resulting in no animals sampled in Patagonia South ever testing positive and no viral activity ever found, would support further evidence of the absence of disease in Patagonia.

10. Diagnostic laboratory capacity

In Argentina, SENASA has one diagnostic laboratory in Buenos Aires with a biosafety level NBS3 Ag (equivalent to BL3) that was approved in 1997. This laboratory is authorized to manipulate FMD virus and other microorganisms that must be handled in BL3 facilities or lower status. The laboratory meets SENASA and OIE biosafety requirements. There are no other official or private laboratories that are authorized to perform FMD diagnostic and surveillance

⁸ Here too, additional studies were carried out in the establishments where animals reacting to the tests have been found. These studies included new samplings of susceptible animals, with EPF (esophagus-pharyngeal fluid) sample collection for isolation and PCR of positives. In all the cases the tests were negative, discarding the presence of infection. [8]

techniques. SENASA Resolution No. 219/95 does allow accreditation of private laboratories by SENASA to produce FMD vaccines. [1, 2]

In 2000, the laboratory was audited by foreign inspectors from the EU and the Pan American FMD Center, among others. The scope of the audits included working procedures, quality programs, and biosafety conditions. The findings were satisfactory.

Security measures in place at the central laboratory include:

- Restricted and controlled access
- Airtight compartments and mandatory showering
- Negative air flow with two HEPA filters
- Heat treatment of liquid effluents (100°C during 1 hour)
- Border autoclave
- Airlock with formaldehyde spraying
- Category II biosafety booths
- Electric energy generator

The Argentinian biosafety requirements to manipulate the FMD virus are stated in former SENASA Resolution No. 219/95.

The staff of the central laboratory is trained in manipulating and diagnosing the FMD virus. 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 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, Dr. Veronica Leedham, director of the general department of animal lab, Dr. Osvaldo Periolo and the head of FMD section, Dr. Eduardo Maradei at the SENASA central laboratory in Buenos Aires on December 1, 2003. Below are some observations from the visit. [10]

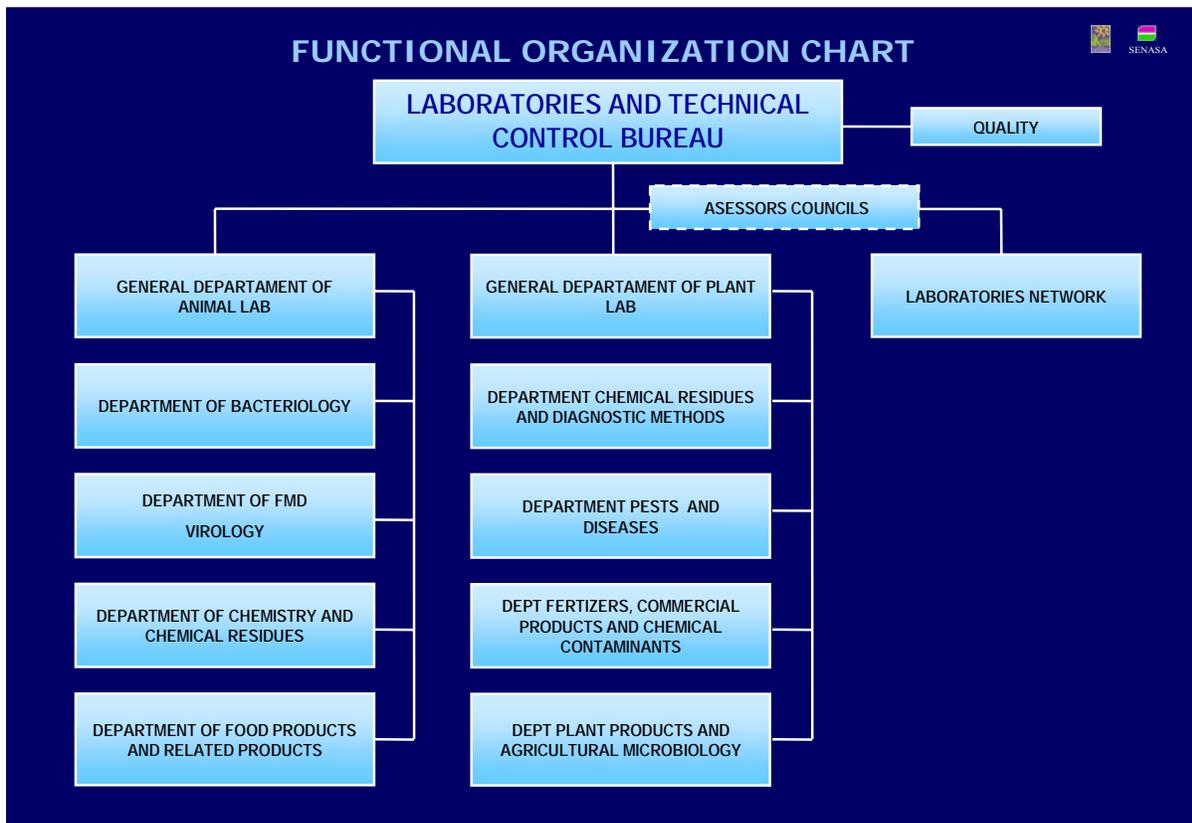
I. Laboratory structure and organization

The DILOCOT (Figure 9) is comprised of 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 Virology Laboratory is staffed with 26 veterinarians, 13 technicians and 3 administrative personnel. BL3 laboratory space is about 150 square meters and it accommodates four people at a time. The laboratory can process 40 epithelial samples a day.

The laboratory uses a laboratory information management system (LIMS) for recoding samples coming in and for typing laboratory results that go out to the epidemiologists. The site review team did not see the actual worksheets for every test being run, but the site visit review team in June 2003 saw similar worksheets in the poultry laboratory. The system appeared effective and adequate for storing data and efficient in retrieval of desired data. The staff was very capable in managing the system.

A new laboratory building is under construction for poultry, equine and small animal diagnostics with BL3 facility for FMD PCR.

Figure 9. Functional Organization Chart of SENASA Laboratory



II. National reference laboratory missions

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 is working towards accreditation by the Argentine Accreditation Organization (Organismo Argentino de Acreditación – OAA) under international standards ISO 17025. The

first audit occurred in November 2004. The food safety department (residues and food control) is now accredited and SENASA is looking into accrediting the biological departments (analytical methods) for the different diseases during 2005.

III. Diagnostic samples

Epithelial tissue samples are preserved and transported in Vallee medium composed of phosphate glycerin (pH 7.2) with phenol red. Received 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 BL3 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 hrs 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 hr and tested for FMD by ELISA. If the ELISA results are negative on the second passage the sample is considered negative. The laboratory receives between 1-2 investigation(s) a year 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.

It is important to note that the serology for FMD is done at the BL2 facility since space is limited in the BL3 facility. Serum from FMD infected animals may contain the virus up to 5 days post infection, so a BL3 facility might be preferable. To minimize the risk of handling a potential live virus outside of containment, the laboratory staff chooses to heat inactivate the sera before running the ELISA. Heat treatment of the FMD virus at 56°C for 30 min has been shown not to be completely effective in inactivating FMD virus. SENASA might consider running samples from suspect cases in biocontainment to minimize the risk of contaminating the BL2 facility.

VIAA is the only test approved by PANAFTOSA to screen sheep for FMD antibody. In the past, SENASA had a regional laboratory network to run VIAA for FMD antibody test, but it is only run at the central laboratory now.

The SENASA laboratory does not have the proper facility to run PCR for FMD. Consequently, samples submitted for PCR testing are partially processed in the BL3 where live FMD virus is

being handled. Test samples are placed in trizol or the RNA is extracted and sent without being safety tested to the non-accredited BL3 INTA laboratory to run the PCR assay. SENASA is planning to have a separate BL3 facility for PCR assays.

Table 17. Number of diagnostic tests for FMD and VS serology 2003.

Test	First semester	Second semester
VIAA	29,690	6,004
3ABC ELISA	32,436	14,620
EITB	3,123	5,750
Structural ELISA	29,690	5,990
Typing ELISA	80	41
VS ELISA	398	524
Total	91,686	32,929

IV. Diagnostic tests capability

Technology for following tests is currently available at the SENASA, INTA and CEVAN laboratories:

1. FMD

- a. Serology: 3ABC ELISA, EITB, VIAA and monoclonal-based liquid phase ELISA are used for serotyping. The virus neutralization test has been used in the past and, at the time the laboratory was reviewed, it was currently encountering problems growing the virus in the cell culture. Definition of conditions for re-optimizing the test was in progress.
- b. Virus detection: Antigen ELISA using reagents produced by the PANAFTOSA laboratory is used. 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 conducted at the INTA laboratory after processing the samples in the SENASA laboratory.

2. Vesicular Stomatitis

- a. Serology: Reagents for the IgG ELISA are purchased from the PANAFTOSA laboratory. The live virus is not handled in the laboratory because of the limited BL3 laboratory space. Therefore virus neutralization test is not currently available.
- b. Agent detection: Ag ELISA is used in the central laboratory. PCR and genomic sequencing are conducted in the INTA and CEVAN laboratories.

3. Swine Vesicular Disease

No test is available. Reagents for the antibody ELISA will be purchased from the OIE reference laboratory in Pirbright to start screening the swine population.

Conclusions

Argentina has the diagnostic capabilities to adequately test samples for the presence of the FMD virus. In this regard, quality control activities within the laboratories are sufficient, laboratory equipment is routinely monitored and calibrated, sufficient staff is available, and there is an effective and efficient recordkeeping system for storage and retrieval of data.

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 (No. 3959/1903) requires all veterinarians in private practice that work in rural areas must 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 Patagonia. Observations by the producers, animal caretakers, transporters and other people who see the animals every day 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.

Veterinarians also take part in passive surveillance. Routine examinations of livestock occur during wool industry-related tasks and official surveillance programs, plus 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 determines to follow a stamping-out policy, SENASA's actions and level of involvement are defined in Resolutions Nos. 1410/2000 and 488/2002. The actions are listed in Resolution No. 779/1999 through which the National Animal Health Emergency System (SINAESA) was created as authorized by Law No. 24.305, Act No. 3959/1903 and Decree Nos. 1585/1996 and 643/1996. By Decree No. 394/2001 that updated Decree No. 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.

At the regional level, the actions required by the SINAESA 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 their 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 in the area).
- 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 additional 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, there is immediate notification of the outbreak or suspicion of FMD to the OIE within 24 hours of detecting the case. 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 rapidly and regularly gives 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 between 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 Nos. 51/2003 and 02/2002 and SENASA Resolution No. 166/2003.

Conclusions

Argentina has the infrastructure and legal authority to declare an emergency and take appropriate action in case of an FMD outbreak. They have a disease control program that is in written form in the *Foot and Mouth Disease: Manual of Procedures for Focus Attention*. The manual sets forth operating standards and is legally authorized by several SENASA Resolutions and Regulations. There are also systems for notification and training that ensure emergency preparedness and response with a legal framework to authorize needed actions.

Release Assessment – Summary of risk factors and mitigations considered

APHIS identified risk factors that might be associated with importing sheep to the US from the export region. APHIS discusses these risk factors in the context of the potential for counterbalancing circumstances or by applying appropriate risk mitigations to reduce the risk of introducing and establishing FMD in the U.S.

Likelihood of FMD introduction into the Argentina Patagonia South region

Risk Factor

1. FMD is endemic in most countries in South America. Consequently, there is an ongoing risk of reintroduction of FMDV from adjacent affected areas into the export region. Therefore, there is a risk that FMD-susceptible species or products from such species destined to the U.S. could originate from or be commingled with animals or animal products from affected neighboring areas.

Discussion: Argentine authorities do not allow live animals to enter the Patagonia South region except from Patagonia North B and FMD-free countries without vaccination for breeding purposes and after extensive testing. Lamb meat is the major product that would potentially be exported to the U.S. Cull animals that are slaughtered are used only for local consumption.

Matured, deboned fresh beef is imported into Patagonia South from areas in Argentina north of the 42° Parallel for local consumption only since beef is not produced in sufficient quantities for local demand. This meat has a low risk of introducing the FMD virus into the export region since it must go through a maturation process that kills the FMD virus, swill which may contain meat scraps must be properly treated before being fed to pigs, and the sheep do not come into contact with the meat since they go directly from the range to the slaughter facilities.

Conclusion: Any sheep or sheep products exported to the U.S. will originate only from Patagonia South. Other products from FMD-susceptible animals are not expected to be exported to the U.S.

Mitigations: If beef exports from Patagonia South to the U.S. are ever expected, certification by a full-time salaried veterinary officer of the Government of Argentina will be required to state that the beef did not originate or was not commingled with other meat from outside the Patagonia South region.

Likelihood of detection of FMD if reintroduced into the Argentina Patagonia South region

Risk Factor

1. Sheep in the Patagonia South 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 supervision. Because some of the farms are extremely large, animals may not be in human contact for significant periods of time. Therefore, close observation of animals might be infrequent, and clinical signs might be missed.

Discussion: In spite of the large size of the farms in Patagonia, staff periodically inspects the animals. Producers, animal caretakers, transporters and other industry staff are well aware of FMD or other vesicular disease symptoms, reporting requirements and available resources to avoid the disease. Routine examinations of livestock occur during wool industry-related tasks and official surveillance programs, plus animals are also inspected at fairs and before and after slaughter.

Conclusion: Husbandry and surveillance practices in Patagonia South 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 – Conclusion

Based on evaluation of the 11 factors and observations from the site visits, APHIS considers that Argentina possesses the legal framework, animal health infrastructure, detection capabilities, reporting systems, and emergency response systems that are necessary for maintaining the Patagonia South region as free of FMD.

Exposure Assessment

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. [13]

APHIS considers that the most likely pathway of exposure of domestic livestock to FMDV in beef is through feeding of contaminated food waste to swine. [15] The likelihood of exposure of FMD-susceptible species to FMD infected beef was evaluated by reviewing previous VS studies. In 1995, VS conducted a pathway analysis to estimate the likelihood of exposing swine to infected waste. [16] The analysis included two pathways for exposure of swine to contaminated waste; namely, exposure associated with illegal household imports, and exposure associated with legal imports. With 95% confidence, VS estimated that 0.023% or less of plate and manufacturing waste would be inadequately processed prior to feeding to swine. [16] Based on this fraction, less than 1 part in 4,300 of imported beef is likely to be fed to swine as inadequately cooked waste.

VS conducted a survey in 2001 of the U.S. swine waste-feeding sector to update a similar study done in 1994. [17] Based on this survey, VS estimated that the proportion of plate and manufacturing waste fed to swine diminished by about 50% between 1994 and 2001 due to a decrease in the number of waste-feeding premises. 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 U.S. saw a 40.5% decrease in the number of waste-feeding premises, Hawaii a 37.5% decrease and Puerto Rico a 52.3% decrease, and
- Institutions and restaurants provide nearly 90% of all plate waste fed to swine.

APHIS considers that prohibiting the feeding of unprocessed plate waste to swine has further 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). [12] 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 considers the likelihood of exposure of susceptible swine to the FMDV through importing inadequately cooked infected beef from the export region to be low.

Consequence Assessment

A consequence assessment describes the biologic and economic consequences of FMD introduction into the U.S. This consequence assessment addresses both direct and indirect consequences as recommended by the OIE. [13]

The magnitude of the biologic and economic consequences following an introduction of FMD would depend on 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. [18] 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. Very high mortality rates in young animals can occur, particularly among pigs and sheep. [19] In pigs, Dunn and Donaldson (1997) [20] estimated a general mortality rate of 40% for two outbreaks in Taiwan in 1997. Geering (1967) [21] cites mortality rates of 40, 45 and 94% 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 10 to 20 percent are reported in FMD-infected livestock [18] if the disease is allowed to run its

course. For example, the drop in milk yield of dairy cattle averages approximately 25% per year. [22] In addition, FMD can cause reduction in the growth rate of animals raised for meat. According to Doel (2003) [23], estimates vary considerably but one study has indicated that cattle would require approximately 10-20% longer to reach maturity. The comparatively greater severity of FMD in pigs would imply at least similar losses to those described for cattle. [23]

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 quarantine measures and movement controls, direct costs related to stamping out of affected and other herds, indemnity payments, vaccination costs, surveillance and laboratory testing, etc.

For disease-free countries like the U.S. 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. [24] A recent study using a stochastic simulation model showed that ring vaccination decreased the duration of outbreaks. However, 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. [25]

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 (2003) [26] 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 FMDV in a cattle population of 2,238 herds and 5 sale yards located in 3 counties of California. The study found that mean herd indemnity payments were \$2.6 million and \$110,359 for dairy and non-dairy 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. (1979) [18] conducted a comprehensive study to assess the potential economic impact of FMD in the whole of the U.S. 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 U.S., the impact of compulsory or voluntary control programs was also considered. A summary of the findings are shown in table 15. The results were updated using the difference in the Consumer Price Index (CPI) in 2001. [27]

Table 18. Economic impacts of FMD adjusted from 1976 dollars to March 2001 dollars by Consumer Price Index¹.

	Consumer Impacts		Program Costs		Totals	
	-----millions of dollars-----					
	1976\$	2001 \$	1976 \$	2001 \$	1976 \$	2001 \$
McCauley estimates						
Endemic FMD w/ voluntary control	\$11,600	\$35,844	na	na	\$11,600	\$ 35,844
Eradication by strict slaughter & quarantine	\$10,600	\$32,754	\$539	\$1,666	\$11,139	\$ 34,420
Eradication by area vaccination	\$11,600	\$35,844	\$690	\$2,132	\$12,290	\$ 37,976
Compulsory vaccination program w/ endemic FMD	\$8,900	\$27,501	\$4,200	\$12,978	\$13,100	\$ 40,479

1. Increase by difference in CPI = 3.09, Bureau of Labor Statistics, US Department of Labor.
Source: Adapted, McDowell 2001, personal communication.

Effect on the Environment

Environmental effects have been considered under all applicable environmental review laws in force in the U.S. 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. [28]

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. FMDV 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. [29]

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, revealed high rates of depression, alcohol consumption and mortality among farmers during the crisis (Lancaster University, Unpublished report). [58]

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 US 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. [30] conducted a study to estimate the potential revenue impact of an FMD outbreak in the U.S. 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 follow: cattle (17%), beef (20%), milk (16%), swine (34%), pork (24%), sheep and lambs (14%), and sheep and lamb meat (10%). Thompson et al (2002) [39] estimated the loss of about 20% 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 U.S.: 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. [31]

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. [31]

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. [32] 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. [13]

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 U.S. via imports of FMD-susceptible species or products from such species from the Argentina Patagonia South region. Although consequences of a FMD outbreak are potentially substantial, the likelihood of an outbreak occurring via exposure of the domestic livestock population to animal products imported from the Argentina Patagonia South region is low.

The consequences of a FMD outbreak in the U.S. 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 US\$37 billion to US\$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 indicated that the likelihood of introduction and establishment of FMD is low.

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

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Appendix 1: Epidemiologic characteristics of foot-and-mouth disease (FMD)

Etiologic Agent

Family *Picornaviridae*, Genus *Aphthovirus*, types O, A, C, SAT 1, SAT 2, SAT 3 and Asia 1.

Status in the U.S.

FMD virus was eradicated from the U.S. in 1929.

Epidemiology

FMD is a highly communicable disease of cloven-hoofed animals caused by an *Aphthovirus* of the family *Picornaviridae*. FMD has seven immunologically distinct serotypes (O, A, C, SAT1, SAT2, SAT3 and Asia 1). The O, A, and C serotypes have historically been found in South America. [33] Research indicates that one serotype does not confer protective immunity against the other six, thus a disease outbreak can be caused by one serotype or a combination of serotypes. [34]

FMD virus can be transmitted by direct or indirect contact or aerosol. Fomites such as feed, drinking water, tools, 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. [35, 36]

The incubation period of the FMD virus is 2-14 days in cattle depending on the viral strain and dose and the level of susceptibility of the animal. [37] Morbidity in unvaccinated herds can be high but mortality usually does not exceed 5 percent. If it occurs during the calving season, calf mortality can be considerable. [38] Young calves may even die before the development of clinical signs usually because the virus attacks the heart muscles. [37]

The respiratory tract is the usual route of infection in species other than pigs. Infection can also occur through abrasions of the skin or mucous membranes. 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. Following initial replication in the pharynx, the virus then enters the bloodstream. Viremia in cattle lasts for 3 to 5 days, and, as a result, the virus spreads throughout the body and establishes sites of secondary infections. [39]

FMD virus localizes in various organs, tissues, body fluids, bone marrow, lymph nodes. [40, 41] Viral replication may reach peak levels as early as 2 to 3 days after exposure. [42, 43] Virus titers differ in different organs or tissues. Some tissues, such as the tongue epithelium, have particularly high titers. Recent data indicate that the most viral amplification occurs in the stratified, cornified squamous epithelia of the skin and mouth (including the tongue). 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. [42, 43]

Immunity to FMD is primarily mediated by circulating antibodies. [44] The host reaction, including antibody production, occurs from 3 to 4 days after exposure and usually clears the virus, except in carriers. In infected pigs, the virus is cleared in less than 3 to 4 weeks. In contrast, around 50% or more of cattle will develop a low-level persistent infection, localized to the pharynx. [45-47] According to Alexandersen (2002)[44], a model for progression of infection can be described as follows: first, virus exposure and accumulation of virus in the pharyngeal area is followed by initial spread through regional lymph nodes and via blood stream to epithelial cells. This is followed by several cycles of viral amplification and spread. [44]

Clinical signs in cattle during acute infection include fever, profuse salivation, and mucopurulent nasal discharge. 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. [37] The animal usually recovers by 14 days post infection provided no secondary infections occur. [39]

Diagnosis of the disease relies heavily on recognizing clinical signs. In unvaccinated cattle and pigs the clinical signs are obvious. However, in small ruminants the disease is often subclinical or is easily confused with other conditions. In addition, in endemic regions, clinical signs in partially immune cattle may be less obvious and could pass unnoticed. [37] Virus isolation and serotype identification are necessary for confirmatory diagnosis. The clinical signs of FMD are similar to those seen in other vesicular diseases. Differential diagnosis of vesicular diseases includes vesicular stomatitis, mucosal disease of cattle, bluetongue, rinderpest, and FMD. Serological diagnostic tests include the complement fixation test (CFT), virus neutralization test (VNT), and an ELISA test. Other diagnostic tests include one- or two-dimensional electrophoresis of the viral DNA, isoelectric focusing of the viral structural proteins, or nucleotide sequencing of the viral RNA. [36]

The FMD virus is relatively resilient. It can survive up to 15 weeks in feed, 4 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. 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 to be the primary factor for inactivation. [48] An acid environment where the pH is less than 6.0 will destroy the virus quickly. [48, 49] 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 and uncured and frozen meat. [41, 48-51] Heating at 50°C [31] and up to 155°F [52] will inactivate the virus.