



Risk Analysis: Foot-and-Mouth Disease (FMD) Risk from Importation of Fresh (Chilled or Frozen), Matured, Deboned Beef from a Region in Brazil into the United States

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LIST OF ABBREVIATIONS

- **APHIS:** Animal and Plant Health Inspection Service
- **BHK-21:** Baby hamster kidney-21 cell line
- **BSL:** Biosafety level
- **BSE:** Bovine spongiform encephalopathy
- **CFR:** U.S. Code of Federal Regulations
- **CONASAN:** National Committee for Animal Health
- **COSALFA:** South American Commission for the fight against FMD
- **CSF:** Classical swine fever
- **CVP:** Permanent veterinary committee
- **DDA:** Department of Animal Health
- **EITB:** Enzyme-linked immunoelectrotransfer blot
- **ELISA:** Enzyme-linked immunosorbent assay
- **ELISA 3ABC:** ELISA test for detecting FMDV nonstructural proteins 3ABC
- **END:** Exotic Newcastle disease
- **EU:** European Union
- **FMD:** Foot-and-mouth disease
- **FMDV:** Foot-and-mouth disease virus
- **GTA:** Animal movement permit
- **LVU:** Local veterinary unit
- **MAPA:** Ministry of Agriculture, Livestock and Food Supply
- **NEPA:** National Environmental Policy Act
- **NSP:** FMDV nonstructural proteins

- **OIE:** World Organization for Animal Health (formerly Office International des Epizooties)
- **PANAFTOSA:** Pan-American Foot-and-Mouth Disease Center
- **PHEFA:** Hemispheric plan for eradication of FMD
- **Probang:** Test for identifying the FMDV in esophageal-pharyngeal fluid
- **SDA:** State Department of Agriculture
- **SIF:** Federally inspected plant
- **SISBOV:** National identification system
- **TB:** Tuberculosis
- **TSE:** Transmissible spongiform encephalopathies
- **U.S.:** United States
- **USDA:** United States Department of Agriculture
- **VIAA:** Virus infection-associated antigen test
- **VS:** Veterinary Services, Animal and Plant Health Inspection Service

Figure 1: Map of Brazil and list of States with their respective acronyms



Acre	AC	Paraíba	PB
Alagoas	AL	Pará	PA
Amapá	AP	Pernambuco	PE
Amazonas	AM	Piauí	PI
Bahia	BA	Rio Grande do Norte	RN
Ceará	CE	Rio Grande do Sul	RS
Distrito Federal	DF	Rio de Janeiro	RJ
Espírito Santo	ES	Rondônia	RO
Goiás	GO	Roraima	RR
Maranhão	MA	Santa Catarina	SC
Mato Grosso	MT	Sergipe	SE
Mato Grosso do Sul	MS	São Paulo	SP
Minas Gerais	MG	Tocantins	TO
Paraná	PR		

EXECUTIVE SUMMARY

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) conducted a risk analysis as a decision-making tool for a proposal to initiate trade in fresh (chilled or frozen), matured, deboned beef from a designated region in Brazil (hereafter referred to as “the export region”). Trade in beef from Brazil has not been allowed because USDA considers Brazil to be a country affected with foot-and-mouth-disease (FMD).

The analysis considers the epidemiological characteristics of FMD that are relevant to the risk of importing beef from the export region and describes mitigations appropriate to reduce that risk. The mitigations under consideration included restrictions on the origin of animals, requirements for maturation and pH testing of carcasses, ante-mortem and post-mortem inspections, and verification by Brazilian officials that the various mitigations were applied appropriately.

APHIS gathered information and data to support this analysis from records of the Ministry of Agriculture, Livestock and Food Supply (MAPA) and from published scientific literature. In addition, APHIS conducted four site visits to Brazil to evaluate Brazil’s animal health infrastructure for FMD eradication and control measures and to verify and complement the gathered information.

Summary of results and conclusions

Release Assessment

APHIS concluded that the surveillance, prevention, and control measures implemented by Brazil are sufficient to minimize the risk of introducing FMD into the United States for the purpose of beef imports, provided that additional mitigation measures are implemented as described.

Exposure Assessment

APHIS considers that the likelihood of exposure of FMD-susceptible species to FMD-infected beef is low. In a 1995 study [1], APHIS estimated that only a small fraction (0.023 percent) of plate and manufacturing waste would be fed to swine while inadequately processed. This is a reduction of three orders of magnitude in the risk at the release level. Additionally, a 2001 study demonstrated that the proportion of plate and manufacturing waste fed to swine declined by about 50 percent between 1994 and 2001 due to a decrease in the number of waste-feeding premises [27].

Consequence Assessment

The consequences of an FMD outbreak in the U.S. would be extremely high. In a 2008 study that modeled the economic impact and disease-spread effects from an hypothetical outbreak of FMD arising from feeding garbage in small farrow-to-finish operations, the total trade losses plus other disease-related costs to capital and management, amounted to between \$2,773 million and \$4,062 million when compared with a disease-free baseline period from 2001 to 2004 [43]. Depending on the magnitude of the outbreak and the eradication strategy, the sum of the consumer impacts, direct costs and trade losses over a 25-year period, would be between US\$37 billion to US\$42 billion (in 2011 dollars) [2, 3].

Risk Estimation

Although the consequences of an 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 beef 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. Furthermore, APHIS concludes that the proposed mitigations are sufficient to initiate trade in fresh (chilled or frozen), matured, deboned beef from the designated region in Brazil. This risk analysis provides the rationale for the above conclusions, based both on the World Organization for Animal Health (OIE) risk analysis criteria and on evaluation of the 11 risk factors that APHIS has defined for evaluating regionalization requests for a region.

I. BACKGROUND

Brazil has officially requested that the Animal and Plant Health Inspection Service (APHIS) allow the importation of fresh (chilled or frozen), matured, deboned beef into the United States from a designated region in Brazil. Given the history of the disease in Brazil and the fact that Brazil vaccinates its cattle population in most States against FMD, APHIS conducted this risk analysis to evaluate the likelihood of FMD introduction and establishment through importation of beef from Brazil. The region under consideration by APHIS (hereafter referred to as the export region) includes the States of Bahia (BA), Distrito Federal (DF), Espírito Santo (ES), Goiás (GO), Mato Grosso (MT), Mato Grosso do Sul (MS), Minas Gerais (MG), Paraná (PR), Rio Grande do Sul (RS), Rio de Janeiro (RJ), Rondônia (RO), São Paulo (SP), Sergipe (SE), and Tocantins (TO) (Figure 1). Consistent with the approach taken by APHIS in the past for evaluating the risk of FMD in beef and ovine meat, the mitigations considered in this assessment include:

1. Beef imported from Brazil will be deboned beef (excluding bovine heads, feet, hump, hooves, and internal organs) from carcasses that are matured for 24 hours at a temperature between 4 and 10°C.
2. Beef will originate from animals in herds certified by governmental veterinary officials to have been born, raised, and slaughtered in the export region.
3. All animals must pass both ante- and post-mortem inspections.
4. All carcasses must be pH tested in the loin muscle and the pH must be less than 6.0.

Data and background information were obtained from Brazilian animal health officials. Much of the supporting information for this analysis consists of records of the Ministry of Agriculture, Livestock and Food Supply (MAPA). In addition, APHIS conducted five site visits to Brazil in 2002, 2003, 2006, 2008, and 2013 to verify and complement the information provided by Brazil. The scope of the 2002 site visit included verification of FMD outbreak controls, an overview of the surveillance program and laboratory capabilities, vaccination practices and eradication activities, and movement and border controls. Particular focus was placed on the regional FMD situation in Brazil and South America and on the risk of reintroducing FMD into Brazil from neighboring countries. The focus of the 2003 site visit was to collect data that APHIS used in its risk assessment. The focus of the 2006 site visit was to evaluate the FMD situation following the 2005-2006 outbreak. The focus of the 2008 visit was to evaluate the Brazilian State of Santa Catarina for freedom from classical swine fever (CSF), FMD, African swine fever (ASF), and swine vesicular disease (SVD). The scope of the 2013 visit included the evaluation of the FMD diagnostic capabilities, FMD laboratories and vesicular disease emergency response.

II. OBJECTIVE

This analysis is being conducted to assess the risk of initiating trade in fresh (chilled or frozen), matured, deboned beef from a designated region in Brazil to the United States. The analysis is used as a decision-making tool for a proposal to allow such trade. It will assess the likelihood that FMD infected beef would enter the United States from the export region and expose U.S. livestock by the most likely pathway, that is, through feeding of infected waste to susceptible animals. In addition, it includes a description of risk factors associated with FMD in Brazil as well as applicable mitigations.

It should be noted that title 9, *Code of Federal Regulations* (CFR), Part 94.1, prohibits the importation of meat from any region in which rinderpest exists, and Brazil is not currently recognized as free of rinderpest in the CFR. Rinderpest virus has never become established in North America, Central America, the Caribbean Islands, or South America. A brief incursion into Brazil occurred in 1921, but was limited in scope and quickly eradicated.

III. HAZARD IDENTIFICATION

Hazard identification, defined by the OIE) [4] as “... identifying the pathogenic agent which could potentially produce adverse consequences associated with the importation of a commodity,” is a critical component of an import risk analysis.

The hazard identified is the FMD virus (FMDV). This risk analysis considers the risk of introducing FMDV into the United States through importation of fresh (chilled or frozen), maturated, deboned beef from a region in Brazil. Epidemiological characteristics of the agent relevant to the import risk it might pose are described in Appendix I.

IV. RISK ASSESSMENT

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 are international recommended components for animal health import risk assessment [4].

A. RELEASE ASSESSMENT

Release assessment is a description of the biological pathway(s) necessary for an importation activity to introduce pathogenic agents into a particular environment, with an estimate of the likelihood of that complete process [4].

This analysis includes an evaluation of information provided by Brazil’s Department of Animal Health (DDA) relevant to the 11 factors used by APHIS to evaluate the animal health status of a region prior to 2012 (title 9, *Code of Federal Regulations* (CFR), section 92.2) [5]. . In 2012, APHIS consolidated the eleven factors listed in 9 C.F.R. § 92.2(b) into eight factors. APHIS introduced this simplification in order to facilitate the application process; however, since the evaluation of this region of Brazil started before 2012, and the topics addressed by the 11 factors are encapsulated in the eight, this report follows the 11 factor format. Appendix II describes the similarities between the eight and 11 factors. Observations and information collected during the site visits were considered as well.

Evaluation of information provided by Brazil relevant to the 11 factors (9 CFR 92.2) [5]

Assessing the likelihood of introducing FMD into the United States requires an evaluation of relevant characteristics of the exporting regions in relation to the epidemiology of the disease. In that regard, APHIS describes 11 factors in its regionalization rule (9 CFR 92.2) that provide a context for evaluating the risk of exporting a foreign animal disease from a defined region into the United States [5]. This part describes APHIS' evaluation of these factors for a designated region in Brazil consisting of the States of Bahia, Distrito Federal, Espírito Santo, Goiás, Mato Grosso, Mato Grosso do Sul, Minas Gerais, Paraná, Rio Grande do Sul, Rio de Janeiro, Rondônia, São Paulo, Sergipe, and Tocantins.

1. Authority, organization and infrastructure

General information

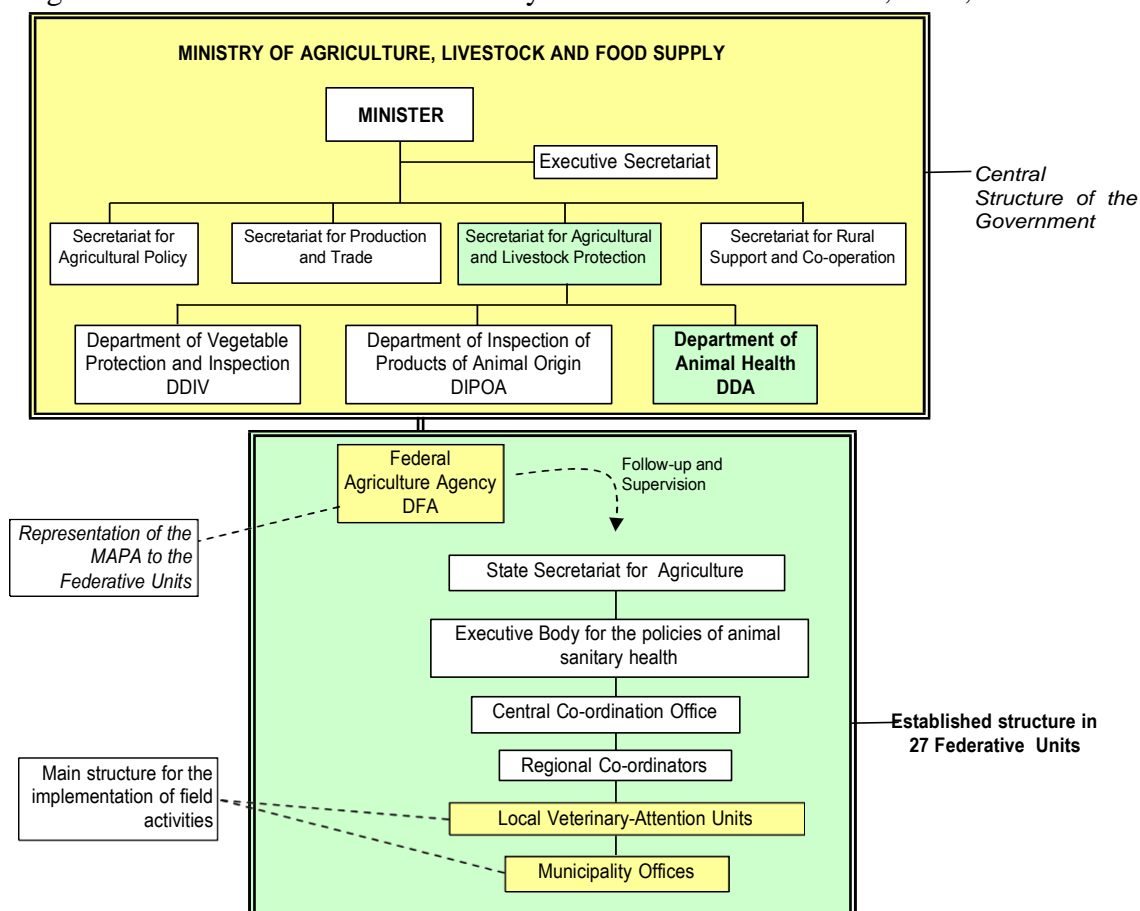
The two main structures for veterinary services in Brazil are the Federal and States authorities. The Department of Animal Health (DDA), which is a unit in the Ministry of Agriculture, Livestock and Food Supply (MAPA), is the main authority for all animal health programs in the country. The MAPA has regional offices in the 26 States in Brazil plus the central offices in the Federal District. A Federal veterinarian is resident in each regional office and is responsible for coordinating all official animal health activities at the State level [6, 7].

Field activities are coordinated through the State Agricultural Secretariat offices. The field structure of the veterinary services in the country consists of 1,419 Local Veterinary Units (LVUs); 3,097 municipal offices; 1,857 veterinarians; and 7,764 technical and administrative assistants and support personnel. At the Federal level, the veterinary service workforce consists of 870 veterinarians and 1,860 technical and administrative assistants [8]. Figure 2 shows the organizational structure of the veterinary service in Brazil [9].

Federal and State interactions are defined and structured. State personnel are responsible for executing Federal programs, laws, and policies at the State level. Responsibilities of State officials for carrying out Federal programs are outlined in standard operating procedures developed in cooperation with Federal officials, and are applicable to defined regions and reflect local circumstances. On November 11, 1999, a law was published authorizing the States to develop the guidelines for animal health programs. Each State has its own regulations but the regulations must complement existing Federal laws [6-8].

The main law that defines veterinary medicine in Brazil is Law 5517. This law established the Federal and regional veterinary medicine councils that govern activities and professional aspects of the profession. Currently, 47,856 veterinarians practice the profession in Brazil with the majority being in the Southeast (47 percent) and South (23 percent) of the country. Veterinarians of the official services are required to participate in specific training programs with respect to different sanitary programs. A total of 505 veterinarians have been trained specifically in exotic animal diseases, including FMD [10].

Figure 2: Organizational structure of the veterinary services in Brazil: Federal, State, and local levels



Source: Adapted from "Expansion of foot and mouth disease free zone with vaccination, State of Rondonia – Brazil 2002" by the Department of Animal Health, Surveillance and Health Programs.

Functions of the Federal Government include coordination and supervision of the overall animal health programs, development of disease control strategies, regulation and control of international commerce in animals and animal products, registration and control of vaccines, laboratory diagnosis, auditing of State veterinary services, inspection of animals and animal products being imported, and training. Generally speaking, the Federal government officials, located primarily in Brasilia, develop policies, laws, and regulations that govern all animal health programs and activities [7].

Programs managed by the Federal authorities include FMD eradication, swine health (especially CSF), tuberculosis and brucellosis, transmissible spongiform encephalopathy surveillance, biological residue control, and traceability. Federal staff of the National FMD Eradication program cooperate closely with State personnel. In this regard, they travel regularly to the Ministry's offices in each State and to the field offices of the State Secretariats of Agriculture in the field to evaluate programs at the local level [7].

State activities are designed to implement the Federal program. Cooperation is achieved by renewal of signed cooperative agreements, which transfer considerable amounts of funding from the Federal budget to State agencies. The Federal program has ultimate authority over conduct of the national eradication program. It uses its authority to allocate financial resources to ensure compliance with

Federal program policy. It provides oversight to ensure that there will be effective financial management of the resources provided. FMD, CSF, and exotic Newcastle disease (END) are the highest priority diseases in Brazil [7].

Veterinary programs are implemented by LVUs. These are field offices with authority over a defined region consisting of one or more municipalities [8]. For example, the LVU in Tocantinópolis covers four municipalities with an area of 2500 km² and contains 1048 rural properties and 64,408 cattle. The LVU at Colinas also covers four counties, but the LVU area is 4000 km² and has 274,000 head of cattle [7]. The LVUs are staffed by veterinarians, animal health technicians, and administrative personnel. LVU report to regional and then State level offices, which ultimately report to and coordinate with the national program in Brasília. Some LVUs are co-located with the regional office, which provides administrative support to other LVUs. However, most LVUs exist as units separate from the regional office [8].

Representative State activities administered by LVU personnel include registration of properties, collection and tracking of census data, monitoring of vaccination and control of vaccine distribution, animal and animal product movement control, reporting of suspicious cases, monitoring and eradication of outbreaks, surveillance activities, monitoring of local animal gathering events (e.g., fairs, expositions, auctions), clinical investigations and sampling, and local training and outreach [7, 8].

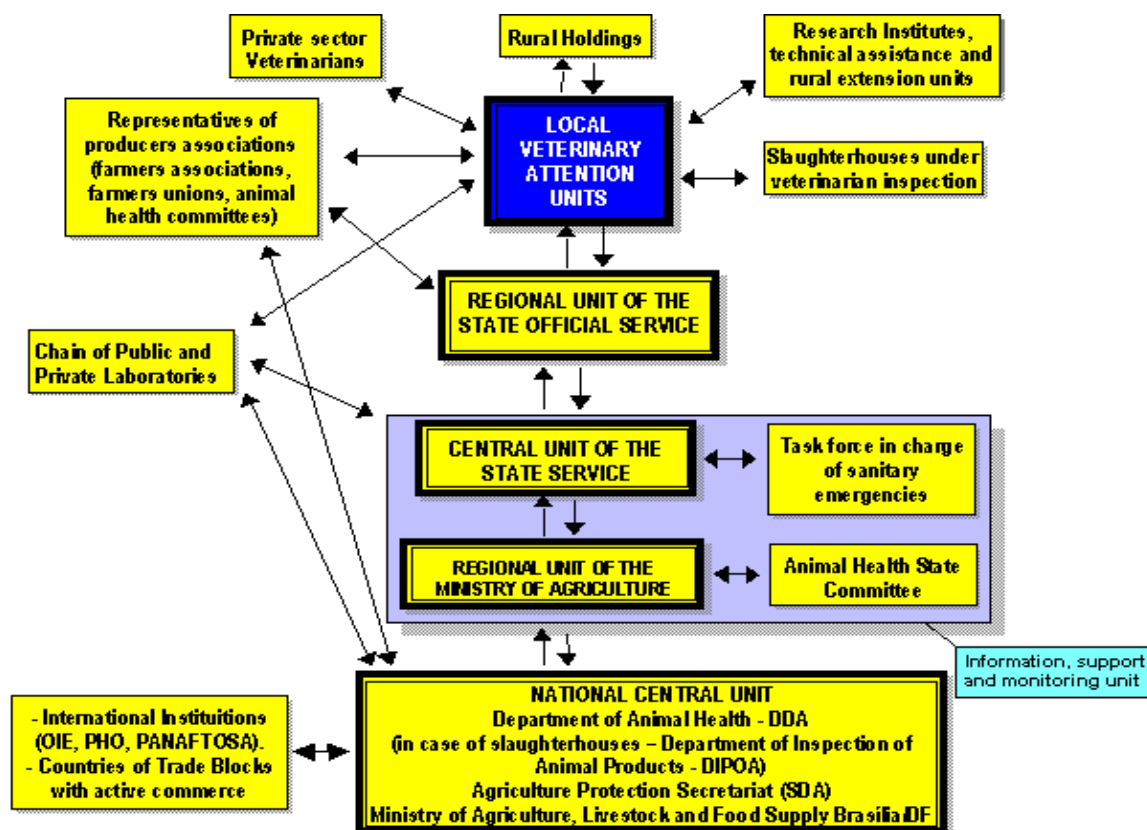
While administering disease programs, LVU personnel collect and receive epidemiological data from various sources within their area. Information is communicated through regional and State offices to the central authorities in Brasília in the form of weekly, monthly, semiannual, and annual reports [7]. In case of observations consistent with FMD, notification is mandatory and immediate. In addition, information exchange and data flow among Federal-State-private sectors is evident. In this regard, weekly and monthly reports are prepared by local and regional offices and are shared among the three sectors [7, 8]. Interaction among local, regional, State, Federal authorities and other private and international organizations is structured and effective (Figure 3).

Veterinary control and infrastructure in Brazil are highly dependent on close interaction between Federal and State offices. Federal and State functions are supported strongly by producer groups. In fact, this interaction with producers is defined in regulation and considered by Brazilian officials to be a significant factor in the control of FMD [6, 8]. For example, in the State of Pará, producer groups actively sponsor field days that provide animal disease training programs for the private sector. Included in these training activities may be lectures and seminars by university faculty members. The training is directed toward producing an educated public that would be able to recognize disease symptoms and deal with animal health issues. Moreover, there is strong commitment by the private sector for general animal health activities as well as FMD eradication and traceability (ID system) systems. This support is demonstrated by substantial financial contributions by the private sector [6, 8].

At the international level, Brazil signed an agreement in 2003 to form a Permanent Veterinary Committee (Comite Veterinaria Permanente – CVP) composed of the four Mercosur countries (Argentina, Brazil, Paraguay, and Uruguay) as well as Bolivia and Chile. This committee is working to improve international relations and collaboration on disease eradication activities. Some of the

committee's objectives include (1) meeting OIE criteria for the region as “free of FMD with vaccination”, (2) evaluating the region periodically for the possibility of declaring it free of FMD without vaccination, and (3) preventing the introduction of BSE into the region [7].

Figure 3: Major links and relationships of the Brazilian veterinary services



Source: MAPA, “Enlargement of the foot-and-mouth disease free zone, where vaccination is practiced – Midwestern and Eastern livestock circuits,” Brazil 2000.

During its site visits to Brazil in 2002, 2003, 2008, and 2013 APHIS received overviews of the activities and structures of the Federal, State and local level activities. APHIS reviewed premises registration, census information, vaccination records, and movement control documents, and visited farms in the export region to observe farming practices. APHIS visited several LVUs located in the northwestern section which served the border between domestic zones that were free with vaccination and affected regions. The offices were in Colinas de Tocantins and Tocantinópolis in the State of Tocantins; Redenção in the State of Pará; and Guajará Mirim, Ji-Paraná, and Vilhena in the State of Rondonia. In addition, APHIS visited LVU in Tangará da Serra and Cáceres in Mato Grosso; Ponta Porã and Nova Andradina in Mato Grosso do Sul; and Alegrete, and Bagé in the State of Rio Grande do Sul. Some LVU were co-located within the regional offices. During the 2008 site visit to the State of Santa Catarina, the regional office in Chapeco was visited, along with two LVUs located within this region: Xanxerê and Seara. APHIS also visited Federal and State offices in the above States. Observations indicated that the structure, effectiveness, and organization of the LVU in the different regions were generally consistent [7].

Indemnity procedures

An indemnity program in Brazil is required by law. The main indemnity procedures are based on Law 569 of December 21, 1948, which establishes measures to safeguard public health or for the purpose of sanitary protection of animals. The Federal government pays indemnity for (1) animals sacrificed due to the presence of FMD or any other exotic disease, (2) all susceptible animals that had the disease, and (3) all susceptible animals that had contact with affected animals. Financial resources for payments are available from the Federal government and from private indemnity funds created and administrated by producers. Federal funds come from the national treasury and are used to complement indemnity funds administrated by producers [11].

The producers' private indemnity fund in various Brazilian States consists of fees paid by producers and slaughter establishment officials for authorization to move and slaughter animals. Private indemnity funds have been set up in seven States in the export region. In the other States, there are contingent funds from State governments for use in possible sanitary emergency actions [7, 11]. For example, total private resources available in eradication funds in the export region were US\$9.0 million at the end of 2002. In the affected zone, the private fund, set up in the States of Acre and Pará, totaled US\$319,300 at the end of 2002 [11]. MAPA reported that in all animal sanitary emergency activities carried out in Brazil, owners have been duly compensated.

In the States that make up the export region, animal health emergency groups were created and appointed through specific legal acts. A group consisting of representatives from the Federal and State Animal Health Services, a private sector representative and a representative of the owner evaluates and documents all indemnity procedures. Brazilian laws require that records of the entire indemnity process be kept, with the documentation being available for auditing in the involved States [11].

Garbage control/swill feeding

Swill feeding to swine is prohibited in all regions of Brazil by Administrative Decree 201 of May 1998 [10].

International airport

At the international airport in Sao Paolo, officials informed APHIS that all waste collected from planes and other confiscated products from passengers are incinerated onsite (See section 7 for details). A quasi-governmental company handles this procedure. A similar setup exists at the Santos port in Sao Paolo. The waste is packed in containers sealed by a government officials and is transported for incineration at another location (70 km). A document trail ensures that the waste is being incinerated [7].

Wildlife

Brazilian officials argue that wildlife populations do not constitute a risk factor for spreading FMD to domestic species. They indicated that wildlife had never been documented as a risk factor for FMD in Brazil. APHIS visited a small farm located adjacent to an Indian reservation in

Tocantinópolis. The farmer expressed concern over the risk of disease transmission from wildlife resident on the reservation. This farmer perceives an increased disease risk due to the presence of a 168,000 hectares reservation next to his farm. He has observed deer, wild pig, large cats and emu near his premises [7]. However, APHIS does not have any evidence available to suggest or substantiate the claim that FMD may exist in wildlife in Brazil.

According to Brazilian Federal and State officials, the experience in South America in controlling and eradicating FMD has demonstrated that the participation of wild animals in the epidemiology of FMD can be considered irrelevant. During outbreak situations, wildlife may become affected by FMD; however, the likelihood that they would become carriers under field conditions is rare. Over the course of many years of combating the disease in Brazil, no consistent relationship between outbreaks of the disease in domestic animals and coexistence of susceptible wild animals has ever been confirmed. The reintroductions of the disease in Argentina and Uruguay, as well as in the State of Rio Grande do Sul, involved only cattle and small number of sheep. These observations reinforced to officials the reduced role represented by wild animals in maintaining or disseminating FMD in South America [11].

Another important piece of information that reinforces this hypothesis is the results of successive serological surveys that have been conducted to investigate viral activity in Brazil including regions where wild animals are in contact with domestic species. These studies have focused on cattle as the most susceptible species, and mainly involve animals in the age groups with highest probability of infections (i.e., cattle between 7 and 24 months old). Results of the surveys have not revealed evidence of viral activity in domestic ruminants that are likely to contact wild animals. If wild animals were carriers or reservoirs of FMD, evidence of viral activity would be expected in domestic species coexisting in the same regions as infected wild animals. The serological surveys are described in further detail under Factor 9 Disease Surveillance.

An example of regions where wild and domestic animals might be in contact would be the Pantanal swampland region in western Brazil, where there is close interaction between wild animals and ruminants. However, no viral activity was detected in ruminants from that region. This observation provides inferential evidence that there is no viral activity in wild animals [11].

Conclusions

MAPA, Brazil's agriculture ministry, has sufficient legal authority to carry out official control, eradication, and quarantine activities. MAPA has a system of official veterinarians and support staff in place for carrying out field programs and for import controls and animal quarantine. Review of veterinary infrastructure with MAPA officials demonstrated an infrastructure adequate for rapid detection of FMD and for carrying out surveillance and eradication programs. The technical infrastructure is adequate, and advanced technologies are utilized in conducting several animal health programs. Import controls are sufficient to protect international borders at principal crossing points. APHIS concluded that sufficient controls exist to prevent the introduction of international waste into the country.

LVU offices appeared to be adequately staffed for the regions covered. Assuming that the offices visited are representative of LVU existing throughout the country, the local contacts, coverage, and

control mechanisms are strong. LVU functions observed in relatively high risk regions demonstrated close contact with individual premises in the regions and strong local controls. Generally, APHIS was favorably impressed with the census information, coverage of premises in the export region, the record-keeping for individual premises, the control of vaccination, and the movement controls documented at the local level in each of these offices. In addition, LVU personnel appeared to be adequately trained in or to have had some experience with clinical signs of FMD. It is expected that they would suspect FMD if they were to see it.

With regard to indemnity procedures, APHIS concluded that sufficient funds may be available to compensate owners for sacrificed animals. In addition, indemnity provisions can be extended to exposed and in contact animals. Livestock producers and other industry groups contribute to and administer private compensation funds, which show the level of commitment and participation of the industry in FMD program activities. Theoretically, availability of indemnity provisions should encourage reporting of the disease and may complement the detection efforts that are carried out by official veterinary services.

2. Disease status in the export region

General information

The export region is located in the southern and central portion of Brazil and is considered by the OIE to be FMD free with vaccination. Of the States in the export region, the last outbreaks of FMD have occurred in Rio Grande do Sul (2000/2001), and Paraná and Mato Grosso do Sul (2005/2006).

Rio Grande do Sul

In 2000, the year that vaccination ended in Rio Grande do Sul, an FMD outbreak occurred in that State. FMD was not detected in Santa Catarina. The Rio Grande do Sul outbreak affected 22 premises in four neighboring municipalities in the northwestern region of the State. The disease was eliminated by stamping out. The eradication program involved the destruction of 11,017 animals (8,185 bovines, 2,106 swine, 722 ovines, and 4 caprines). In addition, officials imposed strict movement controls and biosecurity measures [6, 9, 11, 12]. The disease was linked to a Type O1 FMD outbreak in Argentina that occurred in 2000. Transit of infected cattle in the border region between Argentina, Brazil, and Uruguay was implicated as the pathway of introduction. At that time, vaccination against FMD remained suspended in Rio Grande do Sul [9, 13].

In 2001, another outbreak occurred in Rio Grande do Sul affecting 30 premises in six different municipalities. In this outbreak, in addition to implementing a stamping-out program, officials carried out emergency vaccination for all cattle in the State. A total of 2,348 farms were quarantined and 32,408 animals were slaughtered. No direct epidemiological relationships between the six affected municipalities were identified. Investigation results suggested that the six outbreaks resulted from independent re-introductions, all coming from Uruguay. Direct epidemiological relationships were established between the owner of an affected herd in one municipality and producers in Uruguay. The observation that the first occurrence of disease was farther away from the border than

subsequent occurrences was significant because the owner of the affected herd had been in Uruguay a few days before the outbreak erupted in his herd.

No direct relationship was identified between the outbreaks in the six municipalities and the outbreaks in Argentina since the virus in Argentina was type O and the virus in Uruguay was classified as type A [12]. At that time, vaccination against FMD was reinstated throughout Rio Grande do Sul [9, 13].

Mato Grosso do Sul (2005-2006)

On September 30, 2005, a private veterinarian reported to the local office of the municipality of El Dorado, South of Mato Grosso do Sul clinical signs compatible with FMD at a cattle breeding farm. Subsequent to the report of clinical suspicion of the disease, and prior to confirmation, a number of preliminary FMD control measures were put in place including quarantine, interdiction, and initiation of an epidemiological investigation. Biomolecular characterization and phylogenetic analysis of the samples confirmed FMD type O. Notification of the suspicion was indicated in the SIVCONT (Continental System of Information) and transmitted to the Pan American Foot-and-Mouth Disease Center (PANAFTOSA). The confirmation of the outbreak was immediately communicated to trading partners on October 9, 2005. Cattle were the only affected species.

After FMD was confirmed, the state of Mato Grosso do Sul declared the sanitary emergency banning the movement of FMD susceptible animals, as well as their products and by-products originating within El Dorado and adjacent municipalities. The interdiction of five municipalities (Eldorado, Iguatemi, Itaquiraí, Japorã and Mundo Novo) in the State of Mato Grosso do Sul was reinforced by means of the Official Circular DSA, # 70, of 10.9.2005. Epidemiological and surveillance activities within the State led to the detection of further outbreaks in the municipalities of Japorã, El Dorado, and Mondo Novo (Table 1). As seen on Table 1, the average time between reporting of suspicious disease to the local veterinary unit and visit of the official veterinarian to the farm was estimated to be 24 hours for all the reported outbreaks. For most of the farms the lesions were considered to be around 5 days old (range from 1 to 13 days old). Table 1 also shows the date of notification.

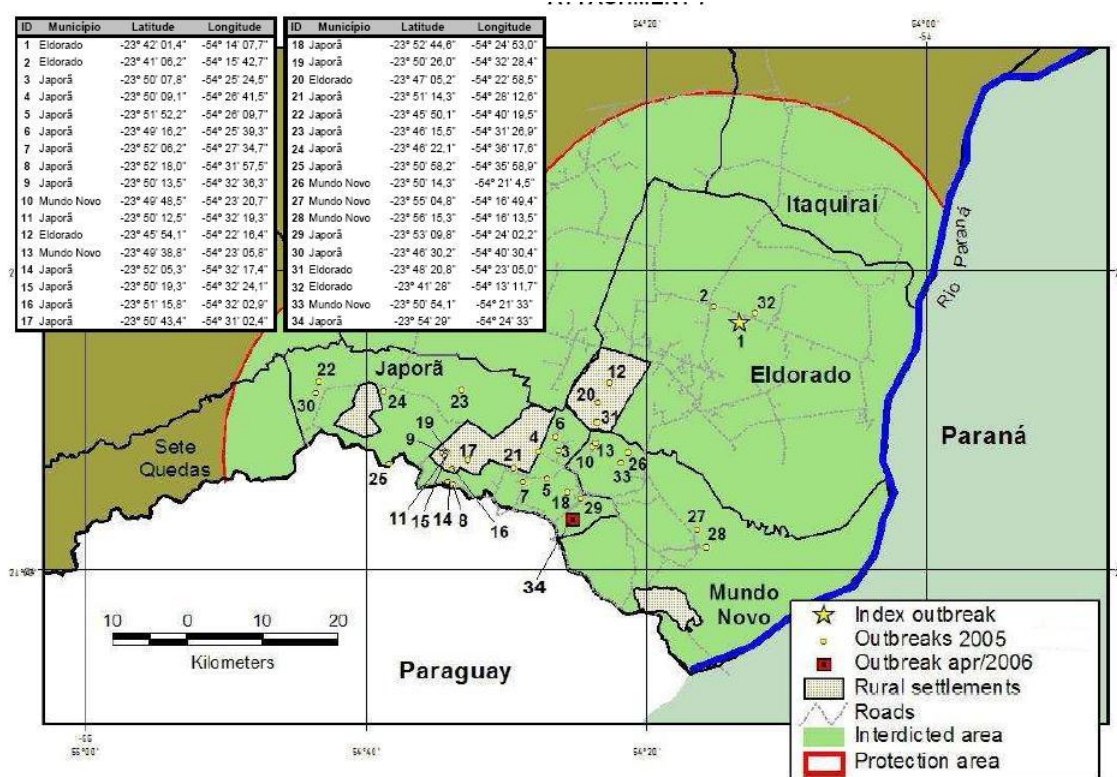
Table 1: Outbreaks registered in Mato Grosso do Sul

ID	City	Property	DIAG	Latitude	Longitude	Notification	Attended on	Probable Start	Reported by
1	Eldorado	Faz Vezozzo	LAB	-23° 42' 01,4"	-54° 14' 07,7"	30-sep	1-oct	26-sep	Owner
2	Eldorado	Faz Jangada	LAB	-23° 41' 06,2"	-54° 15' 42,7"	10-oct	10-oct	5-oct	Inspection
3	Japorã	Sítio São Antônio	LAB	-23° 50' 07,8"	-54° 25' 24,5"	10-oct	10-oct	5-oct	Inspection
4	Japorã	Sítio São Benedito	LAB	-23° 50' 09,1"	-54° 25' 41,5"	11-oct	11-oct	5-oct	Inspection
5	Japorã	Faz Guatira	LAB	-23° 51' 52,2"	-54° 26' 09,7"	11-oct	11-oct	1-oct	Inspection
6	Japorã	Faz Guatambu	LAB	-23° 49' 16,2"	-54° 25' 39,3"	14-oct	14-oct	13-oct	Inspection
7	Japorã	Sítio Boa Vista	LAB	-23° 52' 06,2"	-54° 27' 34,7"	13-oct	14-oct	3-oct	Inspection
8	Japorã	Sítio São Benedito(2)	LAB	-23° 52' 18,0"	-54° 31' 57,5"	17-oct	17-oct	17-oct	Inspection
9	Japorã	PA R Nunes L 199	CITEpi	-23° 50' 13,5"	-54° 32' 36,3"	17-oct	17-oct	17-oct	Inspection
10	Mundo Novo	Fazenda Gazim	LAB	-23° 49' 48,5"	-54° 23' 20,7"	18-oct	18-oct	16-oct	Owner
11	Japorã	Lote 205 PA Savana	LAB	-23° 50' 12,5"	-54° 32' 19,3"	18-oct	18-oct	17-oct	Inspection
12	Eldorado	Floresta Branca Lt 75	LAB	-23° 45' 54,1"	-54° 22' 16,4"	18-oct	19-oct	12-oct	Owner
13	Mundo Novo	Lote 188 Gleba 4	LAB	-23° 49' 38,8"	-54° 23' 05,8"	19-oct	19-oct	19-oct	Inspection
14	Japorã	Faz Fronteira	CITEpi	-23° 52' 05,3"	-54° 32' 17,4"	21-oct	21-oct	20-oct	Owner
15	Japorã	PA R Nunes L 206	LAB	-23° 50' 19,3"	-54° 32' 24,1"	22-oct	22-oct	21-oct	Inspection
16	Japorã	Lote 135 PA Savana	LAB	-23° 51' 15,8"	-54° 32' 02,9"	22-oct	23-oct	21-oct	Inspection
17	Japorã	Lote 120 PA Savana	CITEpi	-23° 50' 43,4"	-54° 31' 02,4"	22-oct	23-oct	21-oct	Third-parties
18	Japorã	Sítio Boa Esperança	LAB	-23° 52' 44,6"	-54° 24' 53,0"	24-oct	26-oct	24-oct	Inspection
19	Japorã	Lote 207 PA Savana	LAB	-23° 50' 26,0"	-54° 32' 28,4"	26-oct	26-oct	26-oct	Owner
20	Eldorado	Floresta Branca Lt 165	LAB	-23° 47' 05,2"	-54° 22' 58,5"	27-oct	27-oct	24-oct	Owner
21	Japorã	Lote 71 PA Savana	CITEpi	-23° 51' 14,3"	-54° 28' 12,6"	27-oct	27-oct	27-oct	Owner
22	Japorã	Fazenda Princesa do Sul	CITEpi	-23° 45' 50,1"	-54° 40' 19,5"	1-nov	1-nov	31-oct	Owner
23	Japorã	Faz Remanso Guapu	CITEpi	-23° 46' 15,5"	-54° 31' 26,9"	7-nov	7-nov	3-nov	Owner
24	Japorã	Aldeia Porto Lindo	LAB	-23° 46' 22,1"	-54° 35' 17,6"	10-nov	10-nov	1-nov	Inspection
25	Japorã	Fazenda Itaipu	CITEpi	-23° 50' 58,2"	-54° 35' 58,9"	14-nov	14-nov	6-nov	Inspection
26	Mundo Novo	Fazenda NG	CITEpi	-23° 50' 14,3"	-54° 21' 4,5"	15-nov	15-nov	10-nov	Inspection
27	Mundo Novo	Chácara São Benedito	CITEpi	-23° 55' 04,8"	-54° 16' 49,4"	18-nov	18-nov	13-nov	Inspection
28	Mundo Novo	Chácara Monte Castelo	CITEpi	-23° 56' 15,3"	-54° 16' 13,5"	16-nov	18-nov	11-nov	Inspection
29	Japorã	Sítio São José	CITEpi	-23° 53' 09,8"	-54° 24' 02,2"	20-nov	20-nov	19-nov	Inspection
30	Japorã	Faz N. S. Aparecida	CITEpi	-23° 46' 30,2"	-54° 40' 30,4"	22-nov	22-nov	21-nov	Owner
31	Eldorado	Floresta Branca Lt 147	CITEpi	-23° 48' 20,8"	-54° 23' 05,0"	23-nov	24-nov	19-nov	Owner
32	Eldorado	Faz Bonanza	LAB	-23° 41' 28"	-54° 13' 11,7"	22-oct	24-oct		Inspection
33	Mundo Novo	Faz Boa Esperança	LAB	-23° 50' 54,1"	-54° 21' 33"	26-nov	27-nov	24-nov	Inspection
34	Japorã	Sítio Medianeira III	LAB	-23° 54' 29"	-54° 24' 33"	12-Abr	12-Abr	30-Mar	Inspection

Source: MAPA, "Information about the occurrence of foot-and-mouth disease in Brazil," Table 3-2006, page 5 of 22. [14]

On April 12, 2006, during inspection by official services, animals presenting signs compatible with FMD were identified in a property within the area interdicted in September 2005. Although no virus was isolated, the animals tested positive to antibodies against nonstructural proteins by enzyme-linked immunotransfer block (EITB). All susceptible species in such property (141 bovines) as well as all susceptible animals in adjacent properties (376 bovine, 71 swine, and 3 caprine) were destroyed. By August 2006, a total of 34 outbreaks were identified. As a result of the outbreaks a total of 33,741 susceptible animals were destroyed. Figure 4 shows the geographic location of the outbreaks. The site visit team that visited Brazil in September 2006 observed that the area where the outbreaks occurred is in the close proximity with the Paraguayan border; in fact, the Brazilian authorities stated that some of the farms within the border area between Brazil and Paraguay were not only owned by the same people but also shared personnel, equipment and other common resources. The APHIS team noted that a large area of the border between Brazil and Paraguay is a dirt road no wider than 50 meters. The border can be easily crossed on foot.

Figure 4: Outbreaks registered in the State of Mato Grosso do Sul



Source: MAPA, "Information about the occurrence of foot-and-mouth disease in Brazil," Attachment 7-2006, page 20 of 22 [14].

On April 18, in accordance with OIE (Appendix 3.8.1. Guidelines for FMD surveillance) sentinel animals (cattle 6 to 12 months, unvaccinated, and negative for FMD structural proteins) were introduced in the municipalities of Eldorado and Mundo Novo. In Japorã the introduction of sentinels started on April 28. The distribution of sentinel animals is described on table 2.

Table 2: Distribution of sentinel animals in the State of Mato Grosso do Sul (2006)

City	Number of groups	Number of Animals	Number of Owners/Properties
Eldorado	7	182	53
Mundo Novo	7	134	11
Japorã	34	1142	402
Total	48	1458	466

Source: MAPA, "Information about the occurrence of foot-and-mouth disease in Brazil," Table 2-2006, page 5 of 22 [14].

The municipalities of Eldorado, Mundo Novo, and Japorã, were repopulated after the sentinel animals tested negative for enzyme-linked immunosorbent assay (ELISA) 3ABC/EITB, showing absence of viral circulation.

Paraná (2005-2006)

On October 21, 2005, Brazilian authorities reported the occurrence of FMD in the State of Paraná. The outbreak was immediately reported to OIE. As a result, the affected properties, as well as those located within the 10-km radius were immediately interdicted. Paraná reported a total of 11 outbreaks (two outbreaks in Maringá, one in Grandes Rios, four in Loanda, and two in Amaporã).

Table 3: Identification and location of the properties showing clinical signs of vesicular disease

ID	City	Property	DIAG	Latitude	Longitude	Serviced on
1	Amaporã	Faz São Luiz	CI/Epi	-23° 06' 16,8"	-52° 52' 04,3"	18/10/05
2	Grandes Rios	Faz Santa Izabel	CI/Epi	-24° 11' 04,6"	-51° 20' 38,1"	18/10/05
3	Loanda	Faz Santa Maria	CI/Epi	-22° 57' 00"	-53° 00' 00"	19/10/05
4	Maringá	Faz Cesumar	CI/Epi	-23° 20' 34,9"	-51° 52' 24,1"	18/10/05
5	Loanda	Faz Alto Alegre	CI/Epi	-22° 59' 47,3"	-52° 58' 08,2"	25/10/05
6	Loanda	Faz São Paulo	CI/Epi	-22° 58' 10,6"	-52° 59' 35,4"	25/10/05
7	Maringá	Faz Pedra Preta	CI/Epi	-23° 19' 57,8"	-51° 50' 59,0"	25/10/05
8	Loanda	Faz Suely	CI/Epi	-22° 54' 49,3"	-53° 00' 09,7"	26/10/05
9	Amaporã	Sítio N. S. Graças	CI/Epi	-23° 04' 33"	-52° 49' 48,8"	26/10/05
10	São Sebastião da Amoreira	Faz Cachoeira	LAB	-23° 27' 58"	-50° 44' 57"	18/10/05
11	Bela Vista do Paraíso	Faz Flor do Café	CI/Epi	-22° 05' 23,7"	-51° 12' 33,1"	18/10/05

Source: MAPA, "Information about the occurrence of foot-and-mouth disease in Brazil," Table 5-2006, page 7 of 22 [14].

Epidemiological investigation revealed that the disease was introduced in Paraná as a result of the movement of 87 heifers on September 27, 2005. These animals originated from a property that was later identified as (1) having had an FMD cases, and (2) being adjacent to two properties with FMD cases. The animals involved remained for 8 days in the municipality of Bela Vista do Paraíso in Paraná, and subsequently sent for an auction and sold in the municipality of Londrina. Clinical, and sero-epidemiological investigations identified 11 properties with suspected FMD.

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By April 2006, a total of 6,781 cattle had been destroyed to fight the outbreak. Officials made several attempts to isolate and identify the virus; however, due to several factors (such as samples taken not being suitable for virus isolation), the laboratory staff could not identify the presence of the FMD virus. Nevertheless, based on the clinical signs and epidemiological links to outbreaks in Mato

Grosso do Sul, the episodes were confirmed as FMD, and officials declared a state of sanitary emergency.

Table 4 shows the introduction of sentinel animals (unvaccinated bovines aged from 6 to 12 months, negative to FMD virus structural proteins by ELISA CFL) into the affected farms. After sentinels tested negative and clinical signs compatible with vesicular diseases were absent, the affected properties were repopulated.

Table 4: Destruction of the animals in the affected farms and the introduction of sentinels.

ID	City	Property	Destructed animals	Destruction date (dd/mm/yy)	Number of sentinels	Introduction of sentinels (dd/mm/yy)	Test results
1	Bela Vista do Paraíso	Faz. Flor do Café	84	10/03/06	5	03/05/06	neg.
2	Grandes Rios	Faz Santa Izabel	39	11/03/06	5	03/05/06	neg.
3	Maringá	Faz Cesumar	144	08/03/06	8	04/05/06	neg.
4	Loanda	Faz Alto Alegre	1.728	28/03/06	87	22/06/06	neg.
5	Loanda	Faz São Paulo	2.745	25/03/06	138	22/06/06	neg.
6	Maringá	Faz Pedra Preta	231	08/03/06	12	04/05/06	neg.
7	São Sebastião da Amoreira	Faz Cachoeira	1.810	18/03/06	90	01/06/06	neg.
			6.781		345		

Source: MAPA, “Information about the occurrence of foot-and-mouth disease in Brazil,” Table 6-2006, page 9 of 22 [14].

Conclusions

APHIS did not detect any evidence to suggest that active outbreaks of FMD exist in the export region. APHIS concluded that MAPA could detect disease quickly, limit its spread, and report promptly, as demonstrated by the FMD outbreaks in 2005 and 2006 in which the cases were quickly identified, disease was contained, and international authorities notified in a timely manner.

3. Disease status of adjacent regions

General information

For the purposes of this evaluation, adjacent regions fall into two categories: the affected zone in Brazil that is adjacent to the export region, and the border countries of Paraguay, Uruguay, Bolivia, and Argentina (Figure 5).

Figure 5: Brazil and bordering countries

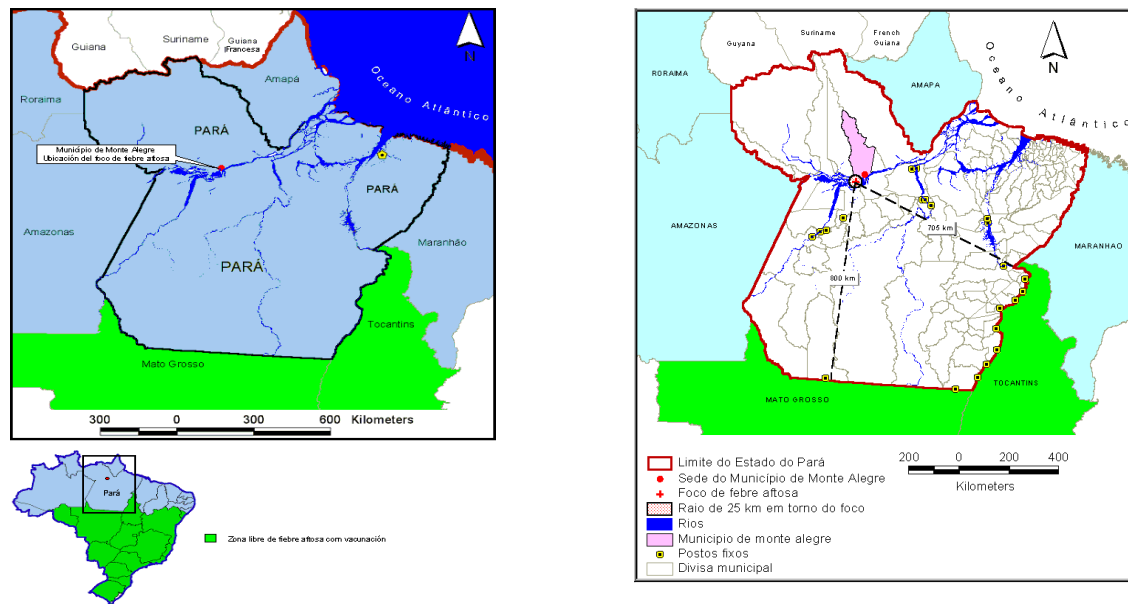


Affected zone in Brazil

The affected zone in Brazil is composed of 12 States at the time of this analysis, consisting of livestock circuits in the north and northeast which are buffer zones of heightened FMD surveillance activity adjacent to bordering countries following the recommendations of the OIE [9]. The States bordering the export region are Acre, Amazonas, Pará, Maranhão, Piauí, Pernambuco, and Alagoas. The OIE currently considers the States of Acre along with two adjacent municipalities of Amazon state, and the middle southern part of the State Pará, to be an FMD-free zone where vaccination is practiced.

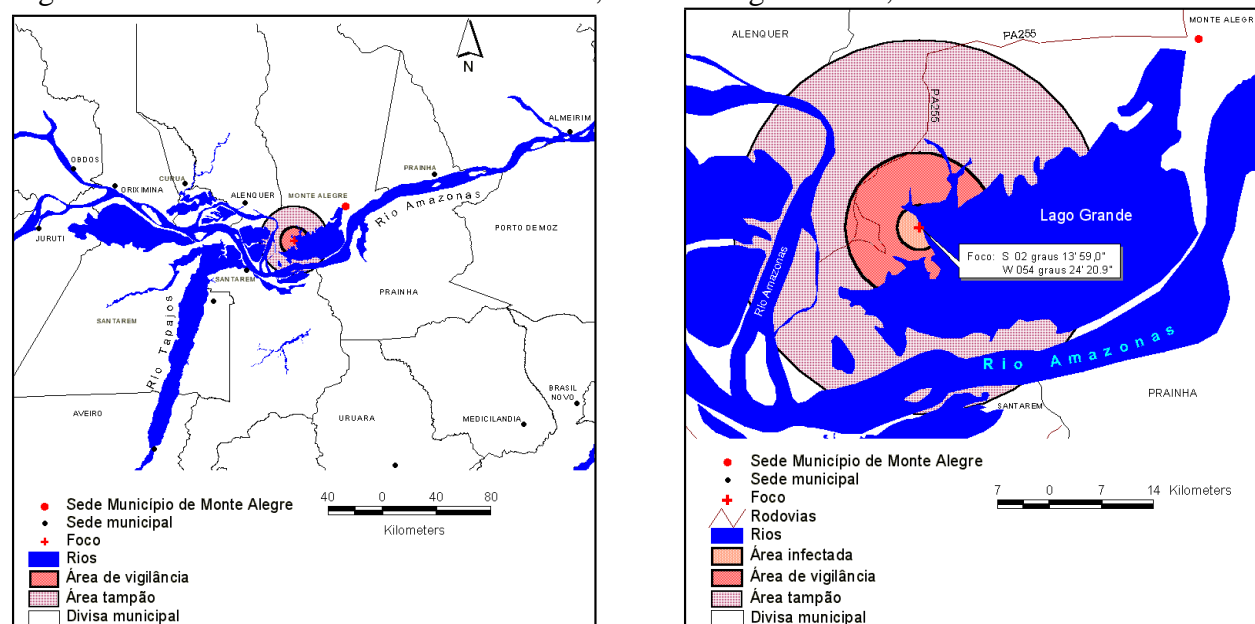
The most recent outbreak in Brazil in the infected zone occurred in June 2004 in the State of Pará, Monte Alegre district. The outbreak is located over 700 km to the north of the export region (Figure 6). The affected farm is located on the left bank of the River Amazon. There are few roads and access is difficult. Movements are mainly by waterway. The property where the outbreak occurred is located approximately 50 km from the town of Monte Alegre, in an area of small communities living on local fishing and livestock rearing [14].

Figure 6: Location of the FMD outbreak in Monte Alegre district, State of Pará – June 2004



A quarantine on the entire municipality of Monte Alegre and neighboring municipalities was implemented, including a ban on the exit of animals and animal products and by-products susceptible to FMD from the area and institution of movement control posts to enforce that ban. Officials implemented a 25-km-radius security zone (Figure 7) around the outbreak, an infected area (3 km around the outbreak), a surveillance area (7 km around the infected area), and a buffer area (15 km around the surveillance area). The official service implemented a surveillance program covering 13 municipalities and villages, which included 453 herds, representing a total of 14,462 cattle, 2,393 water buffaloes, 1,221 pigs, and 142 small ruminants. Vaccination of all existing cattle and water buffaloes in the security zone was carried out by the official service. In addition, a total of 31 cattle that were at risk of contact with animals in the outbreak property were destroyed [14].

Figure 7: Establishment of surveillance zones, Monte Alegre district, State of Pará – June 2004



Before that, the last recorded outbreaks of FMD in the affected zone occurred in 2001 in the States of Amazonas, Roraima, and Maranhão [6, 15]. Five premises with clinically diagnosed FMD were identified between February and April in Amazonas, whereas a single premises infected with virus type A was identified in Roraima in June and another in Maranhão in August 2001. The outbreaks in Amazonas were over 460 km from the closest border with the export region [9]. The species primarily infected was cattle, although a small number of swine were affected in Amazonas [10].

Adjacent countries: Argentina

Argentina borders the Brazilian States of Rio Grande do Sul, Santa Catarina, and Paraná. In July 2000, Argentine officials reported an outbreak caused by virus type O. Additional premises were infected with virus type O through December 2000 in multiple provinces, including Corrientes and Misiones. Detection of separate premises affected with virus type A between August and December 2000 compounded the situation. Subsequently, multiple outbreaks of virus type A occurred between March 2001 and January 2002 throughout Argentina, including 70 outbreaks in Corrientes near the border with the Paraná River. In addition, in September 2003, a single outbreak of virus type O occurred in the northern province of Salta. This outbreak was limited to swine in a single premises and Argentina declared eradication in early October.

In 2006, Argentina reported an outbreak of virus type O in San Luis del Palmar (Corrientes) near the border with Paraguay. This outbreak was contained and eliminated [16]. Molecular characterization of the virus revealed that the strain was indigenous to the region and shares common similarities with the isolates responsible for the type O outbreaks in South America between 2000 and 2005. Specifically, studies showed that the virus presented a high degree of homology (96 percent) with virus types isolated in Pozo Hondo (Paraguay) in 2003 and in Tarija (Bolivia) in 2000, and 92 percent homology with virus isolated in Mato Grosso do Sul (Brazil) in 2005 [16]. The OIE

currently considers the northern area of Argentina except for the high surveillance area to be an FMD-free zone where vaccination is practiced.

Adjacent countries: Paraguay

Paraguay borders the western parts of Mato Grosso do Sul and Paraná in Brazil. Paraguay reported no outbreaks of FMD from September 1994 to October 2002 [17]. A single outbreak of virus type O occurred in October 2002 in the department of Canindeyu, which borders Brazil. This was followed in July 2003 by outbreaks of virus types O and A in the northeastern department of Boquerón, near the borders with Argentina and Bolivia [17]. Paraguay declared control in August 2003.

In 2011, Paraguay reported two outbreaks of FMD type O in the San Pedro region in cattle approximately 250 miles from the Brazilian border.

Adjacent countries: Uruguay

Uruguay borders the southern aspect of Rio Grande do Sul. Uruguay reported a single outbreak of FMD virus type O in October 2000 in the northeastern department of Artigas, which directly borders Rio Grande do Sul [13]. Emergency actions resulted in the OIE reinstating Uruguay in January 2001 as an FMD-free country without vaccination. However, multiple outbreaks of virus type A starting in April 2001 necessitated emergency vaccination of the entire population of cattle and buffalo shortly thereafter. No outbreaks occurred in 2002 or 2003, and the OIE currently considers Uruguay to be an FMD-free country with vaccination [17].

Adjacent countries: Bolivia

Bolivia borders the Brazilian States of Rondônia, Mato Grosso, and Mato Grosso do Sul in the export region, and Acre in the affected zone. Multiple premises were infected with virus types A and O throughout the country prior to 2003, including in the departments of Pando, Beni, and Santa Cruz that directly border Brazil [17]. In July 2003, Bolivia experienced an outbreak caused by virus type O. Bolivia declared this outbreak under control in early October. Brazil has entered into technical cooperative agreements with Bolivia and donated vaccine in an attempt to protect the border in this region [9]. In January 2003, the zone of Chiquitania, which borders Brazil, was designated by the OIE as FMD free with vaccination. On January 25, 2007, the Bolivian Animal Health Service (SENASAG) reported the first of a total of five outbreaks of FMD in farms located near Santa Cruz de la Sierra, about 450 km north of the border with Argentina. The OIE currently recognizes the area of Chiquitania and the area located in the western part of the Department of Oruro as FMD free zones where vaccination is practiced.

Regional approach

A plan to eradicate FMD in all of South America (the Plano Hemisferico de Eradicacao da Febre Aftosa, or PHEFA) was created in the mid-1980s [9, 13]. Under this plan, a regional partnership agreement involving Brazil, Argentina, Uruguay, Paraguay, Chile, and Bolivia — the Convention da Barcia do Rio do Prata — was implemented in 1997. This agreement aims to integrate the various

national and regional FMD programs and to coordinate sanitary measures for FMD control and eradication, particularly in the border regions.

As part of the partnership agreement, the veterinary services in the border regions are jointly preparing maps that demonstrate the commercial flow of susceptible animals in order to pinpoint areas of higher risk. In addition, the local veterinary services of the involved countries meet periodically to discuss available information and conduct joint activities, thereby improving horizontal relationships and disease reporting at the local level. The Convention da Barcia do Rio do Prata is substantiated by audits of the participating veterinary services. So far, two rounds of audits have been carried out.

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 strategies among 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 is comprised of 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.

Bolivia and Paraguay have signed an agreement with Brazil to increase technical cooperation to facilitate the control and eradication of the disease in the borders. Representatives of the three countries meet regularly in an effort to establish an FMD vaccination and a prevention and epidemiological surveillance program in the border area between the three countries. The aim of the program is to mitigate the risk of an FMD occurrence in the area.

Conclusions

APHIS does not consider the countries of South America to be FMD free, with the exception of Chile.

FMD has been introduced into Brazil from neighboring countries. According to Brazilian officials, illegal movement of animals from neighboring countries as well as mechanical transmission of the virus has resulted in introducing the disease into Brazil. In 2000 and 2001, Brazil became vulnerable to the introduction of the disease due to the lack of reporting of the disease by Argentina. In contrast, Brazil successfully instituted emergency measures in 2002 when an outbreak occurred in Paraguay near its border with Brazil. Similar actions in 2003 appear to have resulted in preventing the introduction of the disease from Argentina and Paraguay, and in 2011 from Paraguay.

As long as FMD is endemic in the overall region in South America, APHIS concluded that there is a risk of reintroduction from adjacent areas into the export region.

Risk factors

1. FMD outbreaks have continued to occur in some South America countries over the past several years; consequently, there is an ongoing risk of reintroduction of the FMD virus from adjacent areas into the export region.

4. Disease control program

General information

Brazil has officially sought to control FMD since 1965, at which time it implemented the “Program to Combat Foot-and-Mouth Disease in the State of Rio Grande do Sul.” The program was later expanded to include the States of Santa Catarina, Paraná, São Paulo, Minas Gerais, Bahia, Espírito Santo, Mato Grosso, Goiás, Rio de Janeiro, and Sergipe.

In 1992, the Federal and State governments, with the cooperation of the cattle industry, re-evaluated the policies to combat FMD and, with the assistance of PANAFTOSA, focused on total eradication of FMD in the country on a regional basis, according to the livestock circuits (see factor 8; livestock demographics and marketing practices for a description of livestock circuits). The participation of the interested communities (producers associations, agribusiness, universities, etc.) was considered the main element in all phases and aspects of the program. The goal of the eradication program was to eradicate FMD from Brazil by December 2005 [8].

In 1995, a partnership between the public and the private sectors was formed through the creation of the National Committee for Animal Health (CONASAN), which has proven to be an important forum for deliberations and decisions aiming to promote the eradication of the main animal diseases, especially FMD. In 1998, Rio Grande do Sul and Santa Catarina became the first two States to be recognized by OIE as FMD free where vaccination is practiced [6].

In 2000 and 2001, the Midwestern and Eastern livestock circuit States, which included some of the States listed above with the addition of Mato Grosso do Sul, Tocantins, and the Distrito Federal of Brazil were granted OIE recognition as FMD free. Rio Grande do Sul and Santa Catarina regained OIE recognition as FMD free in 2002. FMD-free status for Rondônia was recognized by the OIE in May 2002 [6-10].

Strategies

Brazil is taking a regionalization approach for eradicating FMD from one region at a time. The strategy consists of defining a region based on the livestock circuit or ecosystem in the export region, in which eradication efforts are coordinated. The program relies heavily on community involvement and joint activities with social groups interested in animal health and production. Brazil formed local groups that work under the coordination of the regional and central offices in the States. One of the main objectives of the program is the decentralization of decision-making to the LVUs where the sanitary actions are taken and technical information is generated.

The DDA coordinates and supervises all aspects of the FMD program and is responsible for the following:

- Development of strategies to combat the disease
- Development of program rules
- Control of interstate and international movement of animals and its products and by-products
- Registration, testing, and control of specific vaccines
- Conduct of laboratory tests for disease diagnosis and virus isolation
- Disease surveillance and information systems at a national and international levels
- Audits of States veterinary services
- Sanitary education and training of program personnel
- Veterinary inspection of animals, animal products and by-products at the origin and after importation
- Provision of financial support through cooperative agreements with the States

Responsibilities for implementing program strategies lie with the States. The States' secretariats are responsible for:

- Execution of the program at the field level, especially the maintenance of an up-dated register of rural holdings
- Promotion and inspection of the FMD vaccination program for cattle and buffaloes
- Supervision of the vaccinations in risky areas or holdings
- Control of intra- and interstate movement of animals and animal products (the interstate control is in partnership with the Federal government)
- Provision of assistance to Federal authorities during outbreaks of the disease and investigation of suspected vesicular disease
- Sanitary education and organization and participation of the community
- Development of animal disease surveillance and information systems
- Inspection of livestock events such as fairs, exhibitions, auctions and public sales
- Inspection of animals and their products and by-products before movement
- Training of program personnel

The participation of the private sector in the national context is through CONASAN and occurs at all levels of administration (national, State, and municipal). The private sector supports the FMD program by providing financial resources and participating in the planning, financing, implementation, and evaluation of the technical and managerial actions within the program. According to Brazilian officials, participation by the private sector has also contributed to the strengthening of official structures and to the improvement of sanitary actions, mainly within the local units of the surveillance system.

The Brazilian Government has promoted and guaranteed the involvement of various groups of CONASAN into a plan called the National Program for the Eradication of FMD. These groups are composed of people interested or involved in livestock production or health, such as rural producers, the people responsible for the industry of livestock products or inputs, trade agents, private veterinarians, farmers' unions, co-operatives, universities, town halls, amongst others. The objective of these alliances is to bring about greater awareness, a wider scope, transparency, and credibility to the Program. The Federal Government coordinates the implementation of the national plan.

Main activities of the FMD program

Disease surveillance: The animal health service in Brazil has a surveillance system that covers all national territory. The LVUs are the base for the collection of the necessary data and for the decision making process. The system's information is supplied by a variety of official and private sources. A network of 2,332 field units collects, receives, and processes data, which are forwarded to the regional offices. This network also comprises 284 regional units (distributed within the States), 27 State central units, and a national unit represented by DDA/State Department of Agriculture (SDA)/MAPA in Brasilia.

The DDA collects data from the States and forwards the information to the OIE and other parties such as the South American Commission for the Fight against FMD – COSALFA. The timing of the reports is as follows:

- Weekly reports on disease notifications
- Monthly reports on the confirmed cases of animal diseases
- Biannual reports of the results of each phase of vaccination against FMD for each federative unit
- Annual full report containing epidemiological and sanitary information

Specific FMD control and surveillance actions recommended by OIE [18]

Following the recommendations of the OIE mission that visited Argentina, Brazil, and Paraguay in December 2006 [18], the heads of the Veterinary Services and PANAFTOSA defined an area of high-level surveillance within the border regions of Argentina, Brazil, Paraguay, and Bolivia. The buffer area in Brazil includes approximately 15 km to each side of the country borders. It comprises the municipalities in the immediate border with Paraguay, the area where the 2005-2006 outbreaks occurred (Japora, Mundo Novo, and El Dorado), and the area near the Lago Itaipu. The program is subject to periodic reviews and evaluations. Most of the financing will be obtained from the World Bank and the Inter-American Development bank.

Among others, the general actions to be developed include:

- Strengthening infrastructure of the veterinary services
- Harmonizing procedures for control, prevention, and eradication of FMD
- Harmonizing vaccination procedures in areas of geographic contiguity
- Conducting vaccinations under VS supervision

Notification and investigation of suspected cases: All official service field staff, community participants, and private sector veterinarians are trained and required to look for signs of vesicular diseases. If FMD is suspected, it must be immediately reported to the local unit or to an authority that would notify the local unit.

Response to a suspected outbreak begins within 8 hours from the time the notification arrives. All actions are carried out as if the herd is infected until proven otherwise. Immediately, the suspect holding is isolated, movement of animals is prohibited, and samples are collected and sent to a

laboratory to confirm the diagnosis. Recent examples of the performance of the emergency measures are presented under factor 11 (Emergency response capability).

Field inspections: Cattle and buffalo are inspected every six months by vaccinators and official veterinarians, when the animals are gathered in corrals for vaccination. LVU personnel carry out special visits to certain herds that are classified as “risky” by the official service. Risky herds are those owned by rural landless producers and Indian tribes, herds in areas densely populated with backyard and street cattle, or herds that have been affected by FMD in the past. In addition, official veterinarians inspect animals prior to their movement into the export region from other regions.

Surveillance at abattoirs and meat packing plants: Animals are individually inspected by personnel from the official service for signs of vesicular disease before slaughtering. Other body parts, including the tongue and feet, are examined during post-mortem inspection.

Surveillance at animal gathering places: All animals coming into fairs, auctions, or exhibitions are clinically inspected by official veterinarians.

Surveillance of animals in transit: Animals in transit are clinically inspected at checkpoints and border control points by official personnel. The checkpoints are strategically located, in accordance with the flow and intensity of animal movement. The conditions under which animals move are based on the sanitary status of the State of origin or the country sharing borders with the export region.

Laboratory diagnosis: Two laboratories can diagnose FMD. They are located in the northern and northeastern livestock circuits. The laboratories are under direct supervision of MAPA. PANAFTOSA, located in Rio de Janeiro, is the reference laboratory for FMD in Brazil and neighboring countries.

Serological monitoring: Serologic studies are conducted under special circumstances, such as in areas where the disease has occurred in the past and in areas classified as high risk due to their characteristics (e.g., prevailing production systems such as small rural farming, presence of animal gathering points, and intense animal movement).

Other measures: All cattle and buffalo are vaccinated every six months with oil-adjuvant vaccines. Other susceptible species are not vaccinated regularly.

Conclusions

Brazil has a control program and a national plan sufficient to respond quickly to FMD emergencies through quarantine and testing. In addition, Brazil maintains an active surveillance program at the field level in farms, at slaughterhouses, and at animal gathering locations. Brazil also conducts serological monitoring in the export region that is targeted to areas of higher risk.

APHIS reviewed Brazil’s FMD control and eradication program during its site visits in 2002, 2003, 2006, and 2008 and concluded that the program is effective at the local and national levels. This conclusion is supported by the prompt and effective response to the 2005 and 2006 FMD outbreaks.

There is effective participation of the community in program activities, which has played an integral role in the motivation and strengthening of the program. The community also participates in notification of disease outbreaks.

5. Vaccination status

General information

Vaccination of cattle and buffalo is mandatory in the export region. Other species are not vaccinated on a regular basis. An inactivated, trivalent, oil-based vaccine is used. Brazilian laws allow only the production of vaccine formulated with FMD viral strains A₂₄, Cruzeiro, O₁ Campos, and C₃ Indaial. Private laboratories produce the vaccine for both the internal market and for export to other countries in the export region. Production capacity for FMD vaccines in Brazil is around 300 million doses per year.

All FMD vaccines produced or used in Brazil must be tested for quality and safety by the official service. Quality control tests of each batch of the vaccine are conducted in the laboratories in Pernambuco and Rio Grande do Sul and strictly follow international standards as set by the OIE. Each vaccine batch is tested. The laboratories utilize the ELISA test to measure antibody responses in 30 cattle, 30 days post vaccination. A vaccine batch will pass the quality control tests when the expected percentage of protection is greater than or equal to 75 percent. APHIS did not detect any evidence to suggest that unacceptable biologics or vaccines are being used in Brazil. The official service maintains adequate control on vaccine supplies and conducts mandatory registration and testing of vaccines for safety and quality [6-8].

Strategies and schedules for vaccination of cattle and buffalo are carried out according to MAPA Directives 121/93 and 82/96 [8]. In general, animals are vaccinated twice a year on a schedule appropriate to each area. In some areas, animals under 2 years of age are vaccinated two or more times per year and some adult animals are vaccinated only once. However, animals must participate in four vaccination rounds before they can be vaccinated only once a year [6, 8].

In certain cases where a need appears (such as in areas inhabited by rural landless and Indian tribes or areas densely populated with backyard and street cattle) vaccination is supervised by and sometimes conducted by LVU personnel. In some areas with relatively large numbers of small and poor farmers, a State employee will vaccinate the cattle at one specific location. The smaller farmers bring their cattle to the central location (usually by foot) [7].

In other cases, large establishments will share vaccine with their smaller neighbors. This helps the small farmer, as the vaccine is sold by the bottle and not by individual animal doses. This means that it can be expensive for the small farmer [7]. Otherwise, farmers may vaccinate their own animals or hire trained professionals (who do not have to be registered or accredited by government officials). Some State offices have emergency funds available to assist with the cost of vaccination on Indian reservations [7, 10].

In addition to verification of vaccination records in the LVU, vaccination records may be verified by field inspectors visiting individual premises. Field inspectors may request copies of the vaccination sales receipt and the vaccination use records [7].

Vaccination coverage was reported to range between 76 and 99.9 percent in the export region. Table 5 provides statistical information on the vaccination schedule and coverage in this region by State for 2002. The table identifies the months in which vaccination is conducted in each State and provides census data for the total number of cattle and buffalos by State as well as the number of animals vaccinated and the percent vaccinated. Despite the fact that State or Federal personnel do not physically observe all vaccinations, records reviewed in LVU offices indicated that vaccination coverage was quite complete [7]. Table 6 shows three vaccination campaigns that took place in the state of Paraná during 2005 and part of 2006. The vaccination coverage was reported to be over 97 percent.

Table 5: Results of FMD vaccination in the export region, 2002.

State	Stage of vaccination	Population of bovines and buffaloes		
		Existing	Vaccinated	%
BA	March - whole herd	8,900,736	8,190,503	92
	October - whole herd	9,242,908	8,484,446	92
DF	May - whole herd	97,123	93,238	96
	November - whole herd	96,856	93,771	97
ES	March - bovines below 24 months	695,689	694,828	99
	September - whole herd	1,688,724	1,655,784	98
GO	May - whole herd	19,600,000	19,516,358	99
	November - whole herd	19,983,681	19,677,060	98
MG	March - bovines below 24 months (east circuit)	8,183,502	7,818,127	96
	May - whole herd (midwestern circuit)	10,929,403	10,695,848	98
	September - whole herd (eastern circuit)	3,826,411	3,597,676	94
	November - whole herd (midwestern circuit)	5,411,123	5,162,762	95
MS	February - bovines below 12 months	4,723,200	4,592,226	97
	May - bovines below 24 months	10,615,233	10,277,704	97
	November - whole herd	20,972,023	20,663,276	99
MT	February - bovines below 12 months	4,697,305	3,587,843	76
	May - bovines below 24 months	8,622,980	8,134,808	94
	November - whole herd	21,615,429	20,897,227	97
PR	May - whole herd	9768,420	9,623,397	99
	November - whole herd	9,945,774	9,720,261	98
RJ	April - whole herd	2,010,404	1,840,925	92
	September - whole herd	1,974,959	1,818,147	92
RO	April/May - whole herd	7,996,654	7,989,807	99.9
	October/November - whole herd*	7,578,712*	7,549,176*	99.6*
RS	February - whole herd	13,736,320	13,431,638	98
	August - bovines below 24 months	5,965,407	4,928,607	83
SE	May - whole herd	755,463	675,585	89
	November - whole herd	737,357	639,144	87
SP	May - bovines below 24 months	13,500,000	13,482,353	83
	November - whole herd	14,120,734	14,035,215	99
TO	May - whole herd	6,800,059	6,606,502	97
	November - whole herd	7,224,421	6,969,219	96

* Data from 2001.

Source: MAPA – Adapted from “Response to specific comments on the 11 factors given in 9 CFR 92.2, Application for recognition of the animal health status of a region,” Brazil 2003.

Table 6: Results of FMD vaccination in the state of Parana (May 2005, November 2005, and May 2006)

Vaccination campaign	Holdings	Bovines	Holdings Vaccinated (%)	Bovines Vaccinated (%)
May 2005	214,988	10,093,894	96.31	98.76
Nov 2005	222,555	10,252,254	96.84	97.58
May 2006	221,350	9,980,225	95.78	97.59

Source: Presentation to site visit team September 9, 2006 – (State of Parana)

The requirement for vaccination and vaccination records provides a vehicle for control of animal movement and for generation of census data at the local level. At each of the LVU visited, the

census information was quite detailed. Registration of herds with the LVU is mandatory. Each owner has a registration number for identification. The LVU maintains a list of individual properties, number of animals, and vaccination records for those animals. In some LVU, premises locations are identified using GPS coordinates. LVU personnel collect census data and information on vaccination compliance and pass it on to Federal officials [7].

LVU personnel monitor vaccination through vaccine sales. Vaccine can be obtained only from designated commercial establishments and can only be purchased during the campaign periods. For example, in the State of Tocantins there are only 30 authorized places to purchase vaccine (8 in the city of Colinas). When vaccine is sold, the record of that sale is filed with the LVU. After a herd is vaccinated, the owner must provide the LVU with a statement/affidavit documenting the amount of vaccine used (number of doses, manufacturer). The statement must be provided within 10 days of vaccination, and vaccination must be completed within a specified period of time after purchase. LVU personnel match the information on the owner's affidavit to the sales records to determine whether the information is consistent. They also use the information to update the census record for the premises [7].

Vaccination records are compared to movement permits (GTA) on a farm by farm basis for auditing and quality control. The records that are maintained at the local level are not yet part of a national database that can interface with the national identification system (SISBOV), although entering the data into the national database could strengthen the system. The LVU must send the vaccination reports to the Central Office within 2 weeks [7].

Brazilian officials believe the overall compliance level for vaccination approaches 100 percent. One office reported a compliance rate of 91 percent, but after written letters of warning, compliance increased to 100 percent. The best compliance officers tend to be neighboring ranchers because they want to protect their animals [6-8, 10]. The high compliance rate is significant since animal identification is accomplished through contacts made during the vaccination process.

Noncompliance with vaccination can be detected by late filing or not returning vaccination forms, by apprehension of illegal movement, or by anonymous callers to a free hotline [7]. The official service prohibits all animal movement from noncompliant farms until the owner produces sufficient evidence that the animals were vaccinated. LVU personnel follow up with a warning letter, which is often hand-delivered, and a visit. If the situation warrants, action may be taken, including levying a fine. If this occurs, a State veterinarian vaccinates the animals at the owner's expense [7].

Failure to vaccinate may result in penalties or fines. In 2001, the official service issued 6,010 fines to owners who failed to vaccinate, and 60 fines for partial vaccination or for missing the reporting date. In addition, 106 fines were issued to commercial farms for failure to comply with vaccine registration procedures.

Following the 2005-2006 outbreak, MAPA implemented countrywide serological sampling to estimate the immunity offered by the FMD vaccine. These samplings, together with other surveillance activities, serve to assess the epidemiological status of FMD in the country and collect specific indicators on the evolution of the disease. Immunity is measured as percentage protection expectancy (PPE). PPE over 75 percent is considered to provide adequate protection against FMD.

A population immunity study was conducted in 2006. Preliminary results indicate that the overall protection was 86, 82, and 67 percent for A, O, and C serotypes, respectively [14].

Brazil is collaborating with Argentina and Uruguay in order to make decisions on vaccination programs and on development of criteria for discontinuation of vaccination. The need for international cooperation and transparency has become very evident as a result of past introduction of the disease into the export region [7].

All States in the affected region in northern Brazil vaccinate for FMD at least once per year using an oil-adjuvant vaccine; in most States, cattle under 2 years old are vaccinated twice per year. Vaccination coverage in the States outside but sharing borders with the export region ranged from 83 to 94 percent in 2001 except in Piauí, where coverage was only 30 percent. This State is in the northeastern region of the country and is not included in the export region [6].

Conclusions

APHIS concluded that Brazil conducts its FMD vaccine production programs appropriately and in accordance with international standards. A system of controls ensures compliance with vaccination calendars by matching vaccination records to movement permits and census data and by conducting field inspections. There is a system in place for levying fines.

Risk factors

1. APHIS cannot totally exclude the likelihood that FMD virus may be circulating in vaccinated populations. In that regard, recent experimental studies in vaccinated susceptible animals have not been able to demonstrate effective transmission in unvaccinated animals [42]. In addition, Brazil conducts serological testing specifically to assess the level of protection afforded by the vaccination program.
2. Vaccination of cattle against FMD introduces risks related to the immunological response within the herd or population of vaccinated cattle. While a large percentage of individual animals in the herd may fully respond to FMD vaccination, some individual animals in the herd may have a limited response, resulting in partial or no immunity.
3. There is still some concern that vaccines produced in some countries may have residual Non Structural Proteins - NSP (depending on the manufacturing process) that could result in the detection of NSP antibodies in vaccinated animals, which in turn would result in positive screening test results.

6. Separation from adjacent regions

General information

The proposed FMD export region of Brazil is separated from the affected zone by natural barriers and buffer zones. The geographic description of the borders between the export region and affected zone in Brazil follows, including a map of Brazil and bordering countries (Figure 8).

Figure 8: States of Brazil and bordering countries



The APHIS site visit team observed many natural boundaries, including large rivers, desolate semi-arid landscapes, and mountainous areas. Domestic boundaries between affected areas and areas that Brazil and OIE considers free with vaccination are designed to follow such natural boundaries whenever possible [6, 8, 9, 13].

Borders

Rio Grande do Sul/Uruguay: The total length of this border is 800 km. Approximately 47 percent of the border lies along the Quaraí and Jaguarão Rivers. The rest of the border is open land or delineated by Laguna Merín (a coastal lagoon).

In addition to the points where permanent inspection stations exist, 47 other points considered as high or medium risk have been identified along the border. DDA has defined high-risk points as locations in which road access for ordinary vehicles is difficult (which hampers inspection) and as areas of open land at the border with many secondary and local roads. Medium risk refers to areas with unfavorable conditions for animal or animal product transport, such as high river banks or dense woods. Also included in this category are points of passage where roads are in good condition, allowing for better inspection capabilities or rural areas controlled by the veterinary service.

Rio Grande do Sul/Argentina: The total length of this border is 680 km. The whole length of the border extends along the Uruguay River. In addition to the points where permanent inspection stations exist, 60 other points that DDA considers as high or medium risk have been identified along the border. High-risk points along this border refers to locations with reduced natural protection, for example where the Uruguay River is less than 400 m wide, or areas with open vegetation or pastures

in the neighboring areas. Medium-risk points are defined the same as described above for the Uruguay border.

Paraná/Argentina: The Iguazu River runs along the entire border and extends to the Paraná River.

Paraná/Paraguay: The Paraná River extends along the entire border.

Mato Grosso do Sul/Paraguay: The Paraguay and Apo Rivers constitute this border. The southern part of the border is characterized by open, dry land (approximately 700 km) with few, if any, physical barriers that would hinder animal movements across the border. Local Brazilian officials identified this border as an area of weakness that requires increased inspection and surveillance activities.

Mato Grosso do Sul/Bolivia: The Paraguay River separates the two countries. The Pantanal region of Brazil, which is a large marshy area with low domestic animal density, also exists in the western region of the state.

Mato Grosso/Bolivia: The rivers Guaporé, Verde, and De Los Patos; the Serra Ricardo Franco mountain range; the Pantanal Region; plus dense forest areas are located along much of the border. Areas where there appears to be more open land are controlled by army posts.

Rondônia/Bolivia: The Guaporé, Mamoré, Madeira and Abunã Rivers, and dense forest conservation areas and indigenous reserves separate the two regions. Many of the areas near the border contain few or no livestock units. The APHIS site visit team observed a border control station in Guajará-Mirim by the Mamoré and a secluded border control station at Rolim de Moura do Guaporé by the Guaporé River along with parts of the Amazon forest.

Rondônia/Acre: The border is made up mostly of Amazon forest. There is only one access road, Federal Road BR-364, connecting the two States. The APHIS site visit team observed the border control station on this road at the Rondônia/Acre border.

Rondônia/Amazonas: Dense Amazonian rainforest occupies the entire border. The APHIS site visit team observed this forest by airplane.

Mato Grosso/Amazonas: The Amazon Forest, indigenous reservations, and the Juruena River form effective barriers along this border.

Mato Grosso/Pará: The total length of this border is 1,015 km. Seventy-two percent of the border contains natural barriers, i.e., the Amazon Forest, indigenous reservations, forestry preserves, and the Teles River. Open areas are designated as a buffer zone.

Tocantins/Pará: The total length of border is 1,320 km. The Araguaia River runs along the entire border.

Tocantins/Maranhão, Piauí: The total length of border is 1,000 km. The Tocantins River runs along the border (435 km). Also, indigenous reservations form barriers along this border. There is a buffer zone at the southern half of the border and also along the border with Piauí.

Bahia/Piauí: This border is part of the buffer zone area with no effectual natural barriers.

Bahia/Pernambuco, Alagoas: The São Francisco River separates part of the border with Pernambuco and the entire border with Alagoas. The western portion of the border with Pernambuco is part of the buffer zone with no effective natural barriers.

Sergipe/Alagoas: The São Francisco River forms the entire border.

Buffer zones [8, 9]

Cattle are the main FMD-susceptible species in the buffer zones except in Bahia, where a large goat population exists. FMD has not been recorded in any of the municipalities comprising the buffer zones and vaccination coverage has been consistently greater than 90 percent since 2000 [8].

Rondônia/Amazonas: There is a small buffer zone in northern Rondônia along part of the border with Amazonas, encompassing an area of 1,987 square kilometers in the municipality of Porto Velho [9]. This area is adjacent to the municipality of Humaitá in Amazonas and can only be accessed by federal road BR-319 and by the Madeira River. There are 286 properties in the area of which 270 raise or breed cattle. Vaccination coverage in the state of Rondônia has been greater than 95 percent since the fall of 2000.

Mato Grosso/Pará: A buffer zone in the municipalities of Novo Progresso and Santana do Araguaia in Pará has an area of 49,961 km². There are 1,413 holdings with 469,900 cattle in this zone.

Tocantins/Maranhão, Piauí: A buffer zone composed of the municipalities of Barra do Ouro, Campos Lindos, Goiatins, Lizarda, Mateiros, Recursolandia, and São Felix in Tocantins has an area of 26,315 km². There are 2,108 holdings with 78,000 cattle in this zone.

Bahia/Pernambuco, Piauí: A buffer zone in the municipalities of Buritirama, Campo Alegre de Lourdes, Casa Nova, Formosa do Rio Preto, Mansidão, Pilão Arcado, Remanso, and Santa Rita de Cássia in Bahia has an area of 56,366 km². There are 11,616 holdings with 147,352 cattle in this zone.

Conclusions

APHIS concluded that many natural barriers exist along international and internal borders that are sufficient in restricting animal movement and even human traffic. Areas in the frontier that may have less surveillance and monitoring tend to have large rivers or forest areas that act as barriers to disease spread. Other areas where open land exists have increased border controls or buffer zones to assist in keeping disease from crossing into the free zone.

APHIS concluded that movement of FMD-susceptible species or products into the export region could occur through international borders where sufficient physical barriers do not exist. However, the international borders are actively monitored and cattle populations surveyed. Brazil has achieved collaboration and border agreements in animal health with neighboring countries. Mechanisms have been implemented for immediate notification between these countries if an outbreak occurs.

Risk factors

1. Border areas along the states of Rio Grande do Sul and Mato Grosso do Sul appear to be highly susceptible to disease ingress and require heightened border security to ensure maintenance of the FMD-free status of these Brazilian States. In that regard, the risk of introduction from Argentina, Bolivia and Paraguay is mitigated by the implementation of the high surveillance area in the international borders, and by following a regional approach to FMD eradication.

7. Movement control from higher risk regions and biosecurity

Domestic movement controls

Movement controls are stringent. The Brazilian Ministry of Agriculture requires that all cattle owners identify their animals with a unique brand [6]. Sheep and swine are identified by a brand in the ear. Each LVU keeps a registry of brands and a complete registry of the cattle holdings in the region with animal populations listed by age group and sex. The latter is updated at least twice per year, during the vaccination period, or when the animals are moved to another place.

The LVU must issue an animal movement permit (GTA), which is required whenever animals are moved [6]. The staff of the local unit is responsible for verifying that the vehicle transporting the animals has been cleaned and disinfected as required by law. A copy of the GTA is sent to the destination. Any inspection associated with animal movement involves checking the documents and verifying the animal information, as well as clinical observation of animal health.

The official veterinary service oversees the process of animal movement within the country. At the request of the potential purchaser, the official service of the State of destination analyzes the risk rating of the State of origin [10]. There are six risk levels: negligible, minimum, low, medium, high, and unknown. The main factors considered in the risk rating are (1) the time since last outbreak, (2) the presence or absence of viral activity, (3) the extent of vaccine coverage, (4) control and inspection of incoming animals and products, (5) the disease status of adjacent areas, (6) the infrastructure of the official services, (7) the level of surveillance, and (8) the degree of community participation [20].

Movement into the export region is prohibited from States rating higher than medium risk [19]. If the risk rating is acceptable, and the properties of destination and origin are suitable for quarantine purposes, the movement process begins [20]. Animals are isolated at the property of origin for at least 30 days, during which time they are serologically tested for FMD. Once moved, the animals are isolated at the property of destination for another 14 days and re-tested. If a single animal tests

positive for FMD, the entire group is denied entry (except for animals moving directly to slaughter) and the official service conducts an epidemiological investigation.

Movement of animals within the export region was quite intense in 2002, especially movement of cattle and swine [19]. Cattle movement permits were authorized for 46 percent of the existing population, primarily for breeding/fattening or breeding/reproduction purposes. Intrastate movement accounted for 95 percent of all permits. Similarly, 90 percent of all swine movement occurred within the export region, but the primary reason for movement was slaughter (67 percent). Only 9 percent of the existing small ruminant population moved under GTA in 2002.

Matured and deboned beef is permitted entry to the export region from States or regions rated medium risk or lower, which in the affected zone includes the State of Acre and the southern region of Pará [10]. Entry of animal products from States classified as high or unknown risk is permitted provided that the products have been subjected to specific treatments that are recognized by the OIE as effective in inactivating the FMD virus.

According to information provided by Brazil, a total of 2,332,478 vehicles were inspected while in transit in the export region from January to August 2002 [10]. As part of movement control activities, 5,064,856 cattle, 1,579,144 hogs, and 610,672 small ruminants were inspected. Of these, 627 cattle, 7,606 hogs, and 317 small ruminants were seized and slaughtered, usually due to lack of official documentation or unknown origin. During this same period, 421,300 liters and 83,041 kg of dairy products were destroyed, along with 526,484 kg of meat products.

During the 2002 and 2006 site visits, APHIS observed movement controls for products and animals at several checkpoints between the export region and buffer zones. One checkpoint visited was Couto de Magalhaes, which is located on a highway between the States of Tocantins (recognized by OIE as free with vaccination) and Pará (designated by OIE as affected). These States are separated along most of their adjoining border by the Rio Araguaia and the checkpoint consists of permanent posts on both sides of the only bridge. Commercial trucks and light trucks, but not passenger cars, were stopped on both sides of the river, opened, and inspected visually. Tax documents were reviewed by customs personnel, and movement permits for animals and animal products were reviewed by veterinary personnel. When records were not in compliance, the truck must be turned back [7].

Brazilian officials informed APHIS that the primary controlled traffic at the Couto de Magalhaes checkpoint is live animals and boned beef. Bone-in beef shipments can move from one affected zone to another via the export region, using a classification of “in-bond.” The vehicle must be sealed, the seal applied at a federally inspected and approved slaughter facility, and the receiving port notified of the expected shipment. The vehicle must travel a specific route and arrive at destination by a certain time. The tax agency assists with this control since vehicles are taxed differently when entering the State versus just passing through. Restricted products can only enter States in the proposed free-with-vaccination region at certain checkpoints and then must follow specific routes [7].

Inspection of ferry traffic was observed at Tocantinopolis, at a ferry crossing on the River Tocantins that serves as a border between the States of Tocantins (classified by OIE as free with vaccination)

and Maranhão (classified by OIE as affected). No live animals or animal products were allowed to enter Tocantins at this crossing, although agricultural products were allowed with a permit. Brazilian officials indicated that checkpoints are located anywhere along the river where it is passable, although this was not confirmed by the site visit team.

Some domestic and international borders in Brazil are characterized as “twin cities,” in which cities on both sides of the border are essentially indistinguishable. These could pose a risk because of the relatively free movement and the amount of traffic moving across the border. Members of the 2002 site visit team observed an example of a “twin city” located on a domestic border between Juazeiro, Bahia (considered free with vaccination by OIE) and Petrolina, Pernambuco (considered affected by OIE). The border was monitored by a checkpoint on a very busy highway at a bridge crossing the river between the two cities. Both mobile and fixed checkpoints were observed at the border, all of which operated 24 hours a day [7].

At a mobile checkpoint in Juazeiro, officials indicated that all refrigerated trucks or trucks carrying live animals are stopped. However, the site visit team noticed that not all trucks that might have been carrying risk materials were stopped, a phenomenon that was attributed to familiarity of the inspectors with the specific trucks or type of trucks passing through the checkpoint. The inspectors indicated that they suspect illegal traffic of animals or animal products and therefore hold periodic “blitzes” to check all vehicles crossing the border. However, nothing illegal has been found during these inspections [7].

During the 2003 site visit, APHIS observed movement controls at a border checkpoint between Rondônia and Acre (both considered free with vaccination by the OIE). This checkpoint is open 24 hours a day, 7 days a week. According to checkpoint officials, usually only trucks or vehicles carrying animals or animal products are stopped; another checkpoint across the border in Acre stops every vehicle [7].

No live animals from Acre are permitted to cross the border. Meat that has been deboned can enter Rondônia; however, meat with bones can only transit the State. Vehicles that transport meat are disinfected and cleaned at the point of origin and then disinfected again at the border station [7].

APHIS also observed a Federal/State inspection post between Rondônia and Mato Grosso (considered free with vaccination by the OIE). The post is staffed 24 hours a day and every commercial vehicle is inspected. Not every passenger car is inspected and drivers are not always asked about live animals. There are signs posted that any animals should be declared to officials and that a GTA must accompany any shipment. Officials check the GTA for each shipment and record it. A fax is sent to the LVU of destination, where the shipment is verified when it arrives at that destination. The Central office in Porto Velho is notified about each shipment as well [7].

International movement controls

There are 19 international land entry points and 24 seaports in Brazil. In addition, there are 20 international airports and 18 inland customs offices. Personnel staffing the control points consist of 378 professionals (veterinarians and agronomists) and 193 support staff and assistants [7]. Brazilian officials identify and monitor risk areas on the borders where outbreaks have occurred or where

illegal movement of animals is suspected. Officials also inspect animals and animal products, passenger baggage, and the travel waste of airplanes, ground transportation, and other vessels entering the export region. The baggage of passengers is checked by sampling according to previously defined risk parameters [8].

Brazil prohibits the import of animals or animal products from countries or zones that OIE does not consider free from FMD, except when products are submitted to thermal or physical processes deemed by the OIE to be sufficient to inactivate the virus [10]. Prospective importers must complete an import request and supply documentation describing the type of product, the manufacturing process, and the form of packaging. Certification from the animal health service of the country of origin should also be included [9]. Brazilian officials then conduct a risk assessment and, if the results are favorable, grant an import permit.

Sanitary controls for live animals, including testing and quarantine procedures, are similar to those described above. Brazil follows the standard and recommendations of the OIE for the international exchange of animals and products.

Brazil provided APHIS with information on imports into the export region, classified according to country of origin, species, and type of product from 1999-2002 [10]. Cattle were imported primarily from the surrounding South American countries. Small numbers of cattle were imported from the United States, Canada, and Mexico. Goat and swine were imported primarily from various European countries, the United States, Canada, and New Zealand. The originating country for semen and embryos varied widely. Brazil imported over 38 million kilograms of frozen boned beef and over 54.5 million kilograms of fresh or cooled boned beef from 1999-2002, primarily from Paraguay, Uruguay, and Argentina.

The 2003 site visit team observed movement controls at Guajará-Mirim, a checkpoint that controls the movement of animals and animal products crossing the Madeira River from Bolivia. Authorities worked with other border officials to monitor traffic and check luggage. Flyers and public notices are available to notify the public of the rules and what is prohibited across the border into Brazil. There are agreements with law enforcement agencies to monitor the border during times when smuggling may be a problem due to exchange rates of currencies [7].

A border control post in Rolim de Moura do Guaporé, located on the Guaporé River, was opened in 2001 to monitor shipments crossing the river in this secluded area. A Bolivian national park is on the other side of the river along with a large cattle ranch. Some ships on this river are large enough to carry 70–80 head of cattle. The post is staffed 24 hours a day. Employees inspect any shipments that move on the river. Any cattle transported on the river must have been vaccinated at least twice [7].

Members of the 2003 site visit team also observed international border crossings with Argentina at Uruguaiana and with Uruguay at Santana do Livramento. In Uruguaiana, approximately 2000–4000 cars cross daily. If the country is on “alert” status, which occurs when there is an FMD outbreak in a neighboring country, all passengers must walk through a foot bath and the cars are driven through an iodine wheel dip. Cargo trucks must arrive to the border clean. If they arrive during an alert status period they are disinfected at the border. The trucks are registered and given 15 minutes to arrive at

the inspection point. Officials keep records of individual items confiscated and submit monthly and annual reports [7].

There is also a quarantine station for live animals. Horses arrive about twice a month. During the site visit, inspection procedures and processing of paperwork were greatly delayed due to a work slowdown by the customs officials, so animal movement was slow [7]. There is good cooperation between Federal agencies and with international counterparts at the land border crossings.

At the Santana do Livramento border crossing, Brazilian and Uruguayan inspection officials are located together in the same building. Live animals that can be imported usually include dairy cattle and slaughter animals. Documents are inspected and then animals are brought to the quarantine station (10 km from the border) for clinical inspection. Animals moving directly to slaughter are not quarantined. If someone wants to export an animal to Brazil they must first apply for an import permit which lists the sanitary requirements. These include 30 days' quarantine at the farm of origin under the supervision of an official veterinarian [7].

Once the paperwork is checked at the border, the animals are given a rest at the quarantine station for 2 to 3 hours before proceeding to the farm of destination for a second 30-day farm quarantine in a previously approved isolated facility. An official veterinarian is advised before the shipment arrives so that he or she can be waiting for the arrival of the truck. After the 30-day period is over, a local veterinarian sends a report and releases the animals. Brazil is currently re-evaluating its system to consider having the quarantine at the station rather than at the farm of destination; however, this would require a system of user fees to accomplish [7].

The quarantine station at Santana do Livramento holds up to 300 animals. Officials test animals for brucellosis, tuberculosis, FMD, infectious bovine rhinotracheitis, bovine viral diarrhea, bluetongue, and vesicular stomatitis. Following the OIE standards, if a country is considered free of a disease, animals are not tested at origin. If a country is considered by DDA to be free of FMD with vaccination, then no test is required. However, documentation must be provided that the animals have been vaccinated with a trivalent vaccine [7].

Individual identification is required for imported dairy and reproduction animals. For slaughter animals, only information on the number of heads, sex, age, and transport in a sealed vehicle are required. These animals must go to a federally inspected (SIF) plant but can only be used for the internal market since they have not been in the country for more than 90 days. If an animal arrives at the border with clinical symptoms of disease, it is sent back to the place of origin; however, animals that show signs of FMD are quarantined and sampled [7].

The 2003 site visit team also reviewed the Guarulhos International Airport in São Paulo. All inspectors are either veterinarians or agricultural engineers, and they cover the airport 24 hours per day. When cargo arrives at the Guarulhos airport, the importer brings the paperwork to MAPA. Infrareo (the airport company) sends a daily summary report of the commodities that will be arriving that day. MAPA checks the paperwork, labels, and packaging; if everything is in order, a number is entered into the computer tracking system. This alerts customs that MAPA has released the shipment. The shipment leaves the airport under MAPA seal, and only a MAPA official can break the seal and open the shipment at the destination. Destinations are always MAPA-approved

facilities. When an import permit is issued, a copy is sent to the destination so that it can be cross-checked upon arrival. About 20 shipments of animal and plant products arrive daily [7].

The site visit team made the following observations regarding the treatment of animal products, international waste, passenger clearance, and live animals at the Guarulhos International Airport [7]:

Animal products: Requirements for products entering into Brazil include (1) MAPA import permit, (2) compliance with all sanitary health requirements, (3) origin from an establishment approved to export to Brazil, and (4) declaration of port of entry and final destination. A veterinarian at the airport receives the documents and waits for the shipment. MAPA inspects the shipment before customs.

According to Brazilian officials, 100 percent of animal products entering the country are inspected. They are subjected to both primary and secondary inspections. An inspection for animal health purposes is conducted, which includes a check for compliance with labeling and packaging requirements. For the secondary inspection, the product is sent to a storage facility that is registered with MAPA for sampling for public health purposes.

If a shipment is rejected, a number of actions may be taken according to Brazilian legislation. The product may be returned to the place of origin, it may be confiscated and incinerated, or it may be retained for possible resolution.

International waste: At the international port of Sao Paulo, all waste from all countries from all planes is incinerated. Waste is collected, stored, and then transported by trucks (which work only in the airport) to the incinerator, which is at the airport. Public health officials supervise the incineration. The Infraero Company owns and operates the incinerator.

Passenger clearance: Brazilian law prohibits all transport of animal and plant products from anywhere in the world without proper permits. Passengers are checked for animal and plant products. The type of inspection depends on the origin of the flight. Prohibited items are confiscated, stored, and later transported by the contract company to the incinerator under MAPA supervision.

Customs will also x-ray a percentage of arriving luggage and confiscate prohibited products. The percentage is greater for luggage from high-risk areas. For example, Brazil has classified high-risk flights to include flights from Spain and Portugal which have small artisan farms with no government oversight, countries with outbreaks, etc. In addition, passengers from high-risk countries are required to walk across a disinfectant mat. All luggage from countries having FMD outbreaks goes through x-ray inspection.

Live animals: Live animals can enter through either Guarulhos or Veracopos Airport. Mainly horses, but also ostrich and cattle, have entered. All animals must have an import permit. After arrival, the plane, transport container, and animals are cleaned and disinfected. Horse hooves are picked and disinfected with hypochlorite. Food and bedding are incinerated.

Members of the 2003 site visit team also observed the Santos seaport in São Paulo. This port is governed by both the Inspection Service and Visiagro. MAPA works closely with other Ministries (Health and Environment), the Federal Police, Port officials and Customs at the port. The findings of the team with regard to the treatment of live animals, agricultural exports and imports, and international garbage at the Santos seaport were as follows:

Live animals: Few live animals arrive at this port. In the last 9 years, the port has received only two shipments of ostriches from Spain and a shipment of cattle from Colombia. Personnel from other ports are contacted to help with live animal shipments to this port, since the team present at this port is not familiar with all of the regulations.

Export of agricultural products: Only one facility at the port is approved by the United States for export (Localfrio Company). Brazil exports approximately US\$3 billion in processed beef and other meat products to the United States annually. To export, MAPA must issue an International Health Certificate at the plant. The product must be containerized, sealed, and arrive with the proper paperwork. The port confirms that the seal is intact and the paperwork is in order before issuing a "Permit to Ship." Surveillance cameras record everything happening at the port 24 hours per day. These recordings are maintained for 30 days.

Agricultural import products: Brazil sends inspection teams on missions overseas to approve facilities to export to Brazil. The exporter must apply for an import permit. If the establishment is approved, DDA issues the sanitary requirements.

Approximately 100 containers of animal and plant products arrive at the port daily (roughly 3 million containers of all types of product arrive annually). All containers holding agricultural products are opened and inspected. The container is then sealed and transported to a SIF. Paperwork is checked three times: (1) when the import permit is being issued, (2) when the product arrives at the port, and (3) when the product arrives at the SIF.

The port authorities receive updates from MAPA in Brasilia on outbreaks and sanitary conditions in other countries. If the sanitary situation of the exporting country changes while the shipment is in route and an import permit has already been issued, port personnel can still refuse the shipment.

International garbage: All ships collect garbage in white plastic bags. These are sealed and placed in containers until transported by contracted trucks (also sealed) to the incinerator, which is located 70 km away in the city of Maua. The Ministry of Health supervises this process. An average of 2 to 3 tons of garbage is incinerated daily, including pallets. The majority of garbage comes from cruise ships, which may leave up to 40 tons of garbage each. From November to February, two to three cruise ships arrive per week. Human and food waste is usually dumped by the boats into the ocean off the coast. Passengers are only inspected by customs if it is their point of departure. Yachts do not arrive at this port. Some ships have their own incinerators on board.

Conclusions

There is a system of permits in place to control animal movement, which is well controlled at the local level. Movement controls are linked to vaccination records, and vaccination coverage in the export region being evaluated by APHIS is high.

There is good cooperation between Federal agencies and international counterparts at land border crossings. At some border locations authorities from the two countries were co-located, which increased efficiency and effectiveness in controlling movement of animal and animal products.

Movement controls at international checkpoints appear to be adequate as long as products are brought in legally. In contrast, movement control measures and biosecurity at airports and seaports were impressive.

APHIS tries to target the riskiest border crossings (and other areas) during a site visit as examples of a type of “maximized risk scenario” in order to address similar, but theoretically lower, risks in the remainder of the export region. APHIS assumes that, if the riskiest pathways are sufficiently mitigated, the overall spectrum of risk issues should be acceptable. Using this assumption and visiting the areas of highest risk in the export region, APHIS concluded that movement control measures for live animals are relatively robust at both domestic and international checkpoints.

Risk factors

1. There is a potential for introducing FMDV through illegal introduction of FMD-infected animals or animal products from affected regions. Brazil has several internal and external border areas with few or no natural barriers. Even where there are barriers or checkpoints, there is a potential that people, cars, and animal products could cross both domestic and international borders illegally.

8. Livestock demographics and marketing practices

General information

Agriculture in Brazil supports the economy, since agricultural commodities constitute 37 percent of total exports. Productivity has increased by 71 percent in the last 10 years. Around 90,000,000 hectares are currently available for agriculture in the country (without having to cut forests down). Brazil has about 2,403,006 cattle establishments. The domestic animal population consists of 183,000,000 cattle, 1,100,000 buffalo, 14,800,000 sheep, 12,100,000 goats, and 33,000,000 pigs. Of these amounts, 84 percent of the cattle population and premises are located within the area that Brazil asked APHIS to evaluate. Animal census data are maintained at the LVU [6-8, 10].

Approximately 40,000,000 animals are slaughtered annually for meat, of which 87 percent is destined for internal consumption and 13 percent for export markets. The State of Mato Grosso do Sul accounts for 50 percent of exports with 24,000,000 beef cattle. Brazil exports fresh and frozen beef to several countries in Europe, Africa, and Asia [6-8, 10].

The zebu breeds predominate in the national beef production in most areas of the country, with the exception of the south and southeast of the country, where European breeds are more common. There is also a growing presence of crossbreeds of zebu and European stock [8]. In 2002, the estimated slaughter rate in the country was 23.7 percent and the average yield of the bovine herd was 26.1 percent. The national herd growth rate, from 1993 and 2001, was 7.3 percent, with an annual growth average of 0.7 percent. The per capita consumption of beef averages around 35 kg per year, reaching an average of 45 kg per year in the southern, southeastern, and midwestern regions of the country [8, 10].

Dairy herds account for 20 percent of the total herds in the country. This production is concentrated in the southern and southeastern regions of the country, which account for 69 percent of the national milk production. In 2001, the total milk production was 20.6 billion liters, a 31 percent increase compared to 1992 [10].

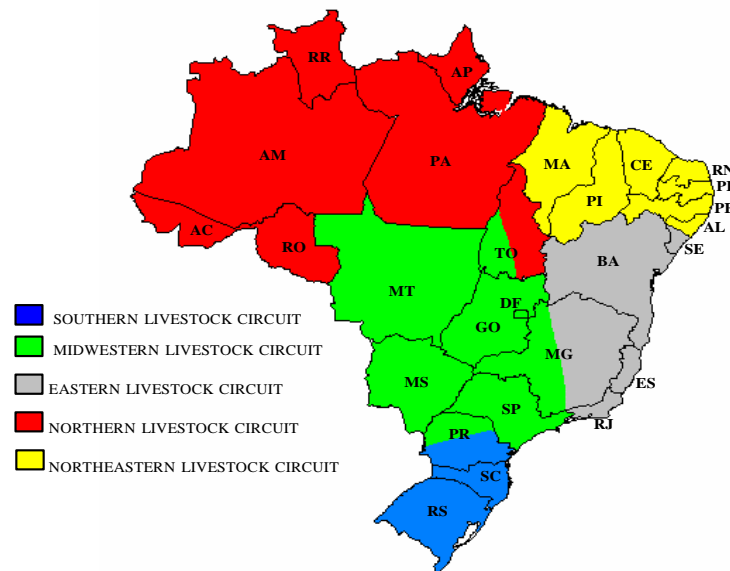
Brazil has the largest swine herd in Latin America. The commercial production is mainly concentrated in the southern and southeastern regions of the country. In 2001, 28.5 million hogs were slaughtered. Most of this production originates from systems integrating raising and processing establishments. The internal consumption represents approximately 95 percent of the national production [10].

The national sheep flock is around 14.8 million head and is concentrated in the southern region of the country, especially in the State of Rio Grande do Sul. The goat population is 12.1 million heads and is concentrated in the northeastern region of Brazil. The production of small ruminants is almost entirely destined for the internal market [8, 10].

Livestock circuits

The Brazilian climate and soil conditions make it possible to raise cattle on pasture year round, across all its territory. However, the huge geographical, economical, and social diversities create different types of livestock production systems across the country. The cattle production ecosystem in Brazil is divided into five livestock circuits (Figure 8). These circuits, defined originally in 1992, represent diverse animal demographic and marketing practices and were formed to facilitate the change in focus of the FMD program from control to eradication. The circuits correspond to livestock ecosystems, quite independent with respect to the various stages of the meat production chain; in other words, there is a high probability that the animals are born, raised, and slaughtered within the same livestock circuit [8, 10].

Figure 9: Livestock circuits in Brazil



Source: MAPA, "Enlargement of the foot-and-mouth disease free zone, where vaccination is practiced – Midwestern and Eastern livestock circuits," Brazil 2000.

Although livestock circuits have no direct affect on the FMD program, they define areas of some internal homogeneity that have been used as regions in which advancements in the program may be defined. Internal borders between regions recognized by Brazil as differing in stage of eradication may or may not reflect livestock circuit boundaries. In some cases, the boundaries between circuits do not correspond to State borders. In fact, these boundaries are determined based on the prevailing flows and intensity of trade among the livestock production sectors [7].

A brief description of each livestock circuit follows [8].

Southern livestock circuit: Comprises the States of Rio Grande do Sul and Santa Catarina and the southern part of the State of Paraná. In the southern part of the circuit in Rio Grande do Sul, the cattle population lives with the largest sheep flock of the country. In the northern area of Rio Grande do Sul, in Santa Catarina and the southern part of Paraná, there are mainly small family holdings dedicated to the integrated farming of pigs, poultry and dairy or mixed cattle breeds. Around 40 percent of the industrial pig and poultry production in this circuit is found within this livestock circuit.

Midwestern livestock circuit: Comprises the States of Goiás, Mato Grosso, Mato Grosso do Sul, São Paulo, Paraná (northwestern part), Minas Gerais (western part), Tocantins (southwestern part), and the Federal District. This circuit includes the largest cattle population of the country (55 percent of total). It has the largest beef market and the highest number of abattoirs and meat processing plants in Brazil.

Eastern livestock circuit: Comprises the States of Rio de Janeiro, Espírito Santo, Bahia, Sergipe, and the eastern part of Minas Gerais (region not included in the midwestern livestock circuit). The States of Bahia and Minas Gerais are the most important livestock States within this circuit. The circuit includes 13 percent of the total cattle population.

Northern livestock circuit: Comprises the States of Acre, Rondônia, Amazonas, Pará, Amapá, Roraima, and Tocantins (part not included in the midwestern livestock circuit). Extensive livestock production systems predominate in this circuit. The cattle population is approximately the same as the eastern circuit (21.6 million heads), with an average of 121 cattle per holding.

Northeastern Livestock Circuit: Comprises the States of Alagoas, Pernambuco, Paraíba, Rio Grande do Norte, Ceará, Piauí, and Maranhão. It has the smallest cattle population of the country (7 percent of total), distributed in a large number of holdings, occupying an area similar to the eastern livestock circuit and twice the size of the southern livestock circuit.

Movement patterns

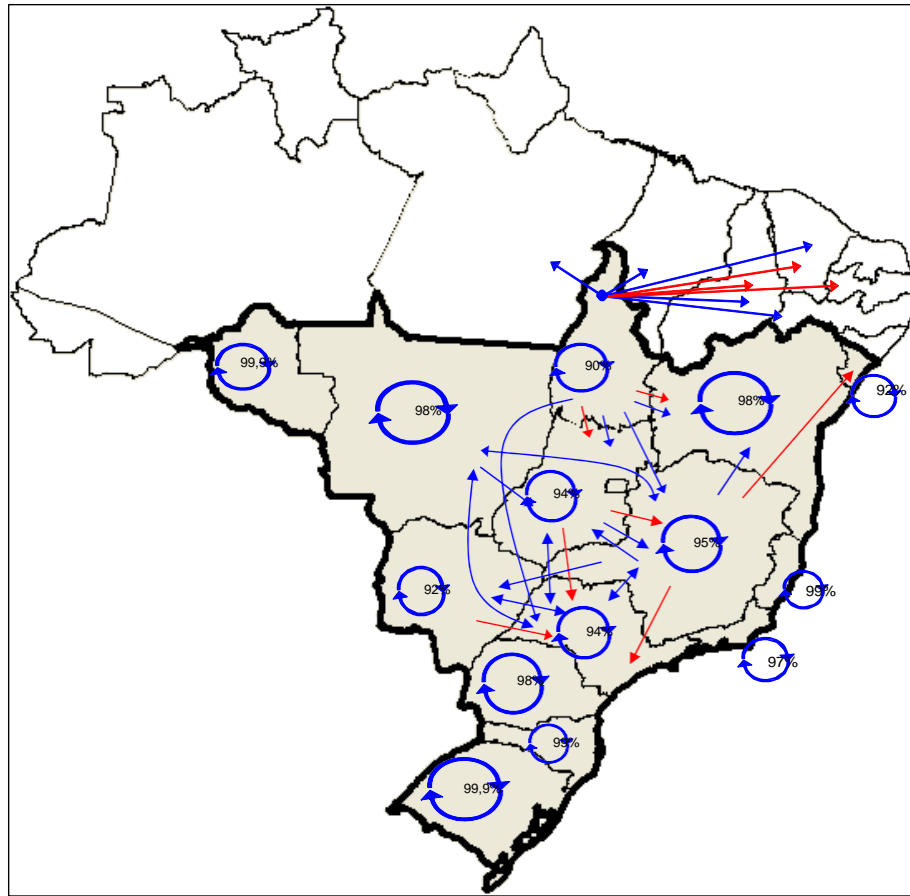
Movement of cattle is concentrated mainly in the States of Mato Grosso do Sul, São Paulo, Goiás, Minas Gerais, and Mato Grosso. Additionally, the marketing and movement patterns of cattle are concentrated mainly within the State with little movement interstate. This indicates that most animals that are received at an export slaughter facility have likely originated from and resided in the same State. With the exception of the Federal District, over 90 and up to 99.9 percent of movement of the cattle population occurs within each State (Figure 9).

Most of the interstate movement of cattle occurs within the export region, with less than 0.5 percent of cattle being moved to the infected zone. On average, 23 percent of cattle moved interstate within the export region, moved to slaughter with the majority of animals transferred to the States of Rio de Janeiro and Sergipe [10].

Movement of pigs follows a pattern similar to cattle. The majority of pig movement occurs within the export region. With regard to small ruminants, movement to other States occurs more frequently. However, no FMD-susceptible species are allowed entry from the infected zone into the export region [10].

Market transactions occur mainly through direct negotiations among owners. A small proportion of cattle (7 percent) are sold at livestock events such as auctions and exhibitions [7, 10].

Figure 10: Schematic representation of cattle movement in Brazil, 2002



Source: MAPA, Additional Information requested in relation to the risk of exporting fresh or chilled beef, September 2003

The auction system

During the 2003 site visit, APHIS discussed the auction system with authorities at the Bage LVU. The first step in the process is for an auction yard official to request a permit to hold an auction at least one week in advance of the actual event. State inspectors (a veterinarian and assistant) are assigned to inspect animals upon arrival. Two GTA are required. One permit authorizes animals to go to the auction and the other authorizes them to leave. If animals arrive without a GTA the inspector fines the producer. If the producer has a farm invoice to prove the origin of the animals, they are permitted to return to the farm of origin. If the producer does not have proof of ownership, then the animals are confiscated and the local police are contacted [7].

On average, auctions occur once or twice per month (less frequently in winter, more in summer). Generally, auctions are held for cattle for fattening prior to slaughter but in the spring. There are also sales for breeding animals and genetic material. The official service regards auctions as the main control point for breeding animals. Imported animals must have resided in Brazil for at least 90 days before they can be sold at an auction. Representatives from slaughterhouses buy animals directly from farms and not from auctions [7].

Animal identification

Brazil has stringent movement controls. MAPA requires that all cattle owners identify their animals with a unique brand. Sheep and swine are identified by an individual brand or notch in the ear. Each LVU keeps a registry of identification systems and a complete registry of the livestock holdings in the region with animal populations listed by age group and sex. The registry must be updated at least twice a year, and whenever animals are moved (farmers must notify the LVU of changes to the animal inventory due to birth, death, or movement off premises and must do so within 30 days [6].

Brazil has implemented the national identification system (SISBOV) for cattle and buffalo. The goal of SISBOV is to individually identify and monitor all cattle and buffaloes born or imported into Brazil. The system is designed to trace animals from birth to death. A unique 17-digit identification code is given to each animal and is registered in a national database managed by MAPA. Additionally, the system includes information on owner's registration, date and place of birth of the animal, breed characteristics, feeding practices, vaccination data, movement records, death information, and other animal health indicators. The animals can only be identified once during their lifetime. At the time of APHIS' 2002 visit, 6.5 million of the 183 million cattle in Brazil had been identified [7, 11]. During the 2002 visit to a farm in Mato Grosso do Sul, APHIS received a live demonstration of the SISBOV system [7]. MAPA reported that between 2002 and 2006, a total of 72,550,928 cattle were registered (34,367,690 of those went to slaughter). At the time of the 2006 site visit, 38,183,238 live cattle were registered in national database.

MAPA accredits private companies to assign the codes and collect the relevant information. The accredited companies select the type of identification used and are responsible for certifying the status of each animal enrolled through them. MAPA audits the companies regularly. There are 8 certified accredited companies, the cost is between US\$0.8 and US\$1 to identify each animal, and a visit by a veterinarian is required to register the animals [7, 11].

Participation in the program is voluntary, except for producers who are planning to export to the European Union. In addition, all cattle farms located in FMD-free States must be integrated into SISBOV no later than December 2005 [11]. At the present time, all farms and animals intended to export to the European Union must participate.

Identified animals that move to slaughter are issued a SISBOV card. The slaughter facility is responsible for checking the documentation and for terminating the registration of slaughtered animals in the national database. In case the slaughter facility does not have Federal inspection, the accredited company is responsible for terminating the registration of slaughtered animals [11].

Slaughter inspection

Brazil has 358 federally inspected slaughter facilities, of which 317 operate within the export region. As of April 27, 2011, 19 facilities have been certified to export to the United States, all located within the export region. In addition, approximately 405 State-inspected facilities exist in the export region; however, beef or products from these facilities can only be sold within the State [10].

Personnel from the slaughter facilities go to farms to buy cattle. Generally, they go to large/high quality farms, but they may go to any farm they wish. All farms are eligible to sell cattle to any slaughter facility. However, due to the economics of transport, a truck needs to be filled to be cost effective; therefore, small farmers mainly ship to State-inspected facilities for State consumption [7, 10]. The EU requires that the animals must reside on the farm for at least 40 days before being moved to slaughter. Other declarations regarding genetic modification, use of animal protein in feed, antibiotics administration, and pesticides application are also required for export to the EU [7].

APHIS personnel visited three slaughter facilities in the export region that were approved to export processed products (other than fresh beef) to the United States: in Goianas and Mozarlandia in the State of Goias and in Campo Grande in the State of Mato Grosso do Sul. The facility in Goianas has the capacity to slaughter 1400 head of cattle per day with an average age at slaughter of 3 years and an average carcass weight of 220 kg. The facility in Mozarlandia has the capacity to slaughter 1500 head per day with an average age at slaughter of 2 to 3 years and an average carcass weight of 280 to 300 kg. The facility in Campo Grande has the capacity to slaughter 1200 head per day with an average age at slaughter of 3 years [7].

Ante-mortem inspection: Brazilian law requires that animals must rest 6 to 24 hours prior to slaughter depending on the distance traveled (the average rest time is 18 hours). The animals receive their first inspection upon arrival by a technician who checks the paperwork (GTA), unloads the trucks, and performs a physical inspection. If a truck arrives with no paperwork, it cannot be unloaded. All trucks must be disinfected before and after unloading. If anything unusual is noted, the animals are moved to the observation corral for the veterinarian to perform a clinical exam [7].

The Federal veterinarian performs two ante-mortem inspections, one 12 hours prior to slaughter and the second 30 minutes before slaughter. Observations are registered on an ante-mortem inspection card that contains basic information on the animals in each pen. Animals with diseases symptoms are separated into observation pens for a closer examination. Holding pens contain animals from one owner and farm, and multiple pens may contain animals from one owner. The animals are grouped into lots. A lot is defined as all animals from the same owner and of the same sex. Pens hold a minimum of 20 animals or one truck load [7].

Suspicious cases are sent to a separate sanitary slaughter building that usually has a necropsy room attached to it. Fallen stock are treated as an emergency slaughter [7, 21].

Post-mortem inspection: Post-mortem inspection includes inspection of the hooves, the head, and associated organs and lymph nodes. Inspections are conducted by Federal technicians on lines labeled A through H, with each line checking a different part of the carcass. When a lesion is found, the technician fills out a form, marks the carcass and then stores it separately in a special area for closer inspection. The field veterinarian then investigates more closely. In particular for FMD, the technicians specifically check the feet, muzzle, and tongue for vesicular lesions. If the technicians have any doubts, they notify the veterinarian immediately. The veterinarians train technicians to perform these inspections. Approximately 1 percent of the animals are condemned per day at some facilities [7, 21].

Maturation and pH testing: The carcasses are matured for a minimum of 24 hours at a temperature of 2 to 10°C. Temperature is measured when the first carcass enters the cooler and again after the last carcass enters and doors are closed. Specific cooling chambers are approved for use for export products and are labeled as such. After 25 hours, trained quality control technicians measure the pH of the meat at one point in the loin muscles in each half of the carcass. The technicians work for the plant but are supervised by the Federal service. If the pH is above 5.9 (per requirements of their current trading partners), the carcass is separated from the export beef and only used for domestic consumption. The carcass halves are pH tested and accepted or rejected independently. The pH inspectors are supervised randomly by the official veterinarian [7].

Federal regulations require calibration of pH meters but it is up to the facility to determine how to accomplish this. For example, the facility in Campo Grande calibrates pH meters twice a day while the one in Goianas calibrates every 25 measurements. However, calibration procedures were written down at all facilities that APHIS visited. Calibration results are recorded as the meter is tested. Standard buffer solutions are always available and are changed daily. The quality control officer trains the technicians every 6 months in pH testing and calibration [7].

Deboning: Deboning consists of removal of bone, lymph nodes, and blood clots. When required, deboning is carried out under supervision of the quality control personnel. All products must pass through the quality control point where a score of acceptability is assigned. If the product is unacceptable, the whole lot must be checked piece by piece. The official service conducts random checks on some lots [7].

Packaging: Meat is packaged in boxes that are labeled with production date, slaughter date, type of product, and weight. Each box has a unique number barcode, which is important for traceability. APHIS observed that lot numbers are not placed on shipping boxes, which may affect traceability once the meat is deboned. At this point, boxes of meat are no longer tracked by lot. Instead, the date of production is used. APHIS recommended to Brazilian officials use of lot numbers to enhance the traceability of meat boxes. Meat is chilled for a maximum of 45 days or it must be sent to local markets or used for dried meat. All shipping containers are cleaned and disinfected before shipping, and must have a certificate of disinfection [7].

Conclusions

APHIS did not identify significant risk pathways to consider commercial operations in the export region as a likely source for introducing FMD into the United States. APHIS concluded that the larger commercial operations are likely to be the source of beef exports from the export region. In that regard, APHIS considers the beef industry in the export region to be well organized and committed to the production of quality product and to preventing FMD outbreaks.

APHIS concluded that Brazil's animal identification system is operational. Its use enhances Brazil's ability to certify the origin of animals entering the export channels.

The auction system in the country is well-organized and tightly controlled by the official service. There is no evidence to suggest that major movements of animals into export channels occur through the auction system.

APHIS concluded that adequate controls and inspection measures exist at slaughter facilities. In that regard, ante-mortem and post-mortem inspections are carried out satisfactorily. APHIS verified pH controls, maturation, and deboning procedures at the three plants, which export to the EU and other countries. APHIS concluded that after maturation, every carcass is tested, to ensure the pH is not greater than 5.9. If greater, the carcass is diverted to local consumption. APHIS examined maturation records and verified actual rejected and approved seals.

APHIS considers that pH testing and calibration of pH meters critical mitigation measure in assessing the risk of importing FMDV in beef from Brazil.

The biosecurity measures applied at the facilities APHIS visited were adequate and there is a high level of awareness and compliance with these measures. In addition, processing facilities are integrated within these operations and are under adequate official control and inspection.

In terms of the importation of matured deboned beef, APHIS concluded that Brazil has adequate control of inspection activities in slaughter plants, and can certify compliance with USDA import requirements. A comparable system for control of commercial shipments also exists and is considered adequate to control import and export of beef products.

9. Disease surveillance

Strategies for FMD surveillance in Brazil

Brazil implements both passive and active surveillance strategies to demonstrate freedom from FMD. The Brazilian FMD surveillance system can be broadly characterized as having two phases: (1) demonstrating freedom from disease in a zone, and (2) monitoring of that zone. Brazil has implemented these strategies in the export region.

Phase I: Demonstrating freedom from disease in the region [6, 8-10, 20]

The basis for demonstrating freedom from infection in the region is through active surveillance, which, in Phase I, constitutes a region-wide campaign of a one-time extensive serological sampling of cattle, sheep, and goats based on a probabilistic sampling design.

Statistical design for selecting animals for serological sampling: The probabilistic sampling design that has been employed in all serological surveys in all phases of the surveillance system in Brazil is a stratified, two-stage cluster sampling design. Under this design, the selection of animals for

serological sampling is conducted in three steps: (1) stratification of the region, (2) first-stage sampling of clusters¹, and (3) second-stage sampling of animals within the selected clusters. A more detailed explanation of these three steps follows [8].

1. Stratification of the region:

The Brazilians stratified² the region according to several stratification³ parameters, such as the area's prevailing livestock production systems, livestock circuits (these concepts are explained below), and the epidemiological conditions in the area.

- a. Livestock production systems: This is an important stratification factor that results in more sampling efficiency. Different livestock production systems in Brazil are characterized by factors such as the breed of the animal, climate, soil conditions and type of pasture. Also, the huge geographical, economic, and social diversities create different types of livestock production systems across the country [20].
- b. Livestock circuits: Similarly, stratifying the region according to livestock circuit can also result in further sampling efficiency. At the present time, there are five livestock circuits in Brazil: Southern, Mid-western, Eastern, Northern and Northeastern.
- c. Regionalization according to risk status: Another important stratification parameter that has been used is the regionalization of the disease based on the risks of transmission and contamination by the viral agent. Six risk levels have been established and used for stratification purposes. (See livestock demographics and movement patterns.)

2. Sampling of clusters (first-stage sampling):

After stratifying the region into different strata (typically three strata), each stratum is viewed as an independent subpopulation within the region. In each stratum, a predetermined number of clusters is selected at the first stage of sampling in such a way to achieve a 95 percent statistical confidence of finding at least one diseased herd (or cluster) at an assumed cluster prevalence, usually 0.5 or 1 percent.

3. Sampling of animals within-clusters (second-stage sampling):

This task involves the random selection of a (predetermined) number of animals from each selected herd in each stratum (i.e., sample size of animals within each herd). The sample size is calculated in such a way as to achieve a 95 percent statistical confidence of finding at least one diseased animal within the herd (or cluster) at an assumed within-cluster prevalence, usually 5 or 10 percent.

¹ A cluster is defined as a large herd or an aggregate of smaller herds.

² In stratified sampling, the population is partitioned into regions or strata, and a sample is selected by some design within each stratum. The selections in different strata are made independently, and the principle of stratification is to partition the population in such a way that the sampling units within a stratum are as similar as possible. Thus, even though one stratum might differ markedly from another, a stratified sample with the desired number of sampling units from each stratum in the population will tend to be "representative" of the population as a whole.

³ The three major advantages of stratification over simple random sampling are (1) more precise estimates, (2) separate estimates for each stratum can be easily obtained, and (3) convenience.

Example: The two-stage cluster sampling design⁴

To demonstrate freedom from FMD in the States of Mato Grosso do Sul, Mato Grosso, Goiás, Tocantins, Minas Gerais, Bahia, Sergipe, Espírito Santo, Rio de Janeiro, and São Paulo, Brazil conducted an extensive serological sample survey in FMD-susceptible animals using the sampling strategy described on the previous page. Two strata were defined that corresponded to regions located in the Eastern and Midwestern livestock circuits.

The null hypothesis

Brazil assumed a 0.5 percent prevalence of FMD among clusters (i.e., herd prevalence). It was also assumed that the within-cluster prevalence (i.e., within-herd prevalence) would be at least 10 percent for clusters holding less than 500 eligible animals and 5 percent for clusters with more than 500 eligible animals. Animals between the ages of 6 and 24 months were eligible.

Testing scheme

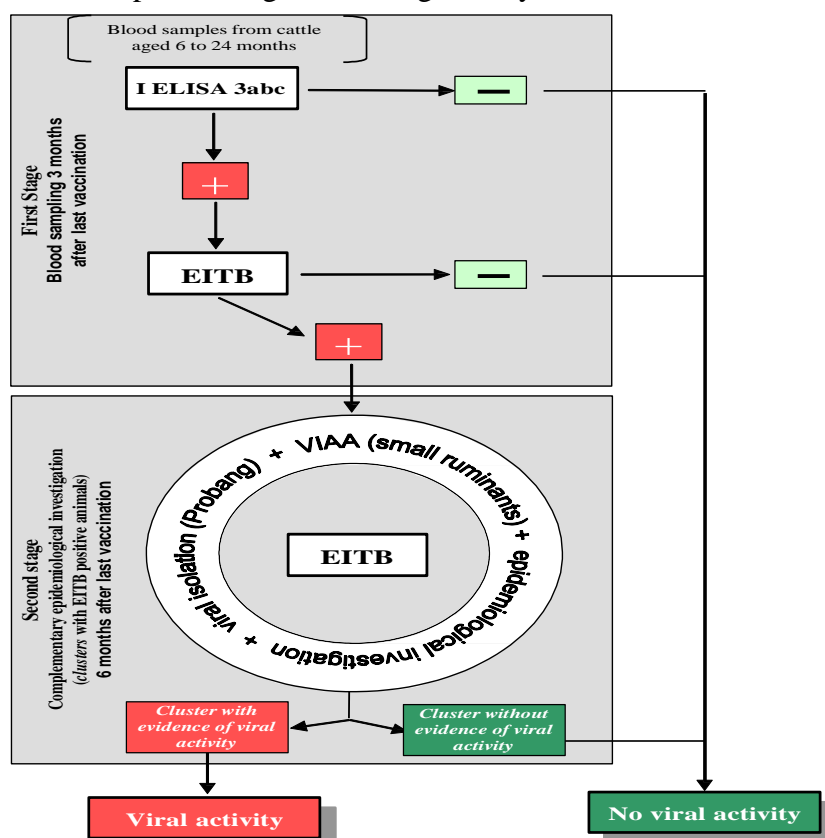
The diagnostic system used in this survey applied a series of tests in order to achieve a high sensitivity of detecting disease in the following sequence:

- 1) An ELISA 3ABC for initial screening to detect antibodies against viral NSP in sera collected around three months after the last vaccination;
- 2) An EITB assay for testing ELISA 3ABC positive animals;
- 3) A second EITB in sera collected around six months after the last vaccination from animals that reacted to the first EITB test.

The rationale for this testing strategy is the assumption that reactions induced by vaccination tend to decline sharply with time. The epidemiological investigation included testing of unvaccinated sheep and goats, using the virus infection-associated antigen test (VIAA) in clusters where cattle reacted to the EITB test. The diagnostic strategy is presented schematically in figure 10.

⁴ This is an example of how the above sampling strategy was used to demonstrate freedom from disease for a new region proposed by Brazil.

Figure 41: Diagnostic and epidemiological investigation system



Source: MAPA, "Enlargement of the foot-and-mouth disease free zone, where vaccination is practiced – Midwestern and Eastern livestock circuits," Brazil 2000.

Results of the serological survey

The number of sampled cattle in this survey was 35,410 within 1,280 clusters: 14,738 animals from 641 clusters in Stratum I and 20,672 animals from 639 clusters in Stratum II (table 7). The results of the sample survey (table 8) show a total of 149 EITB positive reactors in Stratum I and 291 EITB positive reactors in Stratum II. All positive reactors were followed by a series of further tests and complementary epidemiological investigations. The results of these tests indicate false positives.

Table 7: Clusters and cattle sampled per stratum.

	Stratum 1 (East)	% of total	Stratum2 (Midwest)	% of total
Cattle aged 6-12 months	5,594	38%	6,916	33%
Cattle aged 13-18 months	5,816	39%	8,440	41%
Cattle aged 19-24 months	3,328	23%	5,316	26%
Cattle aged 6-24 months (total)	14,738		20,672	
Number of clusters	641		639	

Source: MAPA, "Enlargement of the foot-and-mouth disease free zone, where vaccination is practiced – Midwestern and Eastern livestock circuits," Brazil 2000.

Table 8: EITB-positive cattle and clusters with EITB-positive cattle.

Stratum	Clusters sampled	EITB-positive clusters*	Cattle sampled	EITB-positive cattle**
(1) East	641	94 (14.7%)	14,738	129 (0.9%)
(2) Midwest	639	149 (23.3%)	20,672	291 (1.4%)
Overall	1,280	243 (19.0%)	35,410	420 (1.2%)

* A cluster was classified as positive if at least one animal tested positive

** A bovine was classified as positive if it reacted positively to the sequential testing scheme: I-ELISA 3ABC, 1st EITB (3 months after vaccination), and 2nd EITB (6 months after vaccination).

Source: MAPA, "Enlargement of the foot-and-mouth disease free zone, where vaccination is practiced – Midwestern and Eastern livestock circuits," Brazil 2000.

Complementary epidemiological investigation

Further epidemiological investigation was conducted in all clusters with positive EITB test results. The investigation involved 491 clusters that had at least one EITB positive animal on the first blood sampling, which was taken approximately 3 months after the last vaccination. All herds within these clusters were included in the investigation, whether or not they had any positive result. A total of 1571 unvaccinated sheep and goats — 955 in Stratum 1 and 616 in Stratum 2 — kept in the clusters under investigation were bled and inspected for clinical signs of FMD. The VIAA test results were all negative and the investigation did not indicate evidence of viral activity. Overall, 73 probang tests were carried out in Stratum 1 and 194 samples were processed in Stratum 2. All 267 test positive cattle that were examined for the presence of the virus yielded negative results.

Brazil's observations on survey results

The overall percentage of test-positive clusters was 19.0 percent in this survey (table 8), which was slightly higher than the 16.2 percent value observed in a previous survey carried out in 1999 to demonstrate freedom from FMD. Furthermore, the overall prevalence of test-positive animals of 1.2 percent in this survey was also slightly higher than the 1.0 percent in 1999.

It was also noted that the proportion of EITB-positive animals by age category followed the same trend of the average number of vaccinations by age category. Brazil stated that this increase in the proportion of test-positive animals from 6 through 24 months of age is not consistent with the epidemiology of FMD, as younger animals would have been expected to seroconvert at higher rates.

The proportion of EITB-positive animals after the second EITB test, which was carried out around 6 months after the last vaccination, was markedly lower than the proportion after the first EITB test (taken three months earlier). These proportions were lower by 73, 69, 63, and 54 percent, for animals vaccinated once, twice, three times, or four times, respectively [8].

Stratum 2 (Midwest) showed higher prevalence of test-positive animals than Stratum 1 (East) across all age categories. This difference in observed prevalence of test-positive animals between the two strata could not be attributed to an imbalance in the use of certain commercial vaccines since vaccines were applied to very similar proportions of cattle sampled in each stratum (34 percent in the East and 31 percent in the Midwest). Since it was observed that the average number of vaccinations

per animal of each age category was also positively correlated with test-positive results, the Brazilians argued that the difference was most likely due to a confounding factor, namely, the number of vaccinations per animal.

In order to assess the confounding effect of the number of vaccinations per animal, the Brazilians conducted a statistical test to check for significant differences between the two proportions. The calculation was stratified in three levels: animals that received up to two, three, or more than three vaccinations. The Mantel-Haenszel Chi-Square test statistic indicated that the two proportions were not significantly different, suggesting that the number of vaccinations per animal was indeed a confounding factor. With the effect of vaccination removed, the observed difference in prevalence of test-positive animals between the two strata was no longer significant.

Phase II. Monitoring [6, 19]

Phase II begins once freedom from infection has been established and the zone is declared as free-with-vaccination by the OIE. The main goal in this phase is to prevent the reintroduction of the disease, maintain good sanitary conditions, and provide technical grounds to demonstrate the continual absence of disease and viral activity in the zone. Passive surveillance is the main surveillance used in this phase, although active surveillance is also used. Active surveillance complements passive surveillance primarily by targeting specific “high-risk” areas within the zone for serological sampling and more in-depth investigations.

Passive surveillance

Passive surveillance activities include observations made during (1) animal movement control activities and trade of animal products, (2) farm inspections, (3) slaughterhouse inspection, and (4) inspections during livestock fairs [6]. Data on the above activities are collected annually.

Since passive surveillance relies heavily on community participation and other similar inputs primarily through the LVU, efforts are made to assess the level of community participation by means of reporting any suspicion of vesicular diseases and to continually keep the private community informed and educated about FMD. For example, in 2002, the official service held 9,702 seminars, reaching 213,131 people, with an average of 23 participants per event [6].

Active surveillance

Active surveillance constitutes targeted seroepidemiological surveys in specific “high-risk” areas within the zone that DDA considers free. The surveys aim to prove that the zone remains free of viral activity. Serological testing is also conducted whenever there is a suspicion of disease. High-risk areas are defined as those that: a) have high intensity of displacement of animals; b) are located close to slaughter houses, livestock events, urban waste deposits, international borders, or borders with States where the disease is present; c) are characterized as having a high level of breeding and rebreeding activities; and d) practice intense movement of animals and animal products (e.g., rural and family-owned properties).

All targeted serological sampling surveys follow the same stratified, two-stage cluster sampling design described earlier. Also, all sample size calculations are conducted to achieve a 95 percent statistical confidence that there is no viral activity in the targeted “high-risk” properties.

Example: targeted seroepidemiological monitoring⁵

Since August 2001, Brazil has conducted yearly serological surveys in the export region. The survey is carried out in areas that pose higher risks of reintroduction of the disease as described above. In each identified risk area, the official authority selects rural properties whose animal production systems are significant for beef cattle breeding and reproduction. In addition, selection of high-risk properties takes into account the high entry/exit ratio of animals and proximity to slaughtering establishments, facilities allocated for animal-related events, and landfills for disposal of urban garbage. Monitoring efforts also cover landless farm worker settlements that apply family production systems, featured by intense exchange and introduction of animals from different localities. The selected properties undergo regular clinical inspections and serum samples are collected for laboratory tests. There are currently 5,676 risk properties totaling 2.3 million bovine, 27,800 small ruminants, and 24,400 swine.

Sample collection

A total of 358 high-risk rural properties with bovines 7 to 24 months old were randomly selected for the survey. Serological samples were randomly collected from animals in each property. A 10 percent minimum prevalence was assumed. Total samples collected reached 9,802, which represented an average of 27 samples per property. The EITB test was used at two different times: first, in all collected samples 4 months after the latest vaccination, and second, to test new samples collected from animals that tested positive in the first test 1 to 2 months after the first collection. Animals that remained reactive to the second EITB test were tested for virus by probang sampling.

Results

All probang samples collected tested negative for the virus. All properties with reactive animals were submitted to a supplementary epidemiological investigation, including clinical evaluation of the existing animals with no evidence to indicate viral activity.

The 2013 APHIS site visit team determined that the FMD surveillance strategies were adequate and that the serological surveillance plan (updated in August 2010) appears well designed and executed. The immunological status of the vaccinated bovine population has been appropriately and routinely reviewed, showing excellent levels of FMD-specific antibodies in all age ranges against all three serotypes (A, O, and C).

Conclusions

Brazil has a two-phase surveillance system that effectively uses active and passive surveillance. Its active surveillance is based on an efficiently stratified, two-stage cluster sampling design, and its passive surveillance takes advantage of the community structure in Brazil and relies heavily on the participation of the community. APHIS noted that Brazilian animal health officials have carefully and methodically considered each component of their surveillance system and concluded that their stratified, two-stage cluster sampling design is appropriate, efficient, scientifically valid, and simple to implement. All technical aspects of that design were addressed properly.

⁵ This is active surveillance which constitutes targeted seroepidemiological sampling within the region to complement the passive surveillance efforts

APHIS concluded that Brazilian authorities satisfactorily addressed the confounding issue of the observed positive association between positive test results and the average number of vaccinations an animal had received. APHIS concurs that this linear trend is most likely because older animals have received more vaccinations than younger ones and does not necessarily indicate viral activities among older animal. In addition, APHIS concluded that false positive results were evenly distributed among the target population, which further supports the hypothesis of absence of viral activities.

APHIS verified the validity and results of the statistical tests conducted by Brazil to examine the difference in the number of EITB-positive animals between the two livestock circuits. APHIS agrees with the Brazilian argument that the insignificant difference of the proportions of the EITB-positive results in the two circuits would support the hypothesis that the observed difference was most likely due to confounding by the average number of vaccinations per animal.

APHIS verified that the sample sizes collected were adequate to detect the estimated prevalence, using FreeCalc software. The test specificity of 100 percent that Brazil used is what APHIS would have recommended for determining sample sizes since it would yield a more conservative sample size estimate, i.e., a higher sample size.

APHIS concluded that the Brazilians were particularly effective in their educational campaigns about FMD and its eradication strategy both to all animal health officials as well as community members across the country. APHIS' observation during recent site visits to Brazil lead to the conclusion that their FMD eradication strategy and surveillance steps have been fully communicated, understood, and embraced by all animal health officials in the country. This was evident by the high degree of consistency in implementation and execution of the program at every LVU visited, and with all Federal and State personnel involved in the eradication efforts. In addition, the serological surveillance plan appears well designed and executed. As previously stated, the immunological status of the vaccinated bovine population has been appropriately and routinely determined, showing excellent levels of FMD-specific antibodies in all age ranges against all three serotypes that are used in the vaccination campaigns.

10. Diagnostic laboratory capacity

General information

The Ministry of Agriculture has four laboratories that perform diagnostic tests for FMD and other vesicular diseases. These laboratories are located in the states of Rio Grande do Sul, Pará, Minas Gerais, and Pernambuco. The PANAFTOSA laboratory in Rio de Janeiro is the reference laboratory. At the time of the 2013 visit, only the laboratories in Pará processed infectious material. PANAFTOSA's laboratory work involving any infectious material is performed at the Pará laboratory [7, 9].

The Brazilian government has made funds available to finance the construction of another BL3 laboratory as part of PANAFTOSA [7].

Routine laboratory tests, as performed by the Brazilian laboratories, are listed below:

1. Virus typing: complement fixation and ELISA test (double antibody Sandwich ELISA)
2. Assessment of antibody level: ELISA test in liquid phase (blocking ELISA) and serum neutralization
3. Detection of viral activity: VIAA, ELISA 3ABC, and EITB tests
4. Identification of the virus in esophageal-pharyngeal fluid: Probang test

Two accredited laboratories are part of a network of authorized laboratories that perform certain diagnostics in the FMD program as part of the activities to admit animals into the export region and for serological monitoring. The laboratories perform EITB and VIAA tests and began ELISA 3ABC testing in 2002. Only MAPA laboratories carry out diagnostic activities in response to suspected outbreaks of vesicular diseases and as a part of viral activity studies for the implementation of free zones.

In 2002, APHIS visited three of these laboratories [7]. The findings of the team were as follows:

Diagnostic laboratory in Pedro Leopoldo, Minas Gerais:

- This Federal laboratory had a BSL-2 facility for bacteriology (brucellosis and TB testing) and chemistry laboratory.
- The staff had about 94 people.
- Behind the BSL-2 facility, a new BSL-3 laboratory was under construction.
- The laboratory was about 2,500 square meters in size and had nine laboratories with a double airlock and a separate air zone for each laboratory. There was a separate animal facility with a separate entrance.
- The facility had three rooms for large animals with an individual shower for each room, and three rooms for small animals with a common shower in the hallway.
- The necropsy room had two oversized autoclaves for decontaminating carcasses.
- HEPA filters and the mechanical room were located on the third floor.
- The basement had three 3,000-gallon tanks for decontaminating effluent by boiling at 100°C.

Animal Products Analysis Laboratory (LAPA/Recife), Pernambuco

- This Federal laboratory conducted FMD serology for all of Brazil except the northern part, where FMD was considered endemic.
- Vaccine efficacy was assessed in 5- to 7-day-old mice. FMD vaccine safety testing was tested in the baby hamster kidney-21 (BHK-21) cell line.
- At the time of the visit, the laboratory had five professional staff and three technicians. They tested 30,000 serum samples per month for FMD serology.
- Criteria for conducting follow-up on the positive samples seemed correct and well carried out through EITB and ELISA confirmatory tests. The laboratory used virus isolation, ELISA, complement fixation and IDGA to confirm vesicular disease diagnosis from the regional authorized laboratories.
- The laboratory was also equipped to run the highly sensitive suckling mice inoculation technique for antigen detection, which is used for vaccine security tests.
- The laboratory used ELISA, complement fixation, virus isolation and seroneutralization assays to diagnose differential diseases such as infectious bovine rhinotracheitis, bovine viral diarrhea virus and vesicular stomatitis virus.

The 2008 site visit team visited the Recife laboratory in Pernambuco and found:

- The laboratory provides FMD and CSF serology and FMD vaccine efficacy for all of Brazil except for the northern part, where FMD is endemic.
- The laboratory is working under MAPA Regulation 1 issued January 16, 2007; 2^o Art.; 5,741 Decree of March 30, 2006, and according to the process 21000.004072/2005-19, which defines the criteria for accreditation of MAPA's national agricultural laboratories (Laboratorio Nacional Agropecuario, or LANAGRO). An independent agency regularly audits facilities under this regulation.
- The laboratory also diagnoses the following:
 - FMDV and other diseases with similar clinical signs such as vesicular stomatitis virus, bovine viral diarrhea virus, and bovine rhinotracheitis virus;
 - CSFV and its differentials Aujeszky's disease, swine colibacillosis, porcine erysipela, pasteurellosis and salmonellosis; and
 - 17 other animal diseases.
- Brazil has five FMDV vaccine plants in production. Two are close to Santa Catarina, one in Parana and one in Matto Grosso do Sul. The laboratory visited provided vaccine efficacy for each lot of FMDV vaccine produced.
- The laboratory tests vaccine efficacy and potency using inoculation in 5- to 7-day-old mice and seroneutralization titers in sera from the vaccinated animals. The animals are not given live virus.
- FMD vaccine safety is tested using the BHK-21 cell line.
- The laboratory has 27 professional staff members and 110 technicians or supporting personnel. Seven professionals (veterinarians and chemical and agronomic engineers) provide CSFV-FMDV diagnostics. These individuals have been working at the laboratory for at least 10 years.
- The laboratory is old but well maintained and reasonably equipped.
- The site visit team found the laboratory personnel highly qualified and motivated. The team also found that they have the equipment necessary to detect disease.
- The turnaround time for results is excellent, avoiding the extension of quarantine time on farms and States affected by an epidemiological alert.
- The laboratory has standard operating procedures) and quality assurance control for at least the two tests the site visit team scrutinized. The procedures for FMDV diagnosis are well established and are suited for both detection and confirmation of the etiologic agent. They are:
 - Surveillance and transport certificates and serum samples are sent to accredited laboratories in Rio Grande do Sul, Sao Paulo, Minas Gerais, and Mato Grosso. Inconclusive ELISA/ITB results go to Recife.
 - If a clinical case is reported, the DSA directs that the samples be sent to LANAGRO to perform VIAA or ELISA 3ABC/EITB. If a case ends up with suspected positive results, an alert is sent to the DSA and CGAL (General Coordination for Animal Laboratories) authorities who in turn will implement their control and eradication policies.

The 2013 site visit team visited the LANAGRO laboratories located in the states of Pernambuco, Minas Gerais, and Para. At the time of the visit, a BSL-3 laboratory was near completion in LANAGRO/PE (Recife), and a BSL-3 PANAFTOSA laboratory and BSL-2 LANAGRO/MG laboratory were operating in Pedro Leopoldo. Only the laboratory located in the state of Pará (Belem) processes infectious material. All the other laboratories were accredited for ELISA and EITB tests.

The 2013 team considered that FMD laboratory methods, quality control, and recordkeeping were good; workflow was efficient, facilitating good turnaround times. A review of surveillance, notification, and follow-up of suspects as well as emergency strategies should allow for early detection of cases and rapid emergency response. The immunological status of the vaccinated bovine population was routinely evaluated and showed good levels of FMD-specific antibodies against serotypes A, O, and C in all age groups. Conventional and real-time polymerase chain reaction (PCR) tests have been included as part of the laboratory's FMD diagnostic capabilities in addition to sequencing capabilities. The specific findings of the 2013 APHIS team were as follows:

- The testing procedures were all approved, standard methods recommended by the OIE.
- The LANAGRO laboratories visited were ISO 17025-accredited and meet international standards of testing and calibration.
- The quality control and recordkeeping in the laboratories was good, allowing easy traceability of samples and reagents, detection of human error or reagent deficiencies, and determination of corrective actions when needed.
- The laboratory work flow was efficiently designed, facilitating optimal turnaround times in laboratory results and enabling rapid response.
- The surveillance, notification of suspects, and emergency strategies reviewed were appropriate and allowed for early detection should the virus reappear.
- The serological surveillance plan (updated in August 2010) appeared well designed and executed.
- The immunological status of the vaccinated bovine population has been appropriately and routinely determined, showing excellent levels of FMD-specific antibodies in all age ranges against all three serotypes (A, O, and C).
- A review of the suspect cases from 2012 and 2013 confirmed that the procedures for notification of suspect cases, clinical exam of animals, sampling and management of the samples, were followed.
- The recent addition of conventional and real-time PCR as part of the general battery of diagnostic tests was a significant improvement, and expanded capacity for rapid detection and enhanced sensitivity. The ability of LANAGRO-Minas Gerais to generate sequence data further enhanced its already significant capacity for rapid response.
- Procedures were in place to avoid shipping or handling the infectious virus outside the prescribed special provisions, minimizing the opportunity for accidental virus release.

Conclusions

APHIS concludes that Brazil has the diagnostic capability to adequately test samples for the presence of the FMD virus. The laboratories in Rio Grande do Sul, Pará, Recife, and Pernambuco have adequate diagnostic capabilities to test samples for the FMD virus, including adequate quality

control activities, laboratory equipment, and sufficient staff. The tests used to investigate evidence of viral activity are consistent with OIE guidelines. The staff members at the facilities visited were well trained and motivated. The laboratories have sufficient quality control activities, routinely monitor and calibrate laboratory equipment, have sufficient staff, have an effective and efficient recordkeeping system for storage and retrieval of data, and turn samples around quickly.

11. Emergency response capability

General information

Animal owners, veterinarians, transporters, and others are required by law to notify the LVU in the event that FMD is suspected [6]. Penalties for noncompliance may include significant fines and legal action [10]. The official service is required by law to respond to such reports within 8 hours [6]. If the LVU confirms a probable outbreak by clinical observation, the central offices of the affected State and the DDA in Brasilia must be informed immediately. If the suspected case occurs in an international border region, the local unit of the neighboring country must also be informed.

Following the clinical confirmation of a vesicular disease, the farm involved and others in close proximity are quarantined and all animal movement is prohibited [6]. Unauthorized movement of people and vehicles onto and off the premises is also prohibited. Samples are collected for laboratory analysis and an epidemiological investigation is started. Following laboratory confirmation, a state of sanitary emergency is declared which enables recruitment of the civilian defense and military forces to the effort. In addition, other States, neighboring countries, trading partners, and international organizations are notified of the outbreak [20].

The Brazilian government has developed a Federal contingency plan for FMD, which is triggered by an official declaration of sanitary emergency at the State level [9]. In addition, each State is responsible for maintaining an organization ready to handle health emergencies, establishing coordinating committees and emergency animal health technical groups, defining strategies and plans of action, and, when necessary, carrying out the appropriate control measures within a timeframe compatible with a state of emergency [6].

The Federal contingency plan calls for a 25-km-radius emergency area to be established around the affected farm, in which the movement of live animals and animal products is severely restricted [8, 9]. Within the emergency area, three smaller areas of increasing radius are established: (1) an infected area that includes farms within 3 km of the outbreak, (2) a 7-km surveillance ring around the infected area, and (3) a 15-km buffer zone. An epidemiological investigation is initiated parallel to the actions taken to control the outbreak.

All affected and contact animals in the infected zone are slaughtered by the police force using rifles and buried in plots defined by environmental professionals to minimize contamination of groundwater sources [10]. Indemnity is paid to the owners as defined by State laws through tax funds that are controlled and administered by the private sector [15]. The holdings are cleaned and disinfected, and sentinel animals are introduced after 30 days [6]. These sentinel animals are young bovines, unvaccinated and without history of exposure to FMD; sentinel animals are serologically tested prior to moving onto the property and then again at 15 and 30 days. All animals are inspected

daily for clinical signs. Controlled repopulation with vaccinated cattle is permitted after the sentinel animals have been in place for 30 days. The sentinel animals undergo serologic testing on introduction and at 15 days and 30 days after introduction. They are also subjected to weekly clinical evaluation, including measurement of body temperature. If both clinical exams and laboratory testing yield negative results at the end of the 30-day period, the facility may gradually carry out a controlled repopulation, under the supervision of the official veterinary service. If any of the sentinel animals test positive on serologic evaluation, all other animals are killed and the process starts again. The contingency measures applied in protection and surveillance zones are maintained until the property has been determined to be free of disease.

Animal movement in the surveillance zone is prohibited except for movement to slaughter at abattoirs located within the zone [6]. The meat obtained is for local consumption only and must be deboned and the bones incinerated. All susceptible animals within the zone are inspected for clinical signs, vaccinated and revaccinated as necessary, and a serological survey of susceptible cattle is conducted. Animal movement within the buffer zone is also restricted and similar actions occur without the serological surveillance.

The Federal contingency plan was employed during the outbreaks in the States of Mato Grosso do Sul in 1998 and 1999, in Rio Grande do Sul in 2000 and 2001 [10], and in Mato Grosso do Sul and Parana in 2005 and 2006 [14]. From 1995 to 1999, the average time between the probable start of the outbreak and notification to the local veterinary unit was 6 days [8]. The time between notification and the start of official emergency measures at the holding was approximately 8 hours for the same period. From 1995 to 2000, the percentage of the communities participating in the notification process ranged between 58 and 74%.; the lower levels can be explained in part by outbreak surveillance actions superseding community notification.

There are 10 emergency response teams in the eastern and midwestern livestock circuits, consisting of 190 veterinarians who have received specific training with regard to FMD [8]. Rondônia has 32 veterinarians trained in emergency response, with emphasis on FMD [9]. In addition, all veterinarians in the official service receive periodic training to refresh their skills in FMD surveillance and control. Training sessions usually last 9 days and consist of both theoretical and practical exercises [10]. Training exercises are also carried out periodically in the States with the participation of all sectors, authorities, and institutions typically involved in emergency response [6].

The May 2001 outbreak of FMD in the export region occurred in Rio Grande do Sul, in six municipalities; no direct epidemiological links were found among the municipalities suggesting separate introductions of the virus [13].

Four of the six municipalities involved had secondary outbreaks, although extensive dissemination occurred only in Rio Grande [13]. Laboratory diagnoses were obtained in the majority of cases in municipalities other than Rio Grande, where the advanced stage of the lesions impeded the diagnosis. Clinical signs occurred only in cattle and buffalo, with an average attack rate of 5.6 percent. The affected and contact holdings were interdicted on suspicion of FMD and, following laboratory confirmation, a state of emergency was declared by Rio Grande do Sul on May 6.

Neighboring countries, the OIE, and trading partners were notified appropriately following international standards.

A 25-km-radius emergency area was established that incorporated the 3-, 7-, and 15-km zones described above. Ultimately 2,348 holdings were interdicted involving 345,285 bovines. Fifty-six 24-hour roadblocks were established specifically for FMD surveillance and 118 teams of inspectors controlled the movement of animals and risk products. All sanitary measures, particularly those related to the interdiction of holdings and the prohibition of animal movement, were supported by specific legislation.

Due to the potential for rapid dissemination as seen in Argentina and Uruguay, the State authorized emergency vaccination of the entire bovine and buffalo herd on May 9. Ninety-eight percent of the total herd (13,375,190 animals) was vaccinated within 30 days, and 97 percent (13,268,178 animals) was revaccinated in another 30-45 days. The Federal Government donated 4 million doses of vaccine to the small producers in the State.

The slaughter of affected animals was completed by June 18, the date of confirmation of the last outbreak in the State. The average time from the date of notification to the slaughter of affected animals was 7.6 days. The remaining susceptible animals in contact were slaughtered by October 5. All owners were compensated. After an affected holding was depopulated, cleaning and disinfection activities were conducted. The premises remained empty for 30 days and then sentinel animals were introduced, which remained on the property for at least 30 days with clinical observation. Serological tests were conducted after 15 and 30 days. No evidence of viral activity was found.

Serological investigations were conducted in the infected and surveillance areas in conjunction with the control and stamping out activities. All cattle, buffalo, and sheep in the infected area were tested; ELISA 3ABC (screening test) and EITB test (confirmation test) were used for bovine species and VIAA for sheep. All of the sampled sheep were negative, whereas 8.6 percent of the bovine samples (4,793 animals) were positive. Animals that tested positive were slaughtered for local consumption and the owners compensated.

A serological survey was also conducted in the surveillance zone, focusing on weaned younger cattle. The survey was designed to detect at least one positive animal per herd with 99 percent confidence, assuming a prevalence of infection of 15 percent within the herd. One or more animals tested positive on 214 properties (41 percent). On these properties, all susceptible animals were tested and any animals that tested positive were slaughtered for local consumption.

During the 2003 site visit, Brazil reported that there are two theories about how the 2001 outbreak in Rio Grande do Sul began, both involving mechanical transmission: (1) a farmer with property both in Uruguay and Brazil, or (2) duck hunters driving back and forth across the border without cleaning and disinfecting. Brazilian officials indicated that when Argentina reported cases in 2001, no actions were taken in Rio Grande do Sul except for an increased alert status. When the outbreak began in Uruguay, vehicles were inspected and driven through a wheel dip, and undercarriages were sprayed. People were required to walk across a rug with disinfectant, and public information campaigns were increased. Mobile spray units were used on secondary roads [7]. The emergency response efforts in

place during the 2005 and 2006 outbreak are described in detail under factor 2 “Disease status in the export region.”

The 2013 APHIS site visit team reviewed the vesicular diseases emergency response and contingency plans. The team concluded that FMD surveillance, notification, and follow-up of suspects should allow for early detection of cases and rapid emergency response. A review of the suspect vesicular cases from 2012 and 2013 confirmed that the procedures for notification of suspect cases, clinical exam of animals, sampling and management of the samples, are followed. In addition, procedures are in place to avoid shipping or handling the infectious virus outside the prescribed special provisions, minimizing the opportunity for accidental virus release.

Conclusions

Brazil relies heavily on community notification of FMD outbreaks, as it tends to be the most efficient way to locate disease. Once notification occurs, the Federal contingency plan for FMD is extensive and thorough, and a significant degree of autonomy is built in at the State level.

APHIS concludes that adequate legal authority, funding, personnel, and resources exist at both the State and Federal levels to carry out emergency response measures. Based on the FMD outbreaks in reported since 2001, the emergency response is both rapid and effective.

Release Assessment – Summary of risk factors and mitigations considered

APHIS identified risk factors that might be associated with importing beef to the United States 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 United States. The risk mitigation procedures, which will be defined in the proposed rule, include various forms of verification and inspection that MAPA would need to certify to provide confidence that the beef meets acceptable export criteria.

I. Likelihood of FMD introduction into the export region

Risk factors:

1. FMD is endemic in some countries in South America. Consequently, there is risk of reintroduction of FMDV from adjacent affected areas into the export region. Therefore, there is a risk that beef destined for the United States could originate from or be commingled with animals or animal products from affected neighboring areas.

Mitigations: Based on site visit observations and discussions with Brazilian officials, APHIS considers that veterinary officials in Brazil have adequate controls at the ports of entry for commercial and legal importation and sufficient controls exist at international airports to mitigate risk. Brazil prohibits the importation of FMD-susceptible animals and animal products from affected countries into the export region and controls movement from other areas in Brazil where FMD is known to exist or which has not yet achieved the appropriate

FMD status. In addition, Brazil has stringent requirements in place, including serological testing of animals, for importing susceptible animals or animal products from neighboring countries. Therefore, APHIS concludes that the likelihood that FMD will be introduced via legal importation is low.

APHIS will propose in its rule that MAPA certify that the animals and products originated from the export region and were not commingled with animals or products from areas APHIS considers to be FMD-affected. Specifically, APHIS will require the following certifications for beef exported to the US from the region of Brazil:

- The beef comes from bovines that have been born, raised, and slaughtered in the export region.
 - The beef comes from bovines moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.
 - The beef has not been in contact with meat from regions other than the region of origin or those considered as FMD-free by APHIS as listed under 9 CFR 94.1(a)(2) [22].
 - The beef meets additional certification requirements under 9 CFR 94.11(c) [22]. Generally speaking, these restrictions prohibit the export-approved slaughter establishment from receiving FMD-susceptible animals or animal products that originated, transported, or commingled with animals or animal products from regions that APHIS does not consider as FMD-free. APHIS requests comment on this determination.
2. There is a potential for risk from illegal introduction of FMD-affected animals or animal products from affected regions. Brazil contains several internal and external border areas with few or no natural barriers. Even in areas with barriers or checkpoints, there is a potential that people, cars, and animal products could cross both domestic and international borders illegally.

Mitigations: Brazil's controls, biosecurity procedures, and quarantine operations (the efficacy of which was challenged during known outbreaks in Paraguay, Bolivia, and Argentina) have been successful in mitigating this risk. APHIS evaluated MAPA controls for animals moving into export channels and concluded that risk from illegal importations from affected regions to be sufficiently mitigated. The certification requirements mentioned above will further ensure that animals illegally imported into Brazil will not enter U.S. export channels.

II. Likelihood of detection of FMD if reintroduced

Risk factors:

Cattle in Brazil are primarily grass-fed, 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 are distant from human contact for significant periods of time. Therefore, close observation of animals might be infrequent, and clinical signs might be missed.

Mitigations: APHIS considers that inspection procedures in Brazilian export channels such as ante-mortem examinations are sufficient to mitigate this risk for animals exhibiting FMD clinical signs.

To ensure that the inspection procedures are followed, APHIS will propose that MAPA certify the following:

- The beef comes from bovines that received both ante-mortem and post-mortem veterinary inspections (including inspection of the head and feet) at the slaughtering establishment, with no evidence found of vesicular disease.
- FMD has not been diagnosed in the export region within 12 months prior to exportation of the beef.

III. Likelihood of exporting FMD-infected beef to the U.S.

Risk factors:

Vaccination of cattle against FMD introduces risks related to the immunological response within the herd or population of vaccinated cattle. While a large percentage of individual animals in the herd may fully respond to FMD vaccination, some individual animals in the herd may have a limited response, resulting in partial or no immunity. Therefore, herd immunity may not always reflect individual animal immunity. In addition, there is still some concern that current vaccines may have residual Non Structural Proteins - NSP (depending on the manufacturing process) that could result in the detection of NSP antibodies in vaccinated animals,. Further, there is a possibility that cattle that are early in the incubation period do not show clinical signs of FMD. Therefore infected animals might be missed on ante-mortem inspection, and their beef could be carrying FMDV. These factors increase the likelihood that undetected FMDV-infected cattle could be presented for slaughter, processing, and export of meat.

Mitigations:

To address the possibility, APHIS assessed the effectiveness of maturation, pH testing, and deboning of carcasses. The current maturation practices in Brazil for exporting to the EU consist of the following:

- 1) Chilling the beef sides (half carcasses with heads, internal organs, and hoofs removed) at temperatures between 2 and 10°C for 24 hours.
- 2) Measuring the pH to ensure it is below 6.0 in the longissimus dorsi muscle. If the pH is 6.0 or above, the carcass is diverted to local consumption.

According to the scientific literature:

- The FMD virus is rapidly inactivated at pH 6.0 or lower. At pH 6.0, the inactivation rate is 90 percent per minute [23].
- It is generally accepted that virus is totally inactivated at pH 6 or below after 24 hours at a temperature of 4°C [24]. At higher maturation temperatures, the pH drop rate is faster [24].

- The pH changes may occur at different rates in different muscles; a measurement of pH less than 6.0 in the longissimus dorsi muscle is acceptable as indicating nonsurvival of FMDV in the carcass [25].

APHIS observed during the site visits the following:

- A very small number of carcasses are rejected for having a pH reading greater than 5.9 at 24 hours postslaughter (mean 2.2 percent) [21].
- pH meters are calibrated regularly. Machine error is likely to be very low because periodic calibration of pH meters is carried out at the slaughter plants.

In accordance with the risk mitigation effects, the processes evaluated in the risk assessment will be incorporated into the proposed rule. APHIS will propose to require MAPA to certify that:

- The beef consists only of bovine parts that are, by standard practice, part of the animal's carcass that is placed in a chiller for maturation after slaughter.
- Certain parts of a bovine's head, feet, hump, hooves, and internal organs may reach the necessary pH level during the required maturation process; however, these items can contain lymph tissue, depot fat, and blood clots that may potentially harbor FMD virus that is not inactivated. These parts would continue to be prohibited from importation into the United States — specifically, no part of bovine heads, feet, hump, hooves, and internal organs can be exported.
- All bone and visually identifiable blood clots and lymphoid tissue have been removed from the beef.
- The beef comes from bovine carcasses that were allowed to mature at 40 to 50° F (4 to 10° C) for a minimum of 24 hours after slaughter and that reached a pH of less than 6.0 in the loin muscle at the end of the maturation period.
- The establishment in which the bovines are slaughtered allows a periodic on-site evaluation and subsequent inspection of its facilities, records, and operations by an APHIS representative.

Release Assessment: Conclusion

Based on evaluation of the 11 factors, observations from the site visits, and information provided by Brazil, APHIS considers that Brazil possesses the detection capabilities, reporting systems, and emergency response systems that are necessary for combating FMD in the export region and that the potential that undetected FMDv-infected cattle could be presented for slaughter, processing, and export of meat is effectively mitigated through appropriate processing procedures.

B. 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 [4].

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 [26]. 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 [1]. The analysis included two possible pathways: exposure associated with illegal household imports and exposure associated with legal imports. The latter is the exposure pathway that would be applicable to importing the commodity under consideration in this risk analysis. With 95 percent confidence, VS estimated that 0.023 percent or less of plate and manufacturing waste would be inadequately processed prior to feeding to swine [1]. Based on this fraction, less than 1 part in 4,300 of imported beef that are feed to swine as plate or manufacturing waste is likely to be inadequately cooked.

VS conducted a survey in 2001 of the U.S. swine waste-feeding sector to update a similar study done in 1994 [27]. Based on this survey, VS estimated that the proportion of plate and manufacturing waste fed to swine diminished by about 50 percent between 1994 and 2001 due to a decrease in the number of waste-feeding 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 United States saw a 40.5 percent decrease in the number of waste-feeding premises, Hawaii a 37.5 percent decrease, and Puerto Rico a 52.3 percent decrease.
- Institutions and restaurants provide nearly 90 percent of all plate waste fed to swine.

APHIS considers that prohibiting the feeding of unprocessed plate waste to swine has further contributed to reducing waste-feeding to swine. In that regard, waste-feeder operations must be licensed and inspected regularly by USDA inspectors (9 CFR 166) [5]. 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.

C. CONSEQUENCE ASSESSMENT

A consequence assessment describes the biologic and economic consequences of FMD introduction into the United States. This consequence assessment addresses both direct and indirect consequences as recommended by the OIE [4].

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 [2]. 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 [28]. In pigs, Dunn and Donaldson [29] estimated a general mortality rate of 40 percent for two outbreaks in Taiwan in 1997. Geering [30] cites mortality rates of 40, 45, and 94 percent of lambs in several outbreaks. Mortality in older animals occurs less frequently but may be significant with certain virus strains.

FMD causes significant losses in the production capacity of affected animals. Productivity losses of 10 to 20 percent are reported in FMD-infected livestock [2] if the disease is allowed to run its course. For example, the drop in milk yield of dairy cattle averages approximately 25 percent per year [31]. In addition, FMD can cause reduction in the growth rate of animals raised for meat. According to Doel [32], estimates vary considerably but one study has indicated that cattle would require approximately 10 to 20 percent longer to reach maturity. The comparatively greater severity of FMD in pigs would imply at least similar losses to those described for cattle [32].

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 United States that have a substantial export market for livestock and livestock products, the preferred option for control and eradication has traditionally been to stamp out infected herds without the use of vaccine. In fact, the U.S. policy for FMD emergencies is

to follow strict quarantine measures and stamping-out of infected and contact herds, with ongoing assessment of the need for and implementation of strategic vaccination.

Published studies indicate that FMD eradication without vaccination, if feasible, 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 [33]. 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 [34].

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. [35] 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 five sale yards located in three counties of California. The study found that mean herd indemnity payments per herd were \$2.6 million and \$110,359 for dairy and nondairy herds, respectively. Cleaning and disinfection costs ranged from \$18,062 to \$60,205 per herd. The mean vaccination cost was \$2,960 per herd and the total eradication cost ranged from \$61 million to \$551 million, depending on eradication strategy.

At the national level, McCauley et al. [2] conducted a comprehensive study to assess the potential economic impact of FMD in the whole of the United States. The study estimated the direct costs (control and eradication program costs) and increased costs borne by consumers of FMD introduction over a 15-year period (1976-1990). The study examined several control and eradication options. Relevant to this assessment are strategies employed to eradicate the disease by stamping out or area vaccination. In the extreme event of endemic FMD in the United States, the impact of compulsory or voluntary control programs was also considered. A summary of the findings are shown in table 10. The results were updated using the difference in the Implicit Price Deflator (DPI) in 2011 [3].

Table 10: Economic impacts of FMD

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

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

Source: Adapted, McDowell 2011, personal communication.

In a 2008 study modeling the economic impact and disease-spread effects from a hypothetical outbreak of FMD arising from feeding garbage in small farrow-to-finish operations, the total trade losses plus other disease-related costs to capital and management, totaled between \$2,773 million and \$4,062 million compared with the 2001-2004 disease-free baseline [43].

Effect on the environment

Environmental effects have been considered under all applicable environmental review laws in force in the United States. These are considered in a separate, but related, environmental assessment (APHIS proposed rule). The environmental assessment complies with the National Environmental Policy Act and implementing regulations [36].

Effect on public health

Although public health consequences are not issues under APHIS' regulatory authority, we address the issue in this assessment. FMD may affect humans; however, its occurrence is quite rare. 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 [37].

Perhaps more importantly, an 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 [38].

Indirect consequences

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

In 2002, Paarlberg et al. [39] conducted a study to estimate the potential revenue impact of an FMD outbreak in the United States similar to the one that occurred in the United Kingdom. The study suggested that greatest impact on farm income would be due to loss of export markets and the decrease in demand by consumers. For example, losses of gross revenue for the animal sector were as follows: cattle (17 percent), beef (20 percent), milk (16 percent), swine (34 percent), pork (24 percent), sheep and lambs (14 percent), and sheep and lamb meat (10 percent). Thompson et al. [40] estimated the loss of about 20 percent of the estimated total income from farming in 2001 because of the FMD outbreak in the United Kingdom.

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 [41]. 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.

D. 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 [4].

APHIS concludes from the assessment that the surveillance, prevention, and control measures implemented by Brazil are sufficient to minimize the likelihood of importing FMD into the United States, provided that additional mitigation measures are implemented as described earlier. Furthermore, APHIS concludes that fresh (chilled or frozen), matured, deboned beef under consideration in this analysis is of low risk in view of the certification requirements that will be implemented.

The likelihood of exposure of FMD-susceptible species to FMD infected beef was not evaluated quantitatively in this risk assessment. However, in a 1995 study [1], VS determined that 0.023 percent of plate and manufacturing waste is not adequately processed prior to feeding to swine. This is a reduction in the risk at the release level of three orders of magnitude. Therefore, combining the likelihood of importing FMD-infected beef and exposure of susceptible species to uncooked infected beef scraps would result in an estimate that is at least three orders of magnitude less than the 95th percentile release rate of 1.16×10^{-4} .

The consequences of an FMD outbreak in the United States would be extremely high. The major economic consequence of importing FMD would be export trade losses. The sum of the consumer impacts, direct costs and trade losses over a 15-year period would be between US\$37 billion to US\$42 billion (in 2011 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 an FMD outbreak in the United States would be very high, APHIS considers the risk of FMD-infected beef entering the United States from the export region and exposing the U.S. livestock through feeding of infected materials to susceptible animals to be low, given the findings of the release and exposure assessments.

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Appendix 1. Epidemiologic Characteristics of Foot-and-Mouth Disease (FMD)

Etiologic Agent

Family *Picornaviridae*, Genus *Aphthovirus*, types O, A, C, SAT1, SAT2, SAT3, and Asia 1.

Status in the United States

FMD virus was eradicated from the United States 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 [1]. 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 [2].

FMD virus serotype O (PanAsia strain) has been isolated in over 60 percent of positive samples received by the World Reference Laboratory for FMD in the United Kingdom (Institute for Animal Health, Pirbright Laboratory). Along with being the most prevalent type O strain, the PanAsia strain is also the most widely distributed, causing FMD outbreaks in many parts of Africa, Asia, and South America as well as in Europe since 1998. This virus strain can infect a wide range of species including cattle, water buffalo, pigs, sheep, goats, and gazelle [3-5].

FMD virus can be transmitted by direct or indirect contact or aerosol. Fomites (such as feed, drinking water, equipment, animal products, as well as human clothing, transportation vehicles, rodents, stray dogs, wild animals, and birds) can transmit FMD over long distances. The five main elements that influence the extent of FMD spread are:

- (1) The quantity of virus released;
- (2) The means by which the virus enters the environment;
- (3) The ability of the agent to survive outside the animal body;
- (4) The quantities of virus required to initiate infection at primary infection sites; and
- (5) The period of time the virus remains undetected [6, 7].

The incubation period of the FMD virus is 2 to 14 days in cattle, depending on the viral strain and dose and the level of susceptibility of the animal [8]. 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 [9]. Young calves may even die before the development of clinical signs usually because the virus attacks the heart muscles [8].

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 enters the bloodstream. Viremia in cattle lasts for 3 to 5 days; as a result, the virus spreads throughout the body and establishes sites of secondary infections [10].

The usual route of infection in pigs is through the ingestion of FMD virus-contaminated products, or direct contact with infected animals, or heavily contaminated environments. The incubation period in pigs will vary with the strain, dose, and route of infection. Serotype O, which is highly virulent in pigs, can produce clinical signs within 18 to 24 hours, while pigs with low-level exposures may take up to 11 days to develop clinical signs. Pigs that recover from FMD infection do not become carriers as was thought with ruminants [11].

FMD virus localizes in various organs, tissues, body fluids, bone marrow, and lymph nodes [12, 13]. Viral replication may reach peak levels as early as 2 to 3 days after exposure. 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 [14, 15].

Immunity to FMD is primarily mediated by circulating antibodies [16]. The host reaction, including antibody production, occurs from 3 to 4 days after exposure. In infected pigs, the virus is cleared in less than 3 to 4 weeks. In contrast, around 50 percent or more of cattle will develop a low-level persistent infection, localized to the pharynx [17-19]. According to Alexandersen (2002) [16], a model for progression of infection starts with virus exposure, then accumulation of virus in the pharyngeal area, followed by the initial spread through regional lymph nodes, and then spreads via the blood stream to epithelial cells. Several cycles of viral amplification and spread follows [16].

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 [8]. The animal usually recovers by 14 days post infection provided no secondary infections occur [10]. The most consistent clinical signs in pigs are lesions around the coronary bands and lameness, but fever may be inconsistent. Pigs may develop vesicles on the tongue and snout, but these may be less conspicuous than lesions seen in ruminants. The severity of clinical disease depends on the age of the infected pig. Adult swine may recover or become chronically lame while younger pigs, especially those less than 8 weeks of age, may die from acute myocarditis without developing other clinical signs [11, 17].

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 [8]. 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, virus neutralization test, and an

enzyme-linked immunosorbent assay 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 [7].

FMD virus is a relatively resilient virus. 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 the primary factor for inactivation [20]. An acid environment where the pH is less than 6.0 will destroy the virus quickly [20, 21]. Several studies showed that in tissues where no acidification occurs (e.g., lymph nodes, bone marrow, fat, and blood), the virus may survive for extended times in cured, uncured, and frozen meat [13, 20-23]. Heating at 50° C [24] and up to 155° F [25] will inactivate the virus.

References for Appendix 1

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Appendix II

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