MINISTERIO DE LA PRODUCCIÓN
(MINISTRY OF PRODUCTION)

SECRETARIA DE AGRICULTURA, GANADERIA, PESCA Y ALIMENTOS
(SECRETARIAT OF AGRICULTURE, LIVESTOCK, FISHERIES AND FOODSTUFFS)

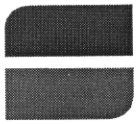
SERVICIO NACIONAL DE SANIDAD Y CALIDAD AGROALIMENTARIA
(NATIONAL ANIMAL HEALTH AND AGRIFOOD QUALITY SERVICE)

S E N A S A

INFORMATION PROVIDED BY SENASA TO ATTAIN RECOGNITION OF ARGENTINA AS A REGION, AS DEFINED IN SECTION 92.2, TITLE 9, OF THE CODE OF FEDERAL REGULATIONS FOR FOOT AND MOUTH DISEASE (FMD)

R E P U B L I C O F A R G E N T I N A

November 2002



National Animal Health and Agrifood Quality Service

(SENASA)

Risk Analysis Unit

QUESTION 1:

AUTHORITY, ORGANIZATION AND INFRASTRUCTURE OF THE VETERINARY SERVICES IN THE REGION

November 2002

1- AUTHORITY, ORGANIZATION AND INFRASTRUCTURE OF THE VETERINARY SERVICES IN THE REGION.

¿WHAT HUMAN RESOURCES ARE AVAILABLE IN THE REGION TO CARRY OUT CONTROL PROGRAMS FOR LIVESTOCK DISEASES?

In Argentina, SENASA (National Animal Health and Agrifood Quality Service) is the government agency responsible for carrying out animal health control programs. SENASA has its own budget within the Secretariat of Agriculture, Livestock, Fisheries and Foodstuffs.

The organizational charts and maps included in Annex I illustrate the structure and organization of SENASA and the Argentine Animal Health System.

Decree # 1585/96 defines the organizational structure of the new SENASA after the former SENASA (National Animal Health Service) merged with IASCAV (Argentine Plant Health and Quality Institute). The new SENASA is responsible for ensuring the health of animal and plant products to protect the health of consumers, animals and plants, and conducting quality controls of local and imported products.

SENASA is also responsible for establishing animal and plant health and quality policies, and ensuring compliance with the applicable current regulations. In addition, SENASA is responsible for all movements of animals within the country and the inspection of imported and exported animals, animal and plant products and byproducts, agriproducts, pharmacological and veterinary products, agrochemicals and fertilizers.

SENASA's staff totals 3536 officials. In Animal Health, there are 4 main areas that report directly to the President of SENASA. These areas are:

- NATIONAL ANIMAL HEALTH OFFICE (DNSA)

- NATIONAL AGRIFOOD INSPECTION OFFICE (DNFA)
- QUARANTINE, BORDERS AND CERTIFICATIONS UNIT (CCFyC)
- LABORATORIES AND TECHNICAL CONTROL OFFICE (DILACOT)

NATIONAL ANIMAL HEALTH OFFICE (DNSA)

DNSA is specifically responsible for animal health control and eradication programs, including the necessary preventive, control and eradication actions to ensure compliance with current statutes. The actions defined by DNSA are carried out by the 316 Local Offices located throughout the country which are staffed by 237 veterinary physicians, 436 animal technicians, and 181 administrative employees. The Local Offices report to DNSA through 25 REGIONAL SUPERVISORS. The EPIDEMIOLOGY OFFICE of DNSA is responsible for carrying out, coordinating, assessing and overseeing the FMD program. DNSA is also responsible for strategic prevention activities, and surveillance and assessment of the vaccination programs. The organization and operational structure of DNSA is defined in SENASA Resolution # 274/2002.

In addition to the Official Veterinary Services (at the Federal, Provincial and Municipal levels of government), the animal health system is strengthened by the support of a participatory structure based on 349 Local Animal Health Offices that were created in 1989 for the FMD Eradication Program. These Local Offices that represent various local organizations, have technical Subcommittees chaired by official or private veterinary physicians that practice in the area that work very closely with SENASA.

At a Regional level, there are 23 Provincial Animal Health Committees (COPROSAS) that participate in the National FMD Eradication Committee (CONALFA) which constitutes a forum for consensus where the provincial governments, SENASA, and represen-

tatives of the farmers' associations define the operational strategies to carry out the zoosanitary policies defined by SENASA.

Diseases for which notification is mandatory must be reported to SENASA authorities (Section 4 of the Animal Health Law Enforcement Authority Act - # 3959 enacted in 1902 - states: "*All owners or persons who in any manner are responsible for providing care or assistance to animals affected by a contagious disease or suspect animals, must immediately report the condition to the local authority stated in the Animal Health Regulations*").

The system of Local Animal Health Offices is an important source of information because their trained staff visits all livestock operations at least twice a year to vaccinate the animals, and the information they gather serves to strengthen the official inspection system of livestock operations, movements of animals, and livestock concentration markets.

There are approximately 5,750 private veterinary physicians working in rural areas that by law, are required to report epizootic diseases (Act # 3959). In addition, these professionals participate in the technical subcommittees of the Regional and Local Animal Health Offices that strengthen the eradication programs.

The National Farming Technology Institute (INTA) which is part of SAGPyA, has a network of experimental and extension facilities in rural areas that receive updated information on the health status of the herds.

The private laboratories accredited by SENASA that participate in the Network of Laboratories are required to immediately report all epizootic diseases. Non-compliance with current regulations implies severe penalties.

NATIONAL AGRIFOOD INSPECTION SERVICE (DNFA).

At a national level, DNFA is responsible for ensuring that slaughtering plants, processing plants, and/or storage facilities for animal and plant products and byproducts (whether edible or inedible), comply with hygiene and health requirements. At the slaughtering plants approved for export, these controls are performed by the Veterinary Inspection Service.

QUARANTINE, BORDERS AND CERTIFICATIONS UNIT (CCFyC).

CCFyC is responsible for the ANIMAL AND PLANT QUARANTINE UNIT, the INTERNATIONAL MOVEMENTS UNIT, and the BORDERS AND SANITARY BARRIERS UNIT that operates the control posts at the inland sanitary barriers and border crossings (ports, airports, and border crossings).

LABORATORIES AND TECHNICAL CONTROL OFFICE (DILACOT)

DILACOT - which has two Units - the Laboratory for Animal Products and Byproducts and the Laboratory for Plant Products and Byproducts - is the National Reference Laboratory for food safety and animal and plant health. In addition, DILACOT has Regional Laboratories and manages a countrywide Network of Laboratories accredited by SENASA. DILACOT:

- Establishes the methods and test protocols to be used at the Central Laboratory and the laboratories that participate in SENASA's National Network of Laboratories.
- Intervenes in dispute resolution.

- Confirms positive test results issued by the laboratories that participate in the Network of Laboratories.
- Carries out and participates in interlaboratory tests.
- Periodically audits the Network of Laboratories.
- Provides assistance to other SENASA offices to assess analytical results.
- Participates in reviewing regulations in its field of action and attends International Fora (Codex Alimentarius, MERCOSUR, O.I.E., etc.).

WHICH ARE THE PROCEDURES FOR SPECIMEN COLLECTION?

The procedures for specimen collection are described in Annex II.

WHAT DIAGNOSTIC PROCEDURES AND TECHNIQUES ARE ROUTINELY FOLLOWED FOR EACH DISEASE AGENT OF CONCERN?

The following techniques for diagnosis and identification of the FMD virus are used in Argentina:

- Antibody identification by ELISA testing
- Typing by ELISA testing
- Complement Fixation
- Virus isolation (in lactating mice and cell tissues)
- Virus identification by monoclonal antibodies
- Serum neutralization
- Seroprotection
- VIAA - IDGA

- 3 ABC ELISA
- EITB
- PCR
- Sequencing
- Inoculation in bovines under stringent biosafety conditions

The above techniques are consistent with those listed in Chapter 2.1.1 - Foot and Mouth Disease - of the O.I.E. *Manual of Standards for Diagnostic Tests and Vaccines* - rev. 2000, and are included in SENASA's *Operational Procedures and Instructions Manual* (Virology Unit - SENASA - 2001).

The techniques used in Argentina for non-vesicular diseases are:

Isolation of Bovine Herpes Virus in cell lines or in primary BFT or BFR cultures collected by vaginal, vulva or penis swabbing, or from lesions of virus infected animals, or necropsy samples (lungs, brain, kidneys, etc.).

Isolation of Bovine Viral Diarrhea (BVD) in cell lines or in primary BFT or BFR cultures, from samples of secretions or necropsy (guts, ganglia, brain, etc.).

Immunofluorescence of non-cytopathic BVD strains.

Techniques to measure antibodies:

For IBR and BVD: serum neutralization. ELISA test - commercial kit.

For Blue Tongue in sheep and cattle: immunodiffusion (PANAFTOSA, PAHO), ELISA test (PANAFTOSA, PAHO).

Vaccine Controls:

For virus strains such as BHV-1, BVD:

Specific safety in cell lines and non-specific safety in guinea pigs, toxicity in mice, serum conversion in guinea pigs.

WHAT LAWS, REGULATIONS AND POLICIES ARE IN EFFECT? (FOR EXAMPLE IS WASTE FEEDING OR WASTE-CONTAINING FEED PERMITTED AND, IF SO, WHAT RESTRICTIONS APPLY)

See Annex III

WHAT SECURITY MEASURES ARE IN PLACE AT PORTS OF ENTRY TO CONTROL IMPORTATION OF MATERIALS THAT MIGHT CARRY DISEASE AGENTS OF CONCERN?

The procedures and criteria applied by Argentina for imported live animals, their genetic material, and animal products and byproducts, are based on the principles of Risk Analysis, Regionalization and Equivalence included in the SPS Agreement of the World Trade Organization (WTO), and the rules approved by the Office International des Epizooties (O.I.E.)

The permits to import live animals, their genetic material and animal products and byproducts must be approved by SENASA's Central Office.

Prior to importing live animals, their genetic material, and animal products and byproducts, the importer must apply for an import permit which is only issued if all the applicable zoosanitary requirements stated in SENASA regulations are met.

The import permit may be issued after an analysis and assessment of:

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

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

Annex IV includes a detailed description of the procedures required at the port of entry.

The products authorized for import shall be safe and shall not constitute a possible source of the FMD virus, as stated in the O.I.E. recommendations.

At the point of entry, the imported products or animals are subject to a physical inspection, verification of correct labelling, and documentation check, even though a complete zoosanitary risk assessment is required prior to the issuance of the pertinent import permit.

In addition, at the Authorized Border Posts with cross-border traffic, vehicles, passengers, and luggage are inspected to identify products that may represent a zoophytosanitary risk.

All imported live animals must be placed in quarantine. SENASA has a Quarantine Facility in the City of Buenos for this purpose. The required quarantine period and quarantine conditions are in accordance with international recommendations. At the end of the quarantine period, the imported animals are placed under observation at the farm of destination for a period of sixty (60) days. After this period, the local SENASA veterinary physician must issue a report certifying that the post-quarantine period has been completed. Ruminant breeding animals and their genetic material are included in the Epidemiological Surveillance System to avoid entry of bovines affected by Bovine Spongiform Encephalopathy (BSE).

Measures have been adopted to reduce the risk and the reintroduction of FMD virus.

These measures are principally centered on mitigating the external risk and maintaining adequate internal controls to promptly detect FMD cases. To this end, specific rules and sanitary actions have been put in place that reduce the possibility of the FMD virus entering our country.

SENASA Resolution # 32/2000 defines the mission and functions of the QUARANTINE, BORDERS AND CERTIFICATIONS UNIT, and SENASA Resolution # 511/2001 assigns responsibility for coordinating and supervising the controls of imported products at the various points of entry.

SENASA Resolutions # 816/2002 and # 1354/1994 define pre-importation procedures and controls, and health certificates requirements for animal products and byproducts, and for live animals and their reproductive material, respectively.

Resolution # 398/1999 states the requirements to import FMD susceptible animals, and animal products and byproducts, as well as all other risk material for FMD.

SENASA Resolution # 99/1999 establishes the creation of the Brigade of Beagle dogs to operate at the main airports. The dogs are trained to detect organic products carried by passengers or in luggage. In addition, scanners to identify any type of organic material were installed at the main Authorized Border Crossing Points.

AFIP (Federal Administration of Government Revenues) Resolution # 636/1999 and SENASA Resolution # 760 jointly approve the Customs Declaration and Affidavit for imported animals, plants, and farm products, which must be completed by all persons entering the country.

At the points of entry into the country, posters and brochures provide information to create awareness about the products that are banned for entry into Argentina for zoosanitary and phytosanitary reasons.

Several agreements with law enforcement authorities (Border Patrol, Coast Guard, and National Aeronautical Police) were signed to have their collaboration in performing the controls at the borders and other points of entry.

National Animal Health and Agrifood Quality Service

(SENASA)

Risk Analysis Unit

QUESTION 2:

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?

November 2002

2- 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?

The last FMD outbreak in Argentina occurred on January 23, 2002.

The FMD outbreaks in Argentina in the period 2000 - 2001 affected 14 provinces, 228 districts (a district is the administrative division of the provinces in Argentina), and 324 quadrants. The last outbreak occurred on January 23, 2002, in Río Cuarto, Province of Córdoba, in the central part of the country.

The disease developed a typical epidemic curve limited by the systematic immunization of the herd. The curve shows the highest number of cases in the week of peak incidence (week # 26 of 2001 - June 24 - June 30).

The prevalence, i.e. the number of active outbreaks at a given time, reached its peak in week 27 of 2001 (July 1 - July 7) with 956 outbreaks.

During this period, morbidity and mortality rates showed no definite trend, averaging 5.4% and 0.03% respectively.

Virus isolation at the beginning of the outbreak identified virus type O and type A. In 2001, only virus A was isolated but as the strain or subtype was different to the A virus subtype that had been isolated in 2000, the strains were named A ARGENTINA 2000 and A Argentina 2001.

The outbreaks caused by the O virus did not persist in time (July to December 2000) and affected a much smaller region.

The behavior of the A virus was different. The outbreaks caused by the O virus were very localized and easily eliminated with stamping-out, or contained with conventional outbreak control measures such as banning of movement of animals, perifocal vaccina-

tion, etc.). The outbreaks caused by the A virus started at the beginning of August 2000 and continued until January 2002 (the last outbreak).

FOR EACH RELEVANT HAZARD, IS THE PEST OR DISEASE AGENT KNOWN TO EXIST IN THE REGION?

The response to this question is included above under: **Is the restricted disease agent known to exist in the region? If yes, at what prevalence? If no, when was the most recent diagnosis?**

IF NO, WHEN WAS THE MOST RECENT DIAGNOSIS OR DETECTION?

The response to this question is included above under: **Is the restricted disease agent known to exist in the region? If yes, at what prevalence? If no, when was the most recent diagnosis?**

WHAT BREEDS OR SPECIES WERE AFFECTED?

The most affected species was bovines (99.9% of the affected premises were cattle farms, whereas only 0.1% were hog farms).

A total of 2,783,930 animals were exposed to the disease.

Of the 152,443 animals that were affected by the disease, 145,866 (95.7 %) were bovines, 6218 hogs (4 %), 116 sheep (0.07 %) and only 6 were goats.

The age of the affected cattle was:

30% under one year of age.

50% between one and two years old.

20% over 2 years old.

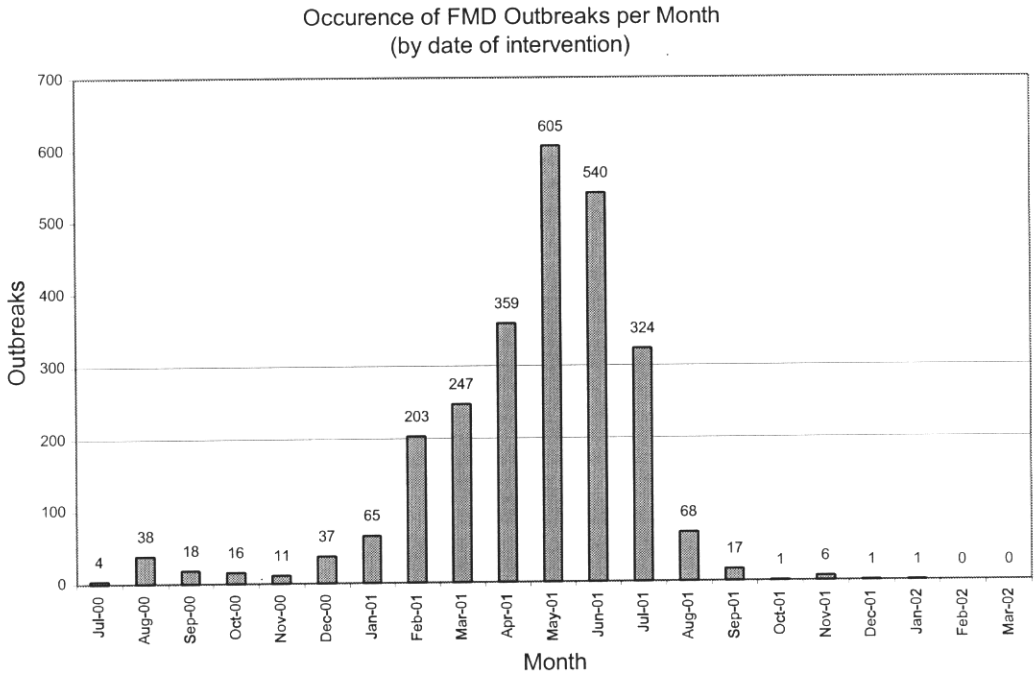
HOW MANY CASES WERE DIAGNOSED AND REPORTED?

The total number of FMD outbreaks per month is shown in Table 1.

Table 1- Total Number of FMD Outbreaks per Month in Argentina at the time of the epidemic in the period 2000 - 2001.

	Month	Outbreaks	No. of Affected Animals	No. of Exposed Animals	Attack Rate
2000	JULY	4	1,560	7,180	21.72
	AUGUST	38	3,609	27,164	13.28
	SEPTEMBER	18	1,301	25,383	5.12
	OCTOBER	16	1,114	28,625	3.89
	NOVEMBER	11	1,655	20,473	8.08
	DECEMBER	37	3,235	83,543	3.87
2001	JANUARY	65	4,307	78,816	5.46
	FEBRUARY	203	12,619	166,278	7.58
	MARCH	247	13,134	223,558	5.87
	APRIL	359	18,276	310,642	5.88
	MAY	605	38,807	726,466	5.34
	JUNE	540	30,290	557,328	5.43
	JULY	324	17,598	394,062	4.46
	AUGUST	68	3,654	73,904	4.94
	SEPTEMBER	17	948	51,318	1.84
	OCTOBER	1	8	28	28.57
	NOVEMBER	7	439	8,240	5.32
	DECEMBER	2	45	406	11.08
2002	JANUARY	1	20	228	8.77
	Total No. of Outbreaks	**2563**			

Graph 1- Epidemic Curve of the FMD Epidemic in Argentina in the Period 2000-2001.



IS REPORTING THE PEST OR DISEASE AGENT REQUIRED IN THE REGION?

Act # 24,305/93 and pertinent regulations require immediate and mandatory reporting of FMD cases in the Republic of Argentina. As stated in the FMD statutes, SENASA has authority to apply severe penalties when a person or company does not report the disease.

IF THE PEST OR DISEASE AGENT WAS PRESENT AND SUBSEQUENTLY ERADICATED, WHAT METHODS WERE USED FOR ERADICATION?

Prior to the re-entry of FMD in 2000, the disease was eradicated with the 1990 - 1992 FMD Control Program and the 1993 - 1997 FMD Eradication Program. Argentina achieved the status of FMD Free with Vaccination in May 1997, and FMD Free with No Vaccination in May 2000. The last outbreak occurred in April 1994; vaccination was suspended in April 1999.

Argentina's strategy to control and eradicate FMD included quarantine, stamping-out, control of animal shipments and vaccination with an oil adjuvant inactivated vaccine. The strategy also established protected and surveillance areas around the outbreaks (focal, perifocal and surveillance areas) and the regionalization of the country based on the different livestock ecosystems.

In summary, the 1990 - 1992 FMD Control Program and the 1993 - 1997 FMD Eradication Program included the following actions and measures:

- Vaccination with local strains (Systematic and Strategic Vaccination).
- Restricted movements of animals to avoid contact between exposed / vaccinated individuals.
- Stamping-out (only in special cases).
- Epidemio-surveillance (for early detection of risk factors).

The consolidation of the national animal health structure that was required by the strategy adopted by Argentina in the 1990's, led to a reorganization within SENASA and the creation of Animal Health NGOs - the FMD Eradication Offices. The idea was to work towards controlling and then eradicating the disease with systematic vaccination, control of animal shipments, and stamping-out actions.

The FMD Program was coordinated at three levels: Central, Regional and Local.

Central Level: SENASA and the National Committee for Eradicating FMD (CONALFA), defined the strategies.

Regional or Provincial Level: The Provincial Animal Health Committees (COPROSAS), carried out the actions based on the sanitary, production, social and economic characteristics of the regions and the strategies defined at the national level.

Local Level: The Local Animal Health Committees that represented various local organizations, with their Technical Subcommittees chaired by official or private veterinary physicians, working closely with SENASA.

The following sectors also participated in the control and eradication of FMD in Argentina:

- Private Veterinary Physicians in rural areas. By law, these professionals are required to report epizootic diseases (Act #3959 Animal Health Law Enforcement Act). They chaired the technical subcommittees of the Regional and Local Animal Health Committees and constituted valuable support for the National Eradication Programs.
- The National Farming Technology Institute (INTA), with its network of Experimental Stations in rural areas that works closely with the farmers.
- The private laboratories accredited by SENASA. The laboratories were required to immediately report epizootic diseases and non-compliance implied severe penalties.

WHAT GEOGRAPHIC AND ENVIRONMENTAL CHARACTERISTICS OF THE EXPORTING REGION MAY INFLUENCE THE PREVALENCE OF THE PEST OR DISEASE AGENT?

FMD in Argentina has proven to be highly sensitive to the variety and size of the livestock ecosystems in the country. The parameters of the patterns which were identified with the epidemiological studies differ significantly between the various regions of the country. Said parameters are based on the classical division of the epidemiological triad as host, agent and environmental factors. The host factors are basically the type, size and diversity of the livestock ecosystems in which the stocking rate, age, distribution, and movement of the animals play an important role. For example, the movement of animals from the breeding areas to the fattening areas has been an important factor in spreading the FMD virus when the disease was present in Argentina. Another significant factor is the immune status of FMD susceptible animals. One of the main advantages of using vaccination as a tool in the eradication campaigns is that it provides a high level of immunity to the herd. The analysis of the FMD epidemiology must include the type of virus. Historically, the types of virus found in Argentina have been A, O and C. The last epidemic (2000 - 2001) was caused by two new subtypes of the strain and were named A Argentina 2000 and A Argentina 2001. The vaccine currently in use contains these new subtypes.

Last but not least, are the environmental factors. Specific programs for the different production, ecological and geographic regions of Argentina were designed. In addition to the environmental factors mentioned above, there are social, economic and political factors that play an important role in the FMD epidemiology of a region and must be taken into account.

National Animal Health and Agrifood Quality Service

(SENASA)

Risk Analysis Unit

QUESTION 3:

STATUS OF ADJACENT REGIONS WITH RESPECT TO THE AGENT

November 2002

3- STATUS OF ADJACENT REGIONS WITH RESPECT TO THE AGENT.

FOR EACH RELEVANT HAZARD, IS THE PEST OR DISEASE AGENT KNOWN TO EXIST, OR HAS IT EXISTED PREVIOUSLY, IN ANY REGION ADJACENT TO THE REGION PROPOSING THE TRADE?

IF YES, AT WHAT PREVALENCE?

IF NO, WHEN WAS THE MOST RECENT DIAGNOSIS?

The FMD status of neighboring countries is stated in O.I.E. - HANDISTATUS, November 2002.

Chile:

FMD free with no vaccination. Chile stopped vaccinating in June 1980 and was recognized by the O.I.E. as an FMD free country with no vaccination in January 1981. The last outbreak reported to the O.I.E. was in August 1987.

Uruguay:

FMD free with vaccination. Uruguay stopped vaccinating in June 1994 and was recognized by the O.I.E. as FMD free with vaccination in May 1995 but in 2001 the country had 2,057 outbreaks involving 32,686 bovines, and 6 outbreaks affecting 226 sheep. Stamping-out was applied and the outbreak was controlled.

Paraguay:

To date (November 2002), Paraguay has confirmed one FMD outbreak in the Corpus Christi District of Canindeyú. SENASA has strengthened and enforced preventive measures to avoid the entry of the FMD virus into Argentina.

Brazil:

The Río Grande do Sul and Santa Catarina States in Brazil that share a border with Argentina, are FMD free with vaccination. In 2001, Brazil reported to the O.I.E. 37 FMD outbreaks in bovines (1,558 animals affected), and one outbreak in pigs (2 animals).

Bolivia:

FMD is endemic in Bolivia. In 2001, Bolivia reported to the O.I.E. 144 outbreaks involving 3,005 bovines, 10 sheep, 11 goats, and 277 hogs.

ARE THERE ANY RELEVANT FACTORS ABOUT THE ADJACENT REGIONS THAT SHOULD BE TAKEN INTO ACCOUNT (E.G., SIZE, DISTANCE FROM ADJACENT BORDER TO AFFECTED HERDS OR ANIMALS)?

Of all the neighboring regions and countries, Bolivia is the only one that is not FMD free. The FMD primary endemic region in Bolivia is located in the El Beni District, to the North of Bolivia, very distant from the Argentine border. Animal shipments from this northern part of Bolivia are mainly to the central part of the country - the area of Santa Cruz de la Sierra - a secondary endemic area with the highest number of outbreaks.

Preventive actions include a buffer zone around the vaccination area in the District of Tarija that shares a border with the Provinces of Salta and Jujuy in Argentina.

SENASA signed a technical assistance agreement with Bolivia which includes collaboration with the Government of Bolivia including transfer of technology and technical assistance in planning an FMD Program. SENASA's Laboratory and Technical Control Office provided training to Bolivian officials in performing and standardizing the techniques for VIAA and EITB testing for FMD. The agreement also includes a donation of 500,000 doses of FMD vaccines for the District of Tarija.

Argentina, as a member of the regional project to eradicate FMD (the Cuenca del Plata Project), collaborates with Bolivia in managing and performing a follow-up of FMD outbreaks, controlling shipments of animals, defining epidemiological follow-up actions, designing and implementing serum sampling programs, specimen collection and remittance procedures, and typing of active strains, among others.

National Animal Health and Agrifood Quality Service

(SENASA)

Risk Analysis Unit

QUESTION 4:

EXTENT OF AN ACTIVE DISEASE-CONTROL PROGRAM, IF ANY, IF THE AGENT IS KNOWN TO EXIST IN THE REGION

November 2002

4- EXTENT OF AN ACTIVE DISEASE-CONTROL PROGRAM, IF ANY, IF THE AGENT IS KNOWN TO EXIST IN THE REGION.

WHAT IS THE EXTENT OF AN ACTIVE DISEASE-CONTROL PROGRAM, IF ANY, IF THE PEST OR DISEASE AGENT IS KNOWN TO EXIST IN THE REGION OR RECENTLY EXISTED IN THE REGION?

The scope of the FMD Eradication Program is defined in SENASA Resolution # 5/2001 (Annex XII) and includes the entire territory of Argentina. The country has two clearly differentiated regions:

- A region with systematic vaccination to the north of the Negro River, Province of Neuquén.
- An FMD Free Area with No Vaccination to the south of the area stated above.

The overall strategy of the Program includes:

- Regionalization
- Systematic vaccination
- Strategic vaccination
- Epidemio-surveillance
- A register of farmers
- Involvement in reported and suspect cases
- Border controls
- Training
- Common strategies with other countries in the region

WHAT EPIDEMIOLOGICAL INVESTIGATIONS ARE CARRIED OUT TO TRACE THE SOURCE OF INFECTION?

Note: all actions required in the event of an outbreak or suspect case of FMD are included in the "Procedures Manual for FMD Outbreaks", November 2001. The manual is attached as Annex V.

The required epidemiological investigations to confirm the origin of the infection in the event of an FMD outbreak are stated in Resolution # 35/2002 that approves the "Epidemiological Investigation Program and Contingency Actions" for suspect cases of FMD". A section of this Program requires an investigation at the place of origin of the disease, follow-up of the animals, persons, vehicles and other possible agents of the FMD virus, in addition to serum testing and inspection of adjacent premises.

ARE INFECTED OR EXPOSED ANIMALS OR PREMISES QUARANTINED? IF SO, FOR HOW LONG?

When an outbreak (or a suspect case) occurs, the operation is restrained, all movements of animals are banned, and movements of persons are restricted. When a case of FMD is confirmed, the restraint order on the farm continues in effect for a period of 30 days after the last diseased animal in the case of slaughter for domestic consumption, for 60 days in the case of shipments of animals to other operations, and for 90 days in the case of shipments of animals to livestock concentration markets (auction markets, trade shows). In addition, perifocal and surveillance areas are restrained for a period of 30 days as of the date of the last diseased animal. Concentration of animals in the affected area is banned while the restraint order is in place. If the suspect case tests

negative, the premises are restrained for a minimum period of 21 days as a preventive measure.

ARE AFFECTED PREMISES MONITORED, AND IF SO, HOW?

While the premises are restrained, the official veterinary physician periodically visits the operation to clinically inspect the animals, and assess the evolution of the disease, the possibility of occurrence, and the spreading of the virus to other operations.

WHAT TESTS ARE PERFORMED PRIOR TO RELEASING THE QUARANTINE?

In the case of an FMD outbreak, Resolution # 35/2002 requires immediate slaughter of all diseased animals, a clinical inspection of contact animals SEVEN (7) and FOURTEEN (14) days after the stamping-out procedure to rule out new cases, and bleeding after TWENTY-ONE (21) days to identify carriers (that must be eliminated).

Test methods include a screening test (3 ABC ELISA) and confirmation by EITB (for non-structural antibodies).

IF DEPOPULATION IS USED, HOW ARE CARCASSES DISPOSED OF (ARE THEY SALVAGED AT ABATTOIRS)?

As stated in Resolution # 35/2002, when an outbreak occurs stamping-out is required to eliminate the diseased animals. Other animals (contact animals) may be subject to sanitary slaughter for domestic consumption only, provided appropriate biosafety and risk mitigation procedures are followed.

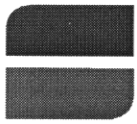
IS INDEMNITY PAID ON DESTROYED ANIMALS?

As stated in Section 24 of Act # 24,305 that establishes the National Foot and Mouth Disease Eradication Program, farmers who own animals that are exposed to an FMD outbreak and subject to stamping-out procedures or that were sent to a restricted destination for sanitary reasons, have the right to receive compensation in an amount equal to the market value of the animals affected.

In addition, Decree # 643/96 (Sections 58 and 59) that regulates the above mentioned Act states that the indemnity shall not be paid in the event of non-compliance with the requirements set forth in the Act or the regulatory Decree.

HAVE PREMISES, THOUGHT TO HAVE BEEN CLEANED UP, LATER BEEN FOUND TO STILL BE AFFECTED?

FMD has not been found on any premises previously affected by the disease.



National Animal Health and Agrifood Quality Service

(SENASA)

Risk Analysis Unit

QUESTION 5:

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?

November 2002

5- 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?

WHEN WAS THE LAST VACCINATION?

The FMD Eradication Program requires two vaccinations per year in bovines. In the 1st campaign of 2001, 53,000,000 doses were administered, and in the 2nd campaign 57,053,383 doses. The first vaccination for FMD in 2002 ended on July 31. In total, 56,113,232 bovines (52,185,300 plus 3,927,926 that were strategically revaccinated because the animals were shipped) were vaccinated. The 2nd 2002 vaccination campaign is currently in progress.

WHAT IS THE EXTENT OF VACCINATION IF IT IS CURRENTLY USED AND WHAT TYPE OF VACCINE IS USED?

The FMD Eradication Program requires systematic and massive vaccination of all cattle to the north of the Negro River and the Province of Neuquén.

Massive vaccination includes two campaigns per year. In 2001 and 2002, 100% of the bovine population was vaccinated in both campaigns. As of 2003, cattle under two years of age will be vaccinated twice and older animals only once a year.

To date, three vaccination campaigns that included all categories of animals (two in 2001 and one in 2002) have been completed. As we write this report, the second 2002 campaign is being completed.

This ensures that all animals slaughtered for export meet the requirements of the O.I.E.'s International Animal Health Code that states that the animals must have at least

two doses of the vaccine, the last dose administered within a maximum period of twelve months and a minimum period of one month before the date of slaughter.

In addition, strategic vaccinations are required as described below, among others:

- Young cattle (calves) at the time of shipment (animals must be vaccinated at least twice prior to shipment);
- All susceptible species in perifocal and border areas with sanitary warning status in situations that may represent a risk.

IS THE OWNERSHIP AND USE OF VACCINE ALLOWED?

Ownership and use of the vaccine is limited to the Local Animal Health Offices authorized by SENASA. SENASA Resolution # 624/2002 (Annex III) defines the current marketing and distribution system for the FMD vaccine.

WHAT TYPES OF VACCINE (LIVE, MODIFIED LIVE, KILLED) ARE USED?

The FMD vaccine used in Argentina provides extended immunity and adequate protection for a minimum period of 6 months in prime vaccinated animals, and 12 months in animals with two doses. The vaccine contains killed virus, an oil adjuvant, and saponin, and is inactivated with bromethylenimine (BEI). The vaccine includes the following strains: O1 Campos, A24 Cruzeiro, A Argentina 2000 and A Argentina 2001. The vaccine is administered intramuscularly and the dose for cattle is 2 ml.

WHO MAY VACCINATE (HERD OWNERS, VETERINARIANS, ETC.)?

The general vaccination strategies were defined by SENASA in the FMD Eradication Program.

Only the Local Animal Health Offices authorized by SENASA may administer the vaccine. These Offices have an Operational Team that performs the vaccination. The team includes a coordinator, a person responsible for preparing the vaccination schedule, and vaccinators. Veterinary physicians and trained employees are authorized to vaccinate. The official SENASA veterinarian audits the vaccination procedure.

ARE RECORDS KEPT ON THE USE OF THE VACCINE?

Each Local Animal Health Office keeps a record of the vaccines used and issues Vaccination Certificates. The Certificate is issued by the person that administered the vaccine when all the animals on the farm that require vaccination have been inoculated. The owner of the vaccinated animals must submit the certificate to the Local SENASA Office to register the vaccination.

WHO PRODUCES THE VACCINE?

The only pharmaceutical company authorized by SENASA to produce the FMD vaccine in Argentina is a private company, Biogénesis S.A., in Garín, Province of Buenos Aires. The company is ISO 9000 certified. Four other pharmaceutical companies have applied for approval (Paul, Sanidad Ganadera, Centro de Diagnóstico Veterinario and Asociación Cooperativas Argentinas).

The vaccine is manufactured under Level 3 biosafety conditions. The FMD virus is replicated in BHK cells, 21 clone 13, and then purified and chemically inactivated with BEI.

The 58 million doses used in Argentina were manufactured between February and April 2001.

SENASA Resolution # 104/1995, restricts manipulation of the FMD virus to pharmaceutical companies that meet the biosafety standards stated in SENASA Resolution # 219/1995. Annex XI.

Biogénesis S.A. has been audited by NAV (North American Vaccine Bank), and by Panaftosa - PAHO/WHO.

IS THE ADMINISTRATION OF SERUM PERMITTED? IF SO, BY WHOM AND UNDER WHAT CONDITIONS?

Administration of serum is not permitted.

National Animal Health and Agrifood Quality Service

(SENASA)

Risk Analysis Unit

QUESTION 6:

DEGREE TO WHICH THE REGION IS SEPARATED FROM ADJACENT REGIONS OF HIGHER RISK THROUGH PHYSICAL OR OTHER BARRIERS

November 2002

DEGREE TO WHICH THE REGION IS SEPARATED FROM ADJACENT REGIONS OF HIGHER RISK THROUGH PHYSICAL OR OTHER BARRIERS

GEOGRAPHIC DESCRIPTION OF THE ARGENTINE BORDERS

The Argentine borders may be described as follows:

1) Border with CHILE (West and South).
2) Border with BOLIVIA (Northeast).
3) Border with PARAGUAY (Northeast).
4) Border with BRAZIL (Northeast and East).
5) Border with URUGUAY (East).

Border with Chile

Total length of the border: 4,591 Km.

Inland border: 4,591 Km.

The Andean Range constitutes a natural border. There are six border crossings authorized by SENASA:

- Jama Crossing (Province of Jujuy).
- Cristo Redentor Crossing (Province of Mendoza).
- Cardenal Samoré Crossing (Province of Neuquén).
- Huemules Crossing (Province of Chubut).
- Coandhaique Crossing (Province of Chubut).
- Integración Austral Crossing (Province of Santa Cruz).

Border with Bolivia

Total length of the border: 765 Km.

River coastline border: 385 Km.

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

Inland border: 380 Km.

The climate and topography along the border with Bolivia decreases from West to East. The average altitude in the West is 3000 meters and only 400 meters in the East. There are 3 Authorized Crossings:

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

Border with Paraguay:

Total length of the border: 1,570 Km.

River coastline border: 1,570 Km.

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

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

To the West, there is an inland border; the flat topography of the Province of Formosa continues into Paraguay with no natural barriers.

The flow of the Pilcomayo River enters Argentina again to the East, in the town of Palmar, Salto.

At present, there are three border crossings into Paraguay authorized by SENASA.

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

Border with Brazil

Length of the border: 1,079 Km.

River coastline border: 1,021 Km.

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

Inland border: 27 Km. (Bernardo de Irigoyen area)

To the North, the border with Brazil runs along the Iguazú River and continues to the South along the Uruguay River. There are six Border Crossings authorized by SENASA:

- Tancredo Neves Bridge (Port of Iguazú, Province of Misiones).
- Bernardo de Irigoyen Crossing (Province of Misiones).
- San Javier Bridge (Province of Misiones).

- Integración Bridge (Santo Tomé, Province of Corrientes).
- Port of Alvear (Province of Corrientes). Staff: 1 Engineer.
- Presidente A. Justo Bridge (Paso de los Libres, Province of Corrientes).

Border with Uruguay

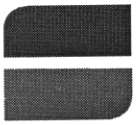
Length of the border: 866 Km.

River coastline border: 866 Km.

- Along the Uruguay River: 491 Km. (Provinces of Corrientes and Entre Ríos)
- Along the De la Plata River: 375 Km. (Province of Buenos Aires).

This border is clearly defined by the Uruguay River to the North and continues along the De la Plata River. There are five border crossings authorized by SENASA:

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



National Animal Health and Agrifood Quality Service

(SENASA)

Risk Analysis Unit

QUESTION 7:

EXTENT TO WHICH MOVEMENT OF ANIMALS AND ANIMAL PRODUCTS IS CONTROLLED FROM REGIONS OF HIGHER RISK, AND LEVEL OF BIOSECURITY REGARDING SUCH MOVEMENTS

November 2002

EXTENT TO WHICH MOVEMENT OF ANIMALS AND ANIMAL PRODUCTS IS CONTROLLED FROM REGIONS OF HIGHER RISK, AND LEVEL OF BIOSECURITY REGARDING SUCH MOVEMENTS.

FROM WHAT COUNTRIES OR REGIONS DOES THE REQUESTING REGION IMPORT PRODUCTS THAT COULD POTENTIALLY CARRY PEST OR DISEASE AGENTS OF CONCERN?

The market for imported live animals susceptible to FMD in Argentina is currently limited due to health status requirements and the possibility of accessing better genetics with imported semen and embryos, among other reasons.

Import procedures and requirements established by SENASA are in line with O.I.E. recommendations.

Argentina requires a risk analysis for all imports of live animals to determine the epidemiological status of the country or region of origin, the existence of national or regional campaigns for the disease, the specific capabilities of the laboratories or quarantine facilities and their staff, and other factors that minimize the risk of importing exotic or high risk diseases into the country. For animal products, Argentina requires risk assessment and risk mitigation to minimize potential risks associated with the importation of some products.

The Table included in Annex VI lists the countries that export products that could potentially carry the FMD virus.

TO WHAT EXTENT IS THE MOVEMENT OF SUCH PRODUCTS CONTROLLED FROM REGIONS OF HIGHER RISK, AND WHAT IS THE LEVEL OF BIOSECURITY REGARDING SUCH MOVEMENTS?

All products and live animals that require approval from SENASA must meet similar security requirements.

Import requirements may be summarized as shown below:

a) Pre-importation authorization.

b) Verification of the health certificate issued by the country of origin.

c) Physical inspection, document control, and verification of the identity of the imported products.

d) A Restricted Transit Permit for shipments of animal products to processing plants with official SENASA veterinary inspection. Live animals must be placed in quarantine at the Official Quarantine Facility.

e) After inspection, the imported products are sampled for the purpose of the CREHA[1] program and the document authorizing the release of the products is issued. In the case of live animals, said document is issued at the end of the quarantine period, if no pathology is found. With this document, the importer may collect the imported goods.

The Customs Office, the Aeronautical Police, Border Patrol and the Coast Guard work with SENASA in performing the controls.

In addition, international luggage check procedures are in place to identify and confiscate products that could represent a zoosanitary or phytosanitary risk for the country.

SENASA has a Procedures Manual for Authorized Border Posts that describes the actions required at the border posts. The manual includes:

- The Legal Framework
- The National and International Zoosanitary Status

- A Glossary
- The list of officials are authorized to sign the International Certificates and a List of Authorized Border Control Posts throughout the country.
- An epidemiological description of the Border Posts.

At present, the Provinces of Salta, Formosa, Chaco, Corrientes and Misiones (all of which are located to the North of Argentina and share a border with either Bolivia, Paraguay or Brazil) have a sanitary warning program to prevent the entry of the FMD virus.

WHAT TEST PROCEDURES ARE USED?

The diagnostic tests used by SENASA are those recommended by the O.I.E. for each agent.

ARE IMPORT PERMITS AND HEALTH CERTIFICATES REQUIRED?

Yes, import permits are required before the imported goods arrive in the country.

The Import Permits are approved by the competent areas at the Central SENASA Office.

The procedures to assess the risk, approve processing plants and processes in the country of origin, etc. are stated in Resolution # 816/02. Other SENASA requirements for imported animals include a health certificate signed by the Animal Health Service in the exporting country. Examples of these certificates are attached as Annex VII.

[1] National Residue Control in Food Products and Hygiene Program

WHAT OTHER PROCEDURES ARE USED?

Other procedures require an approval of the exporting countries based on a technical audit in the exporting countries. The audit also includes abbatoirs and food processing plants in the exporting countries, as required in Resolution # 816/02.

ARE IMPORTED ANIMALS QUARANTINED?

IF YES, FOR HOW LONG AND WHERE?

Imported animals are placed in SENASA's Quarantine facility *"Lazareto Capital"*. The animals that require special conditions or treatment are placed in special quarantine facilities (e.g. zoo animals, ornamental birds or fish).

The duration of the quarantine period varies to allow sufficient time to complete the various tests required, and according to the species and its origin. The quarantine period is between 15 and 60 days. In general, as imported cattle originates from FMD free countries, the animals are quarantined for at least 21 days during which time they receive two doses of the vaccine before they are released.

See Annex VIII.

Annexes referring to Border Controls in Argentina:

Annex VIII A: Control Posts authorized by SENASA

Annex VIII B: Border Patrol Authority: border posts and strategic route crossings in the Provinces of Formosa, Corrientes, Chaco and Misiones.

Annex VIII C: Argentine Coast Guard: border posts in the Provinces of Formosa, Corrientes and Misiones.

Annex VIII D: Quantity of products condemned at border posts under SENASA control.

Annex VIII E: Quantity of products condemned at border posts authorized by SENASA (Border Patrol Authority and Coast Guard).

Annex VIII F: Inspection of animal shipments (September 2001 to September 2002).

Annex VIII G: Legal Framework.

- SENASA Resolution # 1505/2000 – States the actions that must be carried out in response to a sanitary warning.
- SENASA Resolution # 32/2001 – Establishes the QUARANTINE AND BORDERS UNIT.
- SENASA Resolution # 501/2001 – Approves the Border Post Procedures Manual.
- SENASA Resolution # 509/01 – Appoints officials to the border control posts authorized by SENASA.
- SENASA Resolution # 511/01 - Establishes the General Supervisory Office and the Sanitary Barriers and National Traffic Unit, and reassigns responsibilities to the Ports and Airports Unit and the Border Crossings and Inland Borders Unit.
- SENASA Resolution # 462/01 and 538/02 – Describes the procedures for residue disposal and waste management at the border posts.
- SENASA Resolution # 819/02 – Lists the border posts authorized by SENASA.
- Guidelines to Inspect Animal Shipments.