Pan American Foot-and-Mouth Disease Center

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ASSESSMENT OF THE RISK OF FOOT-AND-MOUTH DISEASE INTRODUCTION INTO THE CARICOM COUNTRIES THROUGH THE IMPORTATION OF MEAT FROM ARGENTINA AND URUGUAY

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FOREWORD

The Pan American Foot-and-Mouth Disease Center (PANAFTOSA), Pan American Health Organization/World Health Organization (PAHO/WHO), has a long standing commitment to assist the foot-and-mouth disease (FMD) free countries of the Western Hemisphere in the prevention of the introduction of the disease.

The FMD-free countries of the Caribbean Economic Community (CARICOM) requested the Center at the meetings of the Technical Group of FMD-free countries of the Caribbean subregion held in Jamaica, October 1991 and in Barbados, October 1992, to provide the Veterinary Services of that Region with guidance regarding the risks related to the importation of frozen meat from South American countries. Presently, the CARICOM countries prohibit the importation of uncooked meat and meat products from countries where FMD exists. However, trading policies will in the future be largely dependent on risk management, under the terms of the North American Free Trade Agreement (NAFTA) and the World Trade Organization (WTO). Under these agreements, health requirements cannot be used as non-tariff trade barriers. Instead, international trade must be based on risk management.

An agreement was signed between the PANAFTOSA/PAHO and the Tuskegee University School of Veterinary Medicine (TUSVM) to make a risk assessment for meat from selected Regions in South America. It is my pleasure to present this document containing the results of this important study that provide fresh insights into how to open up trade in meat, while safeguarding the favorable animal health status of the Caribbean Region.

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Content

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EXECUTIVE SUMMARY

In response to the recommendations made at the meetings of the Technical Group of foot-and-mouth-disease (FMD) free countries of the Caribbean subregion held in Jamaica, October 1991 and in Barbados, October 1992, a quantitative risk assessment (QRA) was undertaken to determine the risk of introducing FMD into the Caribbean Region, through importation of frozen deboned meat cuts from Argentina or Uruguay. The study was a collaborative effort of the Pan American Foot-and-Mouth Disease Center (PANAFTOSA/PAHO/WHO) and the Tuskegee University School of Veterinary Medicine (TUSVM). It has two components:

1. *In the country of origin dealing* with veterinary services, epidemiology, regionalization, FMD ecosystems, cattle movements, slaughterhouse practices, meat inspection, meat processing, and survival of FMD virus during processing and transport;

2. *In the receiving country* dealing with import controls, veterinary services, disease emergency preparedness, financial-social-economic consequences of a disease emergency, animal health legislation, containment and destruction of infected materials (incinerators, land fills, etc.).

The present QRA study completed the first component related to the risk of meat importation. The following phase must deal with the second component in the Caribbean Region.

The QRA is based on the norms and procedures for the export of deboned frozen meat to the European Community (EC). This protocol has been very effective, since deboned frozen meat from millions of cattle have been imported by the European countries –even in periods of extensive outbreaks of FMD in South America– without resulting in the introduction of the disease. Also, during the same period more than a million ton of deboned frozen meat were imported by the United Kingdom which remained free of FMD.

The epidemiological situation of a Region is the first consideration for a sound QRA. Therefore, it is important to note that the South American countries within the Region of the River Plate Basin FMD Eradication Project (figure 1) have made significant progress in the control and eradication of the disease. Based on their favorable epidemiological conditions, Uruguay and the Argentine Mesopotamia were considered in the QRA for the exportation of frozen meat to the Caribbean Community (CARICOM) countries.

Uruguay did not register FMD since June 1990. The country was declared "Free of FMD with vaccination" in May 1993 under chapter 2.1.1. of the International Office of Epizooties (OIE) Animal Health Code during the General Session of the OIE in May 1993. This international recognition of the FMD-free status was based on the absence of clinical disease, particularly among susceptible livestock populations of young bovines, unvaccinated sheep which graze mixed with the cattle, and unvaccinated pigs. The absence of FMD virus in the livestock population was further substantiated by serological surveys in bovines and ovines. Uruguay ceased all FMD vaccinations as of June 1994, therefore, the susceptible bovine population of Uruguay will soon dramatically increase.

In the Mesopotamia Region of Argentina the epidemiological situation also is favorable. The cattle population is vaccinated systematically with oil-adjuvanted FMD vaccine and the Region has not registered FMD for several years. The last case of FMD in the Province of Misiones occurred in 1991, while FMD was last registered during 1992 in the Provinces of Corrientes and Entre Ríos. As in Uruguay, there is a susceptible livestock population consisting of unvaccinated sheep and pigs that are indicators for eventual FMD viral activity. Since 1993, livestock and not deboned meat from other areas are prohibited to enter the Region, except for breeding bulls.

Since Mesopotamia and Uruguay did not register FMD for several years, the risk of FMD from meat importation by the CARICOM countries would be the re-introduction of the disease into the Regions. The chance that this happens is small, but, if this were to occur, it was estimated from epidemiological records prior to eradication, that such an outbreak of FMD probably would involve not more than 15 herds, before being detected by the Animal Health Attention Systems operating in the Regions. If the meat is obtained in accordance with the EC directives, the chance at the 95% confidence level, that 100 tons of prime cuts of meat would contains FMD virus is 10^{-10} or less. The **importation risk** = probability of FMD re-introduction x probability of FMD in the meat. Thus, it can be concluded that the risks of FMD arising from the importation of meat from Mesopotamia or Uruguay FMD for the CARICOM countries is exceedingly small .

1. INTRODUCTION

Countries, such as those of North and Central America and the Caribbean, that are free of FMD prohibit the importation of uncooked meat and meat products from countries where FMD exists. This zero-risk position may be untenable under the rules of emerging international trade agreements such as those of the WTO and the NAFTA. Under these agreements, health requirements cannot be used as non-tariff trade barriers. Instead, international trade must be based on risk management, which in turn must rely on risk assessments that are founded on scientific evidence and that are consistent, transparent and well documented. An example of managed risk is the importation of deboned meat by the EC countries, which for many years have imported meat from FMD countries under conditions which reduce the risk of FMD introduction. These measures require specific conditions for the origin of the cattle, slaughterhouse conditions, the slaughtering process and for the maturation and deboning of meat.

QRA is a tool that can be used to estimate risks related to the importation of animals or animal products. This technique has been used for many years in engineering and economics (*9,12*), but is relatively new to veterinary medicine (*1,6,7,10,23,26*). It makes use of various branches of science such as epidemiology, statistics, mathematics, virology and pathology, and in this case, of meat technology.

A QRA starts out with the identification of a hazard, which in this specific instance is the introduction of FMD by the importation of a certain quantity of meat from a country where FMD exits. Next, a pathway of specific events must be identified from the point of origin of the product to its destination. For each point or event in the pathway the following questions must be asked: "What can go wrong?"; "How often is that likely to happen?" and "What are the consequences?". The accumulation of answers to those questions for all of the events constitutes the final risk related to the importation.

A QRA must be consistent, well documented, flexible and transparent (*11,13*). It must clearly present the information and conclusions about the risks involved in such a manner that the results can be readily understood by decision-makers and help them in choosing a course of action.

Consideration of the epidemiological situation of a Region is of fundamental importance for a risk assessment. Therefore, this QRA starts with a review of the FMD situation in the South American countries included in the River Plate Basin FMD Eradication Project (figure 1). This review is followed by an evaluation of the risk of importing meat from two areas within Project Region that have especially favorable epidemiological conditions. The Argentine Mesopotamia (in the rest of this document referred to as Mesopotamia) and Uruguay have not registered FMD for several years. The epidemiological evaluation of the two areas includes the appraisal of different means and likelihood that the disease can be re-introduced.

In the next section a model is developed for a QRA for the FMD import risk of meat sourced and processed according to the EC norms. It starts with a review of the pathogenesis, prevention and control of FMD, particularly with regard to the safe export of meat. That section is followed by the review of rules and conditions for the origin, transport, slaughter and inspection of cattle and meat processing. Based on that information a scenario pathway is developed. Defined are the probabilities that the source cattle are infected with FMD virus and that the virus remains undetected at all steps of the scenario pathway, thus resulting in the contamination of the final product.

The last chapter of this QRA deals with the epidemiological consequences of an eventual re-introduction of FMD in Mesopotamia or Uruguay. The QRA model is used to estimate what would be the likelihood that meat for export would contain FMD virus. The final probability (export risk) that a given quantity of meat would contain contaminated meat was estimated by computer simulation.

The study was made during the first semester of 1994. If possible footnotes were added to reflect the situation at time of printing.

2. REGIONAL INFORMATION ON THE COUNTRIES OF THE RIVER PLATE BASIN FOOT-AND-MOUTH DISEASE ERADICATION PROJECT

River Plate Basin FMD Eradication Project Region during the first phase (figure 1) comprised the South of Brazil (the State of Rio Grande do Sul), Mesopotamia (Provinces Misiones, Corrientes and Entre Ríos), all of Uruguay, and, more recently, the Eastern Region of Paraguay. The goals and strategies of the Project are described in the document "Proyecto Erradicación de la Fiebre Aftosa en la Subregión de la Cuenca del Plata" (*18*). In summary, the Project contemplates the progressive eradication of FMD in the River Plate Region through regional cooperation. The operations of the Project are decentralized and insure active participation of the farmers and livestock industry in the programming, execution, financing and evaluation of the program.

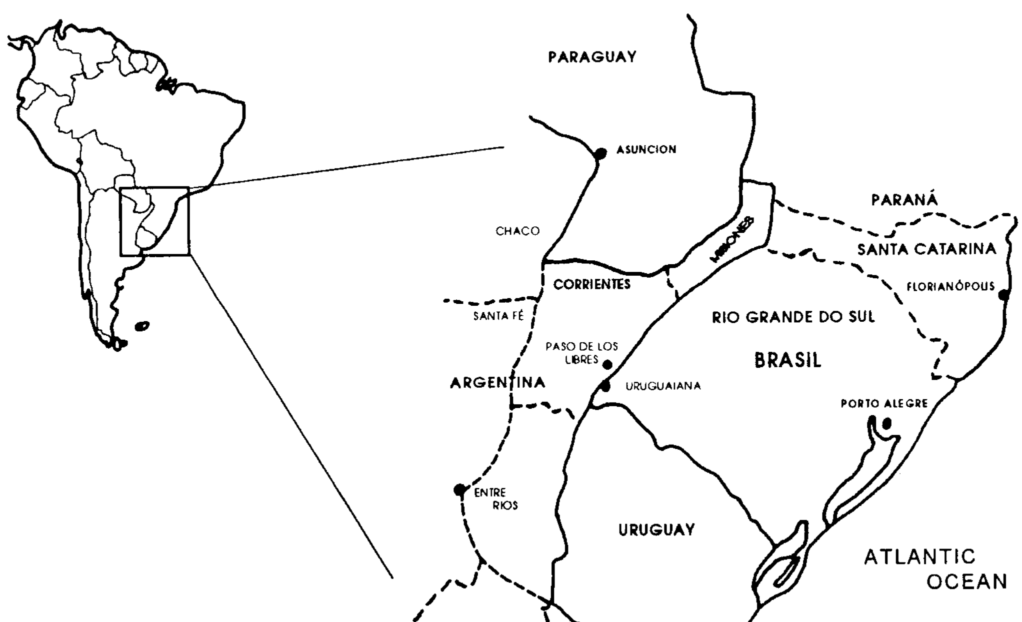

Figure 1. The River Plate Basin FMD Eradication Project Region. An international technical cooperation agreement among the Governments of Brazil, Argentina, Uruguay, Paraguay and the Pan American Health Organization through PANAFTOSA.

Livestock population and production systems . The area of Project is approximately 640,000 km^2 with 500,000 livestock owners, 32,000,000 cattle, 38,000,000 sheep and 4,000,000 pigs (*18*). The livestock production systems and the different FMD ecosystems as defined before the Eradication Plan became operational are shown in figure 2. The definition of the regionalization of FMD ecosystems is given in the Glossary. It can be observed that a large part of the area has an extractive form of livestock production (young cattle leave the area) which coincides mostly with what used to be primary endemic FMD ecosystems. FMD spreads from those areas to what were secondary endemic and paraendemic ecosystems.

Regional animal health surveillance system. The Continental Vesicular Disease Surveillance and Information System is coordinated and maintained by PANAFTOSA (*2,3*). The Project has developed an action-oriented Information and Surveillance subsystem. Each country submits weekly reports on the epidemiological status to all parties of the Project. These reports are also forwarded to the OIE, EC, and PANAFTOSA/ PAHO. The availability of this information is the basis for eventual measures in the border areas and policy decisions. In case of an emerging FMD problem in a neighboring country, the Project specifies the fast direct communication between local veterinary services in border zones, and professional staff visiting border areas as observers and the adoption of commonly agreed sanitary measures.

Epidemiological situation in the River Plate Basin FMD Eradication Project. In the River Plate Region excellent progress has been made in the control and eradication of FMD (*15,16*).

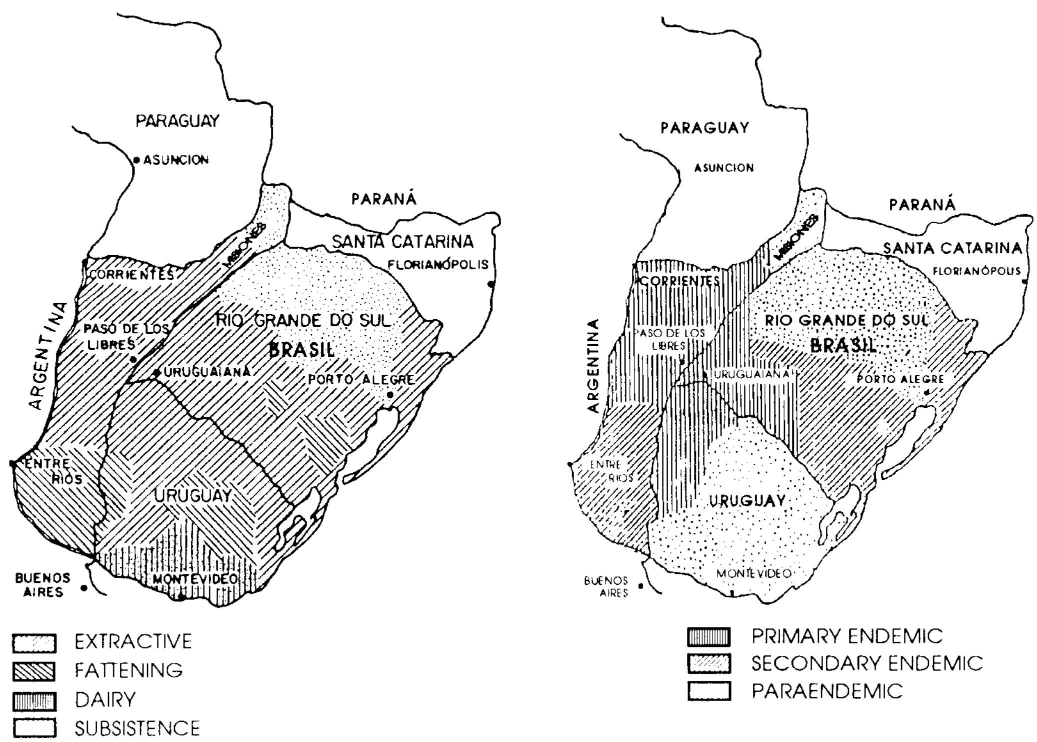

Figure 2. The River Plate Basin FMD Eradication Project

Uruguay does not register a case of FMD since June 1990 and was declared "Free of FMD with vaccination" under chapter 2.1.1 of the OIE Animal Health Code during the General Session of the OIE in May 1993. There are regulations for the slaughter of infected and contact animals, in case of an outbreak of FMD. For the indemnization of the owners a Permanent Fund has been established, derived from a special animal products exportation tax. All FMD vaccinations have been ceased as of June 1994.

In Mesopotamia the last FMD cases occurred in 1992. The cattle in the region are under a systematic vaccination program. On the west Mesopotamia borders with an Argentine region with only sporadic outbreaks*, while the eastern border is with Uruguay which did not register FMD since 1990.

In the State of Rio Grande do Sul, Brazil, the last FMD cases occurred in December 1993 affecting two counties located in the north of the state at a distance of more than 500 km from the border with Uruguay. FMD was found on 11 farms located in the proximity of slaughterhouses that received pigs from the State of Paraná. On those farms 33 cattle had FMD out of a total of 111. The 47 pigs present on these farms remained healthy. The outbreaks were eradicated by the destruction of 23 animals, prohibition of animal movement and perifocal vaccinations in 195 farms with a total cattle population of 2,170 (*19*).

The Brazilian State of Santa Catarina registered the last FMD outbreak in December 1993 in a slaughterhouse also from pigs originated in Paraná. FMD is sporadic in the Brazilian State of Paraná and in Paraguay**.

3. REGIONS WITH A POTENTIAL FOR EXPORT OF MEAT TO THE CARICOM

In view of the epidemiological and livestock situation of the River Plate Region, two areas were considered for the potential export to the Caribbean: Mesopotamia and Uruguay (see figure 1). These Regions will be discussed in more detail with respect to those aspects that have a bearing on the risk assessment for the importation of meat by the CARICOM countries.

3.1 MESOPOTAMIA

The Mesopotamia covers an area of 196,781 km^2 with about 60,000 farms. The livestock numbers are as follows: 9,500,000 head of cattle, 3,700,00 sheep and 200,000 pigs (*18,22)*.

The Region has predominantly an extractive livestock production system based on the production of young cattle for fattening in other regions of Argentina and to a lesser degree for local slaughter.

Animal Health Surveillance System. The National Project for FMD Control coordinates the activities of animal health of both the official and the private sector. The principal component is the National Animal Health Service (SENASA), which has as task the official execution and supervision of the animal health legislation as well as providing scientific and technical reference (*21*).

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*The last registered outbreak in <u>all</u> of Argentina was in April 1994.

**Last registered cases May 1995, Dec. 1992, Sept. 1994, respectively, at the time of printing.

The private sector exercises a predominant role through the Local Animal Health Commissions, the Provincial Animal Health Commissions and the National Commission for Animal Disease Control. These commissions are instrumental in carrying out the policies and strategies developed by SENASA, insuring the viability of the proposed actions and their completion. This system has thus guaranteed the active participation of the livestock community.

The sensitivity of the surveillance system also is increased by the reporting of suspected vesicular disease cases by veterinary practitioners, cooperatives and livestock societies, slaughterhouse inspectors, vaccinators, etc.

Control of livestock movements. The rivers which surround the area of Mesopotamia provide very limited accesses only. Two bridges and a tunnel connect Mesopotamia with other parts of the Argentine territory. There is one bridge with Paraguay, one bridge with Brazil and three bridges with Uruguay. The only dry border is a stretch of land of about 30 km with Paraná. However, both sides of that border are national parks without any livestock. With the exception of bulls for breeding purposes the import of livestock into Mesopotamia is prohibited, but transit without stopovers is allowed for livestock originating from areas with an animal health status similar to that of Mesopotamia.

Vaccination programs. All cattle are vaccinated twice a year with commercial oil-adjuvanted FMD vaccines, prepared with inactivated antigens. Calves are vaccinated at the age of 3-4 months and then enter into the regular vaccination scheme. The vaccine is manufactured in other parts of Argentina. First-order kenetic inactivants are used to prepare the antigens (*17*). All FMD vaccines used in Argentina are safety and potency tested by the official vaccine control laboratory of SENASA, according to established methods (*17*). Sheep and pigs are not vaccinated. Vaccinated cattle and unvaccinated sheep graze mixed together on the same pastures.

Meat trade. In Mesopotamia 14 slaughterhouses are approved by SENASA (*21*). Presently no data are available on the amount of exported meat.

3.2 URUGUAY

Uruguay has a area of 175,215 km^2 with approximately 54,000 farms with a total cattle population of 10 million head, the sheep population was just over 24 million. The cattle and sheep are not kept separately, and graze together on the same pastures.

Vesicular Disease Surveillance System. All livestock producers, private veterinarians and truck drivers transporting livestock are obligated to report any disease with clinical symptoms similar to FMD and all movement should cease until appropriate measures are taken by the authorities. From 1991 to April 1994, 104 suspected clinical vesicular diseases cases were reported and investigated (1991, 27; 1992, 34; 1993, 26; 1994, 17). In all cases diagnostic tests at field and laboratory levels revealed other causes rather than the FMD virus. It is important to note that those suspected cases were mostly reported to the official veterinary service by private veterinarians and the owners or handlers of the animals. This clearly shows the collaboration of the livestock sector in maintaining a high sensitivity of the surveillance system. Also, it is important to note that the response of the veterinary service was immediate and that the average time lapse between reporting the case and the field investigation was four hours.

Movement of livestock. Animal movement is tightly controlled by the Ministry of Agriculture. Movement of any livestock without prior authorization from the Veterinary Services is prohibited.

Special provisions are established for animal movement along the Brazilian frontier of Rio Grande do Sul. Before any movement the producer must report his intention to move animals to the veterinary service staff in the area.

Transit control and public auctions of animals are under official supervision. In Uruguay, there are tick control barriers where cattle are examined individually for the presence of ticks. At the same time, clinical FMD would probably not go undetected.

Control of livestock entering Uruguay. Uruguay has a dry land border with the State of Rio Grande do Sul which permits the movement of livestock with relative ease. The other frontier with Mesopotamia is formed by a large river with only two bridges and a dam. Livestock movements through these accesses area are well controlled.

FMD vaccination program. Uruguay ceased vaccination of all its cattle by June 15, 1994 in an effort to obtain the status of "FMD free without vaccination" by the OIE. Prior to 1988 a portion of the large sheep population of some 24 million head was vaccinated. However, since that year all sheep vaccinations were stopped. There has never been a systematic vaccination program of the pig population of some 350,000 head. Pigs were only vaccinated when they were at risk during FMD outbreaks. PANAFTOSA maintains a stock of 500,000 doses of monovalent FMD vaccine for emergency use, specifically for Uruguay.

Meat trade. In Uruguay, 28 slaughterhouses are approved by the EC for meat export. The Uruguayan annual production averages 350 thousand tons of beef as carcass weight (700 thousand tons on the hoof). Of these 150 to 170 thousand tons are destined for exportation. The permanent export market for Uruguayan beef have been the EC, Israel, Saudi Arabia, Chile, Canary Islands, Hong Kong, Singapore and the United States. Some of these meats are only accepted under specific conditions of thermal processing. However, a large portion of the beef is exported as high quality deboned cuts.

4. CONSIDERATION OF FMD RISK FACTORS FOR MESOPOTAMIA AND URUGUAY

If Regions are "free of FMD", the chances are extremely remote that FMD in meat or meat products from those Regions contains FMD virus. Examples are Australia, New Zealand and North America.

The chances of FMD re-introduction are higher for FMD-free areas bordering with FMD regions, even if this occurrence is only sporadic. Examples for this situation are the EC, Chile, Uruguay and Patagonia. Also, there is a consensus that Regions "Free of FMD without vaccination" represent a lower risk of its meat or meat products than those with the status "FMD free with vaccination", because any virus activity would express itself quickly and more visibly. Thus, a risk assessments for meat from Mesopotamia and Uruguay, must include considerations for eventual risks posed by the epidemiological situation in border regions. Potential FMD introductions into the livestock population, such as tourism also must be considered. The list of possible risk factors in table 1 was used to identify problem areas.

Table 1. Risks Factors for the Introduction of FMD into FMD-free Regions

1. Risk related to movement of FMD virus from infected herds to the FMD free Area:

   Movements of animals
   - Cattle, pigs, other susceptible species (sheep, goats, buffaloes, game, etc.)
   - Movement of meat and meat products movements
   - Movement of dairy and dairy products
   - Movement of genetic material

   Movement of people
   - Farm related
   - Veterinarians, inseminators, etc.

   Movement of vehicles
   - Transport of livestock
   - Farm supplies and farm products

2. Risk related to tourism

   Airports
   Seaports
   Land border crossings
   Number of tourists
   Waste from airplanes
   Waste from ships

3. Risk of FMD virus escape from laboratories handling FMD virus

   Diagnostic activities
   Vaccine production activities
   Vaccine control activities and animal holding facilities

Risk Factors Identified for Mesopotamia

Breeding bulls obtained from other parts of Argentina. A number of breeding bulls were introduced into Mesopotamia, but at the time of writing no numbers were available. It is reported that bulls are submitted to two probang tests which should greatly reduce the probability of introducing carrier animals.

Semen and embryos imported from other parts of Argentina and Brazil. At the time of writing information on the number of semen doses imported was not available. Although it has been shown that under laboratory conditions FMD can be transmitted by semen (*4*), there is very little evidence that this ever has been a practical problem. Semen is collected from basically closed herds at semen collection stations that are well managed with regard to animal health. The probability that semen is collected when clinical cases occur at the station is extremely remote. It could happen however, if all animals at the station would still be asymptomatic. Since semen usually is kept in storage for periods well beyond the incubation period of FMD, that risk is very remote. The number of imported embryos is insignificant. Also, the risk of FMD introduction by bovine embryos is extremely low (*26*).

Deboned meat from other parts of Argentina. Reference can be made to conclusions later in this QRA, which shows that the risk of FMD from the importation of deboned frozen meat is very small. Even in periods of extensive outbreaks of FMD, deboned frozen meat from many millions of cattle have been imported by the EC without resulting in outbreaks of FMD in Europe, and during the same time more than a million ton of deboned frozen meat were successfully imported by the United Kingdom.

Tourists from other parts of Argentina and from Brazil. The risk of the introduction of exotic diseases through tourism exists, but probably is not larger than that of tourism in most other parts of the world. Moreover, the epidemiological situation in the neighboring areas of Brazil and in Argentina has greatly improved during the last years as a result of the River Plate Basin FMD Eradication Project.

Risk Factors Identified for Uruguay

Illegal movement of pigs from Brazil originating from the States of Paraná, Santa Catarina or Rio Grande do Sul. Since the movements of pigs from the Brazilian States of Rio Grande do Sul, Santa Catarina and Paraná are illegal it is difficult to make estimates of the volume of this activity. Brazilian authorities are taking measures to limit the movements of pigs by transit barriers and controls in Rio Grande do Sul, Santa Catarina and Paraná.

Again, with the progressive improvement of the epidemiological situation in these parts of Brazil this risk will decrease. For example, the last case of FMD in the State of Rio Grande do Sul was eradicated in December 1993.

Argentine tourists. About half a million tourists arrive by air, boat or by crossing the bridges between Argentina and Uruguay. The major concentration of tourists is in the summer months along the coast. It can be expected that some Argentine tourists bring their own food with them, which may include fresh meat or meat products. Tourists are now alerted as to the dangers of such illegal imports and check point for luggage inspection have been put in place. If tourism would be a vehicle for FMD it most likely would first appear in the susceptible pig population in tourist areas. However, these pig populations have little epidemiological connection with the meat producing areas. In view of the excellent vesicular disease surveillance system, an FMD outbreak in pigs would most likely be detected before spread to the meat export region would occur.

Escape of virus from laboratories handling FMD virus. The vaccine production and control facilities as eventual sources of FMD were eliminated since Uruguay stopped FMD vaccination and vaccine production as of June 1994. Presently, the official laboratory for vesicular disease diagnosis and FMD vaccine control does not handle infective FMD virus.

5. DISCUSSION OF FMD-FREE STATUS OF MESOPOTAMIA AND URUGUAY

In May 1993, Uruguay has received the international recognition by the OIE to be "Free of FMD with vaccination" and stopped vaccination as of June 1994. The OIE recognition was, among other factors, based on the absence of clinical disease in the livestock population for at least two years. Young cattle serve as good sentinels for FMD.

These are calves born after the last vaccination round and that lost their maternal antibodies, as well as first-vaccination calves that usually develop only a mediocre immunity. In Uruguay the susceptible bovine population will soon increase because of the cessation of vaccination.

Both in Mesopotamia and Uruguay the absence of virus activity was shown also by unvaccinated sheep which graze mixed with the cattle; although it can be argued that clinical FMD is somewhat more difficult to detect in sheep. However, sheep have been shown to be efficient virus samplers from aerosols and are good multipliers of the virus (*20*). The absence of FMD virus in the livestock populations of Uruguay is further substantiated by the results of serological surveys in bovines and sheep (*14*).

There are no significant numbers of pigs in Mesopotamia. The pig population of Uruguay is concentrated in the southern departments, particularly around Montevideo and the coastal areas. These pigs mostly are on small operations and would be particular efficient in detecting FMD virus that might be brought in by tourists from Brazil or Argentina.

Risk factors for the *re-introduction* of FMD virus were evaluated. Mesopotamia imports a limited number of bulls, semen and embryos. Since these products have low risk and the FMD situation is favorable in the areas of origin, the risk of re-introduction of FMD is very remote. The testing protocol for the importation of breeding bulls will greatly reduce the risk of bringing in carrier animals.

The dry land border between Uruguay and Rio Grande do Sul raises some concern, but in both areas livestock transit is well controlled. The main defense for Uruguay is the continued freedom of FMD of Rio Grande do Sul. Uruguay has eliminated an important source of FMD by ending the handling of infectious FMD virus in its territory,

The risk related to tourism for Mesopotamia and Uruguay is difficult to estimate, but is probably not much different from that of most part of the world. Moreover, the epidemiological situation in the River Plate Region as a whole, as well as in the border areas has progressively improved, creating large disease free buffer zones.

6. DEVELOPMENT OF A QUANTITATIVE RISK ASSESSMENT MODEL FOR THE FMD IMPORTATION RISK OF MEAT SOURCED AND PROCESSED ACCORDING TO THE EC NORMS

The objective of this section is to develop a QRA model for the risk for meat and meat products sourced and processed in accordance with procedures established by the EC (*5*). This section starts with basic information on FMD as it relates to risk assessment. Next general aspects of meat processing procedures are briefly reviewed. Based on this information a scenario pathway is developed and the general principles for the quantification of the risk for each of the events of the pathway are defined.

6.1 GENERAL INFORMATION

6.1.1 Foot-and-Mouth Disease

The major part of this information on FMD is extracted from the chapter on Vesicular Diseases of the Foreign Animal Disease Handbook of the USAHA (*24*).

Diagnosis. In the herd several obviously ill animals are likely to be observed with various stages of clinical development: animals with high fever, excessive salivation, drooling, with or without vesicles of the mouth or muzzle, and lameness with vesicles of the coronary band or of the skin of the interdigital space. Older lesions may be necrotic with a foul smell. Very characteristic is the smacking of the lips and the sucking of the sore tongue.

Swine may not want to get up and are very sore footed when forced to move. In this species vesicles the size of a golf ball may develop on the snout.

In sheep and goats the clinical signs often are less dramatic and may be restricted to lameness and erosive lesions in the mouth. Vesicles of the oral epithelium are likely to rupture quickly, leaving only an erosive surface of the mucosa.

Based on the above described vesicular disease signs a presumptive clinical diagnosis of FMD must be made until laboratory investigation rules out FMD or confirms one of the other vesicular conditions. Until than, animal health measures must be taken in the assumption that the disease is FMD.

FMD virus. FMD virus has seven immunological subtypes denominated as: O, A, C, SAT-1, SAT-2, SAT-3 and Asia-1. Within the seven types, more than 60 subtypes have been designated by the World Reference Laboratory, Pirbright, UK.

FMD virus degrades into smaller protein subunits (sedimentation constant 12S) when subjected to heat, low pH or low ionic strength. Since the virus does not have a lipid containing envelope it is resistant to ether and chloroform.

Geographical distribution. FMD is wide spread especially in the major livestock producing countries of the world. It is considered enzootic in Asia, Africa and most of South America. Areas or countries without disease are North America, Mexico, Central America, Panama, the Guyanas, Australia, New Zealand, Japan and most of Europe as well as the Southern Cone of South America.

Hosts. All cloven-hoofed domestic animals are naturally susceptible to FMD including: cattle, sheep, goats, swine, water buffalo and camelids (llamas and alpacas). Many species of wild animals have been shown to be susceptible such as: deer, antelope, bison, feral pigs, hedge hogs, and capybara. Human infections have been reported but most of these were not confirmed by laboratory diagnosis. Horses are not susceptible.

Incubation period. The portal of entry of FMD virus is the upper and lower respiratory tract, although infection by ingestion or through abrasions in skin or epithelium cannot be excluded. Virus growth is first observed in the pharyngeal area, followed by viremia, at which time fever starts and virus is disseminated to all parts of the body. The virus then replicates in the epithelial cells of the mucosa and the skin causing the characteristic lesions. The incubation period of FMD usually is 2-7 days, but may be shorter when animals are exposed to a massive infectious aerosols produced by infected animals. Since these aerosols already are produced before lesions appear, it is not always easy to determine which animals of the herd were the first ones infected.

Signs. Shortly after the virus invades the epithelium, small hyperemic areas appear in lips, tongue, gums, dental pad, rumen pillars, udder, teats, coronary bands, interdigital areas, and skin. These hyperemic foci soon develop into vesicles that measure from 1 mm to 3 cm or more in diameter. Several of these vesicles may coalesce to form large blisters. They are filled with clear yellow fluid which accumulates as the result of hydropic degeneration of epithelial cells. After the vesicles have formed, the signs of illness become even more pronounced as manifested by copious salivation and extensive nasal discharge. Epithelium covering distended vesicles rupture and the overlying epithelium sloughs, leaving a painful easily bleeding, desquamated area. The mucosa of the lips, tongue and palate are most severely involved. Although no gross lesions may appears in the skin, the virus reaches high concentrations and may permanently change the consistency of the hair coats, resulting in unthrifty cattle with a heavy shaggy coat.

Lameness becomes more severe as foot vesicles enlarge, erode, and ulcerate. These lesions occur in the skin of the coronary band and interdigital areas and are complicated by secondary bacterial infection. The hoofs may slough and the lesions may result in permanent deformity of the foot and lameness.

Vesicular lesions of mucosal lining of the pillars of the rumen are found rather frequently. Myocardial lesions are the most common cause of fatal FMD in young calves, lambs, goats and pigs. These lesions appear as small gray foci and streaks of irregular size and shape in the heart musculature, which gives the myocardium a somewhat striped appearance, the so-called "tiger heart".

It must be remembered however, that the first cases observed, even in an FMD free area, may not show these dramatic clinical signs. Also, in countries where the disease is enzootic or where systematic vaccination is practised, the disease signs may be much less pronounced and the morbidity much reduced. Most affected animals will recover in about two weeks. Mortality usually does not exceed 5%, but may be very high in young animals.

Carriers. Most ruminant species can harbor the virus in their pharyngeal tissues for long periods of time. Recovered cattle or vaccinated cattle exposed to the diseased animals can become healthy carriers. Clinical cases are needed to maintain carriers in the population. Although under experimental conditions it has been difficult to demonstrate transmission of FMD from carriers to susceptible livestock, there is strong circumstantial field evidence that carriers may have been the occasional cause of outbreaks (*25*). FMD virus is found only in the pharyngeal area of carriers and in minute quantities, usually bound to antibodies and virus inhibitors. In general, carriers have high levels of circulating antibodies.

6.1.2 Overview of the Chain of Events from Selecting the Cattle to the Meat Being Ready for Shipment

The information for this section is based on the EC norms, and information obtained from official sources and field observations.

Selection of the source. (Area, Herd, Cattle). Source animals must have remained in the Region for at least three months before being slaughtered or since birth in case of animals less than three months old. Source cattle may not originate from herds within a radius of 25 km from a premise on which FMD occurred 60 days previously. The region from which the animals are sourced have regular, officially controlled FMD vaccination programs of bovine animals. This requirement was dropped for Uruguay when the vaccination program ceased. The source animals remain in their holdings of origin for at least 40 days before departure to the slaughterhouse.

Transportation of cattle to slaughterhouse. Source cattle are transported directly to the approved slaughterhouse concerned without passing through a market. They must not come in contact with animals which do not comply with the conditions required for export of their meat to the EC. The trucks are cleaned and disinfected before loading.

Entry of animals - ante-mortem inspection. On arrival at the abattoir, all documents are revised by an official of veterinary services before animals disembark. If everything is in order, the cattle move into a reception pen for ante-mortem inspection. At this point, each animal is identified with the producer's number and the herd number. Animals proceed to an electronic scale to be weighed. It is important to note that cattle from each herd are placed in separate resting pens. All livestock transporting vehicles are washed and disinfected before leaving the abattoir. Animals with pathologies or injuries during ante-mortem inspection are directed to an isolation pen where further inspection is made by a veterinary officer who determines the destination of that animal. Animals which arrive dead at the slaughterhouse are taken directly a the post-mortem room for pathological examination.

Slaughter procedures. After at least 24 hours of rest, the animals are moved by herds to the slaughtering room. Animals are washed completely with pressured water as they make their way to the stunning area. The stunned animal is transported by a mechanized pulley system to be bled and dressed. There are several work posts along the line, each with technicians and equipped with facilities for hand washing and tool sterilization. Throughout the slaughtering process, each carcass and parts are identified. As the skin is being removed, the initial identification numbers are printed on each quarter. Besides, each half carcass, the head, organs and intestines are given the same number to facilitate retrieval of parts if any pathology is observed during post-mortem inspection. Of particular importance is the identification of the head and feet of each individual animal.

Post-mortem examination. A technician washes and inspects the tongue, muzzle and feet from each animal individually for vesicular lesions. Meat inspection technicians are located at each work post to inspect the carcass after the animal has been skinned. If a pathology is observed, technicians tag the area of concern and the entire animal is placed aside, to await the judgment of the veterinary officer. Specific tags are used for different conditions.

Grading. The carcass is graded by meat technologists according to age, fat and general appearance before being chilled.

Chilling/maturation. Maturation of the carcasses is done at a temperature of 3-7°C. After 24 hour of maturation, the acidity level is measured with a pH meter previously calibrated by laboratory personnel. The pH meter is introduced in the *longissimus dorsi* muscle. A pH lower than 6.0 is required for export.

Deboning. In this section laborers perform highly technical tasks. The separation of the muscles is done while the carcass is suspended by the pulley system. The cleaning of the muscle parts is done on metal tables. Technicians in this area do the final examination looking for blood clots, bone chips and pieces of large vessels before packaging.

Packaging. Packaging varies according to the request of the importing country. In all cases, the cut is identified, the date on which it was processed and the abattoir of origin is tagged on each parcel. Parcels are packed in cardboard boxes. The weight of each box is taken on an automatic electronic scale and a printout pasted on the box. An inspector's seal is placed on each package to prevent tempering after final inspection. The boxes are packed in the cold storage compartments depending on the type of export.

Emergency slaughter. Effective ante-mortem inspection permits the separation and selective slaughtering of injured animals as well as those with visible pathologies. The post-mortem examination is done by a veterinary inspector who determines the destiny of the carcass. The room has its own cold storage, waste disposal and digester.

Quality control. The laboratory section carries out physical, chemical and microbiological control of all products. The department is headed by a manager who is assisted by trained technicians. They are responsible for all matters pertaining to the hygienic quality of all processes and the characteristics of the different products.

6.2 SCENARIO PATHWAY FOR THE QUANTIFICATION OF RISK FACTORS

The scenario pathway in table 2 illustrates the flow of events from the farm of origin of meat to the moment of export. It is based on norms, practices and considerations of risk factors described above. In the scenario pathway, all relevant events in the process are taken account of, as are the consequences for meat importation.

Questions asked for each event are: "What can go wrong?", "How likely is that to happen?" and "What are the consequences?".

For instance, if FMD is detected in a source herd, the export of meat will be cancelled. Similarly, if FMD is found in any animal in the slaughterhouse on the day source animals are being slaughtered, the export of meat from that slaughterhouse will be terminated. However, failure to detect FMD in either case may mean that FMD virus containing meat may be processed and exported.

The quantity of meat to be imported is the basis for estimating the number of herds (N_1) required to assemble the total shipment of meat. The prevalence of FMD in the Region (P_1) determines the likelihood of disease in source herds (P_2). Subsequent events in table 2 are the detection of FMD in the source herd by the Animal Health Attention System (P_3) and the detection of FMD during the transport of the source cattle to the

Table 2. Scenario Pathway and Consequences of Risk Events for FMD Transmission by the Importation of Meat sourced and processed according to EC Norms

RISK CALCULATION FOR... TON OF MEAT

N_1 Number of herds required for production of ... ton of meat

		CONSEQUENCE	
P_1	FMD in the cattle population of the Region?	No Yes	→ No risk → P_2
P_2	Herd infected with FMD?	No Yes	→ No risk → P_3
P_3	FMD detected in infected herds by Animal Health Attention System?	Detected Not detected	→ No export → P_4
P_4	Detecting of FMD by transit control?	Detected Not detected	→ No export → P_5
P_5	Detecting of FMD during ante-mortem inspection?	Detected Not detected	→ No export → P_6
P_6	Detection of FMD during post-mortem inspection?	Detected Not detected	→ No export → P_7
P_7	Survival of FMD virus following maturation and deboning?	No survival Survival	→ No risk → P_8
P_8	Survival of FMD virus during freezing and transport?	No survival Survival	→ No risk → RISK

slaughterhouse (P_4). Events P_5 and P_6 relate to the detection of FMD in the slaughterhouse at ante- and post-mortem inspection, respectively. Finally, there are probabilities of FMD virus survival during maturation and the deboning of the carcasses (P_7) and freezing and transportation of the meat (P_8).

Each event is regarded as a unit to be ascribed a mathematical value (table 3), for instance: the probability that source cattle originate from an infected herd or the number of herds required for the total quantity of meat to be exported.

What is shown in table 3 are conditional probabilities: given that a disease is not detected at ante-mortem, what is the probability that it also is not detected during post-mortem inspection, and what is the probability that it also is not detected the third time, etc.

Sequential probabilities are accumulative (*8*). For example, if the probability of selecting an infected herd is P_a and the probability P_b = 0.02 that FMD is not detected in the slaughterhouse during meat inspection, than the risk of FMD remaining in the processing chain that leads to the meat to be exported is P_a x 0.02. If subsequently in 95% of the carcasses the virus is destroyed by the maturation process, than the probability of FMD remaining in the meat is P_a x 0.02 x 0.05 or = P_a x 0.001. The final calculation of the importation risk is shown in table 4.

Usually, it is not possible to state with certainty what is the likelihood that an event will occur. For instance, we do not know with certainty how often or how much FMD virus actually escapes detection. However, on a scale from 0 to 1, it usually is possible to agree on a range of frequencies that an event will occur. For instance, the minimum and

Table 3. Mathematical Units of Risk for FMD Transmission by the Importation of Meat sourced and processed according to EC Norms

N_1	Number of herds required for the production of ... tons of meat
P_1	Prevalence of FMD in the cattle population of the Region
P_2	Probability of including at least one source herds with FMD*
P_3	Probability of not detecting FMD in an infected source herd by the Animal Health Attention System
P_4	Probability of not detecting FMD in the cattle from infected source herds by transit control during movement of the cattle to the slaughterhouse
P_5	Probability of not detecting FMD during ante-mortem inspection in cattle from infected source herds or all other herds present during the time that source cattle are in the slaughterhouse pens
P_6	Probability of not detecting FMD during post-mortem inspection in cattle from an infected source herd or any other cattle at the slaughter plant
P_7	Probability that FMD virus survives in meat of at least one carcass following chilling/maturation and deboning, originating from an infected source herd
P_8	Probability that FMD virus survives freezing and transportation to the importing country in meat from cattle from infected source herds

Probability that ... tons of meat contain contaminated meat from at least one FMD infected carcass = $P_2 x P_3 x P_4 x P_5 x P_6 x P_7 x P_8$

*$P_2 = 1-(1-P_1)^{N1}$. However in the range of the numbers being used. N1 x P_1 basically gives the same numerical result.

Table 4. Quantification of Units of Risk for FMD Transmission by the Importation of Meat sourced and processed according to EC Norms

	Three-Point Estimates:	PROBABILITY Minimum	Most likely	Maximum
N_1	Number of herds required for the production of 100 ton of meat	35	45	55
P_1	Prevalence of FMD in the cattle population (after FMD re-introduction)	.00002	.00005	.0003
P_2	Probability that at least one source herd with FMD is included $[1-(1-P_1)^{N1}]$	.0006	.002	.015
P_3	Probability that FMD is not detected in infected source herds by the Animal Health Attention System	.01	.05	.2
P_4	Probability that FMD is not detected in the cattle from infected source herds during movement to the slaughterhouse	.03	.1	.3
P_5	Probability that FMD is not detected during ante-mortem inspection in cattle from infected source herds or from all other herds at the plant	.005	.01	.03
P_6	Probability that FMD is not detected during post-mortem inspection in cattle from infected source herds or from any other cattle at the plant	.00001	.001	.003
P_7	Probability that FMD virus survives in meat of at least one carcass originating from an infected source herd following chilling/maturation and deboning	.005	.01	.05

maximum estimates of likelihood of an occurrence may be .001 and .3, respectively. Experts and evidence will point to the most likely frequency somewhere within that range, for instance, 1. Such a frequency distribution does not have to be "normal" and, in fact can be quite asymmetrical.

The minimum, maximum and most likely values form what is known as a three-point estimate, which not only express the best knowledge about the event, but also provides a guide to the uncertainty of information related to the event. For an example see the 3-point estimates given in table 4, for the events in the meat importation risk scenario pathway for FMD. These estimates are based on available scientific and practical evidence, etc. A simple mathematical accumulation of the 3-point estimates of all events will provide a final 3-point estimate for the importation risk. However, 3-point estimates do not indicate the relative chance of the likelihood that the event will occur.

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* Lotus and 1-2-3 are registered trademarks of Lotus Development Corporation.

@Risk , Risk Analysis Add-in for Lotus 1-2-3, Version 2.01, 1992, Palisade Corporation, 31 Decker Rd., Newfield, NY 14867.

The Lotus 123 /@RISK computer program*, used for the present risk study, is a software package which permits the construction of a so-called Probability Density Function (PDF) for each event. A PDF shows the range of the probability that the event occurs and the relative chance that the event will occur. A narrow range for the PDF indicates a greater confidence in the estimates than a wider range.

The Lotus 123 /@RISK computer program constructs a PDF for each event through a large number of recalculations, based on a random number generated for each calculation, and the distribution parameters provided, such as the minimum, maximum and most likely probability values. The results of such simulations are presented graphically (figure 3) and as statistical reports (table 6). Of particular interest are the Mean or Expected Results, which are the most likely occurring outcome of the simulation, and the Percentile Probability values, indicating the chance of outcome levels.

The Lotus 123/@RISK computer program also accumulates the PDFs of all individual events to form a final PDF for the import risk, giving a most likely (mean expected) import risk, as well as, the maximum risk at the 95% probability level.

7. QUANTITATIVE RISK ASSESSMENT MODEL FOR THE IMPORTATION OF MEAT IN THE CASE OF RE-INTRODUCTION OF FMD INTO MESOPOTAMIA OR URUGUAY

The QRA model for FMD is applied to the importation of meat from Mesopotamia and Uruguay to evaluate the risk of a hypothetical re-introduction of FMD. The scenario pathway in tables 2 and 3 is used to estimate *the risk for an importing country if FMD were to be re-introduced in Mesopotamia or Uruguay*.

First a quantification of the risks is proposed. That section also shows the statistical elaboration of the risk values and the documentation of all evidence and information used for the proposed risk values. It is followed by the presentation of a spread sheet model (table 5) and a discussion of computer simulation results.

7.1 QUANTIFICATION OF RISK UNITS

Three-point estimates of FMD risk units (tables 2 and 3) in the case of an FMD re-introduction are shown in table 4. The supporting information and evidence for these estimates is obtained from the literature, records, consultations with experts and observations, and can be summarized as follows:

P_I Incidence of FMD following re-introduction. An estimate must be made of the number of farms that would become infected as a result of re-introduction of FMD in Mesopotamia or Uruguay, before being detected. Obviously, there are only few comparable documented cases of this situation. As such, there are the 1953 outbreak in Canada, the Mexican outbreak or the last outbreaks in Great Britain, etc., but the conditions of these occurrences were rather different. It was assumed therefore, that the number of herds classified as secondary FMD outbreaks in Argentina and those in Uruguay, prior to the eradication of FMD, would represent the spread of FMD following an eventual re-introduction of the disease. The probability of the number of herds involved in secondary FMD outbreaks has been estimated from the SENASA records of 1991-1993, and the records of the Dirección General de Servicios Ganaderos of Uruguay for 1989 until 1990. The probability of the minimum number of herds involved in an outbreak due to FMD introduction would be "no spread". The most likely probability of farms involved would be three, while it is unlike that the maximum number would exceed 15. The maximum estimate likely is lower in areas with larger herds. Of course, once the outbreak is detected meat exportation would be put on hold.

In Mesopotamia and Uruguay there are some 60,000 and 50,000 herds, respectively. Consequently, the incidence of FMD following re-introduction, and before being detected by the Animal Health Attention System, would probably be 3/55,000, with a minimum and maximum incidence of 1/55,000 and 15/55,000, respectively.

***N_1* (No. of herds required for the production of 100 ton of meat)**. From each animal 18-20 kg of type "A" cuts can be obtained, which means that some 5,500 cattle must be slaughtered to obtain 100 ton of this type of meat (*21*). Given that the average herd size is 200, but that in the Region the productive part of the herd is likely not more than 60% than most likely N_1 = 5,500/200/.6 = 45 herds with a minimum and maximum of 35 and 55, respectively. Herds for meat export probably would be larger than the average herd size, but the present estimates favors the worst case scenario.

***P_2* Probability of disease on the donor farm**. The probability that FMD occurs in at least one farm of the number of farms required for 100 tons of meat can be calculated by the binomial $1-(1-P_1)^{N1}$. However, in the range of the numbers being used, $N1xP_1$ basically gives the same numerical result (*8*). However, this assumes a random distribution of infected herds. Most likely the infected herds are clustered in which case the values used in the model would favor the worst case scenario.

***P_3* Probability that Animal Health Attention System fails to detect FMD**. The livestock community is well aware of the socio-economic consequences of not reporting a suspicious vesicular disease. Of particular importance are the activities of the local commissions in which there is a high degree of community participation. Certificates must be issued for moving the animal declaring origin of the animal, the freedom of FMD of the herd and of the surrounding area within a 25 km radius for at least 60 days. The probability of 5% that the Animal Health Attention System would fail to detect FMD in the herds designated for meat export is a conservative estimate, but the failure to detect could occur if this would be the first re-introduction in an area with high vaccination coverage, and with all animals still in the incubation period. Note that the worst case is estimated to be a 20% failure rate.

***P_4* Probability that FMD is not detected during transit**. All people related to the transport of livestock have the obligation to report any disease sign that might suggest FMD. In Uruguay cattle must pass barriers for tick control and each animal is searched for ticks individually. If clinical cases of FMD would be present, the chances are remote that the event would go unobserved and unreported. Again, if FMD would still be in the incubation stage, this might be the case and could result in an estimated range from 10% for the most likely occurrence with a maximum of 30%.

***P_5* Probability that FMD is not detected during ante-mortem inspection**. All cattle are identified individually with herd number and only animals belonging to the same herd are kept in the same resting pen. These pens are well lighted and the cattle stay there for at least 24 hours, but not longer than 72 hours. Since FMD has a short incubation period, and if the animals were infected at the farm of origin it is unlikely that lesions would not be observed, in at least a few animals, at ante-mortem inspection. It would be difficult to miss the feverish, salivating or lame animal.

Animals for export are slaughtered first, but even one animal with FMD among hundreds of animals to be slaughtered that day, would cause the cancelation of all meat export from that plant. Therefore, the probability that the inspection process fails to detect at least one FMD animal is low. In the absence of a review of historical slaughterhouse data the most likely failing rate was conservatively estimated to be 1%, but this value probably is too high.

It appears that the healthy FMD carrier is of some concern to regulatory officials of the importing country, since such animals would not be detected anywhere in the scenario pathway. However, in a region without FMD for several years, the number of carriers in the cattle population is extremely low, because in bovines, clinical FMD is required to maintain carriers in the population.

P_6 Probability that FMD is not detected during post-mortem inspection. The basis for dealing effectively with the detection of FMD at post-mortem inspection of the cattle is the identification system of the carcass, head and feet of each animal individually. Of all cattle, the tongue, oral mucosa, muzzle and feet are inspected for acute or recovered vesicular lesions. It is difficult that the inspector misses developing blisters or acute lesions. If the herd was infected shortly before leaving the farm or during transport it is likely that at least one animal would develop lesions at this point in time. As in the whole inspection process, one FMD lesion found in a foot or tongue from any one of the hundreds of animals slaughtered that day, will cause ceasing all meat export operations from that plant. Healing lesions of the convalescent animal are very characteristic and most likely would be found in more than one animal of the herd.

Because of the close individual inspection of each carcass it was estimated that the post-mortem inspection process is at least 10x more sensitive than the ante-mortem inspection. A review of historical slaughterhouse records of meat exported to Europe would probably lower the estimates within a smaller confidence range.

P_7 Probability that FMD virus survives maturation and deboning. FMD virus rapidly disintegrates with a pH of less than 6.0. Maturation for 24 hours at 3-7°C brings the pH of meat down to the point where FMD virus is destroyed. The effectiveness of the maturation mainly depends on the amount of glycogen in the muscle at the time of slaughter, which in turn is influenced among others by the general health of the animal and the resting period. The pH of the meat of each carcass is measured, but human error can not be completely ruled out, both in pH measurements and the deboning operation. For instance, contamination of the meat with clots from large blood vessels, or incomplete removal of the larger lymphnodes might be possible.

No data are available on the kenetics of virus inactivation in meat with a pH of 6 or less. However, it is known that FMD virus is inactivated at a pH of 6 or less and experience with the importation of large quantities of deboned meat by Europe during epidemic periods have demonstrated the effectiveness of the carcass maturation process. In the absence of inactivation kinetics it is not easy to estimate the probability that at least one infectious unit of FMD virus survives in meat of a carcass from a viremic animal.

Therefore, the probability that FMD virus is not completely destroyed in at least one of the carcasses from infected cattle, or that human error occurred, is estimated to be 1-5%, but these values may be unduly pessimistic.

It is very unlikely that virus from the pharyngeal area of healthy carriers would contaminate the meat for export by mechanical means. The virus in the pharyngeal area is present in carriers only in minute quantities in the pharyngeal area and usually is bound to neutralizing antibodies and other inhibitors.

P_8 Probability that FMD virus survives freezing and transport. Since FMD virus resists freezing and keeps well under conditions of frozen meat the probability of virus survival was assessed as being close to 100% and, therefore, not included in the calculations.

7.2 COMPUTER MODEL SIMULATION FOR FMD RISK ANALYSIS FOLLOWING EVENTUAL RE-INTRODUCTION OF FMD

Table 5 shows the Lotus 123/@RISK spreadsheet that was used to assess the risk of the importation of 100 tons of deboned meat from Uruguay or Mesopotamia. The 3-point probability estimates are according to table 4 for which supporting evidence and data were provided in the previous chapter. The "expected result" is the result of one iteration of the @RISK computer program for a triangular probability distribution of the 3-point estimates. The "cumulative result" for an event is the product of the expected result of the event multiplied by the cumulated value of the previous event along the pathway scenario. The cumulated expected results indicate the progressive risk reduction.

For the present simulation study 10,000 iterations were executed, with a different random number for each of the calculations. Figure 3 illustrates the PDFs for each event resulting from those iterations. The frequency of the event occurring is on the X-axis (horizontal), while the probability of the frequencies is on the Y-axis (vertical). The mean or expected result is the midpoint of the curve. A narrow range of the frequencies on the X-axis indicates a greater degree of confidence in the estimates than a wide range. For instance there only is a 10-fold difference between the minimum and maximum values for P_4 (probability that FMD is not detected during transport of the cattle to the slaughter-house), while P_6 (probability that FMD is not detected during post-mortem inspection) has a 300-fold difference between the minimum and maximum value. This would indicate a higher degree of uncertainty for the estimates for P_4, particularly at the lower end of the curve.

Figure 4 shows the cumulative PDF and indicates that the import risk, defined as the chance of FMD virus being present in 100 tons of meat is approximately 10^{-10}. The same results are presented in figure 5 in a cumulative manner. On the X-axis is the range of frequencies of the event. On the Y-axis, –on a scale from 0% to 100%– is the probability that the value is equal to or smaller than that on the X-axis value.

Finally, a statistical summary report on the simulation results is given in table 6. This shows the expected, minimum and maximum probabilities, as well as the probabilities of import risk at different percentile levels.

Table 5. Lotus 123/@RISK spreadsheet for the assessment of the exportation of 100 tons of meat from Mesopotamia or Uruguay after re-introduction of FMD

	PROBABILITY				
	Minimum	Most likely	Maximum	Expected results	Cumulative results
N_1	35	45	55	45	
P_1	0.0000181	0.0000545	0.0002727	0.000115	
P_2	0.000636	0.002452	0.014890	0.005993	
P_3	0.01	0.05	0.2	0.086667	0.000519
P_4	0.03	0.1	0.3	0.143333	0.000074
P_5	0.005	0.01	0.03	0.015000	1.12E-06
P_6	0.00001	0.001	0.003	0.001337	1.49E-09
P_7	0.005	0.01	0.05	0.021667	3.23E-11

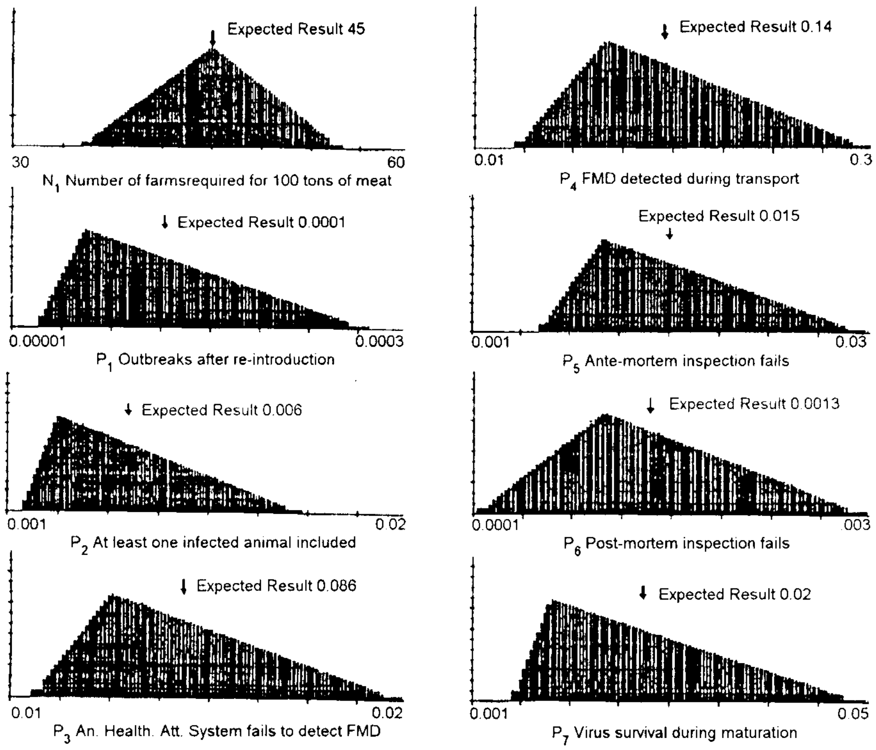

Figure 3. Probability Density Functions of the Three-Point Estimates for the Risk of FMD of deboned meat from Uruguay or Mesopotamia after re-introduction of FMD.
X-axis (horizontal): Frequency of the Event occurring.
Y-axis (vertical): Probability of Frequency.

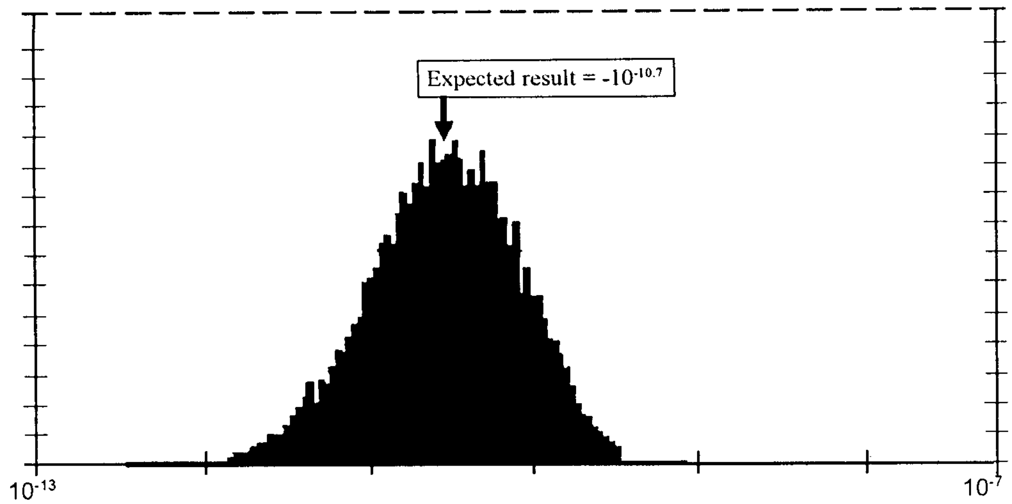

Figure 4. Probability Density Function of the importation risk of FMD of deboned meat from Uruguay and Mesopotamia after re-introduction of the disease.
X-axis: Frequency of Event occurring.
Y-axis Probability of Frequency.

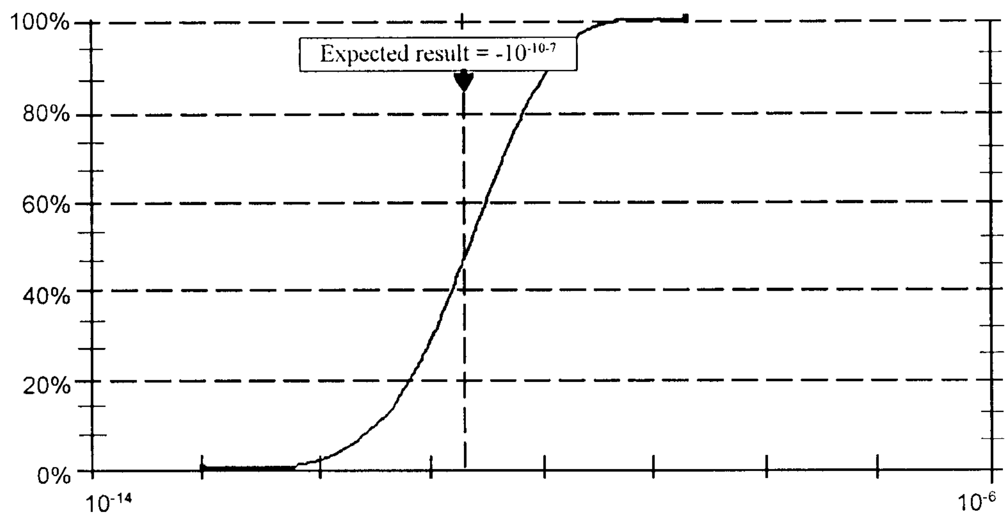

Figure 5. Importation risk of FMD of deboned meat from Uruguay or Mesopotamia after re-introduction of the disease.
X-axis: Probability of occurrence of the Event.
Y-axis: Probability =< than value on X-axis.

Table 6. @RISK: Simulation Statistics

Worksheet: Assessment risk of 100 tons of meat from Mesopotamia and Uruguay after FMD re-introduction

	LOG10 IMPORT RISK
Expected/Mean Result =	-10.79
Maximum Result =	-9.08
Minimum Result =	-13.00
Iterations =	10000
Percentile Probabilities (Chance <= Shown Value)	
0%	-13.00
5%	-11.73
10%	-11.49
15%	-11.34
20%	-11.23
25%	-11.14
30%	-11.06
35%	-10.98
40%	-10.90
45%	-10.84
50%	-10.77
55%	-10.70
60%	-10.63
65%	-10.56
70%	-10.49
75%	-10.42
80%	-10.33
85%	-10.23
90%	-10.11
95%	-9.95
100%	-9.08

7.3 DISCUSSION AND CONCLUSIONS

The import risk is defined as the probability that 100 tons of meat ready for import would contain FMD virus.

Important considerations for the risk of the introduction of an exotic disease such as FMD include:

- the epidemiological situation in the exporting Region, the health status of the source farms and of the farms in the surrounding area;
- the effectiveness of the Animal Health Attention System, composed of the official services, private veterinarians, livestock owners, etc., and the active participation of the community and other sectors of the livestock industry;
- the degree of confidence of the veterinary authorities of the importing country in the surveillance and information system of the exporting Region.

Uruguay and Mesopotamia have not had FMD for several years. Mesopotamia still has a systematic program of vaccination against the disease, but Uruguay has ceased all FMD vaccinations. The vesicular disease surveillance and reporting system in both Regions is very effective and inspires a high level of confidence in the results.

The risk of meat from the region could result from a re-introduction of FMD, particularly from neighboring Regions, where FMD occurs sporadically. Several risk factors were considered qualitatively. It was concluded that the possibility of re-introduction of FMD exists, but that the risk of that event to occur is remote.

All meat for export in Argentina and Uruguay is obtained in accordance with the directives and norms of the EC, involving specific conditions for origin and transport of the cattle, the slaughterhouses, and the slaughtering and inspection process. An important part of the risk reduction is in the maturation and deboning of the meat. The total risk reduction of the scenario pathway of events (tables 2, 3, 4) was calculated. The results show that, if FMD would be re-introduced in Uruguay or Mesopotamia, the probability of FMD contamination of 100 tons of meat would, most likely, be in the order of 10^{-10}; or in other words: a risk of one in 10 billion. There is a 5% chance, however, that this could be as high as one in a 1 billion. Thus, the total importation risk from meat would be equal to the remote risk of re-introduction of FMD multiplied by 10^{-10}, which is exceedingly small.

The risk estimates presented in this document can be easily recalculated if justified by further consideration of existing data and information, or when experience or research generate new information. In practical terms however, it is unlikely that such adjustments would substantially affect the main conclusions of this QRA for the risk of FMD from meat originating from Uruguay or Mesopotamia. It is more likely that new information will remove some of the uncertainties that necessarily have had to be incorporated in the present estimates. This should serve only to increase confidence in the conclusions of this study.

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10. GLOSSARY

RISK ASSESSMENT

Risk analysis. The process that includes risk assessment, risk management and risk communication.

Risk assessment. The process of identifying a hazard and evaluating the risk of a specific hazard, whether in absolute or relative terms. It includes estimates of uncertainty and is an objective, repeatable, scientific process.

Hazard. Elements or events that pose potential harm, an adverse event or adverse outcome. Hazard is specified by describing what might go wrong and how that might happen.

Risk. The likelihood and magnitude (of the consequences) of occurrence of an adverse event, a measure of the probability of harm and the severity of the adverse effects. Objective measurement and scientific repeatability are hallmarks of risk. In risk studies, it is common, especially in oral communication, to use "risk" synonymously with the likelihood (probability or frequency) of occurrence of a hazardous event. In such instances, the seriousness of the consequences is assumed to be significant.

Import risk. The probability that infectious of FMD virus would be included in a specified quantity of meat to be imported.

Risk management. The pragmatic decision-making process concerned with regulating the risk. Risk management is a term used in at least two ways. It refers to risk policy in a political sense. It is also used to describe a risk mitigation procedure (e.g., quarantine or serological testing) which is required before an import can be completed. It is important to recognize the context of the discussion when the term risk management is used.

Safety. The degree to which risks are judged acceptable, a subjective decision of the acceptability of a risk. In the literature, it is generally used when discussing safety for human health. What one individual views as safe, another may view as presenting unacceptable risk. In a regulatory context, managers make decisions about, for example, an importation based on their evaluation of the safety of the action for the health of the national herd.

Risk mitigation measures or risk reduction measures. Any action(s) which reduces the risk of an agent to cause harm. Examples include quarantine, diagnostic testing, inspections, restricted use, processing, and sentinel monitoring.

Unrestricted risk estimate. The measure of risk to animal health if a commodity were to be imported in its usual commercial form with no risk mitigation measures applied.

Negligible risk (also known as tolerable risk, *de minimis* risk). A mutually agreed upon measure of risk so low that all parties agree to accept risks at or below this level under most circumstances,

Risk communication. Open, two-way exchange of information and opinion about risk leading to better understanding and better risk management decisions. It is a tool to provide a forum for interchange of information with all concerned, both inside and outside the veterinary authority, about the nature of hazards, the risk assessment and how the risks should be managed, a tool to assure the unambiguous interchange of information among those affected by the outcome of risk assessment activities.

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Simulation. Repeated recalculation of the risk model with different input values with the intent of getting a complete representation of all possible scenarios that might occur in an uncertain situation.
Iteration. One calculation of the model during a simulation. In the present study 10,000 iterations were made.
Probability density function (PDF). Statistical term for a frequency distribution constructed from an infinitely large set of values where the class size is infinitesimally small. The frequency of an event is plotted on the X-axis (horizontal), while the probability of the frequencies is on the Y-axis (vertical).
Three-point estimate. Estimates for the minimum, most likely and maximum frequency of occurrence of an event.
Triangular distribution. A distribution determined by the three-point estimate of an event. This distribution curve expresses the best knowledge about the frequency of occurrence of an event and the level of uncertainty of information related to the event.
Expected result. The midpoint of a PDF curve. The expected result of a triangular distribution usually does not coincide with the peak of the curve.
Cumulative frequency distribution. A cumulative distribution constructed by cumulating the frequency across the range of a frequency distribution. On the X-axis (horizontal) is the range of frequencies of the event. On the Y-axis (vertical) –on a scale from 0% to 100%– is the probability that the value is equal to or smaller than that on the X-axis value.

FMD ECOSYSTEMS

Primary endemic ecosystem. In this ecosystem the conditions are favorable for the maintenance of FMD. It comprises regions with low turnover of the cattle population with a high percentage of immune or partially immune adults. The calves renew the susceptible population. The cattle density is low and cattle movements are mostly out of the region.
Secondary endemic ecosystem. An endemic system, but with a high rate of renewal because of the influx of susceptible young cattle form primary endemic regions. The cattle density is high and FMD occurs frequently, often periodically depending on the movement and concentration of cattle during certain months.
Paraendemic ecosystem. Areas with livestock production systems, unfavorable for maintaining FMD in the population for prolonged periods of time. The farms are small, often predominantly dairies, and there is little movement of cattle. FMD usually is introduced from the outside and can cause explosive outbreaks, because of the high density of farms and cattle.
FMD free ecosystem. Areas are either free because of natural conditions, such as very low cattle density or a particular geography, or because animal health measures prevent FMD from entering. This ecosystem also comprises the areas from which FMD was eradicated.

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