Animal and Plant
Health Inspection
Service

Risk assessment - Importation of fresh (chilled or frozen) beef from Uruguay

November 2002

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EXECUTIVE SUMMARY

Uruguay has officially requested that the Animal and Plant Health Inspection Service (APHIS) allow the importation of fresh (chilled or frozen), deboned, and matured prime beef cuts from Uruguay, into the US. Uruguay vaccinates its cattle population against foot-and-mouth disease (FMD) and plans to continue vaccination at least until 2003. Given the history of the disease in Uruguay and the fact that Uruguay requested authorization to export a commodity rather than recognition of FMD freedom, APHIS conducted a quantitative risk assessment to evaluate the likelihood of FMD introduction through importation of beef from Uruguay.

Consistent with the approach taken by APHIS in the past for evaluating the risk of FMD in beef imports from Argentina, the mitigations considered in this assessment include:

1. Beef imported from Uruguay will be deboned prime beef cuts from carcasses that are maturated for 36 hours at a temperature between 2 to 10 degrees Celsius.
2. Beef will originate from animals in herds certified by governmental veterinary officials to have been vaccinated with oil-adjuvant vaccine.
3. All animals must pass both ante- and post-mortem inspections.
4. All carcasses must be pH tested in the loin muscle and the pH must be less or equal to 5.8.

BACKGROUND

In April of 2001 an FMD outbreak occurred in Uruguay along the border with Argentina. The first case was identified on April 24, 2001 in the western state of Soriano. A total of 2057 foci were reported by the end of the outbreak. The last focus reported was on August 21, 2001. Due to the magnitude of the outbreak, Uruguay determined that a stamping-out policy was inadequate and initiated a massive vaccination program. As a result of the outbreak the U.S. removed Uruguay from the list of FMD free countries and prohibited beef imports from the country.

APHIS conducted a site visit in July 2002 to gather data and relevant information to assess the risk of importing FMD in beef from Uruguay. APHIS had thorough knowledge of animal health infrastructure in Uruguay as a result of a previous assessment conducted in December 2000 and a history of trade with Uruguay. The scope of the 2002 site visit included verification of FMD outbreak controls, an overview of the surveillance program and laboratory capabilities, vaccination practices and eradication activities, and movement and border controls. Particular focus was placed on the regional FMD situation in Uruguay and South America and on the risk of reintroducing FMD into Uruguay from neighboring countries. The site visit report notes that FMD in South America is a regional problem, as was clearly evident in the outbreaks of 2001 in Argentina, Uruguay, and Brazil. It also notes that Uruguay is maintaining its strategy of vaccinating all cattle until the regional situation is rectified. The July 2002 site visit report is extensively referred to in this risk assessment, and is attached. A summary of the site visit findings is contained in the introduction section of this risk assessment. APHIS used the data obtained during the site visit as well as information provided by Uruguay to conduct this quantitative risk assessment.

SCIENTIFIC SUMMARY

The objective of this risk assessment is to quantify the annual risk of introducing FMD virus into the United States through importation of fresh (chilled or frozen), matured and deboned prime beef cuts from a vaccinated herd population in Uruguay. The analysis estimates the annual likelihood of importing beef from at least one FMD infected and viremic carcass from Uruguay. A scenario was developed to estimate this probability. The initiating event is the selection of herds in Uruguay from which to extract animals for slaughter.

The assessment is based on the premise that FMD infected beef from Uruguay can enter the United States if:

- There is an undetected/unreported FMD outbreak in Uruguay, and
- There is at least one FMD infected undetected herd selected to provide animals for export slaughter, and
- At least 1 animal from the infected, undetected, selected herds
    - is viremic, and
    - is selected for slaughter, and
    - is not detected during ante-mortem and postmortem inspections, and
    - provides meat containing FMD virus that survives maturation and deboning.

A scenario tree showing the potential risk pathway followed in the assessment is presented in Figure 3, on page 14.

Data and background information for the release assessment were collected through Uruguayan animal health officials from the records of the Ministry of Livestock, Agriculture and Fisheries (MGAP), the Division of Animal Health (DSA), Control of Stocks and Animal Movement (DICOSE), Veterinary Laboratories (DILAVE), and Animal Industry (DIA). Additional data were collected during the 2002 site visit. Where applicable, input variables were estimated based on information available in published scientific literature. However, some variables were either derived or estimated qualitatively, because of lack of quantitative evidence.

SUMMARY OF RESULTS

Hazard Identification

FMD virus can survive in frozen and contaminated meat in non-acid environments for up to 80 days. Therefore, APHIS considered presence of FMD virus in meat as a potential hazard.

Release Assessment

APHIS used a quantitative model to estimate the annual probability of importing infected beef into the U.S. from Uruguay. Monte Carlo simulations were carried out on an IBM PC, with the @RISK modeling software. The annual quantity of beef imported into the U.S. (in the simulations), ranged between 12,000 to 24,000 metric tons with a most likely value of 19,000 metric tons. This is based on historical annual exports of beef from Uruguay to the U.S. during 1996 to 2001.

Because vaccination is being carried out in Uruguay and because of the assumption that disease can go undetected for extended periods of time in vaccinated populations, there could be several undetected infected herds in Uruguay from which animals are picked and slaughtered, during a year with FMD. However, there is uncertainty about the potential number of undetected infected herds in Uruguay during a year with FMD. In order to better understand and characterize the uncertainty in this parameter, and how it affects the overall risk, the following two scenarios were evaluated:

- SCENARIO 1: In the first scenario, the number of undetected infected herds (N), varied uniformly between a minimum of 1 and a maximum of 35 [N = RiskUniform(1,35)].
- SCENARIO 2: In the second scenario, the number of undetected infected herds (N), varied from a minimum of 1 to a maximum of 62, with a most likely value of 35 [N = RiskPert(1,35,62)].

APHIS believes that the first scenario provides a more realistic result because it reflects the possible number of undetected infected herds in Uruguay during a year with FMD, and more accurately represents its uncertainty. However, it is important to include the second scenario as a maximized risk scenario.

Under these two scenarios, the annual probability of importing FMD infected beef from Uruguay is estimated. The number of years until the first importation of FMD infected beef is also estimated.

<u>Scenario 1 (The number of undetected infected herds, N varies uniformly between 1 and 35) :</u>

The results of the analysis show:

- A 95% confidence of 1,500 or more years until the first importation of FMD infected beef.
- A most likely annual probability of 7.06×10^{-6} of importing FMD infected beef from Uruguay.
- A 95% confidence that the annual probability of importing FMD infected beef from Uruguay is less or equal to 1.03×10^{-4}.

<u>Scenario 2 (The number of undetected infected herds, N varies between 1 and 62 and has a most likely value of 35):</u>

The results of the analysis indicate:

- A 95% confidence of 800 or more years until the first importation of FMD infected beef.
- A most likely annual probability of 5.57×10^{-5} of importing FMD infected beef from Uruguay.
- A 95% confidence that the annual probability of importing FMD infected beef from Uruguay is less or equal to 1.76×10^{-4}.

These results are summarized in the Table 1 and figures 1-2 below.

Table 1: Release assessment result

Scenario	Outputs	Mean	Most Likely	5%tile value	50%tile value	95%tile value
Scenario1	Annual Probability of importing infected beef from Uruguay	3.51×10^{-5}	7.06×10^{-6}	3.05×10^{-6}	2.47×10^{-5}	1.03×10^{-4}
Scenario2	Annual Probability of importing infected beef from Uruguay	6.67×10^{-5}	5.57×10^{-5}	1.06×10^{-5}	5.12×10^{-5}	1.76×10^{-4}
Scenario1	Number of years until the first importation of FMD infected beef from Uruguay	98,200	9,100	1,500	27,400	359,000
Scenario2	Number of years until the first importation of FMD infected beef from Uruguay	32,500	700	800	13,200	118,800

Figures 1 and 2 present the exceedence probability distributions of the number of years until the first importation of FMD infected beef from Uruguay, for scenarios 1 and 2 respectively.

The exceedence probability, is the confidence one has that the number of years until the first importation of infected beef will exceed a specific number.

In figure 1:

- At 1,500 years, the exceedence probability is 0.95. This means that there is a 95% confidence that the first importation of infected beef will not occur before 1,500 years.
- At 27,400 years, the exceedence probability is 0.50. This means that there is a 50% confidence that the first importation of infected beef will not occur before 27,400 years
- At about 360,000 years, the exceedence probability is 0.05. This means that there is a 5% confidence that the first importation of infected beef will not occur before 360,000 years. Conversely, there is a 95% confidence that the first importation of infected beef will occur during the next 360,000 years

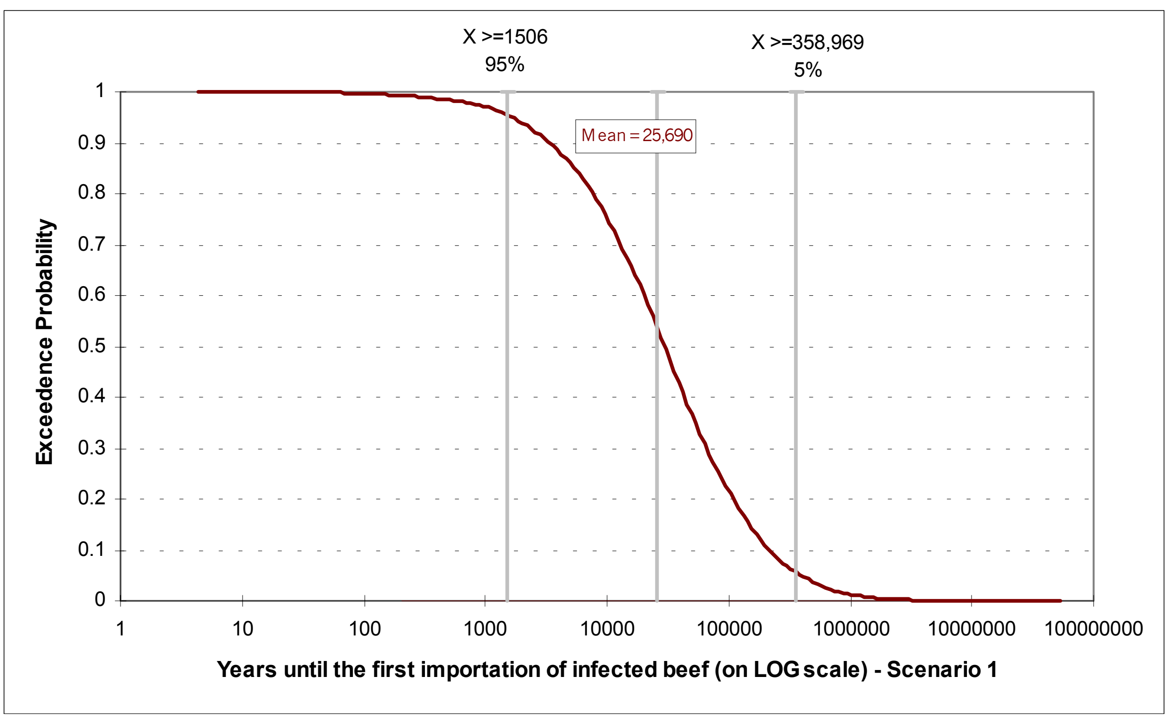


Figure 1. Exceedence Probability Distribution of the Number of Years until the First Importation of FMD Infected Beef from Uruguay (Scenario 1)

In figure 2, for example:

- At 800 years, the exceedence probability is 0.95. This means that there is a 95% confidence that the first importation of infected beef will not occur before 800 years.
- At 12,700 years, the exceedence probability is 0.50. This means that there is a 50% confidence that the first importation of infected beef will not occur before 12,700 years
- At 113,200 years, the exceedence probability is 0.05. This means that there is a 5% confidence that the first importation of infected beef will not occur before 113,200 years. Conversely, there is a 95% confidence that the first importation of infected beef will occur within the next 113,200 years. Conversely, there is a 95% confidence that the first importation of infected beef will occur during the next 113,200 years.

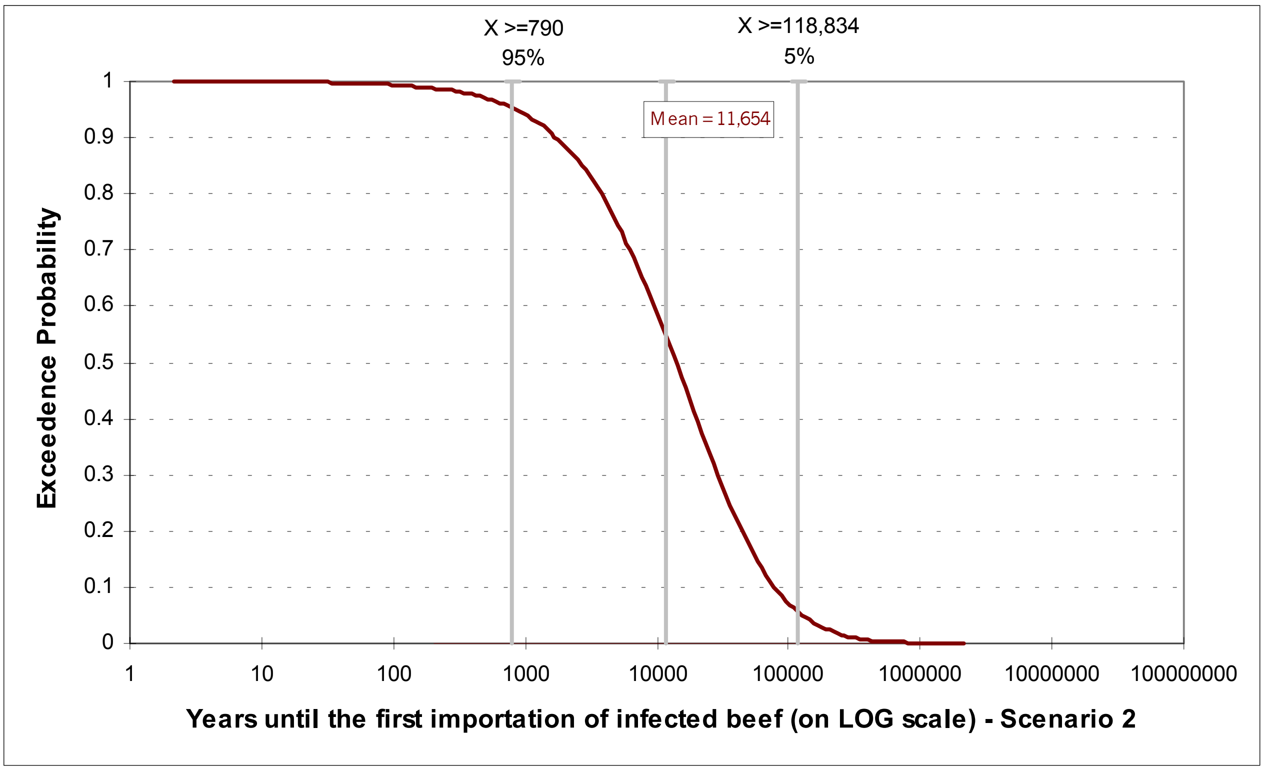


Figure 2. Exceedence Probability Distribution of the Number of Years until the First Importation of FMD Infected Beef from Uruguay (Scenario 2)

Exposure assessment

Exposure assessment is the evaluation of the biological pathways leading to exposure of susceptible species to FMD virus. In the past, APHIS conducted an assessment of the potential pathways of exposure to FMD-infected beef (CEAH 1995 and 2001). APHIS considers that the most likely pathway of exposure of susceptible species to potentially FMD-infected beef would be through feeding food waste to swine (CEAH 2001). Waste-feeder operations are licensed and inspected regularly by USDA inspectors. The licensing process requires that producers cook the waste fed to swine, reducing the probability of survival of foreign animal disease agents in the waste. In addition, the number of waste-feeding operations declined dramatically since 1994 and several states have prohibited feeding food wastes to swine. In a 1995 study by APHIS, the quantity of plate and manufacturing waste not adequately processed prior to feeding to swine was estimated at 0.00023 or less, with a 95% confidence (CEAH 1995). Based on this fraction, less than 1 part in 4,300 of imported beef is likely to be fed inadequately cooked to swine.

Consequence assessment
The consequences of FMD introduction into the United States would be extremely high. Available data do not allow quantification of the number of herds/farms that would be infected if FMD were introduced. Nevertheless, the cost of control, eradication and compensation, if disease were introduced, is likely to be significant. In addition to the direct costs of FMD introduction domestic and international trade losses would be very significant.

Using the difference in the Consumer Price Index (CPI) in 2001, APHIS updated the results of a 1976 study by McCauley et al. that estimated the direct costs (control and eradication program costs) and consumer impacts of FMD introduction over a 15-year period (1976-1990). The result is that the sum of the consumer impacts and direct costs in March 2001 dollars would be:

- 35.8 Billion dollars for endemic FMD with voluntary control
- 34.4 Billion dollars for eradication by strict slaughter and quarantine
- 38 Billion dollars for eradication by area vaccination
- 40.5 Billion dollars for compulsory vaccination program with endemic FMD

In addition to the direct costs of FMD introduction, domestic and international trade losses need to be considered. The value of U.S. exports of beef products alone, which would be immediately lost, was over US$3 billion in 2001 (WTA 2001).The sum of the consumer impacts, direct costs and trade losses, would be between US$ 37 billion to US$ 44 billion, in 2001 dollars. This is an extremely high consequence.

RISK ESTIMATION
Risk estimation consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of risk associated with the hazards identified at the outset. Thus, risk estimation takes into account the whole risk pathway from hazard identified to the unwanted event (OIE, 2002c).

The release assessment found:

- Scenario 1: that the annual likelihood, of importing fresh or frozen, maturated and deboned beef infected with FMD virus, would not exceed 1.03 X 10^{-4} (95% confidence level), and that there is a 95% confidence that the first importation of FMD infected beef from Uruguay will not occur for at least 1500 years, and that there will be at least one year with importations of infected beef in every 9,700 years.
- Scenario 2: that the annual likelihood, of importing fresh or frozen, maturated and deboned beef infected with FMD virus, would not exceed 1.76 X 10^{-4} (95% confidence level), and that there is a 95% confidence that the first importation of FMD infected beef from Uruguay will not occur for at least 800 years, and that there will be at least one year with importations of infected beef in every 5,700 years

The likelihood of exposure of FMD-susceptible species to FMD infected beef was not evaluated quantitatively in this risk assessment. However, in a 1995 study (CEAH 1995), APHIS determined that 0.023% of plate and manufacturing waste is not adequately processed prior to feeding to swine. This is a three orders of magnitude reduction in the risk at the release level.

The consequences of an FMD outbreak in the U.S. would be extremely high. The sum of the consumer impacts, direct costs and trade losses, would be between US$ 37 billion to US$ 44 billion, in 2001 dollars. Although the consequences of an FMD outbreak in the U.S. would be very high, given the findings of the release and exposure assessments, APHIS believes the likelihood of Uruguay beef introducing and establishing FMD is low.

1. INTRODUCTION

Uruguay requested that the Animal and Plant Health Inspection Service (APHIS) allow imports of fresh, chilled or frozen, deboned, and matured beef. Responding to this request, APHIS conducted a quantitative risk assessment evaluating the likelihood that beef from Uruguay would introduce and establish FMD in the United States.

In 1993, Uruguay declared itself free of FMD with vaccination. Vaccination against FMD was prohibited in Uruguay in 1994. In 1997, the United States Department of Agriculture (USDA) recognized Uruguay free of FMD, and allowed Uruguay to export beef to the United States. Uruguay continued to export fresh, chilled or frozen beef to the U.S. until October 2000 when an outbreak (one farm) of FMD (type O virus) occurred in Artigas department located in the northern part of the country. Uruguay had not reported FMD since 1990. The outbreak was eradicated rapidly by stamping out and following strict biosecurity and movement restriction measures. Shortly before this outbreak, APHIS had conducted a site visit in September 2000 to Uruguay to assess its animal health infrastructure and FMD exclusion and surveillance activities.

In response to the outbreak in Artigas, APHIS placed a hold on all animal products imported from Uruguay. After the outbreak was eradicated, APHIS resumed imports from Uruguay with the exclusion of a portion of the country that included Artigas. APHIS conducted another site visit in March 2001 to review measures taken by Uruguay to prevent introduction of FMD from Argentina and to further verify the situation in Artigas.

1.1 Re-introduction of FMD in Uruguay

FMD was reintroduced in Uruguay in 2001. The disease was first suspected on April 23, 2001 in the department of Soriano, clinically confirmed on April 24 and laboratory confirmed on April 25. On May 3, the Pan American Center for Food and Mouth Disease (PANAFTOSA) identified the virus as serotype A. The disease was soon also found in the department of Colonia; most likely due to a separate introduction of the virus. According to Uruguayan officials, the route of entry was probably mechanical introduction from disease outbreaks in Argentina. Uruguay suspected mechanical introduction because the virus type was identical to the type in Argentina and because no evidence existed to suggest that infected Argentine animals had been imported.

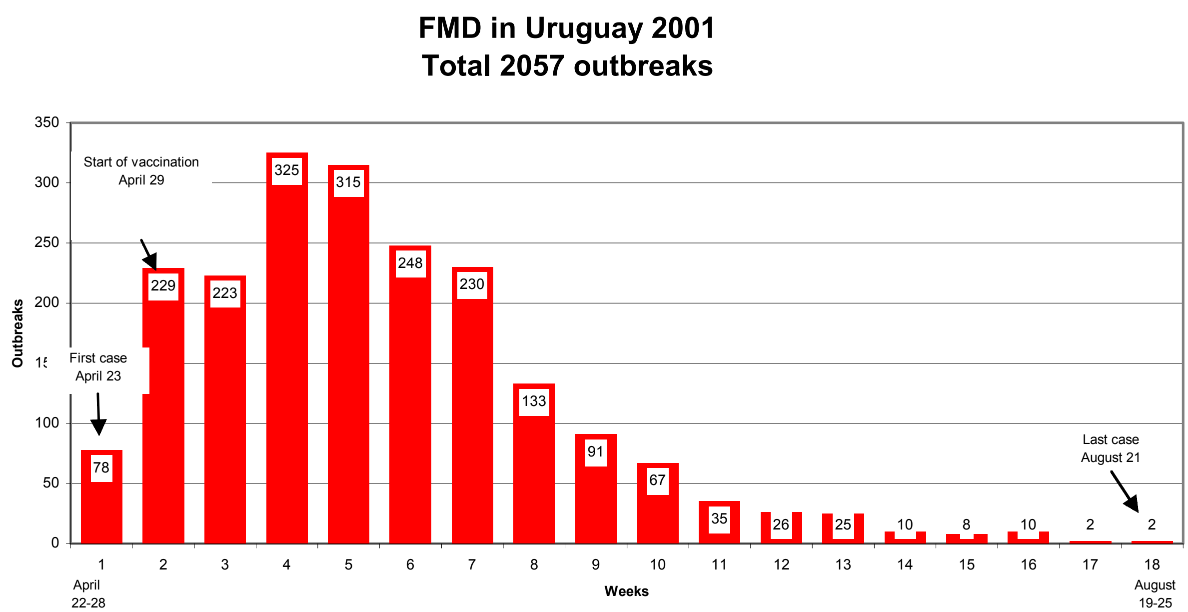


Figure 2: Number of FMD outbreak per week in Uruguay 2001

The last focus of FMD reported by Uruguay was on August 21, 2001. A total of 2057 foci of the disease were registered during the outbreak. A total of 76,842 cattle were affected from a total population of 15,522,399; a total of 228 sheep were affected from a total population of 913,249 animals; and 112 affected pigs from a total population involved of 7,598 animals. Overall the disease was confirmed in 18 departments in the country.

Frequent movement of trucks carrying rice and sorghum, particularly movement toward the eastern part of Uruguay, may have contributed to the spread of the disease (the outbreak began during the sorghum harvest).

1.2 Emergency actions:

On April 24, 2001, Uruguay banned all animal movements in the department of Soriano and began stamping out infected and contact animals. Export certification and slaughter was discontinued. By April 26, the ban on movement of animals was extended to Colonia with police and army support. The ban was extended to the rest of the country on the April 27 and included all slaughter activities, public auctions, and market activities. The ban on animal movement was maintained until June 7, 2001, at the conclusion of the first cycle of emergency vaccination. All major roads were blocked, and all schools, offices, stores, and other public gathering places were closed.

Uruguay adopted emergency ring vaccination coupled with stamping out of animal populations within the outbreak zone, and of exposed cattle within 10 a km radius of affected herds. However, because the spread of the disease was so extensive, Uruguay adopted a mass vaccination policy on May 5, 2001. This will continue at least into 2003.

1.3 Current situation in Uruguay:

Foot-and-mouth disease in South America is a regional problem as was clearly evident with the outbreaks of 2001 in Argentina, Uruguay and Brazil. An effective regional approach should reduce the risk of disease from the region. In fact, the control of FMD is being addressed on a regional basis. Uruguay, Argentina and Brazil participate in the Cuenca del Plata FMD program under the auspices of PANAFTOSA (the Pan-American FMD Center). The main objective of the Cuenca del Plata program is to eradicate FMD with a regional, harmonized approach. Shortly after the outbreaks of 2001, PANAFTOSA conducted inspection visits in the three countries and issued recommendations to strengthen and improve the existing FMD programs. In addition, Uruguay has reviewed its own FMD strategy and as a result strengthened the authority of local offices in border areas, improved communication between local offices, developed a communication and education program for producers and established a National Honorary Animal Health Commission with the participation of producers, private and official veterinarians. Thus the regional situation has greatly improved from 2001 (Site visit report 2002).

The legal authority and organization of the official veterinary services in a country is an important determinant of how successful that country is in preventing the reintroduction and to respond effectively to an incursion of an outbreak of FMD. Over a number of years, APHIS has conducted evaluations and site visits to assess Uruguay's veterinary infrastructure. As a result, APHIS believes that:

- Uruguay has adequate legal authority, policies and infrastructure to carry out FMD control and eradication programs.
- Uruguay has the necessary veterinary infrastructure to detect and respond to FMD outbreaks, control and enforce movement restrictions, enforce compliance with zoosanitary regulations, and certify compliance with international sanitary trade requirements.
- The technical infrastructure is adequate, and advanced technologies are utilized in conducting several animal health programs.

APHIS conducted a site visit in July 2002 to evaluate Uruguay's animal health infrastructure and its FMD control and eradication program. Overall, the site visit team concluded that Uruguay has the ability to detect, control and respond to FMD incursions in an effective way. Following is a summary of the site visit findings (Site visit report 2002):

- Uruguay showed a particular ability in adjusting its emergency response appropriately as the outbreak evolved.
- Uruguayan authorities presented sufficient evidence to indicate that the outbreak was completely under control.
- Uruguay's vaccination of the bovine population should limit the spread of FMDV and eventually lead to eradication.
- The team did not find evidence of presence of FMD in the country.
- In terms of the importation of matured de-boned beef, the team concluded that Uruguay has adequate control of inspection activities in slaughter plants including ante- and post-mortem inspections and verification of maturation procedures and pH controls, and can certify compliance with USDA import

requirements. A comparable system for control of commercial shipments also exists and is considered adequate to control import and export of products.

- Uruguay maintained an open communication policy with its trading partners. The veterinary service has always been timely and transparent in its communications regarding its animal health status. On both of the recent FMD introductions, Uruguay has unilaterally suspended the certification of products for export as a measure to protect its trading partners.
- Uruguay periodically conducts serological surveillance for FMD in cattle and sheep. APHIS believes that surveillance is adequate based on surveys conducted in 2001 and 2002. Proper sampling schemes are in place. However, the possibility of existing field virus can not be totally excluded; more serological surveys would be needed to exclude that possibility.
- The on-site evaluation team determined that the laboratory infrastructure was sufficient to run serological tests for FMD.

APHIS evaluated Uruguay's movement controls (Site visit report 2002). The evaluation concluded:

- Uruguay has a system in place for traceability and control of animal movement, both internal and international
- Only vaccinated animals are allowed to move to slaughter. The animal registration system (DICOSE) and the permitting system for authorizing animal movement are heavily enforced.

APHIS evaluated Uruguay vaccination program to determine coverage, especially for animals moving to slaughter for export (Site visit report 2002). The evaluation found:

- Sufficient evidence demonstrating that Uruguay can achieve high coverage levels (above 99%). The coverage level reaches 100% for animals moving to slaughter as movement permits are not issued without verification of the vaccination status of all animals on the farm of origin.
- During the epidemic and afterwards, FMD vaccines were available from neighboring countries at no cost to producers. This indicates easy access to vaccine supplies.
- The likelihood of unvaccinated animals moving to slaughter is low.

2. HAZARD IDENTIFICATION

According to the Office International des Epizooties (OIE), hazard identification is defined as "The hazard identification involves identifying the pathogenic agent which could potentially produce adverse consequences associated with the importation of a commodity" (OIE, 2002c).

2.1 Hazard

The hazard identified is FMD virus.

2.2 Etiologic Agent

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

2.3 Status in the U.S.

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

2.4 Epidemiology

FMD is a highly communicable disease of cloven-hoofed animals caused by an *Aphtovirus* of the family *Picornaviridae*. FMD has seven serotypes (O, A, C, SAT1, SAT2, SAT3 and Asia 1). The O, A, and C serotypes have historically been found in South America (Hall 1985). Research indicates that one serotype does not confer protective immunity against the other six, thus a disease outbreak can be caused by one serotype or a combination of serotypes (Kitching et al.1989).

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

(1) the quantity of virus released (2) the means by which the virus enters the environment, (3) the ability of the agent to survive outside the animal body (4) the quantities of virus required to initiate infection at primary infection sites and (5) the period of time the virus remains undetected (Mann and Sellers, 1990; Thomson, 1994).

The incubation period of the FMD virus is 2-8 days in cattle. Morbidity in non-vaccinated herds can be high but mortality usually does not exceed 5%. If it occurs during the calving season, calf mortality can be considerable (Seifert, 1996).

The respiratory tract is the usual route of infection in species other than pigs. In cattle and sheep, initial viral replication occurs in the mucosa and the lymphoid tissues of the pharynx. Following an initial viremia, FMD virus localizes in different organs, tissues, body fluids, bone marrow, lymph nodes, etc. (Sellers 1971, Cottral 1969). Virus titers differ in different organs or tissues. Some tissues such as the tongue epithelium have particularly high titers. Cattle with virus circulating in the bloodstream (viremic) are the main concern because they will have virus in their muscles, lymph nodes, bone marrow and organs. In contrast, chronic carrier animals do not have virus in the blood, bone marrow, lymph nodes, or muscle tissue (Sutmoller, et al. 1969).

Virus isolation and serotype identification are necessary for confirmatory diagnosis. The clinical signs of FMD are similar to those seen in other vesicular diseases. Differential diagnosis of vesicular diseases includes vesicular stomatitis, mucosal disease of cattle, bluetongue, rinderpest as well as FMD. Serological diagnostic tests include complement fixation test (CFT), virus neutralization test (VNT) and an ELISA test. Other diagnostic tests include one- or two-dimensional electrophoresis of the viral DNA, isoelectric focusing of the viral structural proteins, or nucleotide sequencing of the viral RNA (Thomson, 1994).

FMD virus is a relatively resilient virus. It can survive up to 15 weeks in feed, 4 weeks on cattle hair and up to 103 days in wastewater. In animal products such as meat and milk, the virus is inactivated by acidification, which occurs naturally. An acid environment where the pH is less than 6.0 will destroy the virus quickly. Where no acidification occurs (e.g., lymph nodes, bone marrow, fat, and blood) the virus may survive up to 80 days when kept frozen and up to 42 days in salted meat. Heat will inactivate the virus at 50°C (Seifert 1996).

2.5 Conclusion

FMD virus could survive in exported frozen and fresh meat that is not adequately maturated.

3. RISK ASSESSMENT

Risk assessment is the evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a pathogenic agent (hazard) within the territory of an importing country (OIE, 2002c). This report considers the four interrelated steps defined by OIE, as follows:

Release assessment – aspects of the biological pathways leading to the potential introduction of FMD virus through the importation of matured deboned beef were described. This section contains a quantitative pathway analysis of the likelihood of FMD entry into the U.S. via importation of beef from Uruguay under the current system using vaccination, inspections, maturation and deboning.
Exposure assessment – a qualitative evaluation of the biological pathways leading to exposure of susceptible species to FMD virus was addressed.
Consequence assessment – the biological and economic consequences from the introduction of FMD were described.
Risk Estimation –the findings from the previous parts of the process were integrated.

3.1 Release assessment

Release assessment is a description of the biological pathway(s) necessary for an importation activity to introduce pathogenic agents into a particular environment, with an estimate of the likelihood of that complete process (OIE, 2002c).

3.1.1 Scenario Analysis

The following scenario describes the probability of FMD infected beef entering the United States:

Infected beef from at least 1 viremic animal can enter the United States if,

- Undetected/unreported FMD exists in Uruguay, and
- At least one infected undetected herd is selected to provide animals for export slaughter, and
- At least one animal from the infected, undetected, selected herds:
    - is viremic, and
    - is selected for slaughter,
    - is not detected during ante-mortem and postmortem inspections, and
    - contains virus that survives maturation and deboning

Figure 3 shows the scenario tree used to quantify the probability of meat from at least one FMD infected carcass being imported into the U.S.

The following parameters are used in the scenario tree:

IE The risk initiating event is the selection of herds in Uruguay to provide animals for slaughter and beef import into the USA.

L1 is the likelihood/frequency of outbreaks in the exporting region during the year. It is a function of the potential reintroduction of FMD into the region. The frequency of outbreaks depends on past history (the number of years with/without outbreaks in the exporting region), as well as trade policy/practices, livestock practices, product movement control, and proximity/separation to/from affected regions.

N is the number of infected, but undetected, herds in Uruguay during a year with FMD.

f1 Fraction of infected undetected herds selected for meat export per Year (Fraction of herds selected)

f2 Fraction of year an infected herd has infected animals

M Number of animals per infected undetected herd (average number of animals per herd in Uruguay)

f3 Proportion of infected vaccinated animals per undetected infected herd

f4 Proportion of animals slaughtered per undetected infected herd

f5 Proportion of infected carcasses not detected by antemortem and postmortem inspections

f6 Proportion of infected carcasses with viable virus after maturation and deboning.

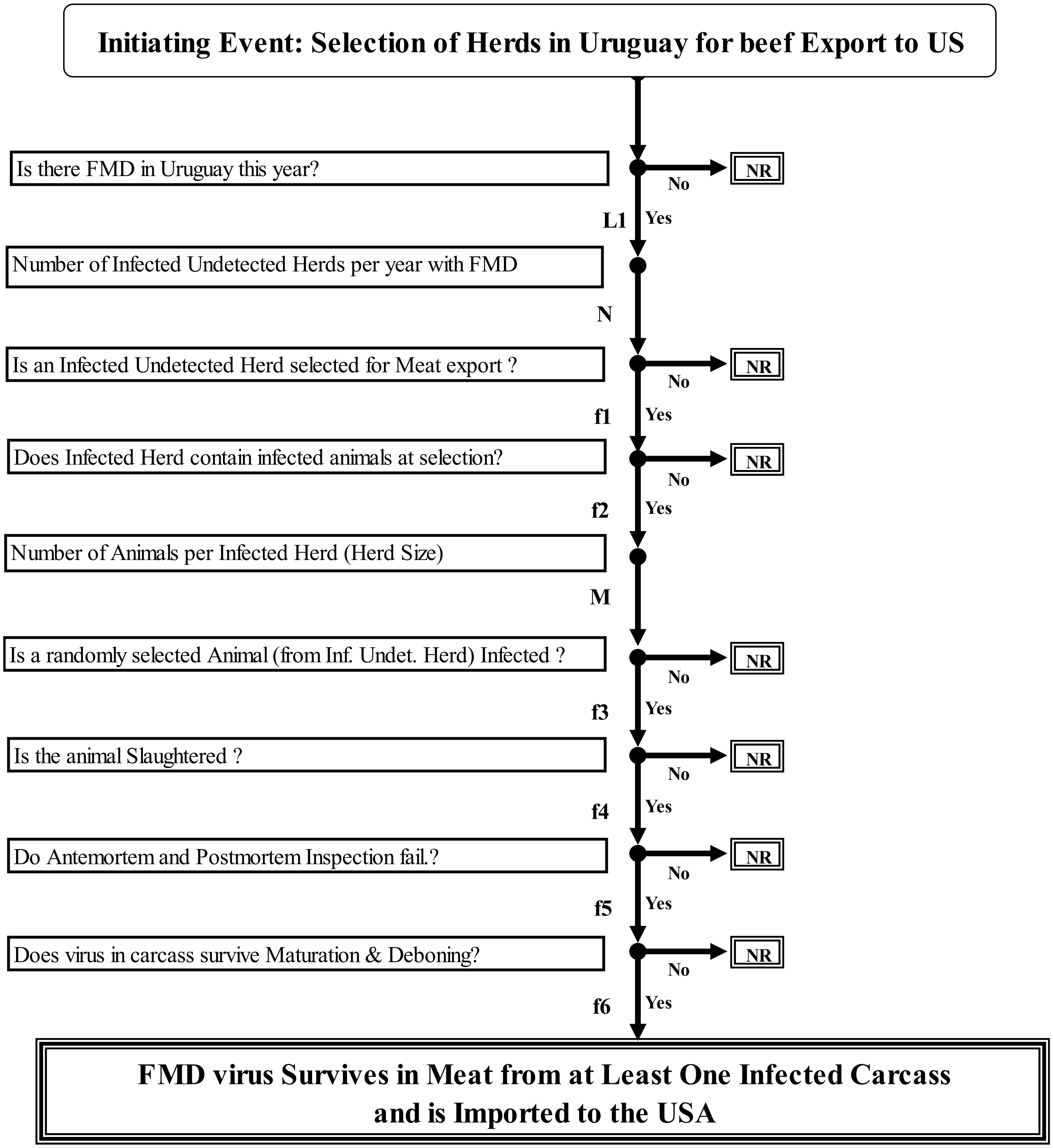


Figure 3 – Scenario tree for the importation of at least one FMD infected carcass into the U.S.

Section 3.1.3 presents a description of the mathematical model relating these parameters to the annual probability of importing infected beef, and the number of years until the first importation of infected beef. Section 3.1.4 presents the quantitative estimates of these parameters.

3.1.2 Model Assumptions

The importation of beef from Uruguay is based on the following conditions:

1. Uruguay has not reported FMD in the last 12 months.
2. Imported beef will originate only from animals in herds certified by the government of Uruguay to have been vaccinated at least twice with oil-adjuvant vaccine.
3. Animals slaughtered for export will be inspected ante- and post-mortem by the government of Uruguay.
4. Beef imported from Uruguay will be from carcasses matured for 36 hours at a temperature between 2 to 10 degrees Celsius, and certified by the government of Uruguay to have reached a pH less or equal to 5.8.

This risk assessment evaluates the risk posed by FMD in vaccinated animals that are unprotected due to partial or complete vaccine failure.

Because vaccinated animals may not express symptoms, they are less likely to be detected if exposed to or infected with FMD. Animals that pose a risk of introducing FMD into the U.S. are those that are viremic but nevertheless do not show symptoms of the disease by the time they are slaughtered. They fall into one of two categories: 1) vaccinated but partially immune animals and 2) unvaccinated animals including both young animals (born in between vaccination cycles) and adult animals missed during vaccination campaigns. APHIS believes that fully protected animals are unlikely to become viremic.

The assessment does not address the risk associated with an unvaccinated animal population, either immature or adult. FMD spreads quickly in an unvaccinated population; APHIS believes Uruguay would quickly detect FMD in such a population. Even with a vaccinated cattle population, some unvaccinated animals or inadequately vaccinated animals may exist. When infected, these animals may be clinically normal, at least for a short period, either because they are incubating the disease or because they are partially immune. These animals are the primary concern of this risk assessment.

Unvaccinated cattle normally show obvious disease symptoms and can be easily detected at the farm-level or at ante-and post-mortem inspections. Unvaccinated cattle (including calves that have lost their maternal antibodies to FMD), if exposed to FMD, will incubate for 2-8 days before showing disease symptoms detectable on the farm, or at ante- or post-mortem inspection. If FMD were detected, it would be reported to the U.S.; the U.S. would then prohibit continued beef imports from Uruguay. APHIS believes Uruguay would detect FMD in an unvaccinated population within a month at most. Because beef shipments require an average of 60 days from selection of animals for slaughter to the arrival of the beef in the U.S., beef from infected unvaccinated animals is unlikely to enter the U.S.

The following assumptions are made:

- Because all herds in Uruguay are vaccinated, if FMD were reintroduced, infected herds (due to unvaccinated or partially immune cattle) may remain undetected as long as one year. During this time, FMD infected animals may be selected from those herds and sent to slaughter for export.
- Vaccinated animals should be resistant to FMD. However, for one or more reasons, vaccinated animals may only have partial or no immunity and may become infected if exposed to the virus. Such animals may have longer incubation times and may not show normal disease symptoms. Consequently, FMD in these animals (or their carcasses) may not be detected.
- Ante-mortem and post-mortem inspections are assumed to fail to detect FMD in partially immune animals 100% of the times.
- Vaccinated animals with full immunity are resistant to FMD, and pose no risk.

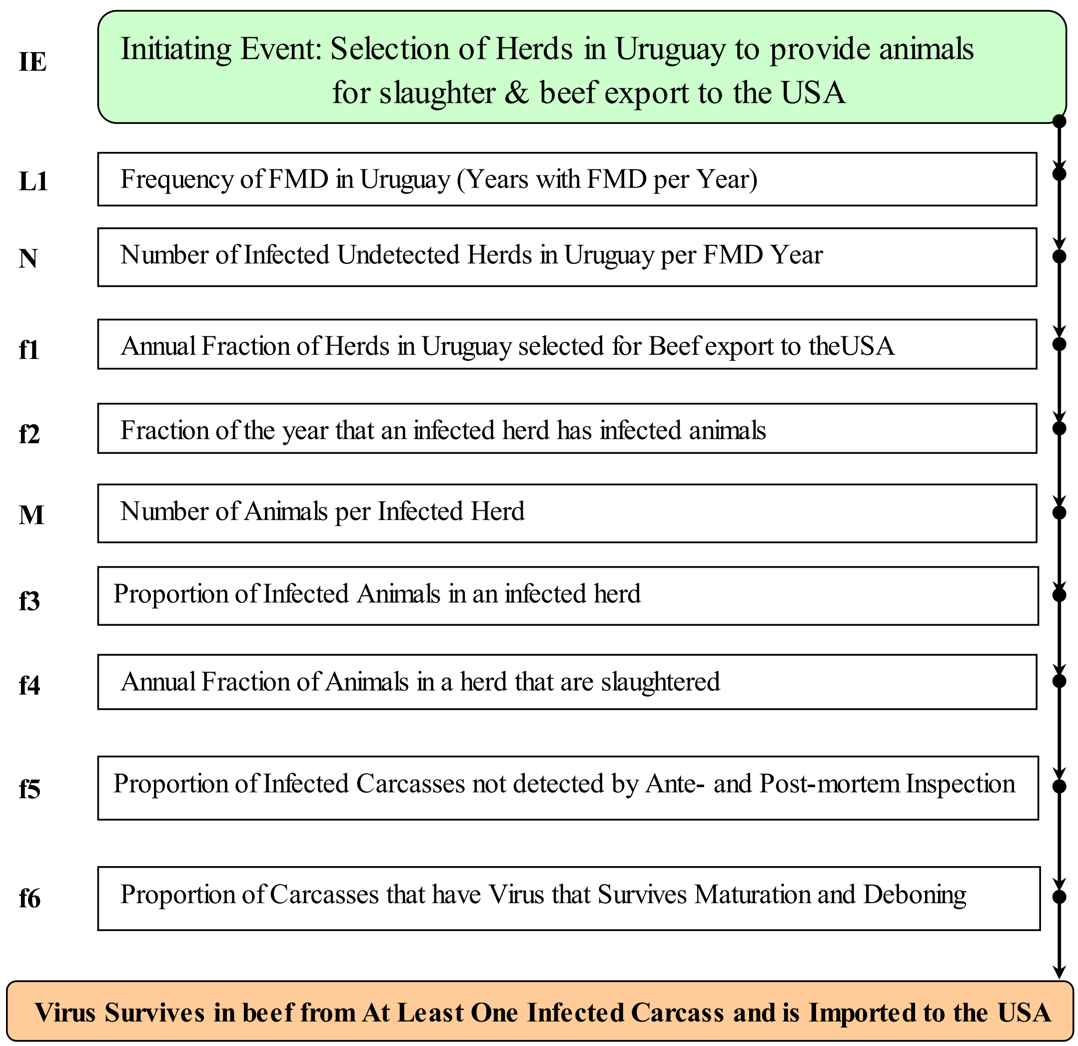
3.1.3 Mathematical Model

A central premise in this assessment is that FMD can exist in a vaccinated cattle population and remain undetected for some time. During this time, infected asymptomatic animals can be selected from undetected herds, slaughtered for export, and maturation and deboning may fail to remove virus from the exported meat.

Therefore, FMD infected product from at least 1 viremic animal can enter the United States if,

- Undetected/unreported FMD exists in Uruguay, and
- At least 1 infected undetected herd is selected for export slaughter, and
- At least 1 animal from the infected, undetected, selected herds is:
  - viremic, and
  - selected for slaughter, and
  - not detected during ante-mortem and postmortem inspections, and
  - not properly deboned and/or maturated.

Following is a presentation of the mathematical relationship between the parameters defined in the diagram below (L, N, M, f1-f6) and the probabilistic output of the model. The parameters f1,f2,f3,f4,f5 and f6 in the scenario tree, are represented by F1,F2,F3,F4,F5 and F6 respectively in the mathematical model (for readability)



Given that FMD is reintroduced into Uruguay and is not detected (because of vaccination or asymptomatic infection in partially immune animals):

Let N be the number of undetected infected herds in Uruguay. This is the annual number of new undetected infected herds in Uruguay, given that FMD exists in Uruguay.

Let F1 be the fraction of undetected infected herds in Uruguay selected for export. If we assume that selection of herds is random, and that infected undetected herds are distributed homogeneously throughout Uruguay, then this fraction is the same as the fraction of total herds in Uruguay selected for beef export to the US.

Let F2 be the proportion of the year that any one infected undetected herd has infected animals.

Then the number of undetected infected herds (with infected animals) selected to provide animals for slaughter per year with FMD in Uruguay, N1, is represented as:

$$N1 = N*F1*F2$$

Let M be the herd size of an undetected infected herd selected for export.

Then the total number of animals in all the selected undetected infected herds, M1, is:

$$M1 = N1*M = N*F1*F2*M$$

Let F3 be the proportion of infected vaccinated animals in an undetected infected herd.
Let F4 be the proportion of animals slaughtered in an undetected infected herd
Let F5 be the proportion of infected carcasses undetected by ante- and post-mortem inspection
Let F6 be the probability that an infected carcasses has viable FMD virus after maturation and deboning.

Then, the probability that an animal from an undetected infected herd is a) viremic, and b) selected for slaughter, and c) undetected at both ante-mortem and post-mortem inspections, and d) not properly matured and deboned, is denoted by P, and is mathematically represented by:

$$P = F3*F4*F5*F6$$

The probability of infected beef from one or more animals being exported per year with FMD disease in Uruguay, denoted as Q, can be found as:

$$Q = 1-(1-P)^{M1}$$
$$Q = 1-(1- F3*F4*F5*F6)^{N*F1*F2*M}$$

The equation for Q is derived as follows:

i) **P** is the probability that an animal selected at random from an infected herd provides FMD infected meat for export
ii) Therefore, **(1-P)** is the probability that an animal selected at random from an infected herd **does not** provide FMD infected meat for export
iii) $\mathbf{(1-P)^{M1}}$ is the probability that **all** M1 animals selected from undetected infected herds **do not** provide FMD infected meat for export
iv) Therefore, $\mathbf{Q = 1-(1-P)^{M1}}$ is the probability that at least 1 animal out of M1 animals selected from infected undetected herds provides FMD infected meat for export.

Let L be the annual likelihood of FMD occurrence/reintroduction in Uruguay.
THEN:

The annual probability of infected beef from one or more viremic animals being exported, R, is:

$$R = L1*Q$$
$$R = L1*\{ 1-(1- F3*F4*F5*F6)^{N*F1*F2*M} \}$$

R is actually the annual likelihood of importing infected beef from Uruguay.
The negative binomial distribution can be used to compute the number of years until the first export of FMD infected beef from Uruguay. The geometric distribution is a special case of the negative binomial that could have been used equivalently.
RiskNegbin(s,p) specifies a negative binomial distribution with “s” number of successes and “p” probability of success on each trial. The negative binomial distribution is a discrete distribution returning only integer values

greater than or equal to zero. When “s” is 1, the negative binomial computes the number of failures till the first success.
Using this analogy:

RiskNegbin(1,R), represents the number of years (without importing FMD infected beef) until the first year that FMD infected beef is imported. This can be computed if R, the annual probability of importing infected beef from Uruguay, is known.

Therefore, **Y, the number of years until the first importation of FMD infected beef from Uruguay is**:

$$Y = \text{RiskNegBin}[1, R]$$
$$Y = \text{RiskNegBin}[1, L1*\{ 1-(1- F3*F4*F5*F6)^{N*F1*F2*M} \}]$$

Appendix 3 contains a description of the RiskNegBin function.

The inputs of the mathematical model are:

- L1 likelihood/frequency of outbreaks in the exporting region during the year.
- N number of infected, but undetected, herds in Uruguay during a year with FMD.
- f1 Fraction of Infected Undetected Herds Selected for meat export per Year (Fraction of herds selected)
- f2 Fraction of Year an Infected Herd has infected animals
- M Number of Animals per Infected Undetected Herd (average number of animals per herd in Uruguay)
- f3 Proportion of Infected vaccinated Animals per infected Herd
- f4 Proportion of Animals Slaughtered
- f5 Proportion of Infected carcasses not detected by AM & PM Inspection
- f6 Proportion of infected carcasses with viable virus after maturation and deboning.

The outputs of the mathematical model are:

R, the annual likelihood of importing infected beef from Uruguay, represented by:

$$R = L1*\{ 1-(1- F3*F4*F5*F6)^{N*F1*F2*M} \}$$

Y, the number of years until the first importation of FMD infected beef from Uruguay, represented by:

$$Y = \text{RiskNegBin}[1, L1*\{ 1-(1- F3*F4*F5*F6)^{N*F1*F2*M} \}]$$

Appendix 1 contains the spreadsheet model with the actual values and distributions used.

Table 2. is a dimensional analysis of the units of each parameter in the model:

Table 2: Dimensional analysis of model parameters

	DESCRIPTION	UNITS	CUMULATIVE UNITS
N	Infected Undetected Herds In Uruguay per Year with FMD	Infected Undetected Herds -------------------------------- Year with FMD	Infected Undetected Herds -------------------------------- Year with FMD
f1	Fraction of Infected Undetected Herds Selected for meat export per Year	Selected Infected Undetected Herds -------------------------------- Infected Undetected Herd	Selected Infected Undetected Herds -------------------------------- Year with FMD
f2	Fraction of Year an Infected Herd has infected animals	Days (of Infection) -------------------------------- Days (in Year)	Selected Infected Undetected Herds -------------------------------- Year with FMD
M	Number of Animals per Infected Undetected Herd (Herd Size -HS)	At Risk Animals -- Selected Infected Undetected Herd	At Risk Animals -------------------------------- Year with FMD
f3	Proportion of Infected Animals per Herd (Proportion at Risk - PAR)	Infected At Risk Animals --- At Risk Animal	Infected At Risk Animals -------------------------------- Year with FMD
f4	Proportion of Animals Slaughtered (Extraction Rate - ER)	Slaughtered Infected Animals --- Infected At Risk Animal	Slaughtered Infected Animals -------------------------------- Year with FMD
f5	Proportion of Infected Carcasses not detected by AM & PM Inspection	Infected Carcasses after AM & PM Inspection --- Slaughtered Infected Animals	Infected Carcasses after AM & PM Inspection -------------------------------- Year with FMD
f6	Proportion of infected carcasses with viable virus after maturation and deboning	Carcasses with virus after maturation and deboning --- Infected Carcasses after AM & PM Inspection	Carcasses with virus after maturation and deboning -------------------------------- Year with FMD
L	Frequency of Years with FMD	Outbreak Years --- Year with FMD	Carcasses with virus after maturation and deboning --- Year

These model parameters are estimated in the following section.

3.1.4 Description of model variables

Node 0: IE - The initiating event:

The initiating event is the selection of animals from herds in Uruguay, for slaughter and production of fresh matured and deboned beef for import into the US. Quantifying this event requires 1) evidence about the cattle population in Uruguay; and 2) calculation of the annual number of herds selected for beef export to the US.

1) The first step is to determine:
- a) The number of bovine herds in Uruguay (TH).
- b) The average herd size in Uruguay (HS).
- c) The proportion of animals in a herd that are slaughtered per year (ER).
- d) The number of animals selected for slaughter from each herd (APH).

a) Total number of herds (TH) TH = 48,518

The total number of herds in Uruguay is 48,518 (MGAP, 2002a) (DICOSE, 2002).

b) The average Herd size (HS) HS = RiskGeneral(205, 7253,{Avg Herd Size},{Rel Freq})

The size of herds in Uruguay is variable. The evidence used to determine the average herd size is:

1. Although all herds in Uruguay are legally eligible for export, in practice only 14,643 herds provide animals for export on a regular basis. This number includes only beef farms having 200 hectares or more (Table 3). These farms have a total of 8,570,874 head of cattle representing 80.9% of the total cattle stock (DICOSE 2001 and MGAP 2002c).

Table 3: The total number of herds and animals eligible for export

Size (Ha)	Number of herds	Number of animals	Avg herd size	Relative frequency
200-499	7,108	1,528,897	215	0.485
500-999	3,765	1,735,503	461	0.257
1000-2499	2,769	2,686,949	970	0.189
2500-4999	787	1,695,720	2155	0.054
5000-9999	181	691,042	3818	0.012
>10000	33	232,763	7053	0.002
Total	**14,643**	**8,570,874**		

The average herd sizes in Table 3 were calculated by dividing the number of animals by the number of herds.

The relative frequencies in table 3 were calculated by dividing the number of herds in each size category by the total number of herds in Uruguay.

Evaluation:

The distribution for the average herd size (represented by columns 4 & 5 of table 3) was determined using a RiskGeneral distribution that proportionally weights by relative frequency the average herd size in each category of holding (Table 3).

HS = RiskGeneral(MIN(Avg. Herd Size), MAX(Avg. Herd Size),{Avg Herd Size},{Rel Freq})
HS = RiskGeneral (205, 7253, {215,461,970,2155,3818,7053}, {0.485, 0.257, 0.189, 0.054, 0.012, 0.002})

c) Animal extraction rate (ER) ER = 0.16

The animal extraction rate is the proportion of the average herd that is slaughtered on a yearly basis.

Evidence:
1. According to the government of Uruguay, the average extraction rate in a beef herd in Uruguay is 0.16 (MGAP 2002a).
2. The average life of a beef cow is 5 years (MGAP 2002a)

Evaluation:

APHIS accepts the GOU number for the average extraction rate of 0.16.

(APHIS notes that a higher extraction rate would result in fewer herds selected for export slaughter and a lower calculated likelihood of importing FMD contaminated beef.)

d) The number of Animals slaughtered per herd (ASPH) ASPH = RiskBinom(HS, ER)

The number of animals slaughtered per herd is dependent on the herd size and the animal extraction rate. The distribution for the number of animals slaughtered per herd is modeled as a binomial distribution as follows:

ASPH = RiskBinom(HS, ER)

Because the selection of animals for slaughter is a binomial process (i.e., animals are either selected or not selected), a binomial distribution is used.

2) The second step is to determine:

a) The amount of beef imported from Uruguay each year. (Kilograms of beef per year, KBPY).
b) The amount of beef from each animal. (Kilograms of beef per animal, KGPA)
c) The number of animals slaughtered to produce the annual quantity of exported beef. (Animals per year, APY)
d) The annual number of herds required to provide the animals for slaughter. (Herds per year, HPY).

a) Kilograms of beef imported from Uruguay per year (KBPY) RiskPert($12x10^6$,$19 x10^6$,$24 x10^6$)

Evidence:

1. Uruguay exported between 12,000 and 24,000 metric tons of meat per year to the U.S. from 1996 to 2000 (MGAP 2002a).
2. Table 4 shows the distribution of Uruguayan beef shipments to the U.S. by month (Kgs. per Month) through the years 1996 – 2000 (MGAP 2002a)

Table 4: Number of kilograms of beef imported from Uruguay by month 1996 – 2000

MONTH	MINIMUM	Average/Mean	MÁXIMUM
January	997,166	1,504,021	2,082,526
February	923,508	1,527,250	1,906,352
March	895,419	1,540,414	1,804,110
April	1,087,671	1,746,932	2,079,328
May	977,176	2,051,704	2,836,096
June	905,007	1,622,276	2,173,213
July	551,380	1,212,912	2,329,195
August	488,713	1,252,154	2,108,958
September	712,436	1,414,594	2,370,489
October	964,289	1,743,336	2,769,289
November	80,709	1,601,919	3,270,427
December	945,332	1,518,839	2,393,484
TOTAL	**11,812,271**	**18,736,352**	**24,316,408**

Source MGAP 2002a [SIC]

3. The GOU determined that the most likely value of the amount of beef to be exported to the U.S. is 19,000 metric tons (MGAP 2002a).

Evaluation

a. Data obtained from Uruguay export records (Table 4) show that from 1996 to 2000 Uruguay exported:
    i. an annual minimum of 12 million kilograms of fresh beef to the U.S.
    ii. a maximum of 24 million kilograms of fresh beef to the U.S

iii. an average of 19 million kilograms of fresh beef to the U.S.

APHIS believes the distribution for the number of kilograms of beef imported from Uruguay per year is described by a pert distribution, as follows:

KBPY = RiskPert(12,000,000; 19,000,000; 24,000,000)

b) Kilograms of beef per animal (KGPA) Pert(40,80,120)

The amount of meat in kilograms each animal provides is necessary to calculate the number of animals slaughtered per year to yield the annual beef import into the US.

Evidence:

1. Depending on the cuts exported, an animal may produce a minimum of 40 kg and a maximum of 120 kg of beef with a most likely value of 80 kg (MGAP 2002a).
2. Animal health officials in Uruguay estimated animals slaughtered for export will provide between 40 to 120 kilograms of beef with the most likely value of 80 kilograms (MGAP 2002a).

Evaluation:

APHIS accepts the GOU estimates for the minimum, most likely, and maximum KGPA. A pert distribution is used

KGPA = RiskPert(40,80,120)

c) Number of animals required per year (APY) APY = KBPY/KGPA

The number of animals required per year for slaughter, and beef import into the US is designated by APY. It is calculated by dividing the kilograms of beef imported per year (KBPY) by the kilograms of beef produced per animal (KGPA), as follows:

APY = KBPY/KGPA

Table 5: Table of Units for the number of animals required per year (APY)

Symbol	Description	UNITS
KBPY	Kilograms of beef per year imported to the U.S.	Kgs of Beef / Year
KGPA	Kilograms of beef per animal	Kgs of Beef / Animal
APY	Animals per year	KBPY / KGPA = ~~Kgs of Beef~~ / Year x Animal / ~~Kgs of Beef~~
		APY = Animals / Year

d) Number of herds required per year (HPY) HPY = APY/ASPH

The number of herds required per year is calculated by dividing the number of animals needed per year (APY) by the number of animals selected per herd (ASPH), as follows:

HPY = APY/ASPH

Table 6: Table of Units for the number of herds required per year (HPY)

Symbol	Description	UNITS
APY	Animals per year slaughtered for beef import to the U.S.	$\frac{\text{Animals Slaughtered}}{\text{Year}}$
ASPH	Animals slaughtered per herd	$\frac{\text{Animals Slaughtered}}{\text{Herd}}$
HPY	Herds per year	$HPY = \frac{APY}{ASPH} = \frac{\cancel{\text{Animals Slaughtered}}}{\text{Year}} \times \frac{\text{Herd}}{\cancel{\text{Animals Slaughtered}}}$
		$HPY = \frac{\text{Herds}}{\text{Year}}$

Node 1: L1 - Likelihood of FMD reintroduction **L1 = RiskUniform(3/7, 1)**

L1 describes the annual likelihood/frequency of reintroduction of FMD outbreaks into Uruguay. It is a function of the potential reintroduction of FMD into the region. The frequency of reintroduction into Uruguay can be derived using the past history of the disease, the quality of the animal health infrastructure, trade policy/practices, livestock practices, animal and product movement control, vaccination status, and proximity/separation to/from affected regions. In principle all possible pathways for reintroduction should be explored; however, this process demands substantial data that are not always available.

Evidence for L1:

Table 7 is the number of FMD outbreaks in Uruguay under mass vaccination programs in 1988 to 1994.

Table 7: Number of FMD outbreaks in Uruguay under a mass-vaccination program 1988-1994

Year	Nº Farms Involved	Bovine Affected	Bovine Exposed	Ovine Affected	Ovine Exposed	Swine Affected	Swine Exposed
1988	10	106	6,891	4	14,443	45	133
1989	62	1,855	64,851	42	96,972	128	616
1990	34	557	20,361	60	22,664	13	98
1991-1994 Exclusive use of FMD oil-adjuvant vaccines							
1991	0	0	0	0	0	0	0
1992	0	0	0	0	0	0	0
1993	0	0	0	0	0	0	0
1994	0	0	0	0	0	0	0
Total	106	2,518	92,103	106	134,079	186	847
Mean	15	360	13,158	15	19,154	27	121

Source MGAP 2002b [SIC]

APHIS observes that during the seven years in which all cattle were vaccinated, Uruguay detected FMD in three.

Evaluation:

Based on Table 7, APHIS believes the minimum frequency of reintroduction of FMD into Uruguay is 3/7 (or 0.43). However APHIS notes that during the years (1991-94) in which FMD oil-adjuvant vaccine was used, FMD was never detected.

Given the regional situation in South America discussed in section 1.3, the possibility exists that FMD might be reintroduced. Given the recent history of two introductions in two years (2000 and 2001), APHIS believes the maximum annual likelihood of reintroduction of FMD into Uruguay is 100% (i.e., once per year).

To describe our uncertainty about the likelihood of reintroduction, the assessment uses a uniform distribution with minimum and maximum values of 3/7 and 1 respectively.

RiskUniform (3/7, 1)

Node 2: N – Number of Undetected Infected Herds per Year **N = RiskUniform(1,35) or RiskPert(1,35,62)**

N, is the number of undetected infected herds in Uruguay in a given year, given that FMD exists in Uruguay. Because disease may remain undetected for extended periods in vaccinated populations, herds from which animals are selected for selected may have undetected FMD.

Evidence:

1. Uruguay currently vaccinates all cattle herds using an oil-adjuvant vaccine (MGAP 2002a-c, Site visit report 2002).

2. Oil-adjuvant vaccines have been proven effective in reducing the number of infected herds. Uruguay progressively introduced the use of oil adjuvant vaccines from 1989-1990. These were used exclusively from 1991 to 1994 when vaccination was prohibited (Table 7, MGAP 2002b).
3. Zero FMD infected herd were reported in 1991-99. (MGAP, 2002b)
4. FMD reoccurred in 2000 and 2001. One FMD infected herd was observed in 2000; 2057 infected herds in 2001.
5. Uruguay eradicated FMD in the 90's with the use of oil-adjuvant vaccines (MGAP 2002a).
6. Using oil-adjuvant vaccines in 2001, the incidence of FMD outbreaks was reduced to zero in 17 weeks (MGAP 2002a).

Evaluation:

The number of infected herds that could remain undetected is difficult to estimate with precision. To estimate the number of undetected and infected herds, the number of infected herds detected during each of the FMD reintroductions into Uruguay in the period 1988-1990, was used to calculate the mean and maximum number of infected herds per year. The years 1988-1990 represent those years during which Uruguay actively and gradually introduced the use of FMD oil-adjuvant vaccines. When oil-adjuvant vaccines were exclusively used, FMD outbreaks ceased to occur, or be detected. In 1994, vaccination was prohibited, and Uruguay was designated FMD free without vaccination.

Given that FMD has already been reintroduced into the cattle population of Uruguay, and not yet detected:

- The minimum number of undetected infected herds possible is 1.
- APHIS believes the most likely number of undetected infected herds is the mean of the number of farms infected in 1988, 1989 and 1990, from table 7. (Average (10,62,34) = 35)
- APHIS believes the maximum number of undetected infected herds is the maximum of the number of farms infected in 1988, 1989 and 1990, from table 7. (Maximum (10,62,34) = 62)

Recognizing the extreme economic consequences of FMD, and desiring to err on the side of caution, APHIS developed two scenarios:

- SCENARIO 1: The number of undetected infected herds (N), varies uniformly between a minimum of 1 and a maximum of 35. APHIS believes this scenario is most realistic. The distribution for the number of undetected infected herds, N, was modeled using a Uniform distribution as follows:

  N = RiskUniform(1,35)

- SCENARIO 2: The number of undetected infected herds (N) varies from a minimum of 1 to a maximum of 62, with a most likely value of 35. APHIS believes this scenario is less realistic but necessary to capture the full range of possible uncertainty. This scenario takes note of the maximum number of observed infected herds in 1989. The distribution for the number of undetected infected herds, N, is modeled using a Pert distribution as follows:

  N = RiskPert(1,35,62)

<u>Node 3: f1 – Fraction of Infected Undetected Herds Selected per Year</u> **f1 = HPY/TH**

The fraction of infected undetected herds selected per year is a derived quantity equal to the fraction herds in Uruguay that are selected to provide beef for export to the US. Assuming that the selection of herds is random, and that infected undetected herds are scattered homogeneously throughout the herd population, then f1 is equivalent to the fraction of herds selected per year for beef import to the US. The fraction of infected undetected herds selected per year is equal to the number of herds selected per year (HPY), divided by the total herd population (TH). Thus,

f1 = HPY/TH

Evidence:

1. The number of herds (HPY) needed to fulfill the beef import to the U.S. was previously defined in Node 0.
2. The total number of herds (TH) in Uruguay is 48,518 (MGAP, 2002a). APHIS accepts Uruguay's estimate of the total number of herds.

Node 4: f2 – Fraction of year that an infected Herd has infected Animals f2=DHI/365=RiskPert(14,28,42)/365

Infected herds are not necessarily infected for an entire year. Determination of the fraction of a year that infected herds remain infected and available to ship viremic animals to slaughter is necessary. This fraction is designated f2.

The fraction of the year that a herd can remain infected is estimated by dividing the average duration of herd infection (DHI), computed below, by the number of days in a year (365).

Average duration of herd infection (DHI) DHI = RiskPert(14,28,42)

The average duration of herd infection was estimated to be around 28 days (two incubation periods) with a minimum of 14 days and a maximum of 42 days. Carcasses of cattle with virus circulating in the bloodstream (viremia) are the main concern because these animals will have virus in their muscles, lymph nodes, bone marrow, organs, etc.

Evidence:

1. FMD virus occurs in different organs, tissues, body fluids, bone marrow, lymph nodes, etc. Virus titers differ in various organs and tissues. Certain tissues such as the tongue epithelium have higher titers. (Sellers, 1972 and Cottral, 1969).
2. Carrier animals do not have virus in the blood, bone marrow, lymph nodes, or muscle tissue (Sutmoller et al., 1969).
3. FMD virus is found only in minute quantities in the pharyngeal area of carriers. This virus usually is bound to antibodies and virus inhibitors (Thomson, 1994).
4. Carriers have high levels of circulating antibodies. Viremia occurs at 17 to 74 hours post-infection (Blood et al, 1989) thus, carrier animals do not have virus in the blood, bone marrow, lymph nodes or muscle tissue.
5. The incubation period for FMD is between 2-14 days (OIE 2002b).

The fraction of the year that a vaccinated infected undetected herd has infected animals is represented as follows:

f2 = RiskPert(14,28,42)/365

Node 5: M – The number of animals per infected herd

M is the number of animals per undetected infected herd (i.e., average herd size). M is equal to the distribution for the average herd size, HS, and is described in the initiating event. APHIS assumes no correlation between herd size and the likelihood of infection. Therefore the number of animals per infected herd is:

M = HS = RiskGeneral(MIN(Avg Herd Size), MAX(Avg Herd Size),{Avg Herd Size},{Rel Freq})

Substituting numbers (Table 3) for average herd size and relative frequency:

M = HS = RiskGeneral (205, 7253, {215,461,970,2155,3818,7053}, {0.485, 0.257, 0.189, 0.054, 0.012, 0.002})

Node 6: f3 - Probability of a viremic animal RiskPert(1/HS,1-vaccine efficacy,0.023)

f3 is the probability that a randomly selected animal in an infected herd is viremic. The analysis assumes that in the event of an outbreak in a herd, all non-protected animals would become viremic. Therefore, the probability that an animal in a herd is viremic will depend on the level of protection of animals which in turn depends on vaccine efficacy, vaccination coverage, and compliance with vaccination.

The probability of a viremic animal (X3) was modeled using a Pert distribution with:

a) a minimum of one viremic animal divided by the average herd size (HS),

b) a most likely value equal to 1 minus the vaccine efficacy (sampled value from the beta distribution from below), and
c) a maximum value equal to 0.23 from the serological evidence below.

Vaccine efficacy **RiskBeta (2162+1, 2170-2162+1)**

The percent protection in cattle twice vaccinated with an oil-adjuvant vaccine in Uruguay may exceed 99%.
Evidence:

1. Uruguay has used trivalent vaccines (virus O_1, A_{24} and C_3) imported from Brazil and Paraguay, and bivalent vaccines imported from Colombia (virus O_1 and A_{24}) and Argentina (O_1 and A_{24}, strain A_{2000}). (MGAP 2002a).
2. All vaccines were approved and certified by the competent sanitary authority in the country of origin (MGAP 2002a). In all cases, safety and efficacy tests used were those established by the Regional Reference Agency PANAFTOSA (Pan-American Centre for FMD).
3. According to reports and studies carried out by PANAFTOSA, the expected percent protection in cattle against the field virus, type A_{24}, identified in Uruguay, is 70% after the first vaccination and reaches 99.98% after re-vaccination (MGAP 2002a).
4. Uruguay conducted a vaccine efficacy study in 2001 measuring antibodies to FMD type O, to assess a response to the vaccine (MGAP 2001). Results of this study show that 2162 animals out of 2170 or 99.6% of vaccinated animals tested had protective antibodies to type O.

The results from the Uruguay study were used to create a beta distribution for the current analysis.

RiskBeta(Protected+1,Vaccinated-Protected+1)

Substituting values from evidence #4:

RiskBeta (2162+1, 2170-2162+1)

Vaccination coverage

Evidence pertaining to the vaccination coverage in Uruguay is as follows:
Evidence:

1. All cattle herds in Uruguay are vaccinated. (Site visit report, 2002 and MGAP 2002a,b,c)
2. Uruguay's vaccination program for 2001, 2002 and 2003 is shown in Table 6.

Table 8: Emergency and regular vaccination schedule - Uruguay 2001 – 2003

YEAR	PERIOD	SCHEME
2001	Emergency vaccination from 5th May to 7th June:	Vaccination of the whole cattle population. **Coverage over 90%.**
	From 16th June to 22nd June, dairy cattle and from 5th July to 23rd July, 2001, beef cattle	Massive re-vaccination of all cattle population (dairy and beef cattle). **Coverage over 99%.**
	Special vaccination from 1st to 30th November, with special controls of calves born in the year and yearlings.	All the calves born during 2000 and those born during the autumn of 2001. **Coverage over 99%.**
2002	1st to 28th February	General vaccination of cattle. **Coverage over 99%.**
	1st to 31st May(*1)	General re-vaccination of cattle
	1st to 30th November(*1)	All calves born during 2002
2003	1st to 28th February 1st to 31st May	General vaccination of cattle Re-vaccination of cattle under two years

Source MGAP 2002a

3. The vaccine is bought by the MGAP and is supplied free of charge to farmers, who apply it under direct or indirect official control (MGAP 2002a). In case of some farms that are considered risky, it is required that the vaccine be applied by a registered private veterinarian. A risky premise is

identified based on location, nationality of owner, or history of non-compliance (MGAP 2002a and Site visit report, 2002).

4. All animals moved to slaughter must be issued a waybill and the premise of origin must have a DICOSE number. For the waybill to be issued, vaccination status and census numbers must be verified by the animal health officials (Site visit report 2002).
5. Owners of cattle must produce official documents from at least 2 vaccination cycles before DICOSE permits movement. DICOSE does not permit movement in the first 15 days of months in which vaccinations are conducted (Site visit report 2002).
6. Animals must have been in Uruguay for at least 90 days and on the specific farm for at least 40 days before DICOSE will authorize movement to slaughter (Site visit report 2002).

Evaluation:
During its vaccination program in 2001 and 2002, Uruguay achieved coverage levels close to 100%. Uruguay has a system for verifying compliance with vaccination schedules either on farms or during authorization of animal movement to slaughter. Because of the high coverage levels, it is unlikely that unvaccinated animals will be sent to slaughter for export.

In vaccinated and infected herds, all unprotected animals are assumed viremic. This overestimates the true probability.

<u>Compliance with vaccination</u>
On-farm inspections and direct vaccination control activities conducted by animal health officials demonstrate a high vaccination compliance level.
Evidence:

1. Approximately 25 - 35% of premises and 35 - 45% of cattle are inspected for vaccination compliance in each vaccination cycle. Premises that MGAP designates as high risk, must be vaccinated by MGAP or an accredited veterinarian. Each region develops a plan to monitor for compliance so that not all the same farms are checked each time, except for the high risk farms which are checked every time when they are vaccinated by an official or accredited veterinarian (MGAP 2002c Site visit report, 2002).
2. Direct vaccination control was carried out during the November 2001 and February and May 2002 vaccinations. During November 2001, a total 15,025 holdings were visited for direct control and 72 farmers were found noncompliant with the date and time assigned for vaccination. The observed lack of compliance was documented to them at the time of vaccine delivery. During February 2002, MGAP reported that out of a total of 16,909 holdings that were visited 116 were noncompliant. During May 2002, a total of 12,542 holdings were visited and 87 noncompliant farmers detected. Noncompliance means that the farmers were not applying the vaccine on the date and time assigned, but all of them applied the vaccine later on, during the established period, under direct official supervision (MGAP 2002c and Site visit report, 2002).

<u>Serological surveillance</u>
In a survey conducted in February of 2002, the prevalence of FMD in the cattle population was estimated to be 2.3%. A prior survey was also conducted in September 2001. The results of the two surveys indicate that the positive serological tests may not be an indication of virus circulation. However, the serological evidence presented is not sufficient to exclude that possibility. Although it is unlikely that those animals with positive tests would be viremic the value 2.3% was used as the maximum limit in the estimation of the probability of a viremic animal. This is a cautious assumption that increases the final risk estimates.
Evidence:

1. Uruguay conducted 2 serological surveys in 2001 and 2002 both in cattle and sheep populations. The objective of the survey was to determine FMD prevalence and viral levels in these species during the FMD epidemic (MGAP 2002a).
2. Surveys were conducted using the 3-ABC ELISA test in cattle to detect antibodies against FMD non-structural protein (NSP) which should distinguish between vaccinated and infected animals.

Because sheep were not vaccinated, the VIAA test was used for detecting levels of neutralizing antibodies (MGAP 2002a).

3. In 2001, the prevalence of FMD was estimated to be 9.26% in cattle and 1.14% in sheep (MGAP 2002a).
4. The second serological survey conducted in cattle in February 2002 found 2.3% sero-positive animals corresponding to 101 animals out of 6883 total sera tested. The animals were distributed among 49 holdings with no apparent geographical or epidemiological relationship (MAGP 2002b).

Node 7: f4 – The proportion of animals slaughtered per infected herd **f4 = ER = 0.16**

F4 is the proportion of animals slaughtered per herd. It is modeled by the distribution for the extraction rate, ER, as presented in section 3.1.4.1; the initiating event. Therefore the proportion of animals per infected herd that are slaughtered is:

f4 = ER = 0.16

Node 8: f5 – Failure of detection at ante- and post-mortem inspections **f5 = 1.0**

f5 is the proportion of infected viremic carcasses not detected during antemortem or postmortem inspection.
Ante- and post-mortem inspections should detect infection in clinically affected animals since all animals receive a thorough inspection including examination of hooves and tongue.

Vaccinated animals exposed to FMD generally do not become infected. However, vaccinated animals, for a variety of reasons, may not be fully protected and can become infected. These partially immune animals will incubate longer and may not show classical disease symptoms. As a result, FMD may remain undetected in such an animal and its carcass. Erring on the side of caution, the assessment assumed that FMD in a vaccinated herd would remain undetected. Again on the side of caution, the assessment now assumes that the probability of failure of ante- and post-mortem inspection to detect FMD in vaccinated animals is 1. The evidence below summarizes information about the slaughter inspection system.

Evidence:

1. Ante- and post-mortem inspection is required for all animals slaughtered for export (Site visit report 2002).
2. The Division of Animal Industry (DIA) controls the waybills accompanying animals sent to slaughter. Three documents must accompany the truck to the slaughter plant: the eartag certificate, the health certificate, and the waybill (Site visit report, 2002).
3. The animals receive arrival inspection at the plant. A DIA inspector checks all documents and registers the day and time of arrival, DICOSE number of origin, location of the farm, and number of animals included classified by species and categories (Site visit report, 2002).
4. All animals must be rested for 12 to 24 hours (Site visit report, 2002).
5. The antemortem examination of each animal is performed immediately before slaughter (Site visit report, 2002).
6. The animals are assigned a "herd number" and placed in a specific pen with a pen card. Herd numbers are painted on the animals, and when the animals enter for slaughter they are accompanied by the pen card (Site visit report, 2002).
7. All animals slaughtered at an approved plant must receive a post-mortem examination of the carcass and all its parts, including offal, by DIA veterinarians (Site visit report, 2002).
8. During post-mortem inspection, DIA veterinarians and technicians examine the hoofs, tongue and muzzle of each animal for FMD lesions (Site visit report, 2002).
9. The inspection system is designed so that DIA can trace where and when a particular herd was slaughtered, as well as the origin and movements of that herd. Specific meat shipments are traceable to a specific production date (Site visit report, 2002).

Node 9: f6 – Probability that FMD virus in an infected carcass survives the export treatment

$$f6=f6a+f6b-(f6a*f6b)$$

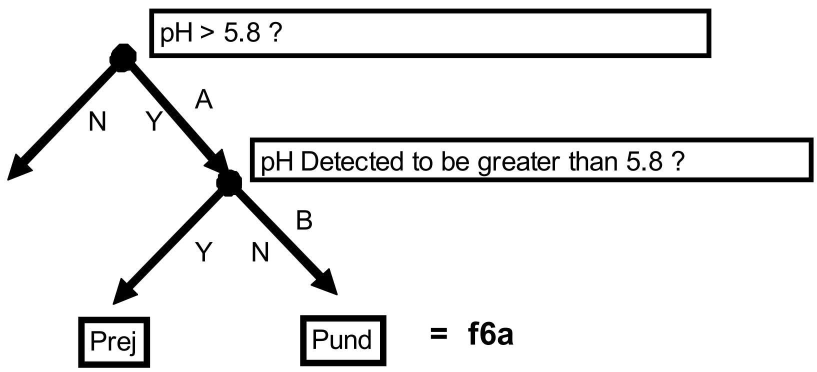
The proportion f6 is the proportion of carcasses that contain virus after maturation and deboning. These carcasses may contain virus either because they were not matured to pH 5.8 or because deboning was incomplete or improperly performed. Thus, f6 equals the proportion not maturated to pH 5.8 (f6a) plus the proportion not properly deboned (f6b) minus the proportion not properly matured and not properly deboned (f6a*f6b).

f6=f6a+f6b–(f6a*f6b

To calculate f6 we need to estimate f6a and f6b.

a. <u>f6a, The proportion of exported carcasses with pH > 5.8</u> f6a = Pund = Prej*P(B)/(1-P(B))

Beef from carcasses with pH greater than 5.8 may be exported only if the carcass is not matured to a pH less than or equal to 5.8 (P(A)) and if the pH greater than 5.8 is not detected (P(B)). This is shown in the following diagram.



Where:

- A is the event that the pH of a matured carcasses is greater than 5.8
- B is the event that inspection (i.e., pH check) does not detect that the pH of a carcass after maturation is greater than 5.8. This may be due to human error during the pH check and/or an error in the pH meter (e.g. calibration).
- Prej is the proportion of carcasses rejected because a pH>5.8 was detected. This quantity is derived below from rejection data reported by Uruguay.
- Pund is the proportion of carcasses not rejected because a pH>5.8 was not detected (f6a). These are the carcasses that will pose risk of FMD introduction into the U.S.

From the diagram above:

(i) Prej = P(A)*(1-P(B))
(ii) Pund = P(A)*P(B)

Since we know Prej and P(B), but do not know P(A), we can solve for P(A) in (i), therefore:

(iii) P(A) = Prej/(1-P(B))

Substituting (iii) into (ii) gives:

(iv) Pund = Prej*P(B)/(1-P(B)) = f6a

Following is the estimation of Prej and P(B):

<u>*Proportion of carcasses rejected (Prej)*</u> Prej = RiskBeta(Total Rejected+1, Total-Total Rejected+1)
The proportion of carcasses rejected because they did not reach a pH of 5.8 was calculated based on data obtained from Uruguay (MGAP 2002).
Evidence:

1. Data obtained during the site visit from eight different plants in Uruguay show that 66,220 out of 694,719 carcasses were rejected for having a pH reading equal to or greater than 6.0 at 24hours post-slaughter (Site visit report 2002).
2. The table below shows the number rejected and the calculated average rate of rejection (MGAP 2002).

Table 9: Total number of carcasses rejected due to pH ≥ 6.0

Plant	Rejected (pH ≥ 6.0)	total	Rate	Average Rate
2	7134	64729	0.110213	
3	8763	94316	0.092911	
8	6278	69084	0.090875	
12	8862	90366	0.098068	
55	8815	92643	0.09515	
379	7627	80356	0.094915	
439	4973	47731	0.104188	
	13768	155494	0.088544	
Total	**66220**	**694719**	**0.095319**	**0.096858018**

Source MGAP 2002

3. Currently all plants in Uruguay operate under the EU requirement at 24 hours of maturation; therefore it was not possible to obtain data on pH rejections at 36 hours of maturation (Site visit report 2002).

The proportion of carcasses rejected because they did not reach a pH of 5.8 was calculated based on data obtained from Uruguay (MGAP 2002). This was modeled using a beta distribution as follows:

Beta(66220+1, 694719-66220+1).

In the past APHIS has required a pH reading of 5.8 or lower with a minimum maturation time of 36 hours (CFR 2001). Although the rejection rate may be expected to be higher at pH 5.8 than the reported rate for pH 6.0, it can be argued that a longer maturation time of 36 hours would not be expected to result in a higher rejection rate than the one currently observed in Uruguay.

Evidence:

1. The FMD virus is rapidly inactivated at pH 6.0 or lower. At pH 6 the inactivation rate is 90% per minute (Bachrach et al. 1957).
2. It is generally accepted that virus is totally inactivated at pH 6 or below after 48 hours at a temperature of 4 C (Pharo 2002).
3. The pH changes may occur at different rates in different muscles, a measurement of pH 5.8 in the *longissimus dorsi* muscle is acceptable as indicating non-survival of FMDV in the carcass (CEC 1986).
4. Carcasses are chilled and allowed to mature for 24 hours at temperature over 2ºC measured when the first carcass entered into the chiller. When the chiller is full the door is closed and the official veterinary inspector locks the door. The inspector records, on the maturation card, times and temperatures when the first carcass enters the chiller, at the moment the chiller door is closed and again 24 hours after maturation has started. Once 24 hours has passed the chiller is opened and the carcasses are moved to the pH control station (Site visit report 2002).
5. All carcasses processed for export must be pH tested (Site visit report 2002).
6. Testing is done by plant personnel under strict supervision by DIA (Site visit report 2002).
7. The pH is electronically measured before deboning, in the longissimus dorsi muscle in cattle and in the psoas muscle in sheep and must be lower than 6.0 in both cases (MGAP 2002a).
8. The instrument used to measure the pH is calibrated daily by trained plant technicians according to the manufacturer's specifications (Site visit report 2002). A regulation issued by Uruguay in July 2002, requires calibration of pH meters every 200 carcasses (MGAP 2002c).

9. Carcasses with a pH reading equal to or higher than 6.0 are identified with a seal reading "**R pH**" (rejected due to pH), and are stored in a separate chiller, and are not exported. Rejected carcasses are diverted to local markets (Site visit report 2002).
10. The number of carcasses approved or rejected for export is registered in the pH control notebook (Site visit report 2002).

Failure of pH reader and human error (P(B)) P(B) = RiskPert(1/10000,1/1000,1/100)

Meat from a carcass with a pH > 5.8 could end up being exported if the pH meter used for checking it fails to take a correct reading, or by human error. Machine error is likely to be very low because of periodic calibration of pH meters carried out at slaughter plants. Human error on the other hand could be greater.

Evidence:

1. The pH readers are verified regularly and calibrated against a known buffer to ensure the difference in reading is less than 0.01 pH (Site visit report 2002).
2. During the site visit to Uruguay, team members verified pH control, maturation and deboning procedures at the San Jacinto plant, which exports to the EU and other countries (Site visit report 2002). APHIS found that after maturation, every carcass is tested, to ensure the pH is not greater than 5.8. If greater, the carcass is diverted to local consumption.
3. Maturation records were examined and actual rejected and approved seals were verified. There is a laboratory in the plant were pH calibration takes place on a daily basis. Calibration and rejection records were examined and verified (Site visit report 2002).
4. Figure 9., above, shows the number of carcasses rejected and the calculated average rate of rejection (MGAP 2002)
5. Procedural documents provided to APHIS by MGAP document the process of pH checking and pH meter calibration(Site visit report 2002).

Evaluation:

It is difficult to assess the combined probability of error due to mechanical failure of the pH meter and process error by humans. Based on observations from site visits, and from procedural documents that MGAP provided, APHIS believes that the combined error would not occur more than once in every 100 carcasses and might most likely happen once in every 1000 carcasses. The minimum likelihood of failure is cautiously set to equal the most likely failure rate of 1/1000.

P(B), the probability of pH meter failure, or human failure to correctly read the pH meter, is estimated by the following triangular distribution:

RiskTriang(1/1000,1/1000,1/100)

b) f6b ,the probability that beef from an improperly deboned carcass is exported. f6b = Pcid * Pcexp * Pcvv

The probability that beef from an improperly deboned carcass is exported, f6b is the product of the following:

- Proportion of infected carcasses that are improperly deboned (Pcid) is the same as the proportion of carcasses improperly deboned. Based on the site visit observations, the Uruguayan system of inspection, and the fact that only prime boneless cuts will be allowed into the US, mechanical failure and human error would be the causes of improper deboning. It is estimated that the maximum value for Pcid is 1/1000. The most likely value is 1/1000. The probability was estimated using RiskPert(0,1/1000,1/1000).
- Proportion of improperly deboned carcasses exported (Pcexp). This probability is the same as the proportion of carcasses exported and is the conjugate of the proportion of carcasses rejected (Prej). It is determined as Pcexp = 1 – Prej. Where Prej is the probability that a carcass did not reach a pH of 5.8 and is rejected.
- Probability that an improperly deboned infected carcass has viable virus (Pcvv). An improperly deboned carcass either has bone in it, or lymphoid tissue. FMD virus in bones would most likely be found in the bone marrow rather than bone itself. Based on this information, a conservative estimate for the maximum proportion of improperly deboned carcasses that could potentially carry live virus is estimated to be 0.5. The maximum value was also used as the most likely value. The probability was estimated using RiskPert(0,0.5,0.5).

Evidence:

As part of the export process, all carcasses must be deboned with major lymph nodes and blood clots removed. This process is manual and there are no available data to quantify whether bone remnants or lymph tissues remain in beef cuts. However, the site visit team to Uruguay visited one of their export plants and verified the process and determined that deboning appears adequate.

1. All carcasses intended for export are deboned (Site visit report 2002).
2. The deboning process consists of removing bones, major lymph nodes, and blood clots (Site visit report 2002).
3. In an export plant visited by the site visit team, meat samples are routinely subjected to a quality control procedure to check for bone chips and metal or other objects (Site visit report 2002).
4. A quality control (re-inspection) procedure to check for defects in beef products is carried out according to regulations and communications established by the Animal Industry Division (DIA) as detailed below. Such regulations establish acceptance and rejection criteria in all export plants. The list of approved regulations for inspection procedures includes:
    a) Resolution by the General Department of Livestock Services, dated December 20, 1996.
    b) DIA Communication number 4/996.
    c) DIA Resolution, dated November 19, 1997.
    d) DIA Communication number 2/998, dated January 16, 1998.
    e) DIA Communication number 4/998, dated August 10, 1998.
    f) DIA Resolution, dated December 2, 1998.

    Defects are classified as minor, major or critical according to the severity, quantity and size of such defect. During the deboning process the following are considered as defects:
    a) blood clots
    b) bruises
    c) bone chips
    d) loose cartilage, ligaments
    e) gastrointestinal content and feces
    f) harmful extraneous material
    g) innocuous extraneous material
    h) hair, wool or leather
    i) injuries with a pathological cause
    j) stains or discolored surfaces
    k) other (including lymphatic nodules)

    Rejection occurs on a per lot basis (amount of processed product between two groups of inspected samples). A rejected sample will result in rejection not only in the lot containing the rejected sample but also of the preceding lot.

    Plant personnel perform quality controls before the Animal Industry Division (DIA) carries out the re-inspection activities described.

Following is a table with all the parameters listed with the distributions used and estimates of the arguments to the parameters.

For convenience, Appendix 1 contains a spread sheet with all model variables and distributions used. A glossary section for distributions used in the model is presented in Appendix 3.

3.1.5 Release assessment results

APHIS used a quantitative model to estimate the annual probability of importing infected beef into the U.S. from Uruguay. A stochastic model was constructed and Monte Carlo simulations were carried out on an IBM PC, using Excel[1] and @Risk[2]. The annual quantity of beef imported into the U.S. (in the simulations), ranged between 12,000 to 24,000 metric tons with a most likely value of 19,000 metric tons. This is based on historical annual exports of beef from Uruguay to the U.S. during 1996 to 2001.

Because vaccination is being carried out in Uruguay, and because of the assumption that disease can go undetected for extended periods of time in vaccinated populations, there could be several undetected infected herds in Uruguay from which animals are picked and slaughtered, during a year with FMD. However, there is uncertainty about the potential number of undetected infected herds in Uruguay during a year with FMD. In order to better understand and characterize the uncertainty in this parameter, and how it affects the overall risk, the following two scenarios were evaluated:

- SCENARIO 1: In the first scenario, the number of undetected infected herds (N), varied uniformly between a minimum of 1 and a maximum of 35 [N = RiskUniform(1,35)].
- SCENARIO 2: In the second scenario, the number of undetected infected herds (N), varied from a minimum of 1 to a maximum of 62, with a most likely value of 35 [N = RiskPert(1,35,62)].

APHIS believes that the first scenario provides a more realistic result because it reflects the possible number of undetected infected herds in Uruguay during a year with FMD, and more accurately represents its uncertainty. However, it is important to include the second scenario as a maximized risk scenario.

Under these two scenarios, the annual probability of importing FMD infected beef from Uruguay is estimated.

The number of years until the first importation of FMD infected beef is also estimated.

<u>Scenario 1 (The number of undetected infected herds, N varies uniformly between 1 and 35) :</u>

The results of the analysis show:

- A 95% confidence of 1,500 or more years until the first importation of FMD infected beef.
- A most likely annual probability of 7.06×10^{-6} of importing FMD infected beef from Uruguay.
- A 95% confidence that the annual probability of importing FMD infected beef from Uruguay is less or equal to 1.03×10^{-4}.

<u>Scenario 2 (The number of undetected infected herds, N varies between 1 and 62 and has a most likely value of 35):</u>

The results of the analysis indicate:

- A 95% confidence of 800 or more years until the first importation of FMD infected beef.
- A most likely annual probability of 5.57×10^{-5} of importing FMD infected beef from Uruguay.
- A 95% confidence that the annual probability of importing FMD infected beef from Uruguay is less or equal to 1.76×10^{-4}.

These results are summarized in the Table 10 and figures 4-6 below.

Table 10: Release assessment result

Scenario	Outputs	Mean	Most Likely	5%tile	50%tile	95%tile
Scenario1	Annual Probability of importing infected beef from Uruguay	3.51×10^{-5}	7.06×10^{-6}	3.05×10^{-6}	2.47×10^{-5}	1.03×10^{-4}
Scenario2	Annual Probability of importing infected beef from Uruguay	6.67×10^{-5}	5.57×10^{-5}	1.06×10^{-5}	5.12×10^{-5}	1.76×10^{-4}
Scenario1	Number of years until the first importation of FMD infected beef from Uruguay	98,200	9,100	1,500	27,400	359,000
Scenario2	Number of years until the first importation of FMD infected beef from Uruguay	32,500	700	800	13,200	118,800

[1] Microsoft Excel 2000. Microsoft Corporation

[2] @Risk 4.5.0. Palisade Corporation

Figures 4 and 5 present the exceedence probability distributions of the number of years until the first importation of FMD infected beef from Uruguay, for scenarios 1 and 2 respectively.

The exceedence probability, is the confidence one has that the number of years until the first importation of infected beef will exceed a specific number.

In figure 4:

- At 1,500 years, the exceedence probability is 0.95. This means that there is a 95% confidence that the first importation of infected beef will not occur before 1,500 years.
- At 27,400 years, the exceedence probability is 0.50. This means that there is a 50% confidence that the first importation of infected beef will not occur before 27,400 years
- At about 360,000 years, the exceedence probability is 0.05. This means that there is a 5% confidence that the first importation of infected beef will not occur before 360,000 years. Conversely, there is a 95% confidence that the first importation of infected beef will occur during the next 360,000 years

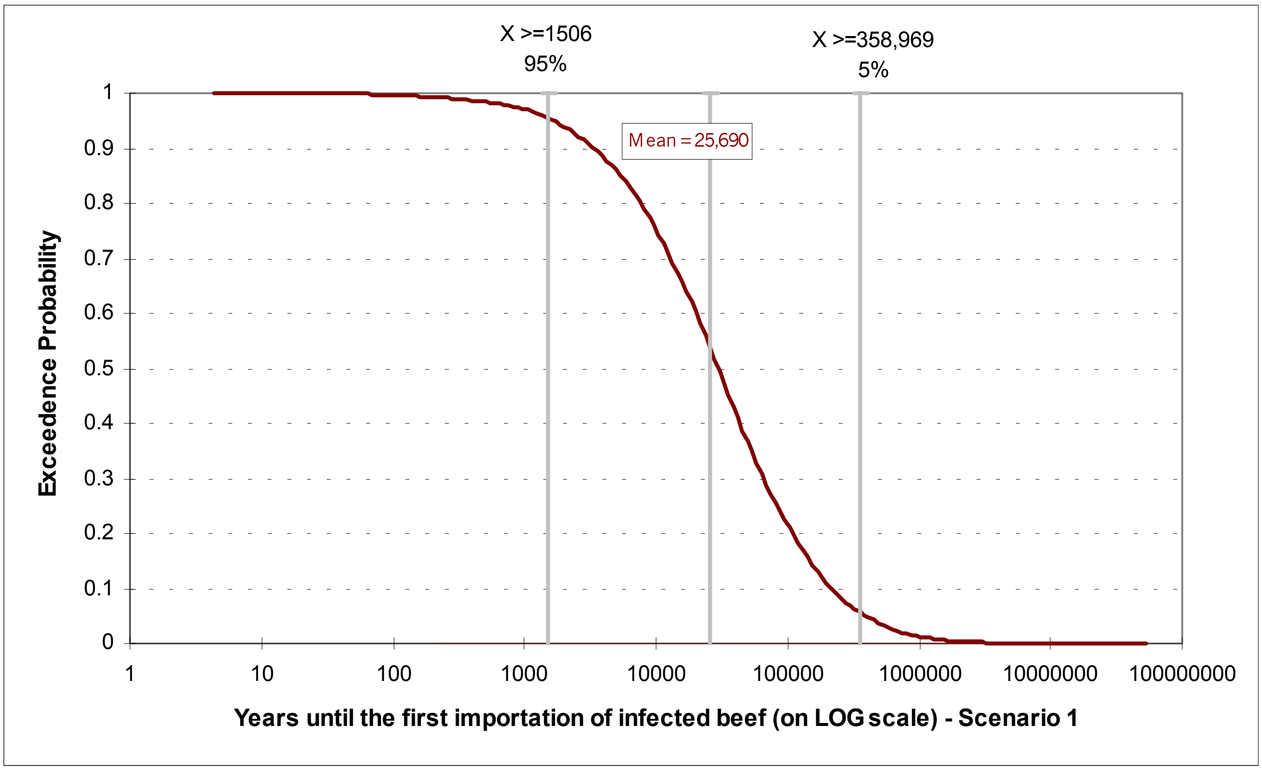


Figure 4. Exceedence Probability Distribution of the Number of Years until the First Importation of FMD Infected Beef from Uruguay (Scenario 1)

In figure 5, for example:

- At 800 years, the exceedence probability is 0.95. This means that there is a 95% confidence that the first importation of infected beef will not occur before 800 years.
- At 12,700 years, the exceedence probability is 0.50. This means that there is a 50% confidence that the first importation of infected beef will not occur before 12,700 years
- At 119,000 years, the exceedence probability is 0.05. This means that there is a 5% confidence that the first importation of infected beef will not occur before 119,000 years. Conversely, there is a 95% confidence that the first importation of infected beef will occur within the next 119,000 years. Conversely, there is a 95% confidence that the first importation of infected beef will occur during the next 119,000 years.

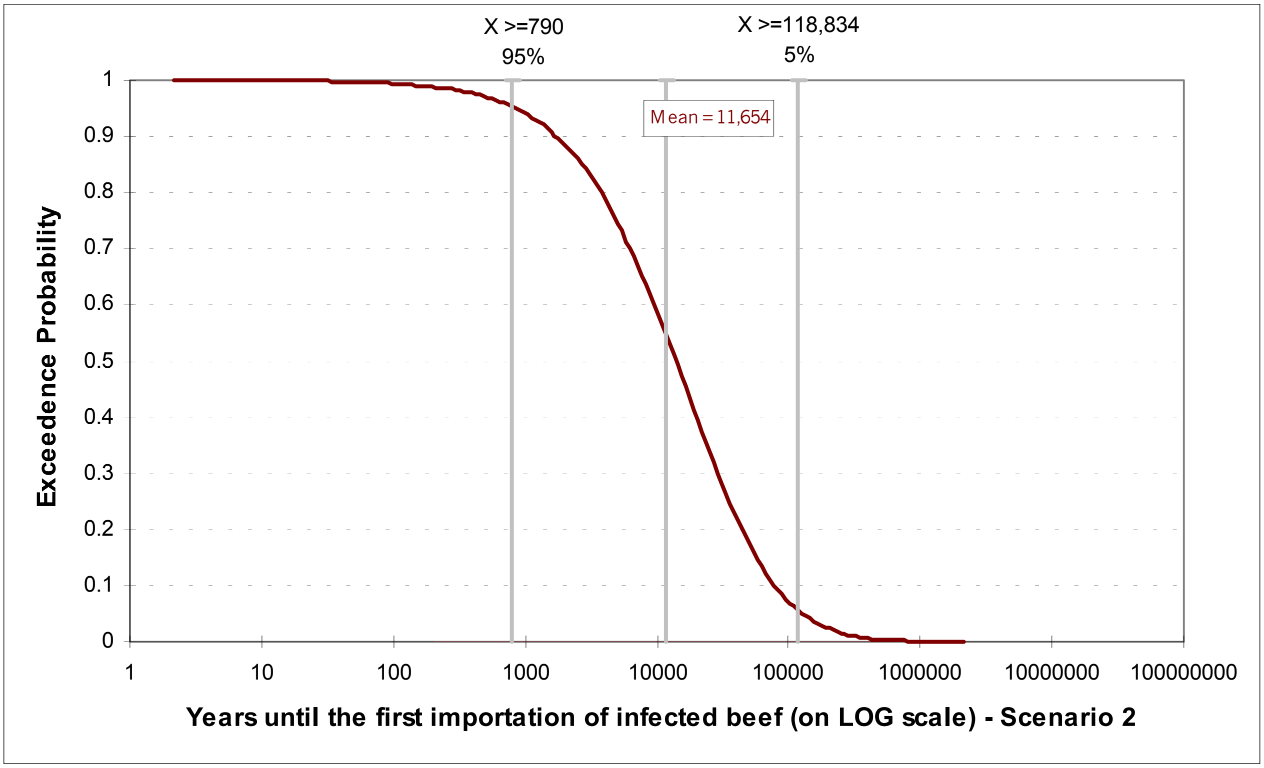


Figure 5. Exceedence Probability Distribution of the Number of Years until the First Importation of FMD Infected Beef from Uruguay (Scenario 2)

Figure 6 and 7 are the cumulative percentile distributions of the annual probabilities of importing infected beef from Uruguay for scenarios 1 and 2 respectively.

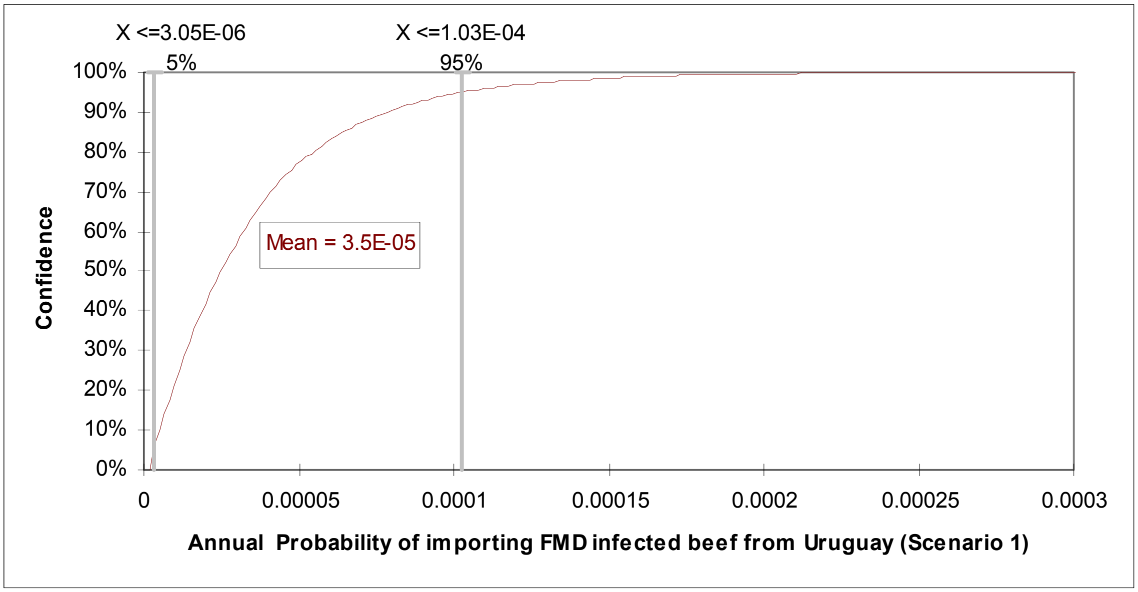


Figure 6. Cumulative Percentile Distribution of the Annual Probability of Importing Infected Beef from Uruguay for scenarios 1

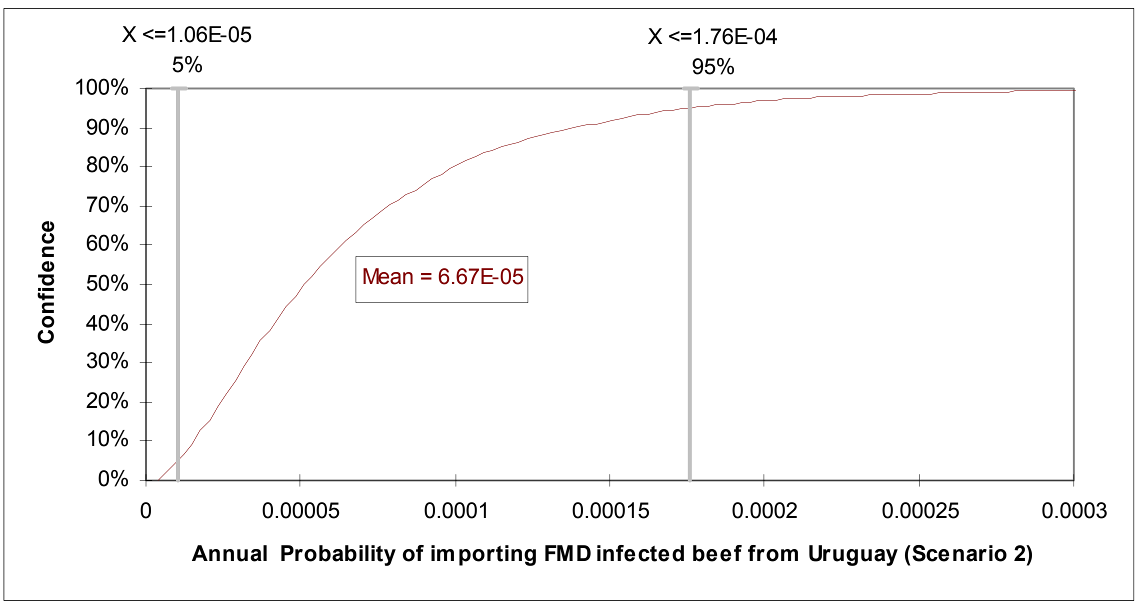


Figure 7. Cumulative Percentile Distribution of the Annual Probability of Importing Infected Beef from Uruguay for scenarios 2

Comparing the two scenarios, it is clear that scenario 2 poses more risk.

3.1.6 Conclusion

The assessment assumes that when FMD is reintroduced into a vaccinated herd population in Uruguay it could spread to as many as 62 herds and go undetected by official authorities. This would not be the case with unvaccinated herd populations, that would be detected quickly, and pose no risk. The release assessment shows that the likelihood of importing fresh or frozen, maturated, and deboned beef infected with FMD virus would:

a) not exceed 1.03×10^{-4} (95% confidence level) for scenario 1
b) not exceed 1.76×10^{-4} (95% confidence level) for scenario 2.

This scenario result reflects an overestimation of the likelihood of importing FMD infected meat. These assumptions intended to maximize the final likelihood estimate and were made because there are insufficient data available to estimate the likelihood of FMD reintroduction into Uruguay under a vaccination scenario.

3.2 Exposure assessment

Exposure assessment describes the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards released from a given risk source, and estimating the probability of the exposure(s) occurring, either qualitatively or quantitatively (OIE, 2002c).

A previous exposure assessment by APHIS found that the most likely pathway of exposure of susceptible species to potentially FMD-infected beef would be through feeding food waste to swine (CEAH 2001). Waste-feeder operations are licensed and inspected regularly by USDA inspectors. The licensing process requires that producers cook the waste fed to swine, reducing the probability of survival of foreign animal disease agents in the waste. In addition, the number of waste-feeding operations declined dramatically since 1994.

In a 1995 study by APHIS, the quantity of plate and manufacturing waste not adequately processed prior to feeding to swine was estimated at 0.00023 or less, with a 95% confidence (CEAH 1995).

In 2001 a survey of the U.S. swine waste-feeding sector was conducted to update a similar study done in 1994 (CEAH 2002). It was found that:

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

3.2.1 Conclusion

The likelihood of exposure of FMD-susceptible species to FMD infected beef was evaluated by reviewing previous APHIS studies. In a 1995 study (CEAH 1995), APHIS determined that 0.023% of plate and manufacturing waste is not adequately processed prior to feeding to swine. Based on this fraction, less than 1 part in 4,300 of imported beef is likely to be fed inadequately cooked to swine.

The decrease in the number of waste-feeding premises since 1994, and the prohibition of feeding plate waste to swine, has reduced this proportion of plate and manufacturing waste fed to swine populations by about 50%..

Based on these previous studies, and the results of the release assessment, APHIS considers the likelihood of FMD-susceptible swine becoming exposed to FMD virus to be very low.

3.3 Consequence assessment

Estimation of consequences must be addressed from both biologic and economic perspectives (WTO 1995, OIE 2002c). The magnitude of the biologic and economic consequences following a potential introduction of FMD would depend on the location of the introduction, ability to detect the disease rapidly, FMD virus serotype introduced, and ease of employing eradication procedures (McCauley et al. 1976). In addition, the rate of spread of FMD virus and whether other environmental conditions at the introduction site facilitate this spread are likely to contribute further to the magnitude of the consequences.

In the event of an FMD outbreak the preferred option for control and eradication would be to stamp-out infected herds without the use of vaccine. However, if the extent of the outbreak were large or if the disease were spreading at a fast rate, vaccine could be used. A recent study using a stochastic simulation model showed that ring vaccination significantly reduced the duration of outbreaks. However, depending on the magnitude of the outbreak and the number of herds involved, the time needed to dispose of vaccinated animals could be prolonged (Schoenbaum and Disney 2002).

Available data do not allow quantification of the number of herds/farms that would be infected if FMD were introduced. Nevertheless the cost of control, eradication and compensation is likely to be significant. In 1976 McCauley et al. conducted a comprehensive study to assess the potential economic impact of FMD in the United States. The study estimated the direct costs (control and eradication program costs) and consumer impacts of FMD introduction over a 15-year period (1976-1990). The study examined several control and eradication options. Relevant to this assessment are strategies employed to eradicate the disease by stamping out or area vaccination. In the extreme event of endemic FMD in the United States the impact of a compulsory and voluntary control programs are also considered. A summary of the findings are showed in table 9. The results were updated using the difference in the Consumer Price Index (CPI) in 2001 (McDowell 2001, personal communication).

Table 11: Economic impacts of FMD adjusted from 1976 dollars to March 2001 dollars by Consumer Price Index[1]

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

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

In addition to the direct costs of FMD introduction, domestic and international trade losses need to be considered. The value of U.S. exports of beef products alone, which would be immediately lost, was over US$3 billion in 2001 (WTA 2001).

3.3.1 Conclusion

The consequences of FMD introduction into the United States would be extremely high.

4. RISK ESTIMATION

Risk estimation consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of risk associated with the hazards identified at the outset. Thus, risk estimation takes into account the whole risk pathway from hazard identified to the unwanted event (OIE, 2002c).

The release assessment found:

- Scenario 1: that the annual likelihood, of importing fresh or frozen, maturated and deboned beef infected with FMD virus, would not exceed 1.03×10^{-4} (95% confidence level), and that there is a 95% confidence that the first importation of FMD infected beef from Uruguay will not occur for at least 1500 years, and that there could be at least one year with importations of infected beef in every 9,700 years.

- Scenario 2: that the annual likelihood, of importing fresh or frozen, maturated and deboned beef infected with FMD virus, would not exceed 1.76 X 10^{-4} (95% confidence level), and that there is a 95% confidence that the first importation of FMD infected beef from Uruguay will not occur for at least 800 years, and that there could be at least one year with importations of infected beef in every 5,700 years

The likelihood of exposure of FMD-susceptible species to FMD infected beef was not evaluated quantitatively in this risk assessment. However, in a 1995 study (CEAH 1995), APHIS determined that 0.023% of plate and manufacturing waste is not adequately processed prior to feeding to swine. This is a three orders of magnitude reduction in the risk at the release level.

The consequences of an FMD outbreak in the U.S. would be extremely high. The sum of the consumer impacts, direct costs and trade losses, would be between US$ 37 billion to US$ 44 billion, in 2001 dollars.

4.1 Conclusion

The assessment found that the likelihood of importing fresh or frozen, maturated, and deboned beef infected with FMD virus would not exceed 1.03 X 10^{-4} or 1 in 9,700 chance (95% confidence level). The likelihood of exposure of FMD-susceptible species to FMD infected beef from previous studies was presented. However, combining the likelihood of importing FMD-infected beef and exposure of susceptible species to uncooked infected beef scraps would result in an estimate that is at least three orders of magnitude less than the release rate of 1.03 X 10^{-4}.

Although the consequences of an FMD outbreak in the U.S. would be very high, given the findings of the release and exposure assessments, APHIS believes the likelihood of Uruguay beef introducing and establishing FMD is low.

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Appendix 1 – Quantitative model

Expected values of parameters are displayed

Initiating Event of selecting Herds in Uruguay

Determining the Number of Animals required per year

		min	ml	max	Value	EQUATION
Tons of beef imported from Uruguay per year	KGPY	12000000	19000000	24000000	18666667	RiskPert(min,ml,max)
Kgs of meat per Animal	KGPA	40	80	120	80	RiskPert(min,ml,max)
# animals required per Year	**APY**				233,333	APY = KGPY / KGPA

Determining f4, the proportion of Animals slaughtered per herd

		min	ml	max	Value	EQUATION
f4 is the Animal Extraction rate from Herds (ER)	**f4**	0.15	0.16	0.22	0.168	RiskPert(min,ml,max) The most likely (ml) value provided in Uruguay official data was ER = 0.16

Determining M, the number of Animals per herd

Average Herd Size in Uruguay

Size (Ha)	Number herds	Number animals	Average herd size	Rel freq.
200-499	7,108	1,528,897	215	0.485
500-999	3,765	1,735,503	461	0.257
1000-2499	2,769	2,686,949	970	0.189
2500-4999	787	1,695,720	2155	0.054
5000-9999	181	691,042	3818	0.012
>10000	33	232,763	7053	0.002
Total	**14,643**	**8,570,874**		

Rel Freq = #Herds/Total Herds

1,442,763.79

		min	ml	max	Value	EQUATION
Average herd size	**M**				**1374**	**ROUND(RiskGeneral(Min,Max,{Avg Herd Size},{Rel Freq}),0)**
APH, the Animals Per Herd selected for slaughter	**APH**				**231**	APH = RiskBinomial(M,f4) = M*f4
Determining the number of Herds needed per Year						
Herds needed per Year	**HPY**				**1009**	HPY = APY/APH

Determining f1 - Fraction of Infected Undetected Herds Selected (FHS)

		min	ml	max	Value	EQUATION
Total number of herds in Uruguay	TH	48,518	48,518	48,518	48518	
Fraction of Herds Selected	**FHS**				**2.08E-02**	FHS = HPY/TH
Fraction of Infected Undetected Herds Selected	**f1**				**2.08E-02**	f1 = FHS

Determining f3, the Fraction of Infected Animals per Herd

			Value	EQUATION
Vaccine efficacy				
Vaccinated			2170	Data from Uruguay
Protected			2162	
Proportion protected			**0.99586**	**RiskBeta(Protected+1,Vaccinated-Protected+1)**
Proportion at risk	PAR		**0.00414**	**PAR = 1 - Proportion protected**
Fraction of animals infected (f3)	**f3**		**0.006717065**	IF(PAR < 1/HS) THEN RiskPert(1/HS,1/HS,0.023) ELSE RiskPert(1/HS,PAR,0.023))

Determining f6, the Probability that meat from a carcass with pH > 5.8 is exported to the USA

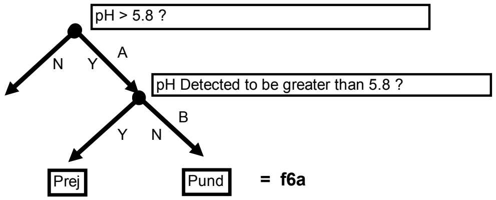
pH rejections in cattle with pH 6.0 or above

Plant	Rejected	tested	Rejection Rate	
2	7134	64729	0.11021335	
3	8763	94316	0.09291106	
8	6278	69084	0.09087488	
12	8862	90366	0.09806786	
55	8815	92643	0.0951502	
379	7627	80356	0.09491513	
439	4973	47731	0.10418805	
	13768	155494	0.08854361	
Total	**66220**	**694719**	**0.09531911**	**0.096858018**

Total Rejected

Total Tested

		min	ml	max	Value	EQUATION
Proportion rejected (Prej)	Prej				**0.09532028**	**RiskBeta(Total Rejected+1,Total Tested - Total Rejected+1)**
Failure of pH reader + human error (P(B))	P(B)	0.001	0.01	0.01	**0.008433993**	**RiskPert(1/1000,1/100,1/100)**



= f6a

i Prej = P(A)*(1-P(B))

ii Pund = P(A)*P(B)

Since we do not know P(A), we need to solve for P(A) in (i), therefore:

iii P(A) = Prej/(1-P(B))

substituting (iii) into (ii) gives:

iv Pund = Prej*P(B)/(1-P(B))

		min	ml	max	Value	EQUATION	
Proportion of carcasses with pH > 5.8 that go undetected (Pund)	Pund				**0.000810769**	**Pund = Prej*P(B)/(1-P(B))**	
Probability carcass with pH >5.8 is exported (= Pund)	**f6a**				**0.000810769**	**f6a = Pund**	
Proportion of (infected) carcasses improperly deboned	Pcid	0.000	0.010	0.010	0.008267327	RiskPert(0,1/1000,1/100)	improperly deboned carcassess / carcass
Proportion of (improperly deboned) carcasses exported	Pcexp				0.90467972	Pexp = 1 - Prej	Exported improperly deboned carcassess / improperly deboned carcassess
Probability that an improperly deboned exported carcass has viable virus	Pcvv	0	0.5	0.5	0.333333333	RiskTriang(min,ml,max)	Exported improperly deboned carcassess with viable virus / Exported improperly deboned carcassess
Probability an improperly deboned infected carcass with viable virus is exported	**f6b**				**0.002493094**	**f6b = Pcid * Pciexp * Pcvv**	Exported improperly deboned carcassess with viable virus / carcass
Probability carcass with pH >5.8 is exported or an improperly deboned infected carcass with viable virus is exported	**f6**				**0.003301842**	**f6 = f6a + f6b - f6a * f6b**	Exported improperly matured or improperly deboned carcassess with viable virus / carcass

Results

	Parameter Description	Equation	MIN	ML	MAX	Value	UNITS	CUMULATIVE UNITS	Cumulative Value
L	**Frequency of Years with FMD**	RiskUniform (3/7, 1)	0.43		1	**0.71**	Years with FMD / Year	Years with FMD / Year	0.714286
			1	2	1	1			
N	**Infected Undetected Herds In Uruguay per Outbreak Year**	RiskPert( )	1	35	62	**18**	Infected Undetected Herds / Year with FMD	Infected Undetected Herds / Year with FMD	18
f1	**Fraction of Infected Undetected Herds Selected for meat export per Year**	See below: Determining f1,			f	**2.19E-02**	Selected Infected Undetected Herds / Infected Undetected Herd	Selected Infected Undetected Herds / Year with FMD	3.94E-01
f2	**Fraction of Year an Infected Herd has infected animals**	RiskPert( ) / 365	14	28	42	**0.077**	Days (of Infection) / Days (in Year)	Selected Infected Undetected Herds / Year with FMD	3.01E-02
M	**Number of Animals per Infected Undetected Herd (Herd Size -HS)**	See below: Determining M			M	**1374**	At Risk Animals / Selected Infected Undetected Herd	At Risk Animals / Year with FMD	41
f3	**Proportion of Infected Animals per Herd (Proportion at Risk - PAR)**	See below: Determining f3,			f	**0.006717**	Infected At Risk Animals / At Risk Animal	Infected At Risk Animals / Year with FMD	0.28
f4	**Proportion of Animals Slaughtered (Extraction Rate - ER)**	See below: Determining f4,		0.16	f	**0.16**	Slaughtered Infected Animals / Infected At Risk Animal	Slaughtered Infected Animals / Year with FMD	0.04
f5	**Proportion of Infected Carcassess not detected by AM & PM Inspection**		1	1	1	**1**	Infected Carcasses after AM & PM Inspection / Slaughtered Infected Animals	Infected Carcasses after AM & PM Inspection / Year with FMD	0.04
f6	**Proportion of infected carcasses with viable virus after maturation and deboning**	See below: Determining f6,			f	**0.00105**	Carcassess with virus after maturation and deboning / Infected Carcasses after AM & PM Inspection	Carcassess with virus after maturation and deboning / Year with FMD	4.66E-05
								Carcassess with virus after maturation and deboning / Year	3.33E-05

	Parameter Description	Equation	Value	Units		Value
P	**Probability of 1 or more Carcasses with virus per year with undetected FMD in Uruguay**	$P = 1-(1-f3*f4*f5*f6)^{(N*f1*f2*M)}$	4.66E-05	Carcassess with virus after maturation and deboning / Year with FMD		
Q	**Probability of 1 or more Carcasses with virus per year**	$Q = L1*(1-(1-f3*f4*f5*f6)^{(N*f1*f2*M)})$	3.33E-05	Carcassess with virus after maturation and deboning / Year		
T1	**Entry into the US of meat from at least 1 infected Carcass in 1/P years with FMD:**	T1 = 1/P	21,469	Years with FMD (1/P)	Log(T1)	4.331807983
T2	**Entry into the US of meat from at least 1 infected Carcass in 1/Q years:**	T2 = 1/Q	30,056	Years (1/Q)	Log(T2)	4.477933129
Y1	**Years with FMD until the first importation of meat from at least 1 infected Carcass**	$Y1 = RiskNegBin\{ 1, (1-(1-f3*f4*f5*f6)^{(N*f1*f2*M)}\}$	21467		Log(Y1)	4.331771356
Y2	**Years until the firxt importation of meat from at least 1 infected Carcass**	$Y2 = RiskNegBin\{ 1, L1* (1-(1-f3*f4*f5*f6)^{(N*f1*f2*M)}\}$	30055		Log(Y2)	4.477916732

Appendix 2: Output and Input Summary Statistics

Name	Description	Minimum	Maximum	Mean	Mode	5% Perc	50% Perc	95% Perc
L	(Sim#1)	0.428574	0.999983	0.714286	0.44857	0.457109	0.714256	0.971386
	(Sim#2)	0.428574	0.999983	0.714286	0.44857	0.457109	0.714256	0.971386
N	(Sim#1)	1.001058	34.99867	17.99998	27.69004	2.69829	17.9974	33.29697
	(Sim#2)	2.669081	61.4001	33.83341	33.94685	14.45836	34.10562	52.24529
f1	(Sim#1)	2.64E-03	0.261276	4.39E-02	2.00E-02	7.40E-03	3.03E-02	0.122257
	(Sim#2)	2.64E-03	0.261276	4.39E-02	2.00E-02	7.40E-03	3.03E-02	0.122257
f2	(Sim#1)	3.94E-02	0.113177	0.076503	7.67E-02	5.27E-02	7.65E-02	0.100267
	(Sim#2)	3.94E-02	0.113177	0.076503	7.67E-02	5.27E-02	7.65E-02	0.100267
M	(Sim#1)	206	7182	1373.589	215	256	1009	3936
	(Sim#2)	206	7182	1373.589	215	256	1009	3936
f3	(Sim#1)	2.22E-04	2.10E-02	6.87E-03	3.68E-03	1.92E-03	6.25E-03	1.39E-02
	(Sim#2)	2.22E-04	2.10E-02	6.87E-03	3.68E-03	1.92E-03	6.25E-03	1.39E-02
f4	(Sim#1)	0.16	0.16	0.16	0.16	0.16	0.16	0.16
	(Sim#2)	0.16	0.16	0.16	0.16	0.16	0.16	0.16
f5	(Sim#1)	1	1	1	1	1	1	1
	(Sim#2)	1	1	1	1	1	1	1
f6	(Sim#1)	2.42E-04	1.40E-03	1.05E-03	7.44E-04	7.38E-04	1.07E-03	1.29E-03
	(Sim#2)	2.42E-04	1.40E-03	1.05E-03	7.44E-04	7.38E-04	1.07E-03	1.29E-03

Name	Scenario	MIN	Max	Mean	Mode	5% Perc	50% Perc	95% Perc
Q	(Sim#1)	1.17E-07	3.26E-04	3.51E-05	7.06E-06	3.05E-06	2.47E-05	1.03E-04
	(Sim#2)	1.04E-06	5.56E-04	6.67E-05	5.57E-05	1.06E-05	5.12E-05	1.76E-04
Y2	(Sim#1)	4	52,392,740	98,198	9,072	1,506	27,420	358,969
	(Sim#2)	2	2,144,978	32,449	663	790	13,211	118,834

Where:

Q is the annual probability of importing infected beef from Uruguay

$$Q = L1*(1-(1-f3*f4*f5*f6)^{(N*f1*f2*M)})$$

Y2 is the years until the first importation of infected beef from Uruguay

$$Y2 = RiskNegBin\{ 1, L1* (1-(1-f3*f4*f5*f6)^{(N*f1*f2*M)}\}$$

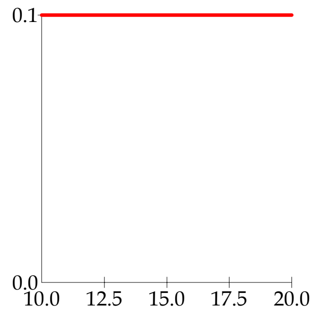
Appendix 3: Glossary of Distribution Types

RiskUniform

RiskUniform(minimum,maximum) specifies a uniform probability distribution with the entered minimum and maximum values. Every value across the range of the uniform distribution has an equal likelihood of occurrence.

Examples:

RiskUniform(10,20) specifies a uniform distribution with a minimum value of 10 and a maximum value of 20.



RiskUniform(A1+90,B1) specifies a uniform distribution with a minimum value equaling the value in cell A1 plus 90 and a maximum value taken from cell B1.

Guidelines:

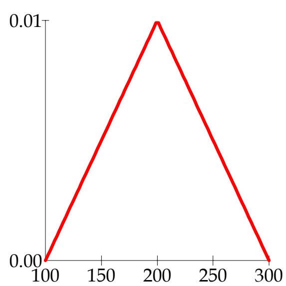
The minimum value entered must be less than the maximum value.

RiskTriang

RiskTriang(minimum,most likely,maximum) specifies a triangular distribution with three points — a minimum, most likely and maximum. The direction of the "skew" of the triangular distribution is set by the size of the most likely value relative to the minimum and the maximum.

Examples:

RiskTriang(100,200,300) specifies a triangular distribution with a minimum value of 100, a most likely value of 200 and a maximum value of 300.



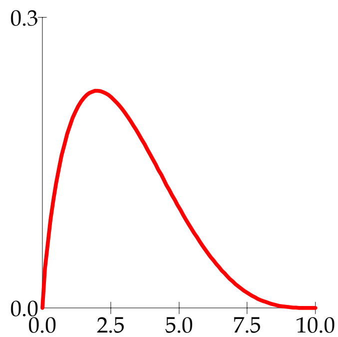
RiskTriang(A10/90,B10,500) specifies a triangular distribution with a minimum value equaling the value in cell A10 divided by 90, a most likely value taken from cell B10 and a maximum value of 500.

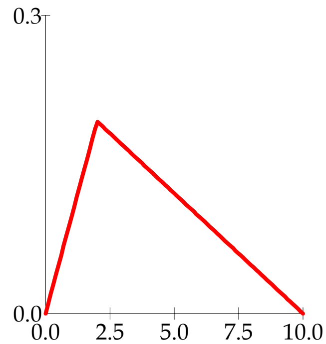
Guidelines

The minimum value must be less than or equal to the most likely value.
The most likely value must be less than or equal to the maximum value.
The minimum value must be less than the maximum value.

RiskPert
RiskPert(minimum, most likely, maximum) specifies a PERT distribution (as special form of the beta distribution) with a minimum and maximum value as specified. The shape parameter is calculated from the defined most likely value.
Examples

PERT(0,2,10) specifies a beta distribution with a minimum of 0, a maximum of 10, and a most likely value of 2.





compare to triangular

PERT(A1,A2,A3) specifies a PERT distribution with a minimum value taken from cell A1, a maximum value taken from cell A3, and a most likely value taken from cell A2.

Guidelines

Minimum must be less than maximum.
Most likely must be greater than minimum and less than maximum.

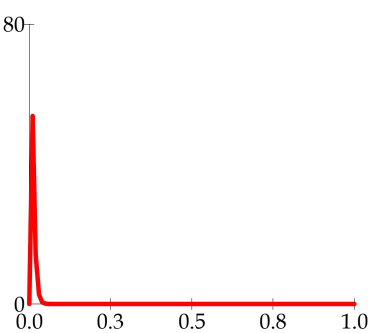
RiskBeta
RiskBeta(alpha1,alpha2) specifies a beta distribution using the shape parameters alpha1 and alpha2. These two arguments generate a beta distribution with a minimum value of 0 and a maximum value of 1.

The Beta distribution can be used to define the probability of an event, if we know how many times we have observed the event (x), and we know how many times we have tried to observe the event (n). In this case, alpha1 = x+1, and alpha2 = n-x+1.

RiskBeta(x+1,n-x) specifies a beta distribution using the number of events observed, x and the number of total observation trials, n.

Examples

In 200 inspections, only once has infection been detected. Therefore, x = 1, and n = 200. RiskBeta(x+1,n-x+1) = RiskBeta(1+1, 200-1+1) = RiskBeta(2,200) specifies a beta distribution using the shape parameters 2 and 200



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Guidelines

Both alpha1 and alpha2 must be greater than zero.

RiskBetaGeneral
RiskBetaGeneral(alpha1,alpha2,minimum,maximum) specifies a beta distribution with the defined minimum and maximum using the shape parameters alpha1 and alpha2.

Examples

RiskBetaGeneral(1,2,0,100) specifies a beta distribution using the shape parameters 1 and 2 and a minimum value of 0 and a maximum value of 100.

RiskBeta(C12,C13,D12,D13) specifies a beta distribution using the shape parameter alpha1 taken from cell C12 and a shape parameter alpha2 taken from cell C13 and a minimum value from D12 and a maximum value from D13.

Guidelines

Both alpha1 and alpha2 must be greater than zero.

RiskNegbin(1,p) - Returns the number of failures till the first success.

RiskNegbin(s,p) specifies a negative binomial distribution with s number of successes and p probability of success on each trial. The negative binomial distribution is a discrete distribution returning only integer values greater than or equal to zero.

Examples

- RiskNegbin(5,.25) specifies a negative binomial distribution with 5 successes with a 25% probability of success on each trial.
- RiskNegbin(A6,A7) specifies a negative binomial distribution with the number of successes taken from cell A6 and a probability of success taken from cell A7.
- **RiskNegbin(1,0.05). E.g. the number of years without importing FMD infected beef, until the first year that FMD infected beef is imported, given that the annual probability of importing it is 0.05**.

Guidelines

- Number of successes s must be a positive integer less than or equal to 32,767.
- Probability p must be greater than zero and less than or equal to one.