

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

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Executive Summary

On February 20, 2001, the United Kingdom (UK) reported an outbreak of foot-and-mouth disease (FMD) in Great Britain. The disease spread rapidly in the UK. The Animal and Plant Health Inspection Service (APHIS) responded by banning imports of animal and animal products from the UK. The UK was then removed by interim rule from the list of countries that APHIS considers free from FMD.

FMD spread subsequently to France, the Netherlands, and the Republic of Ireland. Because of concern that disease might spread even further, APHIS banned importation of animals and animal products from all thirteen remaining European Union (EU) Member States that APHIS considered FMD-free after publication of the interim rule removing the UK from the list of free regions. APHIS drafted an interim rule intended to remove all thirteen Member States from the list of countries considered free from FMD.

The European Commission (EC) argued that such an action was not in compliance with either the Veterinary Equivalence Agreement between the EC and the United States (US) or with obligations accepted by APHIS under the World Trade Organization Sanitary and Phytosanitary Agreement. The EC and several Member States requested that APHIS regionalize the EU and resume trade with unaffected regions. APHIS agreed to evaluate the possibility of regionalization and indicate the results of that evaluation in the interim rule.

APHIS conducted its initial regionalization evaluation at the Member State level, an approach that does not preclude evaluation of a smaller administrative unit in the future. However, it has been routine practice for APHIS to conduct a site visit of an affected country before regionalizing to smaller administrative units. APHIS has not yet conducted a site visit of EU Member States requesting regionalization within country borders.

APHIS assessed the level of risk associated with resumption of trade in susceptible animals and animal products with the thirteen EU Member States that were on the list of FMD-free regions. The evaluation was based on published literature, data submitted by individual Member States, EU legislation, documents and spreadsheets provided by the EU, and reports to the Office International des Epizooties (OIE).

APHIS conducted a descriptive assessment in which it evaluated information on unaffected Member States based on observations of outbreaks in affected EU Member States. APHIS identified risk factors applicable at the Community level and factors applicable at the level of individual Member States. If APHIS identified one or more factors applicable at the Community level as sufficient to categorize the entire EU as a high risk region, it intended to remove all thirteen Member States from the list of free regions. If the evaluation indicated that risk applicable at the Community level could be mitigated by circumstances or legislation in individual Member States or restrictions in US regulations, APHIS intended to base its final evaluation on the risk associated with individual Member States. Member States associated with no or low individual risk attributes could be allowed to remain on the list of free regions.

APHIS identified two risk factors applicable at the Community level. One was the duration of restrictions in EC legislation (30 days), which is significantly shorter than the duration of restrictions specified in OIE guidelines (3 months) or the time observed between outbreaks in a single region (44 days). In at least one documented case, this resulted in release of EC restrictions before a new outbreak occurred and allowed export of risky material.

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

The second risk applicable at the Community level was the movement of disease relatively long distances (up to 100 km). APHIS was unable to identify any pathway for this spread. This suggests that there may be a significant risk of disease transmission outside of established control zones.

APHIS evaluated these risks in the context of its current regulations on import of meat from EU Member States. The evaluation revealed that the current meat regulations include mitigations to address both risks. These mitigations include certifying that meat does not originate from or is commingled with meat from a region that APHIS considers to be FMD-affected. This is relevant because meat may be prohibited from areas from which the EC has released restrictions but upon which APHIS restrictions remain. APHIS can also require appropriate certifications for animals under its current regulations.

APHIS then evaluated the information provided for each Member State to identify risk factors for each. Because the UK and Greece had been removed previously by regulation from the list of FMD-free regions, these Member States were not included in the considerations for regionalization. In the absence of specific criteria for assigning risk levels, the remaining Member States were classified as lower risk or higher risk. Because outbreaks in France, Ireland and the Netherlands did not meet the prescribed OIE waiting period for recognizing a region as free of FMD, APHIS classified these Member States as higher risk. APHIS placed Austria, Belgium, Denmark, Finland, Germany, Italy, Luxembourg, Portugal, Spain, and Sweden into the lower risk category because it did not identify risk factors considered sufficient to assign these Member States to the higher risk level.

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

Introduction

On February 20, 2001, the Chief Veterinary Officer of the UK reported that an outbreak of FMD had occurred in Great Britain. The disease spread rapidly in England, Wales, and Scotland, and was ultimately confirmed in Northern Ireland. UK veterinary officials took quick action to ban the export of risky materials. In addition, APHIS instituted an administrative ban on importation of all animals and animal products. An interim rule supporting the APHIS administrative action and removing the UK including Northern Ireland from the list of regions considered FMD-free [1] was published on March 14, 2001 [2].

FMD spread from the UK to France was confirmed on March 12, to the Republic of Ireland on March 22, and to The Netherlands on March 21. These EU Member States quickly banned export of risky animals and animal products. In addition, on March 13, APHIS instituted an administrative ban [3] and initiated a draft interim rule for administrative clearance that removed 13 EU Member States previously considered FMD-free from the list of FMD-free regions. The initial ban was broad because of concern that the disease would spread further.

The EC argued that the administrative action was not in compliance with either the Veterinary Equivalence Agreement between the EC and the US [4] or with obligations that APHIS has under the World Trade Organization Sanitary and Phytosanitary Agreement [5]. Publication of interim rule removing 13 Member States from the list of free countries would interrupt trade from the EU for a significant period of time because of the time that would be required to publish new regulations to reverse that ruling. Therefore, the EC and several Member States requested APHIS to regionalize the EU in order to allow resumption of trade from unaffected EU Member States in a timely fashion.

APHIS agreed to evaluate the possibility of regionalization. APHIS agreed to indicate the results of that evaluation in the interim rule.

Objective

The objective of this review is to assess the level of risk that would be associated with resumption of trade in susceptible animals and animal products with EU Member States.

APHIS Approach to Regionalization

APHIS requested data from the EC and individual Member States to evaluate FMD risk for individual Member States. APHIS intended to evaluate whether it would be possible to identify lower risk countries within the EU with which trade might be resumed. Lower risk Member States could then be excluded from the countries listed initially in the draft interim rule. This would leave those Member States on the list of countries that APHIS considers FMD-free, and trade could be resumed upon publication of the rule.

Sources of information for this evaluation include published literature, EU legislation [6], documents provided by the EC and individual Member States [7], spreadsheets [8] provided by the EC, and reports to Office International des Epizooties (OIE) [9].

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

Scope of the evaluation

The EU currently has 15 Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, and the United Kingdom (UK) of Great Britain and Northern Ireland [10]. The initial version of the rule reflected consideration by APHIS of the 13 Member States that APHIS recognized as free at the time the administrative action was taken. It excluded from its regionalization considerations only those Member States (Greece and UK including Northern Ireland) that had been removed previously from the list of free countries [1, 11]. Since regulations were in place to define those Member States as FMD-affected and these Member States were not affected by the administrative ban, they could not be considered for regionalization in the context of the interim rule. In this regard, APHIS must publish other rules to change the disease status of these Member States.

Despite the fact that APHIS could not evaluate the UK and Northern Ireland for regionalization, it included information provided by these Member States in its evaluation. In fact, the data were critical to the evaluation of other Member States because they defined the epidemiology of the disease in the region and the risk factors that were associated with the type O virus strain causing the epidemic in the entire region.

The evaluation reported in this assessment is intended to identify whether certain lower risk Member States may be excluded from the draft interim rule. APHIS intends for the interim rule to remove from the list of FMD-free regions only Member States that could not be classified as lower risk or for which the risk could not be evaluated. APHIS defines these as Member States for which there is (a) suspicion of disease, (b) a significant probability that disease could occur, or (c) insufficient information to evaluate risk. Alternatively, If APHIS' evaluation suggests that the risk of resuming trade with a Member State is low, the Member State can be excluded from the interim rule prior to publication, thus allowing trade to resume.

Information requested

APHIS requested information from the EC and Member States on the topics that were identified as most critical to its evaluation. The list of topics was generated from a consideration of the epidemiology of the outbreaks in the UK, France, the Netherlands and the Republic of Ireland. The topics focused on outbreak history, control measures implemented, and movement of high-risk entities. APHIS requested information on the following specific topics:

- Outbreak history in the Member State or region;
- Complete information on Community legislation in force to control spread of disease among Member States, including information on limitations identified in Community legislation in force at the time of the outbreak, changes made to address these limitations, enforcement procedures to implement the changes, and enforcement of compliance;
- Information on surveillance or control measures implemented by individual Member States in addition to Community legislation;
- Statistics on trade in live animals and high-risk animal products within the Community since January 2001;
- Trace back results for animals moving from affected areas;
- Information on practices that might serve to introduce disease (e.g., garbage feeding of swine), surveillance of those practices, and recent or planned legislative changes that might affect these practices;

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

- Mechanisms in place to assure compliance with Community and Member State legislation, as well as mechanisms to identify and correct failures in the safeguarding system; and
- Vaccination practices and vaccination records for the region as applicable.

APHIS indicated further that other factors such as environmental conditions (e.g., prevailing winds) that might contribute to disease spread might need to be addressed.

Community legislation: Summary of control measures applied to FMD outbreaks according to Council Directive 85/511/EEC as amended [6]

In order to assess the risk of introducing FMD into other EU Member States, it is important to understand applicable EU legislation. Council Directive 85/511/EEC provides the basis for EC control of FMD. The directive requires that, upon confirmation of FMD, a protection zone of 3 km radius and a surveillance zone of 10 km radius be established around the outbreak. It also requires the following actions to be taken on affected premises:

- All susceptible animals in the affected premise(s) must be slaughtered immediately and destroyed.
- Meat from affected premises must be traced and destroyed.
- Milk and milk products must be destroyed or treated to eliminate FMD virus.

In addition, the following actions must be taken within the protection zone:

- A census must be taken of all premises with susceptible animals.
- All premises must be subjected to periodic veterinary inspection.
- Animal movements are banned for 15 days except to emergency slaughter under official supervision.
- Measures must be maintained for at least 15 days after all animals on the affected premises have been slaughtered and destroyed and the premises have been cleaned and disinfected appropriately.

Moreover, certain actions must be taken within the surveillance zone that surrounds the protection zone:

- A census must be taken of all premises with susceptible animals.
- Animal movements are banned except to pasture and emergency slaughter under official supervision.
- For the first 15 days after FMD confirmation, no animal movements outside the zone are allowed.
- During the second 15 days, animal movement is allowed outside the zone but to emergency slaughter only.
- Measures must be maintained for at least **30 days** after all animals in affected premises have been slaughtered and destroyed and the premises have been cleaned and disinfected appropriately.

APHIS identified the release of restrictions after 30 days as a critical factor in its evaluation. This period is significantly less than the time period recommended in the international standards set by the OIE [12]. A summary of the OIE guidelines on waiting periods to regain disease-free status is presented in Table 1. Of particular relevance to this discussion is that the OIE recommends a 3-month period waiting after the last case before a region can qualify for FMD-free status, in contrast to the European Union regulations that require only 30 days.

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

Table 1- Summary of OIE recommendations on waiting periods for disease-free status

<p>When FMD occurs in an FMD free country or zone where vaccination is not practiced, the following waiting periods are required to regain disease-free status:</p> <p>a) 3 months after the last case, where stamping-out and serological surveillance are applied; or b) 3 months after the slaughter of the last vaccinated animal where stamping-out, serological surveillance and emergency vaccination are applied.</p> <p>When FMD occurs in an FMD free country or zone where vaccination is practiced, the following waiting periods are required to regain the disease free status:</p> <p>a) 12 months after the last case where stamping-out is applied, or b) 2 years after the last case without stamping-out, provided that an effective surveillance has been carried out.</p>
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Once the outbreaks began to occur and as disease spread, the EC imposed the following additional control measures [10]:

- On February 27, the EC established provisions for the preventive killing of sheep and goats and the isolation of other susceptible animals dispatched from the UK between February 1 and 21, 2001.
- On March 6, the EC imposed a two-week EU-wide ban of markets and assembly points for all susceptible species. In addition, it prohibited transport of all susceptible species except for direct transport from farm to slaughterhouse or from farm to farm and that only after special authorization of the competent authority. In addition, it established a requirement to disinfect tires of vehicles traveling from the UK to other Member States.
- On March 13, the EC required horses transported from the UK to other Member States to have a health certificate stating that they had not been in a protection or surveillance zone during the 15 days prior to certification.
- On March 27, the EC established the following movement restrictions on susceptible animals in all Member States except the UK:
 - Movements had to be authorized by competent authorities of the place of departure and destination.
 - Notification had to be provided to authorities at the destination point at least 24 hours prior to movement.
 - During transport, the animals were not allowed to contact animals from another holding unless they were being transported for slaughter.
 - Animals transported from farm to farm or from farm to slaughterhouse through an assembly center were required to have resided in the holding of dispatch within the previous 30 days.
- On April 4, strict precautionary measures for zoos were implemented.

Risk Assessment Format

The format of this document is consistent with OIE guidelines [13]. These guidelines define four components of a risk assessment: a release assessment addressing the probability that affected animals or products will be exported from the region being evaluated (the EU) to the region performing the evaluation (the US); an exposure assessment addressing the biological pathways necessary for exposure in the US; a consequence assessment describing the consequence of exposure, and a risk estimation.

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

Of note is that the OIE guidelines indicate that if either a release or exposure assessment demonstrates no significant risk, the risk assessment may conclude at that step in the process.

Information on FMD in EU Member States in which outbreaks have occurred

To date, outbreaks have been reported only in the UK (including Northern Ireland), Ireland, France and the Netherlands (Figure 1). All outbreaks have been attributed to FMD virus type O.

United Kingdom-Great Britain

Outbreak Summary [9, 14-18]

Primary outbreak:	Early February 2001
Index case detected:	February 19, 2001
Index case confirmed:	February 20, 2001
Number of outbreaks to date (May 16, 2001):	1,604 outbreaks
Suspected source of infection:	Swill fed to swine
Lag between infection and detection:	2-3 weeks

EU Measures Applied to the UK [10]

Feb. 21	Ban on movement of animals and untreated animal products
Mar. 7	EU-wide ban of markets and assembly points Standstill of transport of animals except for slaughter and from farm to farm Disinfection of vehicles from the UK
Mar. 14	Restrictions on the transport of horses from the UK
Mar. 30	Protective vaccination in Devon and Cumbria allowed
Apr. 11	Measures implemented for zoos Emergency vaccination allowed for endangered species, rare breeds, irreplaceable research animals when outbreaks are detected within 25 km of the holding. Vaccinated animals may not be traded or enter the human food chain (however vaccination has not been applied in the UK)

Comments

Of note is an outbreak confirmed in Somerset in May 2001. The outbreak is notable because it occurred in area that had been declared free of disease 12 days previously. Before the May outbreak, Somerset had only one confirmed case.

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

United Kingdom-Northern Ireland

Outbreak Summary [9, 15, 16, 19]

Primary outbreak:	February 19, 2001
Index case detected (same as primary)	February 27, 2001
Index case confirmed:	February 27, 2001
Number of outbreaks to date (April 24, 2001):	3 outbreaks
Suspected source of infection:	Animal movement from a market in England
Lag between first infection and detection:	8 days

EU Measures Applied to Northern Ireland [10]

Apr. 3	Lift on the ban on the dispatch of meat, meat products, milk, milk products, semen, embryos and ova originating from susceptible species from Northern Ireland, while leaving it in place for the Newry and Mourne districts of Northern Ireland's Armagh County where a FMD case was detected late February. All exports of live animals from Northern Ireland remain prohibited.
Apr. 13, 15	New cases reported in Tyrone and Antrim
Apr. 18	Total ban on exports of susceptible live animals, untreated meat and products until May 18

Comments

Although the efforts in Ireland have limited the number of outbreaks effectively to only three in total, the second case occurred on April 13, ten days after restrictions for the export of products and germplasm were lifted. There was a lag of **44 days** between the first and second cases. The second and third cases occurred in two separate areas approximately 70 and 80 km away from the primary case (Figure 2).

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

Ireland

Outbreak Summary [9, 16, 20-22]

Primary outbreak:	March 20, 2001
Index case detected (same as primary):	March 20, 2001
Index case confirmed:	March 22, 2001
Number of outbreaks to date (April 24, 2001):	1 outbreak
Suspected source of infection:	Close contact with outbreak in Northern Ireland (the affected herd was 3 km away from the affected herd in Northern Ireland)
Lag between first infection and detection:	3-5 days based on the appearance of the lesions (OIE report)

EU Measures Applied to Ireland [10]

March 22	Ban on movement of animals, germplasm to other countries. Ban on untreated products from county of Louth to other provinces and countries
April 19	Lifting of measures (31 days after the outbreak)

Comments

Ireland's actions have limited the number of outbreaks to a single one that is related to the primary case in Northern Ireland. It occurred 29 days after the Northern Ireland case within the protection zone established to control that outbreak. In addition to this outbreak, serologically positive animals with no clinical signs were identified two adjoining premises. Ireland took strict measures and depopulated 46,988 sheep, 1,045 cattle, 277 deer, 55 pigs and 243 goats.

**FMD Risk Assessment for the Export of Animals and Animal Products from European Union Member States to the United States
May 2001**

France

Outbreak Summary [9, 16, 23-26]

Primary outbreak:	Sheep imported from the UK from an affected premise were slaughtered on February 27, 2001
Index case detected:	March 12, 2001
Index case confirmed:	March 13, 2001
Number of outbreaks to date (April 24, 2001):	2 outbreaks
Suspected source of infection:	Primary outbreak: sheep imported from the UK. Index case: Close proximity to primary outbreak
Lag between first infection and detection:	At least 14 days

EU Measures Applied to France [10]

Mar. 14	Ban on movements of animals and germplasm to other countries Ban on untreated products from Mayenne and Orne Valid until Mar. 27
Mar. 20	Prolongation of measures until April 4. Shipments of meat to processing plants from restricted areas allowed. Lifting of restrictions on animal movements with the exception of Mayenne and Orne planned for Mar 28
Mar. 23	Second outbreak
Mar. 27	Extension of measures until April 12
Apr. 2	Restriction measures applied only to Seine-et-Marne, Val-d'Oise and Seine-Saint-Denis departments, on condition that no new FMD outbreaks had occurred
Apr. 13	All of the EC measures relating to movement restrictions on live animals and trade in products applied to France were lifted

Comments

Surveillance and rapid control activities in France have effectively limited the number of outbreaks to two. A total of 19,660 sheep were imported directly from the UK to 17 departments; these sheep were further distributed to a total of 25 departments. They were all traced and slaughtered.

A further 9,372 sheep had been exported from the UK to the Netherlands and re-exported to France. Approximately 10,000 sheep had been slaughtered before February 21. Carcasses were detained and either destroyed or sent back to the UK.

A total of 49,227 animals (corresponding to 104 farms distributed in 37 departments) have been euthanized, i.e. 20,621 sheep and 1 pig, all originating from the UK, as well as 27,507 contact sheep, 537 contact cattle, 364 pigs and 197 contact goats.

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

A further 8,563 animals (corresponding to 13 farms distributed in 10 departments) were euthanized, i.e. 131 cattle, 3,477 pigs, and 505 small ruminants all originating from the Netherlands, as well as 451 cattle; 2,602 pigs, and 1,487 contact small ruminants.

As a result of the trace-back of animals imported from the UK; 5,048 samples have been tested. Twenty-eight tested positive by ELISA. These came from six farms that had received sheep from the UK. The information provided does not specify if the seropositive animals were of French origin (which might suggest viral transmission) or UK origin.

As a result of the trace-back of animals from the Netherlands, 328 samples were tested. All of the results were negative.

Netherlands

Outbreak Summary [9, 16, 27, 28]

Primary outbreak:	February 24, 2001
Index case detected:	March 21, 2001
Index case confirmed:	March 21, 2001
Number of outbreaks to date (April 24, 2001):	26 outbreaks
Suspected source of infection:	74 calves present on the farm in Oene originated from Ireland. Investigations revealed that they were imported through France and stayed at a staging point in Mayenne (France). In the days before the calves arrived, English sheep were present at this staging point. These sheep originated from outbreak No. 11 in the United Kingdom. The calves arrived in the Netherlands on February 24, 2001. As it seems, these calves could have caused the outbreak of FMD in the Netherlands.
Lag between first infection and detection:	25 days

**FMD Risk Assessment for the Export of Animals and Animal Products from European Union Member States to the United States
May 2001**

EU Measures Applied to the Netherlands [10]

Mar. 21	Ban on movements of animals and germplasm to other countries Ban on animals and untreated products from Gelderland, Overijssel, Flevoland and Noord-Brabant. Valid until Apr. 4
Mar. 22	Suppressive vaccination requested by Netherlands
Mar 23	Suppressive vaccination allowed
Mar 26	Suppressive vaccination begins
Mar. 30	Protective vaccination requested
Apr. 4	Protective vaccination allowed in Oene, prohibiting for a period of at least one year after the last outbreak of FMD the movement of vaccinated cattle from this area to other parts of The Netherlands and to other Member States (without prejudice to Decision 2001/282/EC) and allowing the use of meat and milk of vaccinated animals provided they have been treated to destroy the FMD virus (pasteurization of milk and maturation of meat)
Apr. 4	Measures prolonged until April 25. Products allowed to move under certain conditions
Apr. 10	Meat stamped with "NL" from restricted areas allowed to be dispatched within the Netherlands
Apr. 11	Outbreak in Friesland occurred outside of restriction zones. Ban on animals and products from the entire territory
Apr. 23	Meat stamped with "NL" from restricted areas allowed to be dispatched in the Netherlands, processed in approved cutting plants Release of measures in certain areas

Comments

Most of the cases registered in the Netherlands have been in the eastern province of Gelderland (21 outbreaks). However, two outbreaks occurred in the northern part of the Netherlands, in the province of Friesland. The distance between these two dairy farms and the other outbreaks (in the provinces of Overijssel and Gelderland) is about 100 km. Up to now; no links with the other outbreaks have been found.

Information on EU Member States in which no outbreaks have been detected

All countries are subject to EU legislation described in Council Directive 85/511/EEC. In addition, Member States are subject to new legislation imposed as a result of the outbreaks [10]. Much of this legislation is summarized in the details provided previously surrounding the above-named council directive. It includes restrictions on movements and gatherings of susceptible animals. In addition, however, Member States have instituted measures unique to individual Member States.

The following is a summary of general information presented for individual countries. The summary is intended to address issues relevant to the probability that affected animals or products would be exported to the US if trade restrictions were lifted.

Austria [29]

- The last outbreak in Austria was in 1981.
- No susceptible animals were imported from the UK, Ireland or France in 2001.
- Although 500 pigs were imported from the Netherlands, all of them tested negative by serology.

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

Belgium [30]

- The last outbreak in Belgium was in 1976.
- Policies for destruction of waste products from ships and planes have been tightened.
- Animals (mostly sheep) imported from the UK and their contacts have been traced and slaughtered. A total of 5,095 import and contact animals have been slaughtered.
- Six hundred and eighty six animals (cattle and pigs) were imported from France to 34 farms. One consignment of 50 pigs was imported from Mayenne, France on March 14. Although they were not slaughtered, they were placed under surveillance.
- Farms with imported swine are checked clinically every 4 days for at least 3 weeks, and farms with imported sheep and goats are checked clinically and serologically every 8 days for at least 4 weeks.
- Animals imported from the Netherlands prior to March 22 were placed under surveillance; pigs imported from known infected areas in the Netherlands were killed.
- All test results animals have been negative.
- Animal movements within Belgium are restricted.
- Imported products from affected countries have been traced and destroyed.
- Meat and meat products from slaughterhouses, cooling units, and cutting plants that were considered to present a risk were seized.
- Belgium has permanent border controls.

Denmark [31-35]

- The last case in Denmark was in 1983.
- Denmark shares a border only with Germany, a country not known to be affected.
- A ban on private import of certain animal foodstuffs has been in effect since March 5, 2001.
- No susceptible animals were imported from affected Member States during the risky periods.
- Serological tests of 305 samples from investigations were negative.
- Meat of sheep and goats imported from affected Member States during risky periods was destroyed.
- Certification of processing date for imported meat and meat products is required.
- Random sample checks are conducted of individuals at the border.
- Airport waste is destroyed.
- Vehicles transporting animals are cleaned and disinfected at the border.
- Feed imports from EU member states with FMD are prohibited.
- Feeding of waste food is prohibited.
- Government officials recommend disinfection of machinery used to spread manure.
- A 48-hour quarantine is recommended for people in contact with susceptible species and all foreign visitors.
- No susceptible animals have been imported since February 11, 2000.
- Live animals have not been imported from countries outside the EU in 2001.
- Imports of live animals from FMD affected countries is banned .
- Cattle embryos and semen were imported from the Netherlands, France and Ireland in 2001. All semen and embryo imports were collected prior to January 23, 2001, prior to the outbreaks.
- Hunting trophies from the UK are banned.

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

Finland [36, 37]

- The last case in Finland occurred in 1959.
- Finland is surrounded by the Baltic Sea. It borders with Russia on the east. The last FMD occurrence in Russia was in June 1995.
- There have been no imports of susceptible animals from France, Ireland, the Netherlands or the UK in 2001.
- Twenty-one cattle imported from Sweden and Denmark in 2001. This is the total number of animals imported from EU.
- No cloven-hoofed animals have been imported from the UK or France since the 1980's.
- Special controls are in place for passengers arriving from risk areas, and border controls have been enhanced. In this regard, footwear is disinfected on arrival, and guidelines have been established for disinfection of persons and clothes.
- Finland has a ban on swill feeding.

Germany [38]

- Germany has instituted border controls, including closing some border crossings to control movements.
- Animals imported during the 21-day period prior to confirmation of an outbreak in each Member State have been traced.
- Serological tests were performed as considered necessary. German authorities report that a total of 10,789 samples was tested.
- APHIS understands that no documented evidence has been provided regarding these test results nor have these results been confirmed by reference laboratories [49].

Greece [9, 39, 40]

- Outbreaks occurred in 2000.
- Greece shares border with Turkey, an FMD affected country.
- Information is provided to international travelers.
- Greece has instituted an internal temporary ban on trade and purchase of animals.
- Advance notification is required for the importation of animals from EU member countries.
- Animals imported from third are inspected countries (identity, physical and lab).
- Greece conducted trace-back of all imports from affected Member States, unaffected Member States, and from developing countries. There were no imports from the UK, Ireland or the Netherlands during the risky period.
- Ten consignments came from France. They were traced and sampled randomly and tested for type) and ASIA 1, according to the following standards: 15% of animals in all consignments from Member States; 10% of animals in all consignments from third countries. Of 706 samples tested, all were negative.
- Preventive measures are in place to be implemented before, during, and after the entry of allied forces coming into Greece from Kosovo

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

Italy [41, 42]

- The last outbreak occurred in 1993.
- Italy has traced imported animals from the UK and other FMD-affected countries. Cattle (1,710) imported mainly from France and other Member States tested negative. Sheep (1,120 imported from the UK and France tested negative. Pigs (1,000 imported from the UK and other unaffected Member States) tested negative. A total of 23,203 serological tests were performed.
- Virological tests (145) were negative.
- Italy shares a border with France.
- Measures have been adopted for incoming passengers at ports and airports.
- Swill feeding of swine is allowed under official control.
- Waste from airplanes is destroyed.
- Restrictions are in place for animal movements within Italy.
- Animal imports from unaffected Member States and third countries are prohibited except under official approval (mainly from Eastern Europe for slaughter and fattening).

Luxembourg [43]

- The last outbreak in Luxembourg was in 1964.
- Luxembourg shares borders with France (FMD-affected), Belgium, and Germany (unaffected). No significant natural barriers exist.
- Animal products from FMD-affected countries have been subjected to surveillance and have been confiscated.
- No susceptible animals were imported from the UK or Ireland in 2001.
- One hundred and eighteen sheep imported from the Netherlands were slaughtered. Some of these were sampled serologically. Test results were negative.
- Cattle imported from France were tested serologically. The test results were negative.
- A suspicious case was reported on April 10, 2001; however, confirmation results were negative.

Portugal [44, 45]

- The last outbreak occurred in 1984.
- Portugal has banned bullfights.
- Animal imports from FMD-affected countries are prohibited. There have been no imports of susceptible animals from UK or Ireland in 2001.
- Imported animals from unaffected EU countries are tested serologically. Additional serological testing was conducted on contact animals.
- One hundred and twenty nine breeding cattle were imported from France. One hundred and six breeding cattle were imported from the Netherlands. No animals were imported from the UK or Ireland.
- Imported animals from Member States that have not been affected with FMD have been serologically tested with a minimum of 10% of the animals with a minimum of 30 samples. A total of 2,755 samples have been tested. To date, all tests have been negative, although the results are pending on 117 samples.

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

Spain [46]

- The last outbreak occurred in 1986.
- Spain conducts trace-back and slaughter of animals imported from the UK.
- Transportation of animals within Spain is restricted.
- Spain requires destruction of all foodstuffs carried by passengers and travelers entering Spain from France.
- A ban on animal concentrations (markets, fairs) has been instituted.
- Spain shares a border with France.
- Cleaning and disinfection of vehicles coming from France is required.

Sweden [18, 47]

- The last outbreak occurred in 1966.
- Sweden banned feeding swill to swine on March 2, 2001. Before this, swill feeding was allowed, subject to registration and heat treatment.
- Sweden prohibits importation of horses from FMD affected countries.
- Importation of hay and straw from FMD-affected countries is prohibited.
- No susceptible animals were imported from the UK, Ireland, France or the Netherlands in 2001.
- Border controls were enhanced.
- All product imports from FMD-affected countries have been traced.
- Import of meat, milk and products has been banned. However, the ban was "Lifted as soon as the situation looked more stable."

Release Assessment: Summary and Approach to Evaluation of Risk Factors

Risk factors identified during the evaluation were assigned to one or both of two categories. The first category is comprised of factors applicable at the Community level, i.e., risk factors that might apply to all Member States. The second category is comprised of risk factors that were identified in the evaluation of individual Member States. APHIS intends to consider the Community factors alone and in combination with risk factors associated with individual Member States in the following context:

If one or more factors applicable at the Community level is sufficient to categorize the entire EU as a high risk region, APHIS intends to include all 13 Member States in its interim rule, thereby removing all EU Member States from the list of regions considered FMD-free. Before reaching this risk estimation, however, APHIS will review information provided by individual Member States to establish whether the high risk at the Community level is mitigated by circumstances in the Member State, actions taken by the Member States, or restrictions in US regulations.

If no risk factor applicable at the Community level is sufficient to categorize the entire EU as a high-risk region or if there is evidence that the risk identified can be mitigated, APHIS will base its final evaluation primarily on the risk associated with individual Member States. Member States that display attributes associated with high risk will remain listed in the interim rule. Member States associated with no or lower individual risk attributes will be excluded from the interim rule.

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

Risk factors applicable at the Community level

Duration of restrictions

As previously noted, EC legislation requires that restrictions remain in place for only 30 days, whereas OIE international standards recommend a waiting period of 3 months before a zone may be recognized as free. In fact, restrictions were lifted in three locations prior to occurrence of new outbreaks in those regions, raising the possibility that risky material could have been exported to other EU Member States.

In the first example, although all exports of live animals from Northern Ireland continue to be prohibited, restrictions on the export of meat, meat products, milk, milk products, semen, embryos and ova from susceptible species were lifted on April 3, 2001 (with the exception of the affected area in the Newry and Mourne districts). However, on April 13, 2001 (44 days after the last case), new outbreaks were reported in two new locations outside the restriction zone. This left a window of 10 days in which risky products could have been traded with the rest of the EU.

The second example is an outbreak confirmed in Somerset in May 2001. The outbreak occurred in an area that had been declared free of disease 12 days previously, again raising the possibility that risky material could have been exported from the region.

In the third example, the single case in the Republic of Ireland occurred within the restriction zone set in place for the first case in Northern Ireland. However, the case occurred 29 days after the case in Northern Ireland. This suggests that new cases can be detected after a free period lasting the equivalent of several incubation periods of the virus toward the end of the of the required period before restrictions may be lifted [12], and raises further concerns about adequacy of the 30-day restriction period specified in EU regulations.

Spatial aspects of outbreaks

The two outbreaks in Friesland in The Netherlands occurred 100 km outside the restriction zones set up in the affected areas. The origin of these outbreaks remains unknown. This demonstrates that outbreaks can spread to distant locations and that all possible pathways of transmission have not yet been identified.

The occurrence of FMD outbreaks outside restriction zones in Northern Ireland and the Netherlands highlights the risk of FMD transmission while virus availability remains high. As long as virus continues to circulate in one or more Member States, there is a risk that disease could continue to spread out of these Member States.

Available mitigations

APHIS considers the short restriction period specified in EU legislation to be a significant risk factor. The risk gains even more significance given the open border policy existing within the EU under normal circumstances. The EC policy on release of restrictions would allow animals and products to move from a region from which the EC had released restrictions but which APHIS still considered to be affected.

However, risk mitigations are available to address this issue. Some of these are already implemented in APHIS regulations applied to EU Member States [1]. In this regard, the APHIS regulations place special restrictions on meat from FMD-unaffected regions that supplement their national meat supply by the importation of fresh (chilled or frozen) meat from regions infected

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

with FMD; have a common land border with regions designated as FMD-affected; or import live animals from FMD-affected regions. First, even though the EC may release restrictions, APHIS would continue to consider the Member State affected and would apply restrictions. In summary, APHIS will require certification that the meat did not originate from a region APHIS considered FMD-affected and had not been commingled with material from a region that APHIS considered FMD-affected. Under existing regulations, APHIS will require similar permit restrictions for live animals [48].

APHIS also considers the observation that disease can move relatively large distances (100 km) without obvious explanation to be a significant risk factor. However, this is likely to constitute more of a risk for Member States immediately adjacent to affected areas such as Northern Ireland, the Netherlands, and France. Therefore, this issue will be considered as it applies to individual Member States that are immediately adjacent to Member States with a relatively high virus load.

Risks factors applicable to individual Member States

APHIS evaluated information provided for each Member State to identify specific risk factors that apply at the Member State level. A summary of the overall factors identified for each Member State in the previous section that could be characterized as a risk factor for that Member State is reiterated here. Where relevant, an explanation for excluding them for consideration is provided for Member States that APHIS did not consider for regionalization.

Austria [29]

- No specific risks factors were identified.

Belgium [30]

- Belgium borders with France (last case March 23, 2001) and the Netherlands (last case April 22). The areas under restriction in The Netherlands are less than 100 km away from the border. No significant natural barriers exist.

Denmark [31-35]

- No specific risk factors were identified.

Finland [36, 37]

- No specific risk factors were identified.

France [23-26]

- France has had two outbreaks. The last was on March 23.
- At a minimum, APHIS intends to apply the OIE criterion for a 3 month waiting period after the last diagnosis of disease before restrictions on the entire country may be lifted. At the time of this evaluation, France did not meet this criterion. However, it may be possible to regionalize to smaller administrative units with appropriate verification.

Germany [38, 49]

- Germany shares borders with the Netherlands (last outbreak on April 22, 2001) and France (last outbreak on March 23, 2001).
- Germany imported feeder pigs from the Netherlands and sheep from the UK. Animals were traced and tested. Test results were negative.
- German test results have not been confirmed.

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

Greece [39, 40]

- Greece was not considered for regionalization because it was not considered FMD-free at the time of this evaluation. Revision of its status will require another publication of a separate rule.

Ireland [20-22]

- Ireland has had an outbreak. The outbreak occurred on March 22, 2001.
- At a minimum, APHIS intends to apply the OIE criterion for a 3 month period after the last diagnosis of disease. At the time of this evaluation, Ireland did not meet this criterion. However, it may be possible to regionalize to smaller administrative units with appropriate verification.
- Ireland is adjacent to Northern Ireland, where the disease occurring near the border spread up to 100 km without clear explanation.

Italy [41, 42]

- Swill feeding of swine is allowed under official control (Italy is not the only Member State that allows this, but the practice was documented in its submission).
- Italy shares a border with France.

Luxembourg [43]

- Luxembourg shares a border with France.

Netherlands [16, 27, 28]

- New outbreaks continued to occur up to April 22, 2001. OIE criteria for FMD-free status are not met.
- A vaccination program has begun.

Portugal [44, 45]

- No specific risk factors were identified.

Spain [46]

- Spain shares a border with France.

Sweden [18, 47]

- No specific risk factors were identified.

United Kingdom - Northern Ireland

- The United Kingdom (including Northern Ireland) was not considered for regionalization, not only because outbreaks continued to occur at the time of this evaluation but also because APHIS had previously published an interim rule recognizing the region as FMD-affected. Revision of its status will require publication of another rule. The FMD status of the UK will be addressed separately.

Risk Rating

From its summary of the information provided or known for each Member State (e.g., legislative action; trade statistics; traceback, surveillance and control activities; outbreak history), APHIS selected factors that might contribute to the risk associated with the region. APHIS evaluated these factors for individual Member States. In the final evaluation, APHIS considered an occurrence of an outbreak in a Member State to be the most critical risk factor for that Member State, although, during its evaluation, APHIS concluded that might be possible to regionalize to smaller administrative units after a site visit is conducted.

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

Because of the importance of an FMD outbreak in the country, APHIS considered the higher risk Member States as France, Ireland, and the Netherlands. The situation in the Netherlands may require a longer period to resolve because of the vaccination program that has been initiated.

APHIS considered the risk of borders shared between unaffected and affected Member States. Germany and Belgium share borders with the Netherlands and France. Italy, Spain, and Luxembourg share a border with France. However, since the outbreaks in France were more than 100 km from the borders, border controls have been instituted, and new outbreaks have not occurred in France since March 22, 2001, APHIS did not consider a shared border with France as a high risk factor for Italy, Germany, Luxembourg, and Spain.

Germany and Belgium share borders with the Netherlands. Although the outbreaks in the Netherlands were not separated by a distance of 100 km from the borders, other mitigations applied to the Member States. In this regard, Belgium and Germany conducted tracebacks and surveillance of imported animals and instituted border controls. In addition, an outbreak has not occurred in the Netherlands since April 23.

APHIS understands that supporting documentation for test results from Germany have not been provided and the results have not been confirmed at reference laboratories [49]. Although this may be a cause of some concern, further evidence would be necessary for APHIS to justify assigning Germany to the higher risk category at this time.

APHIS notes that Italy reported that it allows swill feeding. However, although some Member States have banned it, other Member States still allow swill feeding. Since the practice is routinely conducted under official control and is regulated by Community legislation [50], APHIS does not consider the practice sufficient to require assignment of a Member State to the higher risk category.

A team of staff officers from APHIS, Veterinary Services, evaluated the risk factors and developed a consensus opinion on the relative risk for individual Member States. In the absence of specific criteria to assign risk levels, risk categories applied were "lower" and "higher." Based on its evaluation of the information available, APHIS was unable to identify a risk factor or factors that would justify a higher risk rating in Member States that had experienced no outbreaks. The following table summarizes the final categorization.

Table 2: Risk Classification of Individual Member States

Lower	Higher
Austria	France
Belgium	Ireland
Denmark	Netherlands
Finland	
Germany	
Italy	
Luxembourg	
Portugal	
Spain	
Sweden	

**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

For practical purposes, since some Member States were assigned a relatively low risk category with regard to likelihood of exporting infected animals or products to the US, the assessment concluded at this point. This is allowed by OIE guidelines [13].

Exposure analysis: Risk of introduction into the United States

In part, because insufficient data were available, APHIS did not conduct a separate exposure analysis.

Consequence analysis: Estimate of consequences if FMD were to be introduced

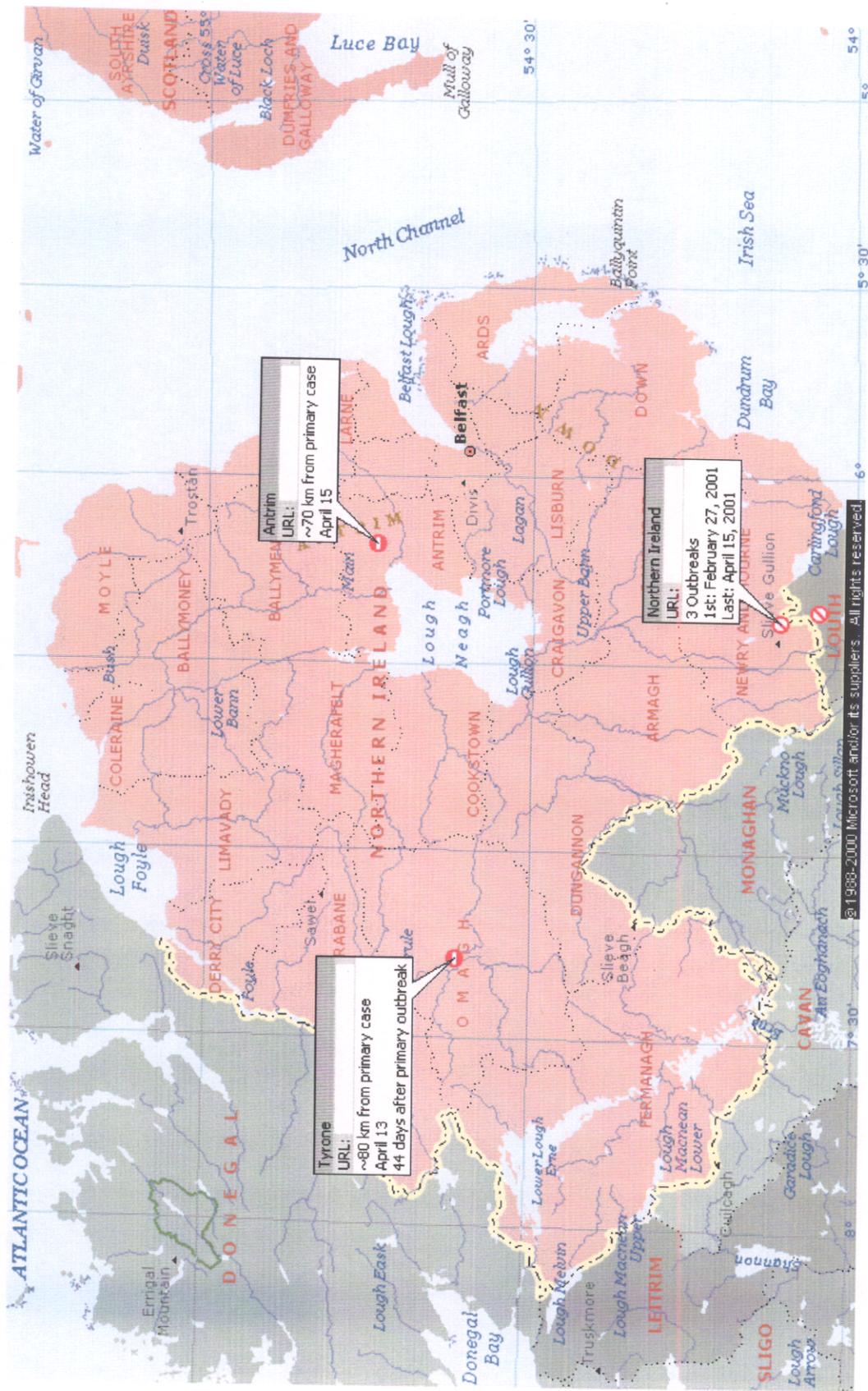
A specific analysis of consequences of FMD introduction into the US was not included in this evaluation. However, it is obvious that economic consequences at the producer level, consumer level and loss of trade would be devastating.

Risk Estimation

APHIS bases its final risk estimation on the results of the release assessment for states associated with lower levels of risk. It did not attempt to conduct a precise risk estimation on Member States associated with higher levels of risk or regionalize to smaller administrative units at this time.

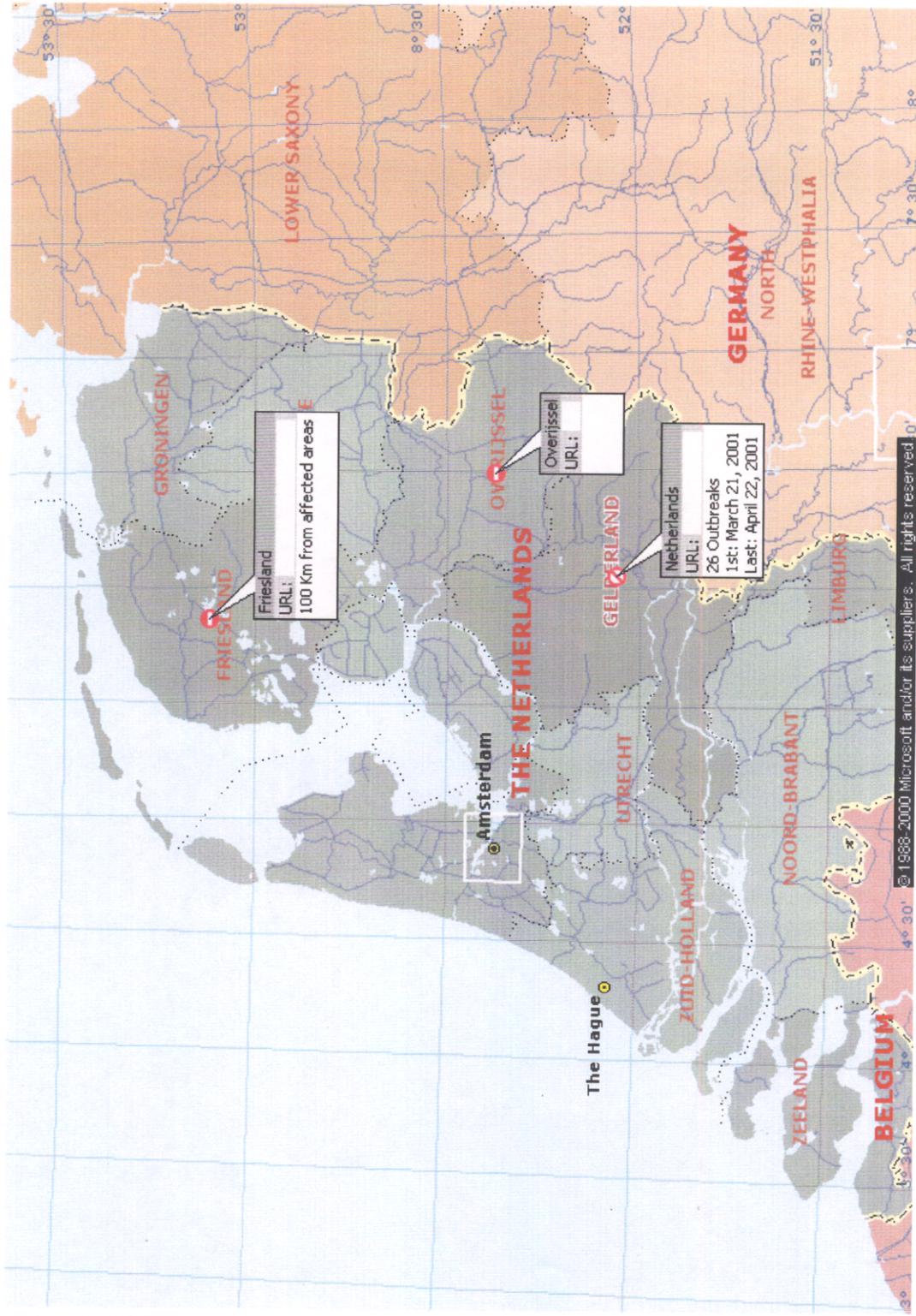
FMD Risk Assessment for the Export of Animals and Animal Products from European Union Member States to the United States
May 2001

Figure 2. FMD in Northern Ireland



FMD Risk Assessment for the Export of Animals and Animal Products from European Union Member States to the United States
May 2001

Figure 3. FMD in The Netherlands



**FMD Risk Assessment for the Export of Animals and Animal Products from European
Union Member States to the United States
May 2001**

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May 2001

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May 2001

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