Risk assessment and risk regionalisation, based on the surveillance system for foot and mouth disease in South America

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Summary
Within the framework of the International Animal Health Code of the Office International des Epizooties (OIE), important contributions have been made by the Animal and Plant Health Inspection Service/United States Department of Agriculture (APHIS/USDA), the Ministry of Agriculture of Canada, the Ministry of Agriculture and Fisheries of New Zealand and other organisations, by the development of risk assessment methods and regionalisation criteria for risk assessment. The authors attempt to contribute to these efforts by proposing a regional risk evaluation of foot and mouth disease (FMD) in South America. Two examples of risk assessments for international trade, i.e., in bovine embryos and in meat, are used to demonstrate the importance of an effective disease surveillance system as the basis for risk regionalisation for international trade in animals and animal products. As a result of progress in the control and eradication of FMD in South America, it is expected that major livestock production regions will soon be in low- to very low-risk categories.

Keywords

Introduction
The past decade has been characterised by the strengthening of trading policies and international economic relations based on the competitive advantages of countries and market economies. The Uruguay Round of the General Agreement on Tariffs and Trade (GATT), the World Trade Organisation (WTO) and the formation of trading blocks are manifestations of such negotiations. These new realities have important repercussions on the global trade in products of animal origin. With the increase in levels of international trade in these products, there is a need to review plant and animal health regulations with regard to their transparency, consistency, equivalency and harmonisation.

Under the rules of the WTO and agreements such as GATT, it will no longer be justifiable to quote health requirements per se as reasons for non-tariff trade barriers. Trading policies for
animals, for animal products and for many other commodities will depend largely on risk management which, in turn, must be founded on risk assessments which are consistent, transparent and founded on valid scientific evidence. In regard to animals and their products, the Office International des Epizooties (OIE), based in Paris, France, has been designated by the WTO as the scientific reference body for trade disputes. As such, the OIE may be called upon in the future to arbitrate on the validity of risk assessments.

Quantitative risk assessment is a rapidly developing technique, which has been used for many years in engineering, economics and finance (7, 11), and its use in veterinary medicine (1, 3, 5, 6, 8, 10, 12) as a tool to facilitate global movement of animals and animal products is expanding rapidly. Moreover, this technique provides sufficient assurance of the protection of the animal health status of disease-free countries.

Each assessment begins with the identification of a hazard, e.g., the introduction of a specified foreign animal disease through an importation of animals or animal products (7, 10). Next, a pathway of potential risk events is traced from the point of origin to the final destination of the animals or products. At each potential risk event along the pathway, the following questions are asked:

- what can go wrong?
- how probable is it that this will happen?
- what are the consequences?

The accumulation of the quantitative answers to these questions for each event on the pathway constitutes the measure of risk incurred by the importation (10).

Risk assessment, in the first place, depends on accurate information about the prevalence of the disease in the exporting country and on the reliability of the disease surveillance system in that country. Risk assessment also makes use of various disciplines such as epidemiology, statistics, pathology and microbiology. Expert opinion or any other verifiable pertinent information may also be used to estimate the probability of the occurrence of any one of the adverse events on the scenario pathway. However, in order to ensure that a risk assessment is transparent for users, the information used must be carefully documented.

One example is a hypothetical importation of animals in which three events on the pathway determine the risk of introduction of disease into an importing country: isolation of the animals on the farm of origin, quarantine and diagnostic tests during that quarantine.

If the disease is detected during isolation on the farm, the export will be cancelled. However, there remains a possibility that the disease agent is present without being expressed. What is the risk or probability of this occurring (\(P_3\))? The next risk is that of a similar failure at the quarantine station. There is a possibility that the disease agent is present, but that none of the animals or their sentinel contacts shows clinical signs. The probability of this event occurring is \(P_2\). Finally, there is the risk or probability (\(P_3\)) that diagnostic tests fail to detect the disease agent. The probability that the disease agent slips through the complete import procedure is \(P_1 \times P_2 \times P_3\). Suppose the values for these probabilities are 10%, 2% and 5%, respectively. The final risk estimate is \(0.1 \times 0.02 \times 0.05 = 0.0001\). Thus, according to this very simple model, there is a chance of only one in 10,000 that the disease agent would not be detected during the importation procedures.

Based on a similar but much more developed model, the Pan American Foot and Mouth Disease Center (PANAFTOSA) has produced two risk assessments. One concerns the risk of disease transmission through bovine embryos from a country with foot and mouth disease (FMD) (20). The other concerns the risk of introducing FMD into the Caribbean region through meat from selected regions of South America (18).

**Risk analysis of bovine embryos from a region infected with foot and mouth disease**

Foot and mouth disease virus in cattle is among several disease agents categorised as 'agents for which sufficient research evidence has accrued to show that the risk of disease transmission by embryo transfer is negligible, provided that between collection and transfer the embryos are handled as recommended by the International Embryo Transfer Society' (2, 19). Even though it is accepted that embryo transfer is the safest method for moving animal genetic material, progress to relax regulations permitting legal movement of embryos between countries with a different animal disease status has tended to be slow. A possible reason for the apparent reluctance of some national veterinary authorities to relax requirements for the importation of embryos may be that the term 'negligible risk' has not been precisely defined.

To evaluate the risk of disease transmission by embryo transfer, a scenario pathway must cover at least the following probabilities of risk:

- the specified infectious disease is present in the region in which the embryos are collected
- the disease is present on a donor farm
- the animal health surveillance system fails to detect the presence of the disease on the donor farm
- the embryo collection team fails to detect the infection on the donor farm
- the infectious agent contaminates embryos while they are in the genital tract of the donor

\(P_3\)
- the embryo collection team fails to detect that embryos have a non-intact zona pellucida, the membrane which surrounds the embryo and which is an effective barrier against micro-organisms
- the embryos are inadequately washed
- some residual infectious agent adheres to adequately washed embryos
- the disease is not detected on the donor farm while the embryos are in storage pending export
- laboratory tests on collection fluids from infected donors fail to detect the infectious agent.

To evaluate the risk assessment model, a hypothetical batch of 200 embryos was collected for export from Zebu cattle on farms in an FMD-endemic region. The region is an important source of quality Bos indicus genetics for the Western Hemisphere and is served by an effective surveillance system. Many estimates had to be made to test the model realistically, but all were based on published scientific data or on the opinions of experts. An important conclusion which emerged from this exercise was that there are three main levels of defence against the introduction of an exotic disease, such as FMD, by embryo transfer. These levels are as follows:

- the first line of defence encompasses the disease risk situation in the exporting country or region, the health status of the farms and donor cows from which the embryos are collected, and the pathogenesis of the specified disease agent
- the second line depends on the use of accepted standards for handling and processing embryos by the embryo collection team (13, 19). In this case, the risks involved are related mainly to the possibility of human error and to the competence and integrity of the embryo collection team
- the third line of defence includes post-collection surveillance of the donors and donor farms. This line also includes the testing of embryo collection fluids for the presence of the disease agent. This defence line is very important, but the resulting risk reduction may vary according to the disease under consideration.

Details of the risk estimates and on the calculation of this risk assessment have been published recently (20). In the final analysis, the predicted probability that one or more FMD-contaminated embryos would be included in the batch of 200 embryos from the selected region is of the order of one in one hundred billion ($10^{-11}$).

It is of interest that the predicted probabilities of failure at each of the three lines of defence differed substantially in magnitude. The first line of defence has a most likely probability of failure of one in a million ($10^{-6}$). The probability of failure at the second line is one in a hundred ($10^{-2}$). Thus, the possibility of 'human error' during embryo handling and processing is very high, making strict adherence to International Embryo Transfer Society regulations extremely important. At the third line of defence, comprising post-collection surveillance and the testing of collection fluids, the risk of failure has a probability of one in one thousand ($10^{-3}$).

The risk of foot and mouth disease from Argentinean and Uruguayan meat for the Caribbean

In response to the recommendations made at the meetings of the Technical Group of FMD-free countries of the Caribbean sub-region, held in Jamaica, October 1991 and in Barbados, October 1992, a quantitative risk assessment was undertaken to determine the risk of introducing FMD into the Caribbean region through the importation of frozen deboned meat cuts from Argentina or Uruguay. This study (18) has been a collaborative effort between PANAFTOSA and the Tuskegee University School of Veterinary Medicine (TUSVM).

The study has two components, as follows:

- the country of origin: in relation to Veterinary Services, epidemiology, regionalisation, FMD ecosystems, cattle movement, abattoir practices, meat inspection, meat processing and survival of FMD virus (FMDV) during processing and transport
- the receiving country: in relation to import controls, Veterinary Services, disease emergency preparedness, financial, social and economic consequences of a disease emergency, animal health legislation, containment and destruction of infected materials (such as in incinerators, landfills, etc.).

The risk assessment conducted by PANAFTOSA and TUSVM for the first phase was based on the norms and procedures for the importation of deboned frozen meat established by the European Community (EC). This protocol has been very effective, in that deboned frozen meat from millions of cattle has been imported by EC countries, even during extensive outbreaks of FMD in South America, without introducing the disease. During this period, more than a million tons of deboned frozen meat were imported by the United Kingdom, which remained free of FMD.

The region selected for consideration consisted of Uruguay and three provinces of Argentina, collectively known as Mesopotamia. As with the previous study on embryos, the epidemiological situation of the region where the meat originates is the very first consideration for a sound risk assessment. The South American countries within the River Plate Basin FMD Eradication Project have made significant progress in the control and eradication of the disease (15, 16, 17). For instance, Uruguay had not recorded FMD in the
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The FMD-free status of Uruguay was based on the absence of clinical disease, particularly among susceptible livestock populations of young bovines, unvaccinated sheep which graze with the cattle, and unvaccinated pigs. The absence of FMDV in the livestock population was further substantiated by serological surveys in calves and sheep, using the virus infection-associated test (EITB) tests developed at PANAFTOSA. These tests have the advantage of discriminating between vaccinated and convalescent animals (4).

The epidemiological situation in Mesopotamia is also very favourable. The cattle population is vaccinated systematically with oil-adjuvanted FMD vaccine and the region has not reported any cases of FMD for several years. The last case of FMD in the province of Misiones occurred in 1991, while FMD was last reported in the provinces of Corrientes and Entre Ríos in 1992. As in Uruguay, there is a substantial susceptible livestock population consisting of young bovines, unvaccinated sheep and pigs, which would be effective sentinels for any FMD viral activity. In addition, the results of serological surveys of young cattle and sheep indicate the absence of FMDV in the region.

As Mesopotamia and Uruguay have not reported FMD for several years, the risk of FMD from meat importation by Caribbean countries might arise from an eventual re-introduction of the disease into Uruguay or Mesopotamia. This probability was evaluated qualitatively for the most part, and it was concluded that the chance of re-introduction is small. However, the risk assessment was still based on the assumption that a re-introduction could occur.

In the absence of firm import estimates, the risk assessment was based on a yearly importation of 100 tons of prime cuts of beef. The following probabilities by which FMDV could enter the meat supply chain were considered:

- that FMD exists in the cattle population of the region (P1)
- that at least one source herd with FMD is included (P2)
- that the Animal Health Attention System fails to detect FMD in a source herd (P3)
- that there is a failure to detect FMD in the source cattle during transit to the abattoir (P4)
- that there is a failure to detect FMD during ante-mortem inspection of the source cattle or of all other herds present in the abattoir pens (P5)
- that there is a failure to detect FMD during post-mortem inspection of the source cattle or of any other cattle at the abattoir (P6)
- that FMDV survives in the meat of at least one carcass following chilling/maturation and deboning (P7)
- that FMDV survives freezing and transportation to the importing country (P8).

The probability that 100 tons of meat contain meat from at least one FMD-infected carcass equals \( P_1 \times P_2 \times P_3 \times P_4 \times P_5 \times P_6 \times P_7 \times P_8 \).

Solving this equation, provided that the meat is obtained in accordance with the EC directives, results in a prediction that the probability is less than one in a billion \((10^{-10})\) that 100 tons of prime cuts of meat contain FMDV. This extremely low risk for Caribbean countries, in combination with the low probability that FMD has been re-introduced into the exporting regions, makes the total import risk for deboned meat from Mesopotamia or Uruguay exceedingly small.

A report on the results of the quantitative risk assessment contains detailed information on the scenario pathway, probability estimations, calculations and documentation (18).

**What was learned from making these risk assessments**

In the first place, such risk assessments showed the necessity of considering the whole chain of events, from the origins of the product to the destination. For instance, the embryo transfer industry maintains, based on scientific data, that washed embryos can safely be moved internationally. But the regulatory veterinarian may object, asking how he or she may be sure that the washing was conducted correctly. The weakness of each of these approaches is that each party is considering only one link in the chain of events. Neither the embryo transfer industry nor the regulatory veterinarian realises that each link in the chain provides a certain level of protection against disease transmission, and that it is the total scenario which determines the safety of the importation.

Similarly, in respect to the trade in meat from FMD-infected countries, it is not only the deboning and maturation of the meat which is important. Overall safety results from an efficient animal health surveillance and information system and from effective procedures in the selection of herds and at the abattoirs.

It has also been learned that certain steps in the chain of events are much more important than others, and that a risk assessment highlights the points at which risk reduction measures might be most cost-effective.

An important aspect of risk analysis is communication of such risks to those who make the decisions based on the risk assessment information. This proved to be a major challenge. For example, in this case, potential users of the results of
Embryo risk assessment usually have very different backgrounds. Members of the embryo industry are interested principally in the production of valuable, good-quality, viable embryos and in developing new markets. Some of these people may not have a strong background in infectious disease control. At the same time, regulatory veterinary officials in the exporting and importing countries may not be fully aware of all the details of the embryo transfer procedures, which cumulatively determine the safety of the embryos. Veterinary officials are often comfortable with a zero-risk policy and are reluctant to change regulations that seem to have worked well for a long time. Somewhere in between is the desire of the livestock industry to market or to obtain superior genetic material, whether this be legally or illegally.

A risk assessment must be transparent, consistent and well documented. It must include discussion on the pathogenesis and epidemiology of the disease and on the procedures to which an animal product is submitted. Only then can regulatory officials use such an assessment to make policy decisions or to address effectively such different user groups.

Quantitative risk analysis should not be simply an academic exercise, but a tool to facilitate global movement of animals and animal products. Such analysis should open up new markets, while also providing adequate protection for the animal health status of disease-free countries. Given the importance of the first line of defence, it is essential to have detailed and reliable epidemiological information and characterisation of the disease situation in the region where the product originates. Therefore, risk analysis for the international trade in animal products is intimately related to disease surveillance systems and to regionalisation.

Vesicular disease surveillance and regionalisation

The Continental Animal Disease Surveillance and Information System co-ordinated by PANAFTOSA is an important instrument for risk analysis and regionalisation, as reliable information is essential in determining the quality of risk analyses. Based on the information obtained from this system, the authors have attempted to divide South America into different regions with regard to FMD risk. The letters A to D will be used to denote the different FMD status of each region, where A indicates the lowest FMD risk for an importing country and D, the highest risk. The criteria used for this regionalisation are shown in Table I. It should be noted that such classification is a continuous dynamic process.

It should also be noted that this risk regionalisation is intended to show the levels of risk in regard to the international trade in animals and animal products. Risk regionalisation is not the same as the regionalisation of FMD ecosystems, based on FMD epidemiology and livestock production systems, which has, as an objective, the development of strategies for FMD control and eradication programmes. However, the evolution of FMD ecosystems is closely related to such risk regionalisation. As these ecosystems are transformed from areas in which FMD is endemic to FMD-free areas, the risk in such regions will tend to approach zero.

The primary consideration is the length of time for which clinical cases have been absent, and whether or not FMD vaccination has been used. In regions classed A, FMD must not have occurred for at least 5 consecutive years, vaccine must not have been used for at least 1 year and an FMD-prevention programme must be in operation. The next consideration is the FMD situation in the surrounding regions. For instance, A regions which share borders with regions classified as C or D, but which are separated from the latter by natural or by artificial barriers.

In regions classed as B, FMD vaccination is used with the objectives of eradicating the disease, and a prevention programme must be in place. In B class regions, FMD must not have occurred for at least two years; at the B level this period is between one and two years. In order for a region to be classified as B, there must be sufficient evidence, obtained by survey methods or otherwise, to demonstrate the absence of viral activity in the livestock population.

Table I
Classification of the risk of foot and mouth disease (FMD) in regions of South America

<table>
<thead>
<tr>
<th>Classification</th>
<th>Occurrence of FMD</th>
<th>Viral activity</th>
<th>Vaccination</th>
<th>Programme objectives</th>
<th>Bordering regions</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>No FMD &gt; 5 years</td>
<td>No</td>
<td>No</td>
<td>Prevention</td>
<td>A2, A3, B1</td>
</tr>
<tr>
<td>A2</td>
<td>No FMD &gt; 3 years</td>
<td>No</td>
<td>No</td>
<td>Prevention</td>
<td>A3, B2, B3</td>
</tr>
<tr>
<td>B1</td>
<td>No FMD &gt; 2 years</td>
<td>Insignificant</td>
<td>Yes</td>
<td>Eradication and prevention</td>
<td>C, D (a)</td>
</tr>
<tr>
<td>B2</td>
<td>No FMD for 1-2 years</td>
<td>Not known</td>
<td>Yes</td>
<td>Eradication and prevention</td>
<td>C, D (b)</td>
</tr>
<tr>
<td>C</td>
<td>Sporadic FMD</td>
<td>Yes</td>
<td>Yes</td>
<td>Advanced control</td>
<td>D</td>
</tr>
<tr>
<td>D</td>
<td>Endemic FMD</td>
<td>Yes</td>
<td>Yes</td>
<td>Control</td>
<td></td>
</tr>
</tbody>
</table>

a) Requires natural barriers
b) According to serological and virological surveys
C class regions must experience only sporadic cases of FMD and these regions must have an advanced control programme with the aim of eradicating the disease. Regions classified as D are those in which FMD is endemic, but which have a control programme based on strategic FMD vaccination.

Using such classifications, the map in Figure 1 shows how this regionalisation would have looked in 1985. Most parts of Chile, Patagonia, Surinam and French Guyana would have been classified as A1. The Chocó region of Colombia, Guyana and the northern part of Chile are at the A2 risk level. The rest of the continent would be in the C or D categories. The map in Figure 2 illustrates the situation in 1995: the central part and the south of Chile, in addition to Patagonia, Surinam and French Guyana, are still A1, but Uruguay has been added to this group. Guyana, the Chocó region of Colombia and the north of Chile remain classified as A2, but large parts of South America, including a majority of the best cattle-raising regions, are now classified as B. Mesopotamia is a B1 region.

Table II shows this progress in terms of numbers of livestock and extension of the low-risk regions. It can be seen that, prior to 1988, there were just under 4 million cattle in 250,000 herds in regions without FMD. In 1993 these numbers increased to 13 million cattle in 310,000 herds, respectively. At the time this paper was written (December 1995), 94.8 million cattle in 1.33 million herds and at least some 52.5 million sheep inhabited regions which have been free of having been without FMD for more than two years. Paraguay, the rest of Argentina and the states of Rio Grande do Sul, Santa Catarina and the southern part of Paraná, Brazil, are classified as B2.

The remaining regions of South America remain at either the C or D risk level, but several of these areas have moved from D to C.
Table II
Progress of the control and eradication of foot and mouth disease (FMD) in South America

<table>
<thead>
<tr>
<th>Year</th>
<th>Absence of foot and mouth disease (totals in South America)</th>
<th>Regions in which foot and mouth disease is absent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior to 1988</td>
<td>Cattle: 3.9 million, Herds: 0.25 million, Km²: 1.6 million</td>
<td>Guyana, Surinam, French Guyana, Chile, Patagonia (Argentina), Choco (Colombia)</td>
</tr>
<tr>
<td>1993</td>
<td>Cattle: 13 million, Herds: 0.31 million, Km²: 0.174 million</td>
<td>Uruguay, 34 months without FMD, 9 million cattle, 26 million sheep</td>
</tr>
<tr>
<td>December 1995</td>
<td>Cattle: 94.8 million, Herds: 1.33 million, Km²: 4.906 million</td>
<td>Uruguay, 34 months without FMD, 18 months without vaccination, Argentina, 18 months without FMD, 55 million cattle, 18 million sheep, Brazil: Rio Grande do Sul, Santa Catarina, 22 months without FMD, 15 million cattle, 8.5 million sheep, 7 million swine, Paraguay, 14 months without FMD, 9.8 million cattle</td>
</tr>
</tbody>
</table>

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the disease for at least one year. If this favourable trend continues, major regions of South America will be classified in the low or lowest FMD risk categories and, it is to be hoped, will be in a position to safely export livestock products to the rest of the world.

Évaluation et régionalisation des risques, basées sur le système de surveillance de la fièvre aphtueuse en Amérique du Sud

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Résumé
Dans le cadre du Code zoosanitaire international de l'Office international des épizooties (OIE), le Service d'inspection zoosanitaire et phytosanitaire du Département de l'agriculture des États-Unis d'Amérique (APHIS/USDA), le ministère de l'Agriculture du Canada, le ministère de l'Agriculture et de la Pêche de Nouvelle-Zélande et d'autres organismes ont contribué à l'élaboration de méthodes d'évaluation des risques et à la définition de critères de régionalisation applicables à l'analyse des risques. Les auteurs s'inscrivent dans cette perspective en proposant une évaluation régionale des risques de fièvre aphtueuse en Amérique du Sud. À partir de deux exemples d'évaluation des risques associés aux échanges internationaux, à savoir les risques liés aux embryons et ceux liés à la viande bovine, ils démontrent l'importance d'un système efficace de surveillance sanitaire comme base de la régionalisation en matière de risques pour le commerce international des animaux et des produits d'origine animale. Compte tenu des progrès accomplis dans les domaines de la
Evaluación y regionalización de riesgos basadas en el sistema de vigilancia de la fiebre aftosa en América del Sur

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Resumen
Con la elaboración de métodos de evaluación de riesgos y la definición de criterios para la regionalización de estos riesgos, el Servicio de Inspección Zoosanitaria y Fitosanitaria del Ministerio de Agricultura de Estados Unidos (APHIS/USDA), así como el Ministerio de Agricultura de Canadá, el Ministerio de Agricultura y Pesca de Nueva Zelanda y otras instituciones han contribuido de forma notable a desarrollar las disposiciones del Código zoosanitario internacional de la Oficina Internacional de Epizootias (OIE). Con el propósito de sumarse a tal esfuerzo, los autores proponen una evaluación del riesgo regional de fiebre aftosa en América del Sur. Mediante dos ejemplos de evaluación de riesgos para el comercio internacional, concretamente los riesgos asociados a los embiones y a la carne vacuna, intentan demostrar la importancia que tiene un sistema eficaz de vigilancia sanitaria como base de una regionalización de los riesgos ligados al comercio internacional de animales y productos de origen animal. A la luz de los progresos experimentados por el control y la erradicación de la fiebre aftosa en América del Sur, cabe esperar que las principales regiones de producción ganadera queden adscritas muy pronto a las categorías de zonas de riesgo «bajo» e incluso «muy bajo».

Palabras clave
References


