

The risks posed by the importation of animals vaccinated against foot and mouth disease and products derived from vaccinated animals: a review

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Summary

The *Terrestrial Animal Health Code* of the OIE (World organisation for animal health) (the *Terrestrial Code*) makes recommendations for international movements of live animals and animal products because of a possible generic risk of foot and mouth disease (FMD) for these different commodities. For instance, international movement of vaccinated live animals or products of such animals is restricted due to the possible masking of clinical disease as a result of vaccination and to the perceived risk of persistently infected animals among vaccinated livestock.

In addition, bilateral agreements between exporting and importing countries on the importation of animal products can be based on the 'equivalence' of the animal health conditions in both countries, or on formal or informal risk assessments in accordance with the norms and recommendations of the *Terrestrial Code*. In this regard, an exporting country may be required to prepare a complete and transparent document describing the animal health situation, including the factors required to assess the risk involved. Furthermore, expert committees of importing countries regularly evaluate and verify these conditions in exporting countries. The level of confidence in the information obtained by the expert committee can then be entered into the risk analysis equation.

An important FMD risk reduction factor for the importation of animals and animal products is early recognition of the disease at the source of the commodity by alert stakeholders, such as official and private veterinarians and the chain of the livestock industry. This is true for all countries irrespective of their vaccination status.

The risk posed by the importation of vaccinated animals becomes negligible when an adequate protocol – in compliance with the norms and recommendations of the *Terrestrial Code* – is applied. However, recently, export of live animals from countries that do not practise vaccination has also proven to pose a significant risk and the rules governing such transport may have to be reviewed.

Disease surveillance, biosecurity at the farm level, traceability and control of the source cattle and slaughterhouse inspections are the main risk reduction measures for meat and meat products from vaccinated cattle. If these animals are slaughtered and processed under good management practice – in accordance with the norms and recommendations of the *Terrestrial Code* – these

products present a negligible risk for the introduction of FMD. Risk reduction by maturation and deboning is an important procedure, but is probably over-emphasised. Mechanical contamination of cattle carcasses with 'carrier virus' from the pharyngeal area during slaughter and processing is very unlikely.

Risk assessments showed that the importation of milk products from countries or zones that practise vaccination of dairy herds poses a negligible risk.

Risk assessments also demonstrated that the importation of bovine embryos from vaccinated cows – in accordance with the norms and recommendations of the *Terrestrial Code* – poses a negligible risk. Likewise, the risk from the importation of semen from vaccinated bulls is also negligible when an adequate test protocol is applied in accordance with the *Terrestrial Code*.

Keywords

Bovine embryo – Foot and mouth disease – Import risk – Meat – Milk – Risk assessment – Semen – Vaccination.

Introduction

The World Trade Organization (WTO) has designated the OIE (World organisation for animal health) as the body responsible for setting standards and developing guidelines for the safe international movement of animals, animal products and germplasm (42). These standards, for animal diseases such as foot and mouth disease (FMD), are detailed in the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) (26).

In these regulations, there are several restrictions to the international movement of animals and animal products from countries or zones where FMD vaccination is practised. The restrictions are based on the possibility that vaccinated animals and their products may contain FMD virus (FMDV), and thus may pose a risk when introduced into countries or zones that are free from FMD. However, events in 2001 demonstrated that animals originating from countries with the status 'Free from FMD without vaccination' may not be risk-free. The United Kingdom (UK) had that favoured status, but FMD was still introduced by live animals into France, Ireland and the Netherlands (40). A legitimate question therefore is how this risk compares to the risk of importing vaccinated animals or their products.

Risk assessment is an important tool for quantifying and comparing risks associated with imported animals and animal products (1, 11, 45). The aim of risk assessment is to provide importing countries with an objective and defensible method for assessing the disease risks associated with the importation of animals, animal products and animal genetic material. Once the risks are identified, management strategies can be formulated to protect the health of livestock in the importing countries. However, to be useful for the decision-making and regulatory processes, risk assessments must be transparent, well documented and easy to update.

Qualitative and quantitative pathway analysis can be used to assess the level of risk (1, 24, 45). Risk assessment commences with the identification of a hazard likely to be associated with a commodity at the origin, in this case FMD. A pathway is then traced of all the events to which the animal or product is subjected, from the origin in the exporting country to the likely exposure of susceptible animals in the importing country. The risk is eliminated if the disease is detected anywhere in the pathway or if the commodity is suitably processed to eliminate the virus. Conversely, if the virus remains in the pathway during all the events, then susceptible animals in the importing country may be exposed. The total likelihood of this occurring is calculated by multiplying all the probabilities that the virus remains undetected, or is not destroyed, by the various events in the pathway.

Trade in several commodities (the *Terrestrial Code* [26] definition of 'commodity' includes animals) is considered a potential vehicle for the spread of FMDV. In this paper, the authors discuss only those commodities that have significant political or economical influence on the decision-making and regulatory processes related to FMD. In sequence, the authors will address and compare the FMD risk posed by the importation of live animals vaccinated against FMD, the importation of meat, milk and milk products, and the importation of semen and embryos originating from FMD-vaccinated and non-vaccinated animals.

The *Terrestrial Code* recognises 'countries or zones free from FMD with vaccination' (26). Pursuant to Article 2.1.1.2 of the *Terrestrial Code*, these countries or zones must have a record of regular and prompt animal disease reporting as well as a system of intensive and frequent surveillance for detecting any viral activity. The vaccines used must comply with the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (25).

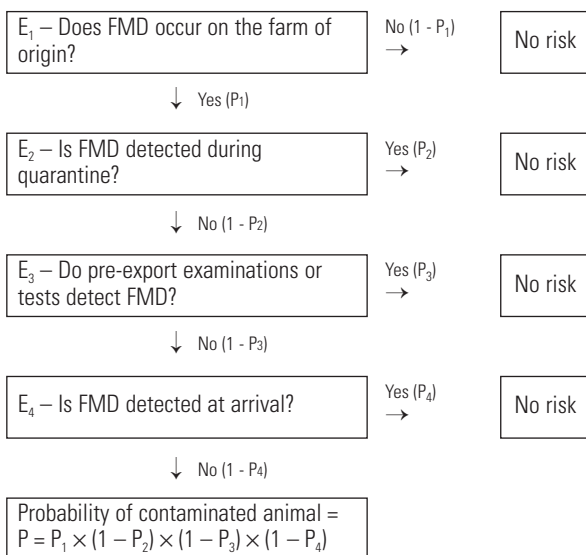
To be recognised by the OIE as 'free from FMD with vaccination', the countries or zones concerned must

demonstrate, to the satisfaction of the international animal health community, that their vaccination campaigns have resulted in the elimination of FMDV. When referring to ‘well-vaccinated herds’ or ‘attainment of high levels of herd immunity’ the authors mean this type of vaccination status and not the vaccination status of those parts of the world where insufficient vaccine coverage continues or where vaccines of doubtful quality are used. Furthermore, according to the understanding and experience of the authors, expert committees, as part of the evaluation, will verify animal health conditions, including the efficiency of the veterinary services, in the exporting countries. The level of confidence in the information obtained by such expert committees can then be entered into the risk analysis equation.

Live animals

When importing live domestic ruminants or pigs, the *Terrestrial Code* (26) recommends a series of risk reduction measures regarding the origin of the animals, such as pre-quarantine isolation, quarantine and diagnostic tests. Figure 1 illustrates a pathway for such importation of live animals from an FMD-infected country. In this example, four events determine the probability of disease introduction by the importing country, as follows:

- E₁ - isolation of the animals at the farm of origin
- E₂ - quarantine
- E₃ - results of diagnostic tests during quarantine
- E₄ - detection of FMD at arrival of the animals.



FMD: foot and mouth disease

Fig. 1
Scenario pathway for determining the risk that an animal is infected with foot and mouth disease

Should FMD occur at the farm of origin of the animal (E₁) and be detected at the source, the export will be cancelled. However, the disease may not have been expressed clinically or may not have been observed. The risk or probability of this occurring must be assessed. Similar failure to detect the disease may take place in the quarantine station (E₂). The FMDV may be present, but none of the animals or their sentinel contacts show clinical signs. The probability of this occurring must also be evaluated. Finally, diagnostic tests may fail to detect FMDV infection (E₃) and the disease may not be apparent at the arrival of the animals (E₄).

The probability (P) of the disease slipping through the complete import procedure is the product of probability P₁ and of the three probabilities of failure (1 – P₂, 1 – P₃, and 1 – P₄) to detect infection.

For E₁, the *Terrestrial Code* (26) requires the presentation of an international animal health certificate for all animals stating that the animals showed no clinical signs of FMD on the day of shipment. For domestic ruminants and pigs from FMD-infected countries or from FMD-free countries that practise vaccination, there are also requirements concerning the animal health status of the country and the farm of origin and the length of time the animal has to remain in the country prior to export.

For FMD-free countries (with or without vaccination), there are no requirements for E₂. However, for countries or zones that practise vaccination, the *Terrestrial Code* (26) requires, in addition, that export animals not be vaccinated and show a negative response to tests for antibodies against FMDV (E₃).

If risk assessment criteria are used, the following must be considered to determine the risk posed by the importation of vaccinated live animals from countries that practise vaccination:

- vaccination may mask clinical disease and therefore evidence of infection
- vaccination with an inactive antigen alone cannot give rise to the carrier status; a vaccinated animal must be exposed to active FMDV to become a carrier
- vaccination suppresses or eliminates the amount of FMDV (released or discharged) in the environment with the result that carriers are less likely to be induced in vaccinated herds
- carriers among vaccinated cattle have not caused FMD outbreaks among susceptible non-vaccinated livestock populations such as young cattle, sheep and pigs, nor have they hampered FMD eradication efforts (40)
- tests to differentiate between vaccinated non-infected herds and infected herds are presently available (40).

Risk is principally determined by factors such as the efficacy of the animal health system and border controls, passive and active disease surveillance, traceability of animal movements, as well as the awareness and alertness of official and private

veterinarians, of the production chain and of the agricultural community as a whole. In addition, the efficacy with which routine vaccination is conducted, i.e. attainment of high levels of vaccine coverage and herd immunity must be considered. As stated above, importing countries should verify and evaluate these conditions in the exporting country before authorising the importation of live animals.

When these conditions are found to be favourable and when an adequate protocol is applied in compliance with the *Terrestrial Code* (26), the risk ($P = P_1 \times [1 - P_2] \times [1 - P_3] \times [1 - P_4]$) posed by the importation of vaccinated animals is negligible.

Recently, the exportation of live animals from countries that do not practise vaccination has proven not to be risk-free (39). In these cases, failure to detect FMD infection at farm level (E_1) or at the time of arrival in the importing country (E_4) resulted in international movement of animals with pre-clinical or sub-clinical disease. These highly contagious stages of the disease were at the root of the recent dissemination of FMD in the UK, Ireland, France and the Netherlands. In addition, there were no risk reduction measures in place at the E_2 and E_3 levels. Vast numbers of non-vaccinated animals are moved internationally and consequently, these concepts require urgent attention as demonstrated by the trans-border spread of FMD that occurred in countries in Europe in 2001 and in the southern cone of South America in 2000 and 2001 (40).

Meat and meat products

Risk mitigation measures to reduce the risk associated with importing beef from countries affected by FMD consist of controls at the farm of origin, inspection of slaughterhouses and maturation and deboning of carcasses.

Importation of fresh meat of susceptible animals from countries or zones which are free from foot and mouth disease where vaccination is not practised

The *Terrestrial Code* (26) recommends that the source animals must be slaughtered at an approved abattoir and must have been subjected to ante-mortem and post-mortem inspections with favourable results.

Importation of fresh bovine meat (excluding feet, head and viscera) from countries or zones which are free from foot and mouth disease where vaccination is practised

The *Terrestrial Code* (26) requires the presentation of an international veterinary certificate attesting that the entire consignment of meat comes from animals which:

a) have been kept in the FMD-free country or zone where vaccination is practised since birth, or which have been

imported in accordance with Article 2.1.1.9, Article 2.1.1.10 or Article 2.1.1.11

b) have been slaughtered in an approved abattoir and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

According to Article 2.1.1.21 of the *Terrestrial Code*, if fresh meat or meat products of pigs and ruminants other than bovines originate from FMD-free countries or zones where vaccination is practised, the animals must not be vaccinated, and maturation and deboning is not required.

Importation of fresh bovine meat (excluding feet, head and viscera) from foot and mouth disease-infected countries or zones, where an official control programme exists, involving compulsory systematic vaccination of cattle

In addition to the above-mentioned rules, the *Terrestrial Code*, Article 2.1.1.22 recommends the following as regards the transport of cattle and conditions at the abattoir:

a) that source cattle be vaccinated at least twice with the last vaccination not more than twelve months and not less than one month prior to slaughter

b) that the cattle be kept in an establishment for the thirty days prior to slaughter and that FMD must not have occurred within ten kilometres during that period

c) that the meat come from deboned carcasses:

– from which the major lymph glands have been removed

– which, prior to deboning, were subjected to maturation at a temperature above + 2°C, for a minimum period of 24 h following slaughter, and in which the pH value of the meat was below 6.0 when tested in the middle of both *longissimus dorsi*.

Most of these regulations were adopted following the extensive FMD outbreak in Britain in 1968 (17), but have been submitted to continuous adjustments as reflected by the present *Terrestrial Code* (26).

Quantitative risk assessments were performed with regard to FMD for beef originating from South America and imported into the Caribbean and the United States of America (3, 4, 5, 27). These risk assessments used pathways similar to the one presented in Figure 2. The risk of beef being contaminated from an infected source herd with FMD ($E_1 = 1$, $P_1 = 1$) was determined in one study (5) by evaluating the probability that:

– the disease would not be detected at the source or during transportation of the animals to the slaughter plant (E_2)

– the ante- and post-mortem examinations would fail (E_3)

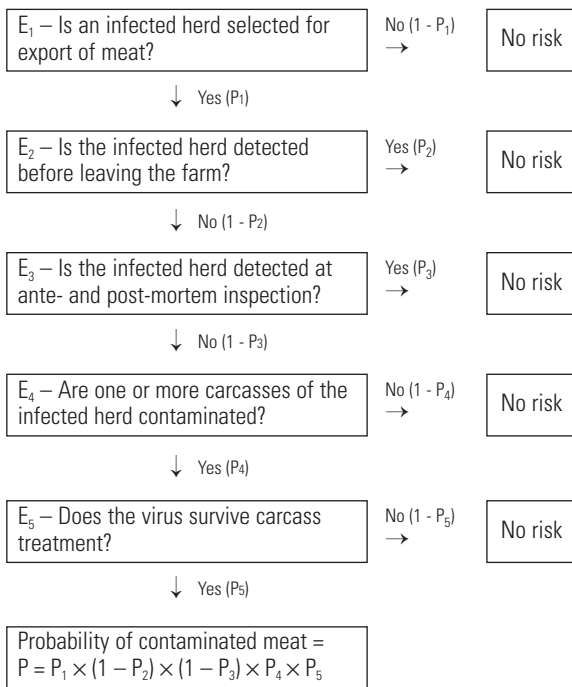


Fig. 2
Scenario pathway for the risk of meat being contaminated with foot and mouth disease virus

- one or more carcasses would be contaminated with FMDV (E_4)
- the virus would survive deboning, chilling and processing (E_5).

These assessments concluded that a very large risk mitigation factor ($P = P_1 \times [1 - P_2] \times [1 - P_3] \times P_4 \times P_5$) would be obtained by adhering strictly to *Terrestrial Code* (Articles 2.1.1.20-23) standards (26) or to European Union (EU) requirements (5) for the harvesting of beef for export. This conclusion is reinforced by the observation that frozen, deboned meat of many millions of vaccinated cattle was imported from South America to Europe according to the above regulations, without resulting in any outbreaks of FMD. Similarly, more than a million tonnes of deboned, frozen beef were imported into the UK (4, 5).

Using a similar pathway, Suttmoller (38) evaluated in detail the effect of OIE recommendations on the mitigation of the risks presented by meat from cattle with FMD for each of the different stages of the disease. The four disease stages considered were the incubation period, the period of clinical signs, convalescence and the carrier stage.

Efficient animal health systems, disease surveillance, and ante-mortem and post-mortem inspection of all source cattle effectively reduce the risk of FMDV transmission from cattle slaughtered during the period of clinical signs or convalescence

(E_1, E_2). However, because of the absence of clinical signs, these risk reduction measures fail if cattle are slaughtered during the incubation period (E_3). Cattle in this stage of the infection are likely to be viraemic, with FMDV present in skeletal muscles (E_4).

Maturation (E_5) of carcasses of viraemic cattle reduces the risk of viral presence in the beef. In addition, deboning and removal of the principal lymph nodes and large blood vessels (E_5) eliminate a FMDV source of contamination of the beef. However, in viraemic cattle, this elimination may not be complete (12) and in addition, virus in organs from these animals will not be affected by maturation and deboning.

An important aspect that seems to have been overlooked in the *Terrestrial Code* (26) is that maturation and deboning are only rational risk reduction measures if there is a probability of virus being present in the carcass, as occurs during viraemia. Another aspect not considered is the gross environmental viral contamination of the abattoir facilities where viraemic cattle are slaughtered, bled and processed (38). In such cases, the maturation process could even create a false sense of security.

Vaccination reduces FMD morbidity in cattle and thus decreases the risk of slaughtering viraemic cattle in the pre- or sub-clinical stage of disease. In addition, neutralising antibodies in vaccinated animals are probably the best guarantee for meat, blood, lymph nodes, bone marrow and organs being free of virus. Thus, the *Terrestrial Code* (26) recommendation that cattle from FMD-infected countries be vaccinated at least twice makes sense.

For vaccinated animals, an antibody test (for instance by enzyme-linked immunosorbent assay [ELISA]) of a blood sample at the time of slaughter could provide a high margin of assurance of the absence of virus from the carcass. This would probably not interfere any more with the meat processing than the presently required pH measurement of the meat in the middle of both *longissimus dorsi* muscles.

The risk of meat from carrier animals being contaminated, whether from cattle, sheep or goats, is negligible or close to zero, because these animals have high levels of antibody and do not have virus in the bloodstream, muscles, lymph glands or other organs (32, 33).

However, superficial, mechanical contamination of meat by virus present in the throat is a risk that must be considered. Suttmoller concluded that the risk of mechanical contamination of a cattle carcass with carrier virus from the pharyngeal area is negligible during slaughter and processing (38). With slaughter at industrial scale under good management practise norms, offal from the pharyngeal area of cattle is destroyed and the chance that pigs will be infected from this material is close to zero. Thus, the fear of mechanical contamination of a cattle carcass or organs with carrier virus from the pharyngeal area

during slaughter and processing is unfounded. However, extra precautions may be required in local abattoirs, particularly after an FMD epidemic.

Slaughtering procedures of small ruminants may vary in different parts of the world, but blood containing high levels of antibodies is likely to neutralise any free FMDV in the throat area during the bleeding of the animal. With non-industrial slaughter and processing of sheep and goats, the risk of mechanical contamination of carcasses with carrier virus in the pharyngeal area may be somewhat higher than with industrial procedures, but such meat is unlikely to enter international trade.

Milk and dairy products

In 1932, Terbruggen noted that an important epidemiological feature of the disease was that FMDV is excreted in milk (41). In experimental studies, Burrows demonstrated virus excretion in milk before the onset of clinical signs (9). Infected milk was shown to play a role in the spread of FMD in Great Britain during the 1967 to 1968 epizootic (15), particularly because infected cows excrete large quantities of virus in their milk before signs of the disease are observed (8, 10, 19). Persistence in the udder for periods as long as seven weeks has been shown only under experimental conditions after intra-mammary inoculation of fully susceptible (non-vaccinated) cows (10). Dilution of contaminated milk and pasteurisation in dairy processing plants do not guarantee the absence of FMDV in, for instance, skim milk or whey, which may cause secondary outbreaks in pigs or calves fed with these products.

Hyde and colleagues (20) and Leeuw and colleagues (22) demonstrated that virus in milk from infected cows was more temperature-resistant than free virus, due to protection afforded by the cells, proteins and fat in milk. The remarkable heat-resistance of FMDV in milk (7, 14, 20) suggested that conventional pasteurisation might be insufficient to inactivate the virus in milk and dairy products. These findings caused considerable concern among veterinary authorities of countries free from FMD. As a result, measures were taken to prevent the perceived risk attached to the importation of milk products from countries that are not considered free of the disease. These included countries where systematic vaccination against FMD of all cattle was carried out, even if no outbreaks had occurred for a number of years. This has resulted in serious obstruction of long established trade in milk products (21).

Donaldson reviewed factors for the transmission of FMD by milk and dairy products such as the quantities of virus excreted in milk, the survival of the virus under various management and manufacturing conditions and the minimum doses required to initiate infection in susceptible animals by different routes (16). His studies concluded that the risks must be

considered in terms of both the probable amount of infectious virus present in a product and the route by which animals might be exposed. According to Donaldson, too often in the past, these considerations have been either ignored or overstated, resulting in the imposition of unnecessary restrictions on trade (16).

Several investigators were unable to detect viraemia in immunised cattle exposed to FMDV infection (18, 23, 32). The FMDV is thus unlikely to reach the udders of exposed, immunised cows. Leeuw and colleagues were unable to isolate FMDV from the milk of vaccinated cows that were infected experimentally (21). Although the virus multiplied in the oropharyngeal tissues, no virus was detected in the milk of these animals. According to the researchers, vaccinated cattle exposed to FMD are unlikely to excrete virus in milk, and even if excretion did occur, the concentration of virus would not approach the levels observed when fully susceptible cows become infected. In addition, milk from healthy, vaccinated cows contains sufficient antibody to have a neutralising effect when mixed with milk from diseased animals. Investigators from the Netherlands found that bulk milk samples obtained from cows that had been vaccinated under field conditions inactivated 90% to 99% of FMDV (21).

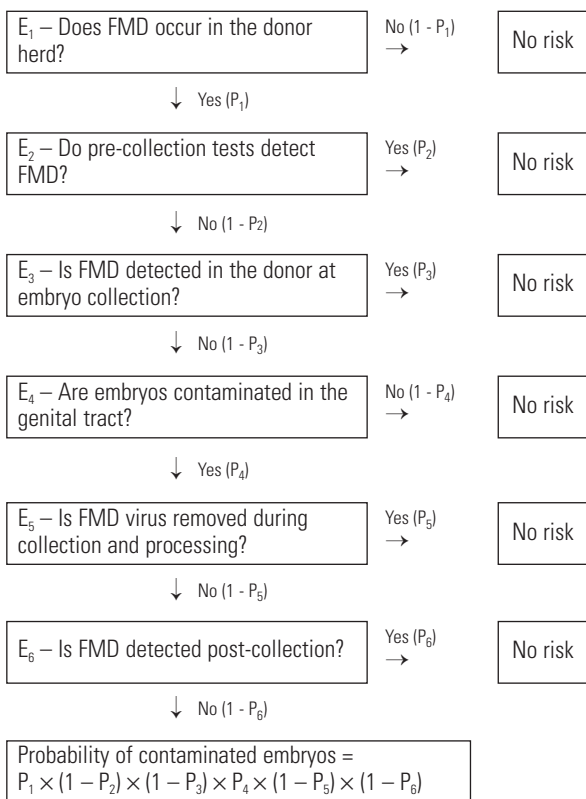
The probability of dissemination of FMDV by milk from vaccinated carriers is also close to zero because the virus does not persist in the udder, and milk from well-vaccinated herds contains neutralising antibodies. In addition to the normal processing procedures of milk that would inactivate the virus, pooled milk from an infected premise would be further diluted with antibody-containing milk from other vaccinated dairy farms during transport and processing.

Thus, considering all the above factors in a risk assessment, the importation of dairy products from countries with a programme of regular vaccination of the dairy herd, as stated previously, poses a negligible risk. This is supported by the notion that the importation of milk and dairy products from countries that practise vaccination has never been shown to cause FMD in livestock.

Bovine embryos

The Import/Export Committee of the International Embryo Transfer Society (IETS) has categorised FMDV as 'an agent for which sufficient research evidence has accrued to show that the risk of disease transmission by embryo transfer (in the bovine) is negligible, provided that the embryos are handled as recommended in the IETS *Manual* between collection and transfer' (2). Based on that classification, Articles 2.1.1.16-17 of the *Terrestrial Code* provide norms and recommendations for the importation of *in vivo*- or *in vitro*-derived bovine embryos, including those of vaccinated animals (26).

Sutmoller discussed some of the disease transmission risk factors related to bovine embryo transfer (34), and Sutmoller and Wrathall (35, 36, 37) attempted to quantify levels of FMD risk reduction that would be achieved by adhering to the recommendations of the IETS *Manual* (31). They used scenario pathways such as the one shown in Figure 3. The conclusion from those studies showed that three main lines or levels of defence exist against the introduction of diseases via embryo transfer.



FMD: foot and mouth disease

Fig. 3
Scenario pathway for the risk of embryos being contaminated with foot and mouth disease virus

The first line of defence (E₂-E₄) encompasses an evaluation of the disease situation in the exporting country and/or region, the health status of the farms and donor cows from which the embryos are collected and the pathogenic characteristics of FMD. The second line (E₅) depends on the use of accepted standards for handling and processing embryos, including washing the embryos ten times (31). The third line of defence (E₆) includes post-collection surveillance of the donors and donor farms, and also possible post-collection testing of embryo flushing and washing fluids for the presence of FMDV.

The geographical area chosen for the study of Sutmoller and Wrathall (36) showed a moderate level of endemic FMD (one herd with FMD per 1,000 herds per year). When routine risk reduction measures were applied, the probability that a batch

of 300 embryos contained one or more embryos contaminated with FMD proved to be in the order of one in 100 billion. This risk ($P = P_1 \times [1 - P_2] \times [1 - P_3] \times P_4 \times [1 - P_5] \times [1 - P_6]$) is close to zero for several reasons. For instance, embryos are very unlikely to be collected on farms with FMD because of the close contact of the professional embryo collection team with the donor herd and their knowledge of the health status of the donor cows. Handling and processing according to the recommendations of the IETS by accredited embryo collection teams will reduce any risk even further. Finally, donor cows can be observed for FMD during the time that the embryos are stored.

The authors stress that these considerations are valid both for vaccinated and unvaccinated donor cows. In addition, the carrier state is irrelevant with regard to the risk of FMD transmission by bovine embryo transfer because the probability that the virus would contaminate embryos – not counting virus removal by processing and handling – is extremely remote.

Unfortunately, the possibilities of salvaging valuable genetic materials by means of embryo transfer were not used during the 2001 outbreaks of FMD in the UK or the Netherlands. In the UK, the rapidity with which stamping-out (the killing of infected and contiguous herds) proceeded precluded the collection of embryos from valuable breeding stock or from rare breeds. In the Netherlands, although vaccination of all livestock in the vaccination zone provided somewhat more flexibility of action, two factors were decisive in ruling out the salvage of valuable genetic materials by embryo transfer, as follows:

- the wish to obtain the ‘FMD-free status’ at the earliest possible time by killing all healthy vaccinated livestock, and
- the prohibition of movement of any product of animal origin, including embryos, from the vaccination zone (Pluimers, personal communication, 2001).

Semen

Articles 2.1.1.14-15 of the *Terrestrial Code* (26) provide recommendations for the importation of semen of domestic ruminants and pigs from countries or zones where vaccination is practised. Important factors are the health status of the area, the donor animal, vaccination status, results of antibody tests for FMDV, and quarantine of the frozen semen post-collection.

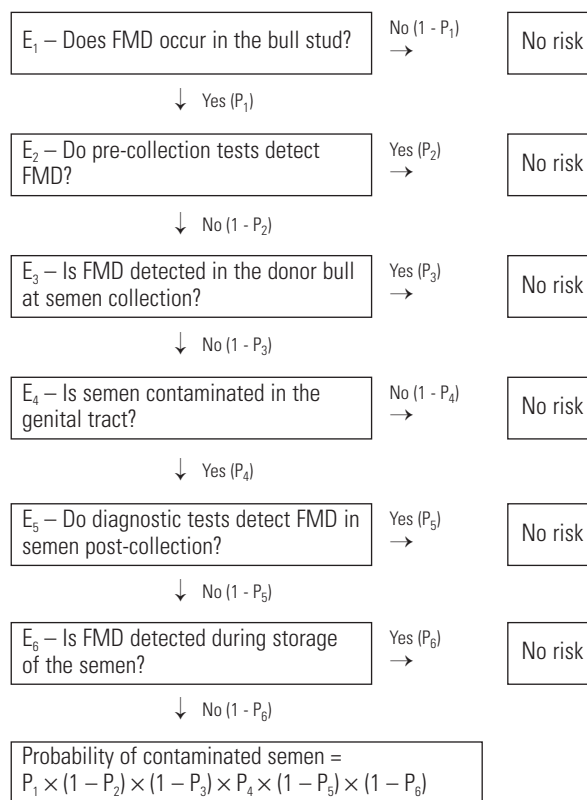
Cottral and colleagues reported large quantities of virus excreted in the semen of artificially infected susceptible bulls (13). Virus was already present in the semen at least 7 h before the development of clinical signs (13, 29), but not beyond day 8 post-inoculation (13). Cottral and colleagues were able to infect heifers with the contaminated semen by artificial insemination (13). According to Thomson (44), there is a statement in a discussion document to the effect that FMDV was detected intermittently in the semen of a bull for up to

forty-two days. As a general rule, FMDV recovery beyond twenty-eight days post-infection is considered viral persistence (32, 39, 40, 44).

Pustigliani claimed that seven of twenty-two bulls that had not suffered from FMD for at least six months had FMDV in their semen (28). There are no other reports either to support or contradict these findings. However, Bastos and colleagues suggested that sexual transmission of FMDV by African buffalo (*Syncerus caffer*) bulls to domestic cows could occur (6). They were able to isolate South African Territories (SAT) 3 virus from semen and sheath-wash specimens of three of twenty male buffalo in the Kruger National Park, where the majority of buffalo are persistently infected with SAT viruses in the throat. Foot and mouth disease is unique in sub-Saharan Africa, not only because three virus types, SAT 1, 2, and 3 are almost exclusively endemic to the region, but also because of the role which wildlife, particularly African buffalo, play in the epidemiology of the disease (43). Whether this special relationship depends on the SAT virus, on the buffalo or both is unknown. Therefore, whether these findings can be generalised to other virus types and other species or represent a specific SAT virus/African buffalo relationship remains to be determined. However, domestic bulls were incriminated in the few historical cases in which healthy, convalescent cattle were likely to have caused outbreaks in clean herds (40). If sexual contact were an important risk factor for FMDV transmission, this issue certainly warrants further investigation under strict biosafety conditions.

A scenario pathway for the estimation of the risk posed by semen is presented in Figure 4. For semen to pose a risk for an importing country, FMD must be present in the semen collection centre. In an unvaccinated bull stud, this would be a bull in the highly contagious pre-clinical or sub-clinical stages due to accidental introduction of FMD, for instance, by personnel or feed. However, routine health examinations (E_2 , E_3) probably would not miss clinical FMD in unvaccinated bulls. In a well-vaccinated bull stud, the virus could be present in the form of persistent infection. In the experience of the authors, sufficient virus is unlikely to be introduced into a semen collection centre approved for export to create a carrier among vaccinated bulls.

The probability of FMDV reaching the genital tract of a bull (E_4) is not the same for susceptible non-vaccinated bulls as for vaccinated bulls. In susceptible bulls that were infected, Cottral and colleagues showed that FMDV reached the genital tract before the development of clinical signs and could be detected in high concentrations in semen (13). In vaccinated bulls, circulating antibodies will block the virus from reaching the genital tract, even after contact exposure. Sellers and colleagues exposed vaccinated bulls to clinically diseased pigs and found no virus in the semen (30).



FMD: foot and mouth disease

Fig. 4
Scenario pathway for the risk of semen being contaminated with foot and mouth disease virus

While in storage (E_5), representative aliquots of semen can be tested for the presence of FMDV. The risk of dissemination of FMDV by semen is further reduced by observation of the health of the semen donors and the other bulls at the collection centre (E_6) after semen collection.

Thus, bovine semen is a low risk product, because of the following:

- the likelihood of FMDV exposure of bulls in semen collection centres is minimal
- bulls in FMD endemic or epidemic-affected countries will be well and regularly vaccinated and have high levels of protective antibodies
- bull studs are under constant veterinary control in semen collection centres
- semen can be tested for pathogens prior to export and bull studs can be observed for any change in health status.

Thus, if the probability of P_1 is very low and the probabilities of failure of $P_2 - P_6$ are low to very low, the risk of international movement of semen of vaccinated or non-vaccinated bull studs

is negligible ($P = P_1 \times [1 - P_2] \times [1 - P_3] \times P_4 \times [1 - P_5] \times [1 - P_6]$). The risks associated with semen from other species could be assessed in a similar manner.

Practical experience also proves that international movement of semen represents a low risk for FMD dissemination. While tens of thousands of doses of semen have been successfully imported by FMD-free countries from FMD-infected countries under stringent quarantine and test protocols, considerable quantities of semen from zebu cattle (*Bos indicus*) have also been smuggled from South America into FMD-free non-vaccinating countries in the Northern hemisphere without causing FMD in those countries.

Conclusions

Bilateral agreements that govern the safe international movement of animal products can be based on 'equivalence' of animal health conditions in the exporting and importing country, according to the norms and recommendations on

FMD of the *Terrestrial Code* (26). However, the international movement of vaccinated live animals and their products is restricted due to the perception that clinical FMD may be masked by vaccination or that vaccination may produce persistently infected animals. In this paper, risk assessment was used to evaluate and compare levels of risk related to the importation of vaccinated and non-vaccinated animals and their products.

One of the most important FMD risk reduction factors for the importation of animals and animal products is the early recognition of the disease at the source of the commodity by alert stakeholders, such as official and private veterinarians and the chain of the livestock industry. This is true for all countries, irrespective of their vaccination status. Risk assessment also demonstrated that the risk posed by the importation of vaccinated animals or their products is negligible when adequate protocols – in compliance with the *Terrestrial Code* (26) – are applied. ■

Étude des risques liés à l'importation d'animaux vaccinés contre la fièvre aphteuse et de leurs produits

P. Suttmoller & R. Casas Olascoaga

Résumé

Le *Code sanitaire pour les animaux terrestres* de l'OIE (Organisation mondiale de la santé animale), ci-après dénommé le *Code* terrestre, contient des recommandations concernant le transfert d'animaux vivants et de produits d'origine animale à l'échelle internationale. Ces recommandations trouvent leur justification dans l'existence d'un risque de portée générale de fièvre aphteuse lié à ces produits. Par exemple, les restrictions qui pèsent sur le transfert international des animaux vivants et des produits provenant de ces animaux s'expliquent par l'occultation possible des signes cliniques de la maladie du fait de la vaccination, et par la perception d'un risque lié à la présence d'animaux porteurs d'une infection persistante au sein du bétail vacciné.

De plus, les conventions bilatérales régissant l'importation de produits d'origine animale peuvent reposer sur l'existence de conditions zoosanitaires « équivalentes » dans les pays importateurs et exportateurs, ou sur des évaluations formelles ou informelles des risques, conformément aux normes et recommandations du *Code terrestre*. À cet égard, un pays exportateur pourrait être astreint à préparer en toute transparence un dossier complet sur sa situation zoosanitaire et à préciser les facteurs nécessaires à l'appréciation du risque. Par ailleurs, les comités d'experts des pays importateurs procèdent régulièrement à des évaluations et vérifications de ces conditions dans les pays exportateurs. Le niveau de confiance accordé aux informations recueillies par le comité d'experts pourra être pris en compte dans l'équation d'analyse des risques.

Le dépistage précoce de la maladie sur le lieu d'origine du produit par des acteurs vigilants (vétérinaires privés et officiels et professionnels du secteur de l'élevage, par exemple) constitue un important facteur de réduction des risques

de fièvre aphteuse lors de l'importation d'animaux et de produits d'origine animale. Ceci s'applique à tous les pays, indépendamment de leur statut en matière de vaccination.

L'importation d'animaux vaccinés présente un risque négligeable lorsqu'un protocole adéquat, conforme aux normes et recommandations du *Code terrestre*, est en vigueur. Toutefois, il s'est avéré récemment que l'exportation d'animaux vivants en provenance de pays ne pratiquant pas la vaccination présentait un risque significatif et que les règlements régissant ce transport devraient faire l'objet de réaménagements.

La surveillance des maladies, la biosécurité au niveau des élevages, la traçabilité et le contrôle des bovins à la source, de même que les inspections d'abattoir, figurent parmi les principales mesures de réduction des risques inhérents à la viande et aux produits carnés issus de bovins vaccinés. Le risque d'introduction de la fièvre aphteuse par le biais de ces produits est négligeable, pour autant que ces animaux soient abattus et transformés en respectant les bonnes pratiques de gestion ainsi que les normes et recommandations du *Code terrestre*. La pratique de maturation et de désossage des carcasses a un impact important, quoique probablement surestimé sur la réduction des risques. La contamination mécanique des carcasses de bovins par « virus porteurs », issus de la zone pharyngée au moment de l'abattage et de la transformation, est très peu probable.

L'évaluation des risques a également démontré que l'importation de produits laitiers en provenance de pays ou de zones pratiquant la vaccination des troupeaux laitiers présentait un risque négligeable.

Il en est de même des embryons de vaches vaccinées importés conformément aux normes et recommandations du *Code terrestre*. Le risque lié à l'importation de semences de taureaux vaccinés est également négligeable lorsqu'un protocole adéquat de tests a été mis en place, conformément au *Code terrestre*.

Mots-clés

Embryon de bovin – Évaluation des risques – Fièvre aphteuse – Lait – Risque lié à l'importation – Semence – Vaccination – Viande.



Repaso general de los riesgos ligados a la importación de animales vacunados contra la fiebre aftosa y de sus derivados

P. Sutmoller & R. Casas Olascoaga

Resumen

En el *Código Sanitario para los Animales Terrestres* de la OIE (Organización mundial de sanidad animal), o *Código terrestre*, se formulan recomendaciones sobre el movimiento internacional de animales vivos y productos de origen animal para paliar el riesgo genérico de fiebre aftosa ligado a todos esos productos. Se imponen limitaciones, por ejemplo, al desplazamiento internacional de animales vivos vacunados o sus derivados porque existe la posibilidad de que la vacuna enmascare síntomas clínicos de la enfermedad y porque se teme que entre los bovinos vacunados pueda haber ejemplares que sufren de infección persistente.

Por otra parte, los acuerdos bilaterales entre países exportadores e importadores relativos al comercio de productos animales pueden basarse en la 'equivalencia'

del estado zoonosario en ambos países o en procesos oficiales u oficiosos de determinación del riesgo, acordes con las normas y recomendaciones contenidas en el *Código terrestre*. En este sentido, cabe exigir a un país exportador que presente un documento en el que describa de forma exhaustiva y transparente el estado zoonosario, comprendidos los parámetros necesarios para determinar el riesgo que la transacción conlleva. Los países importadores cuentan además con comités de expertos que evalúan y verifican periódicamente el cumplimiento de esas condiciones por parte de los países exportadores. Ulteriormente puede incorporarse a la ecuación de análisis del riesgo un parámetro correspondiente al grado de confianza que merezca la información obtenida por el comité de expertos.

En las importaciones de animales y productos de origen animal, hay un factor que reduce considerablemente el riesgo de fiebre aftosa: la pronta detección de la enfermedad en el lugar de origen del producto por parte de determinados colectivos (por ejemplo veterinarios oficiales o privados o profesionales que formen parte de la cadena de producción bovina). Este principio es válido para cualquier país, con independencia de su situación en materia de vacunaciones.

El riesgo que entraña la importación de animales vacunados llega a ser insignificante cuando se aplica un protocolo apropiado, acorde con las normas y recomendaciones del *Código terrestre*. Sin embargo, recientemente se ha comprobado que la exportación de animales vivos desde países donde no se practican vacunaciones también entraña un riesgo significativo, lo que acaso indique la conveniencia de revisar las normas por las que se rige ese transporte. Las principales medidas para reducir el riesgo ligado a la carne y los derivados cárnicos de animales vacunados pueden resumirse en las siguientes: vigilancia sanitaria; seguridad biológica en la explotación; rastreabilidad y control del ganado de origen; e inspecciones en el matadero. Si en el sacrificio y procesamiento de esos animales se han aplicado buenas prácticas de gestión, acordes con las normas y recomendaciones del *Código terrestre*, el riesgo de introducción de fiebre aftosa que presentan es insignificante. La técnica de maduración y deshuesado es una medida de reducción del riesgo útil, aunque quizás no tan importante como se ha dicho. La probabilidad de que se produzca una contaminación mecánica de las canales bovinas por 'virus portadores' procedentes de la región faríngea durante las operaciones de sacrificio y procesamiento es ínfima.

Las determinaciones del riesgo pusieron de manifiesto que la importación de productos lácteos desde países o zonas donde se vacuna a los rebaños lecheros entraña un riesgo insignificante. Otro tanto cabe decir de la importación de embriones engendrados por vacas vacunadas, siempre y cuando se cumplan las normas y recomendaciones del *Código terrestre*, y de la importación de semen de toros vacunados cuando se aplica un protocolo de prueba adecuado y acorde con lo dispuesto en el *Código terrestre*.

Palabras clave

Carne – Determinación de riesgos – Embrión bovino – Fiebre aftosa – Leche – Riesgo ligado a las importaciones – Semen – Vacunación.



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