Appendix 63

Discussion Paper on the risks posed by FMD carriers occurring amongst vaccinated cattle

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Abstract
The presence of FMD in many parts of the world implicates that veterinary authorities and stakeholders in Europe always will have to accept the risk of incursions of FMD.
Although vaccination by itself does not produce carriers, vaccinated ruminants when exposed to FMD virus some can become carriers (*vaccinated carriers*). When discussing vaccination policies as a means of controlling FMD outbreaks, the perceived "carrier risk" appears to be the main argument against such policy.
Historical evidence shows that healthy bulls occasionally transmitted FMD to susceptible livestock. However, so far such evidence does not exist for vaccinated carriers. Also, under a variety of experimental conditions, transmission of FMD from recovered as well as vaccinated carriers has not been demonstrated. Still, (according to the norms of the OIE Terrestrial Code) if vaccination is used to eradicate FMD it takes longer to obtain the FMD free status than after stamping-out.
Is that policy justified? What is the level of risk of the presence of vaccinated carriers and how does it compare with other FMD risks that the European society and international trade organizations have been willing to take?

The purpose of this discussion paper is:
- to explore if a "benchmark" for acceptable risk can be defined;
- to explore the types and accepted levels of FMD risks Europe has been exposed to in the past;
- to compare, those risks to the levels of risk posed by recovered and vaccinated virus carriers.

We conclude that current policies for controlling outbreaks and the consequences for export trade as yet are not based on risk assessment but on a "zero risk" approach. Reconsideration of that approach is needed to give veterinary authorities and livestock industry the best and safest options for FMD control while enabling safe international trade.

1 Introduction to risks and risk perception

As long as we live we have to deal with dangers or hazards. The *probability* that a danger becomes reality we call a risk. This risk may be dependent on natural or geographic conditions (earthquakes, storms, floods etc.), but also on human action (i.e. eating, crossing a street, driving a car, flying etc.). Humans often accept risks for economical (financial) reasons, or for having certain experiences that are considered as pleasant or exciting or both (e.g. parachute jumping). What one person may experience as an acceptable risk is unacceptable to others.

A risky situation may be more acceptable when it produces clear, demonstrable benefits for certain (powerful) groups or to society as a whole (e.g. transport in general, transport of dangerous chemicals or explosive materials). If people feel that they have control over a situation it is perceived as less risky (e.g. driving a car). When they are not in control, the situation is often perceived as a higher risk (e.g. flying an airplane as a passenger).
The question is *"Is it possible to examine potential risky situations in a qualitative or quantitative fashion and thus give people and their representatives facts on which to base essential (political) decisions intended to minimize particular risks?"*

2 Risks of introduction of FMD

FMD-free countries run a constant risk of introduction of the disease simply because FMD occurs in many parts of the world. Many human activities that increase that risk are accepted or are considered as inevitable, as for instance travel and trade. The last is particularly risky when it comes to trade of animals that are susceptible to FMD and products from such animals.
The events in 2001 clearly showed in South America and in Europe that even importation from countries with an OIE status "free of FMD without vaccination" is not without risks. In other words, trading of animals or animal products means acceptance of the risks of FMD introduction.

We have experienced escapes from diagnostic and research laboratories and vaccine production facilities that were perceived to be safe. In the eighties, vaccines considered to be well inactivated have caused

outbreaks. The recent occurrence of type C in Brazil – after almost 10 years of absence – is another indication that such risks still might exist.
Europe has – under certain conditions - imported millions of tons of meat from areas in the world where the disease occurred. Travel is increasing and with it illegal imports of animals and animal products from all over the world. Even the "circle culling" that has been applied to control FMD outbreaks can be considered a risky undertaking.

With respect to FMD there are a number of ways to look at those risks (Starr et. al. 1976):

- Evaluation of a risk immediately after the occurrence of an adverse event. Results of that evaluation can be used to make policy decisions for eventual similar events in the future (e.g. risks of swill feeding, risks of rest stops for cattle like in Mayenne and risks of markets where FMD has been transmitted).
- Statistical evaluation of risk, based on available data such as series of epidemiological FMD data. In the case of rare events, statistical analysis is often not very useful.
- Analysis of risk scenarios to evaluate the probabilities that something in a procedure may go wrong and the consequences of such a failure. That method uses objective and subjective data, as well as historical information. It makes allowance for the amount of uncertainty of the available data and information. The method is suitable for the analysis of risks related to the import of animal and animal products (Vose, 1997)
- Perceived risk, usually based on intuitive interpretation of anecdotal/historical and/or scientific information. The unknown size of the risk and fear of politicians of being hold responsible if things go wrong often lead to excessive safety measures to minimize or prevent that risk (e.g. risks of BSE being transmitted to humans).

3. Risks of carriers

The risk that carriers may cause FMD outbreaks is generally perceived as an unacceptable risk (Salt, 1993). Since vaccinated cattle when exposed to diseased livestock may become healthy carriers (in this paper they will be referred to as *vaccinated carriers),* the importation of vaccinated animals into countries that are free of FMD is prohibited (Article 2.1.1.10 of Appendix 3.8.6 of the OIE Code).
Also, the *perceived* risk of vaccinated carriers is reflected in same Appendix, Art. 2.1.1.7. For a country to recover the free status, the waiting period after an outbreak in accordance with this is:

- sub b) **3 months** after the slaughter of all vaccinated animals where a stamping-out policy and serological surveillance are applied ;
- sub c) **6 months** after the last case or the last vaccination where a stamping-out policy, emergency vaccination **NOT** followed by the slaughtering of all vaccinated animals, and serological surveillance are applied, provided that a serological survey based on the detection of antibodies to nonstructural proteins (NSP) of FMD virus demonstrates the absence of infection in the remaining vaccinated population.

Clearly, the risk that cattle from sub-clinical infected herds outside the culling zones may become carriers is not considered. The risk of vaccinated carriers and the consequences for export trade have been used as arguments against the use of vaccine to control outbreaks or to justify the wholesale killing of healthy vaccinated livestock (like in The Netherlands). Although the bad experiences in Europe with the circle culling practiced during the 2001 outbreaks has favored the use of vaccination to control and eradicate future outbreaks in the EU, export will still be hampered by longer periods which results the loss of markets. No compensation payments are made for these types of damages and losses.

Since we cannot exclude that some vaccinated cattle might come in contact with diseased livestock and thus may become carriers, it is legitimate to ask:

- *"How large would be the chance that they become carrier?"*
- *"How large would be the risk that such vaccinated carriers would come in contact with susceptible animals?"*
- *"How large would be the risk that, in that case, they will transmit FMD?"*

A further question would be: *"Would the risk posed by vaccinated carriers be larger than the risk of (sub-clinical infected) carriers remaining after large scale stamping-out operation?"* Finally, *"How do these risks compare with other risks of FMD introduction that are accepted by the international community?"*

4. Accepted risks with respect to FMD introduction

Europe has accepted the risk of FMD virus incursions under various circumstances. However, the veterinary authorities of the European countries have become more and more risk adverse because the

EU was practically FMD free for more than a decade. The discontinuation of systematic vaccination of the cattle in 1992 resulted in fully susceptible populations in Europe. This created a risky situation because several outbreaks occurred on the borders of the EU that were dealt with by zonal or ring vaccination and stamping-out (Sutmoller et al., 2003). Even after the catastrophic outbreaks in the U.K. and The Netherlands in 2001 authorities apparently accept these consequences of the present eradication policies because of trade benefits.

To complicate matters even more, different sectors of the livestock industry have different priorities. For instance, under present regulations, certain livestock sectors may prefer large-scale stamping-out measures, only because export of their products will open up earlier. In addition, supermarket chains do not want products from European animals vaccinated against FMD, because they expect consumer resistance, even though such products have never shown to be a human or animal health risk (Sutmoller et. al 2003, Sutmoller & Casas 2003). It is interesting to note that consumers readily accept meat from vaccinated cattle from South American countries and have done so for decades.

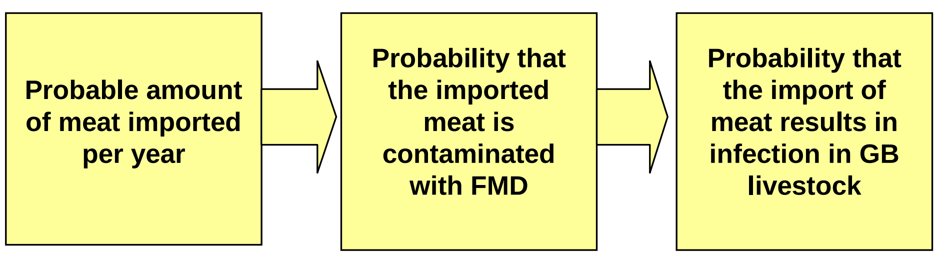
Therefore, in view of these social and economic different interests, any acceptable risk must be defined in terms of: "for whom and under which circumstances".

Can we develop a "benchmark" for acceptable risk (of carriers) that would accommodate these different positions? If the level of carrier risk would be equal or less than that benchmark, would that influence the position of the veterinary community with regard to the length of the waiting periods to obtain the FMD free status after the last case of FMD had occurred?

A way to develop such a benchmark might be to look at other FMD risks that Europe has been exposed to and has accepted, such as, the risk of illegal importation of animal products and the risk of legal large scale importation of meat from South America.

5. Risk of importation of illegal animal products.

At the 35th General Session of this Commission, Hartnett et al., presented a paper on a risk assessment for the illegally import of meat and meat products contaminated with FMD virus into Great Britain and the subsequent exposure of GB livestock.
The model consists of three modules each describing a distinct stage in the process that could lead to an outbreak of FMD in GB. The model framework is shown in the figure below:



Together, these modules would represent the various transfer pathways of the virus from the country of origin to the infection of livestock in GB.

In the first module the illegal flow of meat and meat products from different regions was estimated. The estimated gross annual illegal flow into GB would amount to 700 tons of meat and meat products. Ship and airline waste were excluded from the scope of the study.

For the second module, the probability that illegally imported meat or meat products would contain FMD virus was derived from:

- the annually incidence of FMD in each of the countries of origin;
- the length of time the animals have infectious FMD virus in the tissues (viremic animals);
- the virus load of contaminated products;
- the persistence of FMD virus in each contaminated product as a consequence of processing and storage time.

The information on FMD incidence in countries of origin was mainly obtained from OIE and the WRL, but with a factor of 40% for the global average level of under-reporting. The number of viremic animals was calculated from the incidence level.

The estimated amount of contaminated meat and meat products illegally imported per year, according to the results of the second module, had a mean value of 95 kg, with 90% certainty of a volume between 30 and 244 kg per year. However, these values are likely very uncertain and possibly underestimated, in view of the over-simplification of that module.

In addition, the third module was very complex and estimated the probability that through several pathways, contaminated, illegally imported meat and meat products would infect livestock in GB.

The final conclusions, combining the results of the 3 modules were:

- With 90 % certainty there would be a probability of 1 FMD outbreak in GB within a range of 41-1100 years, with a mean of 1 outbreak in 130 years as a result of the illegal import of meat.
- Approximately 95% of the estimated risk would be associated with illegal meat arriving in personal baggage in quantities that are destined for commercial use.

Could the results of above risk assessment be used to approximate the involuntary risk for the whole of Europe as a result of illegally imported meat and meat products?

The following items might be considered:

1. *Flaws in the design of the model.*
2. *European borders are more open than those of GB and have larger links with endemic areas.*
3. *Europe has a much larger number of foreign national residents than GB and a massive tourist interchange of people carrying animal products.*
4. *Absence of database(s) required to estimate inflow of illegal meat into Europe.*
5. *Ship and airline waste.*

Considering the above factors we can conclude that Europe probably is running a risk that is at least a ten times higher than was calculated for GB for illegally imported meat. In that case Europe would run a risk of one outbreak within 4 to 100 years with a most likely probability of one outbreak within 13 years.

6. Risk that Europe has been willing to take with the importation of meat from South America

In addition to the risk caused by illegally imported meat and other animal products Europe has accepted the risk of legally imported meat from South America and some other countries (e.g. Botswana) with sporadic FMD or with a fair chance of FMD introduction.

The importation of South American meat can be divided in 3 different phases of risk:

- Prior to the years 1967-68 the risk that meat from infected animals was exported must have been considerable, because of the many outbreaks in South America and the lack of efficient controls.
- Following the epidemic of 1967-68 in Great Britain, risk reduction measures were introduced that resulted in the development of a high level of technology and inspection in slaughterhouses and packing plants in South America. In spite of the enormous volumes of these imports and many FMD outbreaks that still occurred in the countries of origin, there were no further introductions of FMD.
- During the third phase several of the South American countries obtained the status “FMD free with or without vaccination”. The OIE Code established long waiting periods and severe requirements to obtain such status. Presently, in addition, the countries have to demonstrate the absence of infection and circulation of the virus in the livestock population. The perceived risk of carriers, justifiable or not, played a predominant role in the rationale for the development of these rules.

Several papers have described the risk of the importation of meat from South America in qualitative or quantitative terms (Astudillo 1997, CCE/CISFAPS 1997, Sutmoller 2001a, Yu et.al 1997). Basically all use the scenario pathway as shown in Figure 1. The probability of a “Yes” or “No” answer for each of the events in the scenario must be evaluated to obtain the final level of risk of exporting FMD contaminated meat.

To obtain an answer to the first and second question in Figure 1 the epidemiological situation of the exporting country must be evaluated, as well as the number of herds required for the volume of meat to be exported The third question in Figure 1 evaluates the degree of compliance and probabilities of failure of the EU export requirements. This set of risk mitigation measures are based on strict rules and controls of the source of the cattle and conditions of slaughter plant. They were developed following the extensive FMD outbreaks in the U.K. during the period 1967-1968. In addition, EEC Directives (EEC 1986) required the maturing of carcasses and removal of bones, lymph nodes and large blood vessels from the meat, in order to destroy or remove FMD virus and reduce the risk of importation of quantities of FMD.

Risk assessments done so have supported the contention that under present EU requirements - inspection at the farm of origin, systematic vaccination of the cattle, slaughterhouse and meat inspection, maturing and deboning of carcasses - import of meat, even from regions that are not FMD free, are an acceptable risk. Carriers are not an issue in this respect (Sutmoller 2001b)

For the past decades the EU has been importing annually some 250,000 tons of meat from the Southern Cone of South America (Argentina, Brazil, Paraguay and Uruguay; data obtained from FAOSTAT, 2004) and has accepted the risk related to that importation.

Astudillo et al. (1997) estimated that if an infected farm would send cattle to the slaughterhouse the probability that a contaminated carcass would pass all inspections when following the EU rules would be just over 1:1000, (90% confidence limit). However, the virus load of the contaminated meat would decrease with a factor of 100 by maturation and deboning.
Sutmoller (2001b) estimated the risk of importing 10,000 ton of meat obtained from a FMD free zone with 500,000 cattle herds, that suffered a limited incursion of FMD. The calculated with probability was $10^{-6.6}$ (1: 4,000,000, 90% confidence limit) that 10.000 tons of meat would contain meat from at least meat from one infected herd. The estimated reduction of the virus load of the contaminate meat due to maturation and deboning was 95%. With an annual importation of 250,000 ton by the EU the probability would be >1:100,000 that all inspections would fail.
If the zone would have and 500 infected herds per year the risk would be 100 times higher, but with that number of outbreaks meat export operation would already have been put on hold.

Thus the levels of risk for meat imported according to EU rules are extremely small and justifiably acceptable.

7. Carriers as a source of FMD outbreaks
The risk of carriers in the context of this discussion paper is the likelihood of carriers transmitting FMD to susceptible livestock causing new FMD outbreaks. To study this problem we may have to quantify how many carriers remain after the various methods of dealing with an outbreak. A compilation of the results of surveys done after recent outbreaks in Europe and South America might provide such an answer. Next we can ask *"What is the evidence that carriers transmitted FMD to susceptible livestock?"*

7.1 Historical evidence
Fogedby (1963) made an extensive review of historical evidence of carriers transmitting FMD to susceptible animals. We completed the data from his review with other sources (Machado 1969, Salt 1993, Sutmoller et al., 1967, Sutmoller et al. 2003, Thomson 1996) which resulted in Tables 1 and 2

Table 1 shows that for the past 150 years there have only been 9 documented cases in which transmission occurred, 7 of which involved healthy bulls. Thomson (1996) reported on two events in Zimbabwe during 1989 and 1991. The cattle were moved around in Zimbabwe before they reached the herd where the outbreak occurred and there was suspicion that might have transmitted FMD from earlier outbreaks. Although the RNA sequences of the viruses involved were quite similar, there are a number of question marks with respect to the evidence that these animals did indeed cause the outbreaks. The carrier status was not verified for the cattle that supposedly caused the outbreak and only one carrier was found in the herds from which they originated.. The gender of these animals was not reported, but there might have been bulls in the cattle that were moved. In our view the evidence that carriers were involved in these two events in rather disputable.

Table 2 shows field evidence that transmission of FMD by carriers has not been shown in numerous experiments, carried out under a large variety of circumstances, to study FMD transmission from carriers to susceptible contact cattle or pigs. These negative results were obtained even though the total number of overall contact days is very large.

7.2 Controlled transmissions experiments
Controlled experiments to study FMD transmission from carriers to susceptible contact cattle or pigs have all given negative results although the total number of overall contact/days in these experiments was very large as well. Dr Tenzin at Utrecht University is reviewing all the literature and compiling the

information on this subject. A statistical analysis is carried out, but results are not availabl yet (pers. com. Tenzin & Stegeman, 2004)

7.3 Sexual transmission

It is striking that bulls are involved in practically all the historical cases with circumstantial evidence of carriers causing outbreaks in susceptible herds (Table 1). *"Is there other evidence that in the past carrier bulls could have been responsible for transmission of FMD?".* Pustiglioni (1973 reported that 7 of 22 bulls that had not suffered from FMD for at least 6 months had FMDV in their semen. There are no reports either to support or contradict these findings. More recently, field evidence was reported of sexual transmission from carrier buffalo bulls to susceptible animals (Thomson, 1996). Bastos et al. (1999) suggested that sexual transmission of the disease from carrier buffalo bulls to buffalo cows or domestic cows could occur, because FMD virus SAT3 was isolated from both semen and from sheath washes from a naturally infected African buffalo. They considered this a persistent infection since the virus genotype was not recently circulating in the buffalo herd. They speculated that virus in the sheath-wash of the buffalo bull presumably originated from the mucosal epithelial tissues of the prepuce. The finding could explain the mechanism of the maintenance of FMD of the SAT virus types in small isolated buffalo populations. Further investigation of FMD transmission by sexual contact with recovered bulls is urgently required. To our knowledge, in the numerous "regular" contact experiments sexual contact was never considered or attempted. However, if sexual transmission of FMD by recovered bulls would occur, it could explain why the contact experiments only produced negative results. Most importantly, it also could explain most of the historical evidence on which the perceived carrier risk is based. It might be the missing piece of the puzzle that has kept us occupied for the past 50 years!

Discussion

In the late fifties and early sixties, in the absence of systematic vaccination in endemic areas, the percentages of carriers in the cattle populations were very high (Van Bekkum, 1959, Sutmoller & Gaggero, 1965). However, surveys by staff of the Panamerican FMD Center in later years showed a very much reduced percentage of carriers in endemic areas when vaccine was commonly used to control FMD outbreak situations. In addition to vaccination, other zoo-sanitary measures such as - immediate quarantine and slaughter of outbreak farms and a movement stand still of animals - will further reduce the number of carriers in a vaccinated population.

We have pointed out in a previous paper (Barteling and Sutmoller, 2002) that over the past decades the control of more then 15 outbreaks by vaccination was always successful and that there have been no cases of recurrent disease. Also in Uruguay recurrent disease did not occur even though the extensive outbreak in 2001 was controlled by vaccination of cattle only, sharing the pastures with young cattle, pigs and millions of unvaccinated sheep.

Thus, although all available evidence indicates that the probability of transmission of FMD by vaccinated carriers to susceptible livestock is extremely low – in fact there are no well-documented cases - still this risk is perceived as serious and justifies a longer ban on export trade than when outbreaks are not controlled by stamping-out. It is this perception that in its consequences has lead to the killing of millions of cattle and sheep (in the U.K.) and to the killing of hundreds of thousands healthy vaccinated livestock (in The Netherlands).

However, levels of risk – not perceived risks - must be considered when developing regulations and guidelines for the international movement and trade in animals and animal products. It must also be the most important consideration when deciding on the various options to deal with an outbreak.

Export restrictions of animals and animal products place a heavy penalty on the use of FMD vaccine. As a consequence countries with an important export of livestock or livestock products have - for the earliest regaining of their FMD free status - omitted the use of vaccine after an incursion of FMD. If vaccination had been used, healthy vaccinated cattle were slaughtered in order to avoid long export bans. It is curious that vaccinated pigs also must be destroyed even though pigs have not been shown to become carriers.

However, in all those cases where outbreaks of FMD were controlled by vaccination without slaughter of the vaccinated animals no recurrent FMD occurred caused by vaccinated carriers (Barteling and Sutmoller 2002). Also, products from these animals went into the normal consumption circuit without causing new outbreaks. Sutmoller & Casas, 2003 concluded that with adequate protocols products from vaccinated animals represent an acceptable, "close to zero" animal health risk.

By further analysis of the outbreak in Uruguay (Sutmoller et al., 2003) we can try to get some insight in the size of the risk represented by carriers.

In short, during 2001 Uruguay suffered an extensive outbreak of FMD with over 2057 infected farms among total of 47,057 livestock farms of which 28.795 had cattle and sheep. Only in the first cases stamping-out was applied (total of about 7000 animals were killed) with an immediate movement control of all livestock. At the height of the epidemic there were 40-60 new cases per day with some 20.000 animals. Vaccination was started within a week after the start of the outbreak, first as ring vaccination of the cattle population, but soon vaccination was extended to whole cattle population. Sheep were not included in these vaccinations, even though cattle and sheep used the same pastures. After the first vaccination round the movement restrictions were relaxed, followed by a revaccination of cattle. The epidemic lasted for a total of 8 months.

	Cattle	Sheep	Pigs
Livestock population Uruguay	11,080.980	10,801.376	293,874
Population at risk*	1,518,965	947,879	7,598
Clinically diseased	76,579	236	112
Attack rate	5%	0.02%	
Average farm size of population at risk	738	460	

**population at risk: animals on infected farms and obvious contacts.*
(Sources MGAP 2002a & 2002b, Cámara de Representantes 2001)

According several authors (a.o.: Salt 1993, Sutmoller & Gaggero, Sutmoller et al. 1967) it is most likely that about 50- 90% of the susceptible cattle that became clinically diseased on the 2057 infected farms developed the carrier state. In addition there must have been contacts with the clinically affected animals, both cattle and sheep that also resulted in carriers. This means that we can safely assume that during the epidemic some 50.000 carriers have been generated. These carriers used common pastures with unvaccinated sheep (often the sheep/cattle ratio is 1:1, but often higher) and in several districts roaming pig are numerous. Also, in any vaccinated population there are calves with decreasing maternal antibody levels becoming susceptible for the disease. *Still there was no recurrent disease in the year following the last case*. From that we can conclude that one carrier animal represents a risk of transmitting disease in Uruguay was less than 1: 50.000. Of course this risk decreases with time. Systematic vaccination of the cattle population as done in Uruguay also will accelerate the decrease of the number of carriers.
From all the other outbreaks occurring globally during the past decades that were controlled by vaccination - all with no incidents of recurrent disease - we may conclude that likely this risk is even less

In a relatively limited outbreak situation - like the one in The Netherlands – that is rapidly controlled the number of vaccinated carriers will be small when by stamping out of diseased herds is being applied together with immediate stand-still of all livestock movements and ring or zonal vaccination. Elbers et al. (2003) made a sero-survey of wildlife in the epidemic area. For that survey samples were tested from suspect wild deer and farmed deer thought to be at risk or possibly exposed to FMD virus. All samples were negative, but there still the existence of a small number of carriers in the cattle population can not be excluded.

If in the Netherlands the vaccinated animals (and - for arguments' sake – 100 carriers) had been left alive - then the likelihood of carriers causing a recurrence of FMD would be 1:500 (one outbreak as a consequence of 500 epidemics of the size of the 2001 outbreak). However, in view of the findings of Elbers et al. (2003) the total risk may be much smaller – how much smaller we don't know.
This risk could have been further reduced by screening for potential carriers by an a-NSP test and removing potential carriers from the herds. The remaining carrier risk would have been magnitudes smaller and of the order of other accepted FMD risks. Therefore, the use of vaccine should not be hampered by additional trade restrictions, a conclusion that was already made by other arguments (Barteling and Sutmoller, 2002). Also, if rules for export trade had been based on risk evaluation, in the Netherlands the destruction of some 250,000 healthy vaccinated cattle would not have been necessary

In addition, whatever timeframe for the waiting periods to regain the FMD-free status would be agreed upon, it is be crucial that after any outbreak, the veterinary service should - to the satisfaction of the international trading community - show the absence of FMD virus circulation, before normal export can be resumed. However, trade in animal products can be resumed as soon as the survey is satisfactorily completed and the absence of FMD virus circulation has bee proven.

Conclusions and Recommendations

The subjects that have been considered in this discussion paper can be summarized as follows:

- Science-based risk assessments should be made to compare the different risks associated with different eradication methods trad in animal and animal products.
- For illegally imported meat Europe may run a risk of one outbreak within 4 to 100 years with a most likely probability of one outbreak occurring in 13 years.
- For the importation of 250,000 ton of meat from South America by the EU, produced in accordance with OIE rules and guidelines, the probability is extremely low (less than 1:100,000) that this volume contains meat from at least one infected herd. Carriers do not contribute to that risk.
- One carrier animal represents a risk of transmitting FMD to susceptible contact animals that is likely much less than 1:50,000 (there are no well documented cases of transmission).
- Considering that the risk posed by vaccinated carriers is extremely low and considering the levels of risks that Europe of illegally and illegally imported meat has accepted, the policy of restrictions on export trade when part of the livestock population is vaccinated for controlling outbreaks should be reconsidered.
- If serological surveys after an outbreak are carried out rapidly and efficiently, it shows the international community, that veterinary and laboratory services are efficient and well-organized. Because this is one of the most important risk reduction factors within the risk equation, this element should be fundamental for recovery or obtaining the FMD-free status. Export restrictions should be lifted as soon as the tests have been carried out with negative results.

If the vaccination option is used at an early stage, it will cause the least disruption of social and economic life. If outbreaks are kept limited, e.g. by vaccination, with limited consequences for export trade, it will stimulate veterinary services and stakeholders to notify the disease and to take proper action in the earliest stage possible. This will be another element to safeguard the international community from spread of this disease.

Also, we strongly recommend to investigate whether carrier bulls are able to transmit disease by the sexual route.

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<table>
<tr><td colspan="2">Are herds infected with FMD?</td><td>→No</td><td>No risk</td></tr>
<tr><td colspan="2">↓ Yes</td><td></td><td></td></tr>
<tr><td colspan="2">Is at least one infected herd selected for export of meat ?</td><td>→No</td><td>No risk</td></tr>
<tr><td colspan="2">↓Yes</td><td></td><td></td></tr>
<tr><td colspan="2">Is the infected herd detected at ante- or post-mortem inspection?</td><td>→Yes</td><td>Stop all exports</td></tr>
<tr><td colspan="2">↓ No</td><td></td><td></td></tr>
<tr><td colspan="2">Are viremic* cattle in the herd?</td><td></td><td></td></tr>
<tr><td colspan="2">↓ Yes</td><td></td><td></td></tr>
<tr><td colspan="2">Have viremic carcasses been subjected to maturation and deboning?</td><td></td><td></td></tr>
<tr><td>↓ Yes</td><td>↓ No</td><td></td><td></td></tr>
<tr><td>Virus survives?</td><td>Virus survives?</td><td></td><td></td></tr>
<tr><td>↓ Yes</td><td>↓ Yes</td><td></td><td></td></tr>
<tr><td colspan="2">Contaminated meat</td><td></td><td></td></tr>
</table>

** Carcasses of cattle with virus circulating in the bloodstream (viremia) are the main concern because those animals will have virus in the muscles, lymphnodes, bone marrow, organs etc. In addition, during exsanguination, slaughter and processing of these animals most likely gross environmental contamination of the slaughter plant will take place.*

Figure 1. Scenario Pathway for the assessment of risk of FMD contaminated meat being exported. The probability of a "Yes" or "No" answer for each event must be evaluated to obtain the final level of risk.

Year	Country	Animals involved	Time after being recovered / sub-clinical infected	Time after introduction in susceptible herd
1871/ ‘ 72	Australia (1)	Bulls from U.K.	unknown	unknown
1897	Sweden (2)	Bull from The Netherlands	unknown	2 weeks
1898	Sweden (2)	Bull from The Netherlands	unknown	5 months
1924	U.K. (2)	Bull and heifer	7 months	1 month
1926	U.K. (2)	Bull and cow	15 months	8 months
1926	U.K. (2)	Bull and heifer	15 months	8 months
1946	Mexico (3)	327 Brazilian Zebu bulls	unknown	2 month
1989	Zimbabwe (4)	Cattle* Zimbabwe	2 years	unknown
1991	Zimbabwe (4)	cattle* Zimbabwe	2 years	Unknown

* Gender of animals not reported.

Table 1. Outbreaks with circumstantial evidence that they are caused by carriers as reviewed by Pullar, 1965 (1), Fogedby, 1963 (2), Machado 1969 (3), Thomson 1996 (4).

Year	Country	Animals involved	Time after being recovered / sub-clinical infected	Size of susceptible contact herd
1914	U.S.A.(2)	740 cattle	3 months cattle 3½ months pigs	50 (young) cattle 50 pigs
1924-‘27	Sweden (2)	1500 cattle	1 m - 2½ year	> 10.000 cattle
1926	Argentina (2)	600 cattle	20 days	50 cattle
1926 and following	Argentina (2)	100 – 800 cattle	> 15 days	> 1000 cattle
1928	Switzerland	20 cattle	2-12 months	35 cattle 4 pigs
1945	Mexico (3)	120 Brazilian Zebu bulls	unknown	Mexican national herd
1951 - 1957	South Africa (2)	Approx. 250.000 (aphtization) cattle	4-5 months	Free movement into susceptible herds

Table 2. Experience from the field with potential carriers where no transmission of disease occurred as reviewed by Fogedby 1963 (2), Machado 1969 (3)