

**Strategy for
Emergency Vaccination against
Foot and Mouth Disease (FMD)**

**Report of the
Scientific Committee on Animal Health and Animal Welfare**

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Strategy for Emergency Vaccination against Foot and Mouth Disease (FMD)

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1. Background

Foot and mouth disease has been eradicated from the European Union (EU). The last outbreak occurred in Greece in 1996. However, the risk for Member States remains extraordinarily high as a consequence of:

- * the presence of countries where foot and mouth disease is endemic on the periphery of the EU;
- * the possibility of illegal introduction into the EU, because of price differences, of infected animals, especially sheep/goats, or meat, meat products, milk and milk products contaminated with foot and mouth disease virus;
- * the movement of tourists and migrants¹ from infected areas which may carry infective fomites.

Compulsory prophylactic vaccination of cattle against foot and mouth disease ceased in the EU during 1990-91, in the framework of a policy laid down in Council Directive 85/511/EEC as amended by Council Directive 90/423/EEC. The measures adopted to control possible outbreaks and eliminate the virus should it gain entry are based on the strategy of killing infected herds with appropriate disposal of potentially infective material (stamping out) and controlling the movements of live animals, meat, meat products, milk, milk products, animal by-products, persons, vehicles, farm fomites and any other substance liable to transmit the virus. This strategy alone might not be sufficient to eradicate the virus and therefore Council Directive 90/423 (art. 13.3) permits the use of emergency vaccination, as an adjunct to the control and eradication measures.

In the past, emergency vaccination has been applied to protect ruminant and in particular cattle populations against FMD when local outbreaks had occurred and when the circumstances indicated that an 'exotic' strain had been introduced, against which protection by annual vaccination was not guaranteed. This was most frequently the case

¹ The Committee considered the possibility of foot and mouth disease being a zoonosis and reviewed the literature. The Committee considers that there is no convincing recent evidence that the disease can be a zoonosis. In any event, human infection is unimportant in the epidemiology of the disease.

when pigs had been infected through swill feeding, e.g. Germany 1976 (Boehm and Kaaden, 1978). Emergency vaccination was also applied as a supplementary instrument to reinforce protection in cattle or ruminants in general when a local outbreak of FMD occurred which was elicited by a 'classical' virus strain. The effectiveness of such a measure, which was always accompanied by other control measures, was most often assumed when there was no further spread of the disease and no development of an epidemic (Roehrer and Olechnowitz, 1980).

More recently (Leforban, 1996), regional vaccination against FMD has been applied in some countries on the Balkans area. This was based on recommendations from FAO (FAO, 1997).

2. Terms of Reference

The Scientific Committee on Animal Health and Animal Welfare has been requested to:

- * establish the criteria leading to a decision to implement emergency vaccination against foot and mouth disease;
- * establish guidelines for a vaccination programme;
- * prepare guidelines for the movement of animals and animal products within and out of the vaccination zone(s).

3. Rationale for the possible use of emergency vaccination

In 1990/91, the EU decided to cease routine prophylactic vaccination. The control procedures are now total stamping out of the disease in affected herds and movement control in the surrounding area. This policy was effective in eradicating foot and mouth disease in Italy in 1993 and in Greece in 1994 and 1996. However, in the future there may be certain circumstances when these measures may need to be supplemented by the use of an emergency vaccination (Donaldson and Have, 1996; Amadori, 1997).

3.1 Rationale

The rationale for using emergency vaccination for foot and mouth disease is:

1. Fear that after the introduction of FMDV into a free region, it may spread out of control;

In particular, outbreaks in areas containing high densities of susceptible animals and inadequate resources of manpower or rendering plants for the slaughter and disposal of animals or outbreaks involving a predicted risk of airborne virus spread beyond the protection² zone;

2. Availability of high potency vaccines.

It has been demonstrated (Salt et al., 1994 and 1996) that a high level of immunity can be induced by potent vaccines within a few days in both cattle and pigs. These experimental data were confirmed on several occasions under field conditions.

3. Availability of new tests that will differentiate between infected and vaccinated animals

The availability of these tests allows the vaccine to be used in a similar fashion to a marker vaccine.

² The protection zone is a zone defined by the competent authority with a minimum radius of 3km around the infected holding, itself contained in a surveillance zone of minimum radius 10km. Zones should take account of geographical, administrative, ecological and epizootiological factors e.g. Council Directive 92/119/EC.

4. Responding to public opposition to the implementation of total stamping out and the demand for an alternative approach or the impossibility of carcass disposal because of concerns about water (carcass burial) or urban air pollution by smoke of carcass burning.
5. The successful implementation of emergency vaccination will limit the number of animals experiencing the symptoms and poor welfare associated with FMD infection.

3.2 Objectives

The objectives of emergency³ vaccination are:

1. to create a zone of vaccination outside the protection zone to protect animals against airborne infection (*'protective' emergency vaccination*);

'protective' emergency vaccination is vaccination carried out on holdings in order to create an immune zone and protect the animals within the area being vaccinated against airborne infection from the infected area;

2. to reduce the quantity of virus spread within the suspected infected area (*'dampening down' emergency vaccination*)

'dampening down' emergency vaccination is vaccination which should be used only in conjunction with a pre-emptive slaughter policy in a known foot and mouth disease infected area where it is considered that there is an urgent need to reduce the amount of virus circulating and the risk of spread beyond the area. This may be indicated as a measure to assist pre-emptive slaughter particularly in the following circumstances: a high density of animals (especially pigs); an overwhelming of the capacity to kill and dispose of carcasses within a short time period, poor infrastructure, inadequate manpower or delayed stamping out. In

³ In this context the shape of the vaccination zone could vary depending on the epidemiological and geographic situation.

the event that this emergency vaccination is applied, stamping out procedures should continue and be applied to the animals, irrespective of the implementation of vaccination.

3. to assist the completion of stamping out and disposal of carcasses and materials from infected premises by minimising virus transmission while this is taking place;
4. to reduce the severity of 'direct' economic losses.⁴

It should be noted, however, that during the 14 days following the vaccination of cattle and 7 days following the vaccination of pigs, virus transmission can occur from those species to susceptible animals in contact with them (Donaldson and Kitching 1989; Salt et al. 1998).

It is emphasised, however, that with effective surveillance, rapid reporting of suspected cases, rapid diagnosis and the implementation of control measures without delay, foot and mouth disease can be controlled and virus eradicated before outbreaks develop into epidemics. On the other hand, should the circumstances be appropriate for the implementation of emergency vaccination then the decision to do so must be made quickly.

Farmers whose herds/flocks are vaccinated and who suffer losses as a result of the restrictions placed on them should be fully compensated. If not, they are unlikely to cooperate with an emergency vaccination programme.

4. Vaccines and Tests

Vaccines

⁴ If a policy of emergency vaccination is implemented the trade restrictions imposed on the vaccinated area (region) and/or country will be in place for longer than if stamping out only, is used. Therefore emergency vaccination will result in an increase of 'indirect' costs. For countries with a large export trade in animals and animal products this economic consequence will be the strongest argument against the implementation of emergency vaccination

The EU has recognised the need for the provision of emergency vaccines in the national contingency plans of Member States and has established a Community Vaccine Bank in which concentrated inactivated FMDV antigens are stored at three sites, viz. Brescia, Lyon and Pirbright (Council Directive 85/511/EEC as amended by Directive 90/423/EEC; Commission Decision 93/590/EEC and Council Decision 91/666/EEC). In addition, some Member States have established National Banks of antigens and/or vaccines, but these banks would not be accessible to other Member States.

Currently, FMD vaccines are typically inactivated vaccines containing whole virus in a semi-purified state. Vaccines may include one or several of the serotypes. The vaccine strain used should be as homologous as possible with the field strain. In addition to aluminium hydroxide adjuvanted vaccines, oil based vaccines have become available. These are of comparable quality. However, oil-adjuvanted vaccines should be used whenever possible since they can be expected to produce an acceptable immune response in all foot and mouth disease susceptible species, whereas aluminium hydroxide formulated vaccines are effective in ruminants but not in pigs. (Pay, 1984)

In the case of emergency vaccination, emphasis must be put on highly potent, safe vaccines, capable of inducing early protection and dramatically reducing virus replication in vaccinated livestock when exposed to infection (Amadori and Berneri 1996; Salt et al., 1998). Formulated foot and mouth disease emergency vaccines (inactivated antigens being stored as concentrates over liquid nitrogen) must have been validated as potent vaccines. High potency is essential (at least 6 PD50 E.P.) to achieve rapid development of immunity and a broad antibody response in vaccinated animals. Therefore, in circumstances when there is a lack of homology between a field virus and the vaccine strain then the broader response induced by a highly potent vaccine can compensate in part for the lack of antigenic homology. (Barteling and Swam, 1996; Kitching et al., 1989)

Non structural proteins (e.g. 3ABC) should not be present in the vaccines because this could interfere with differential diagnostic tests. Batches must be tested to verify this.

Diagnostic procedures on FMDV isolates should include the provision of information about the degree of relationship to vaccine strains ⁵. In this context, Council Decision 91/666/EEC listed 10 antigens to be stored in the EU Bank, but not all of these have been purchased by the EU. Some strains now appear extinct, but other antigenically distinct strains have appeared. Therefore, the suitability of the strains of antigens held in the EU Bank should be continually kept under review.

The criteria for deployment of vaccine produced from the stored antigens for emergency use have not been clearly defined. Delays are to be avoided at the time of an emergency and it is therefore essential that the procedures governing the chain of events from formulation of antigen into vaccine, through the bottling and labelling procedures, to delivery to the region where it is to be used, are clearly specified and efficiently implemented. At present, these issues are unresolved and so it is critical that they are addressed as a matter of urgency.

4.2 Differentiating infection from vaccination

4.2.1 Tests for Non Structural Protein (NSP)

The differentiation of herds or flocks which have been infected from those which have been vaccinated is a critically important follow-up activity to 'protective' emergency vaccination.

Antibodies to the capsid (structural) proteins of foot and mouth disease virus are produced by animals following either vaccination or infection. It is not possible, therefore, to use tests based on the detection of antibodies to structural proteins of foot and mouth disease virus (OIE Manual of Standards 1996) to differentiate animals which have been infected from those that have been vaccinated.

⁵ The Animal Health Institute, Pirbright (UK) was designated as Community Reference Laboratory (Council Decision 85/511/EEC as last amended by Directive 90/423/EEC). Contract ended March 1995. The OIE World Reference Laboratory will provide services instead.

Viral replication during infection results in the production of a number of non-structural proteins (NSP), some of which are antigenic. Sera from naive or vaccinated animals are usually negative; in contrast, the majority of infected or vaccinated-infected animals produce detectable antibodies to the 3ABC non-structural protein, irrespective of the FMDV serotype causing the infection. Foot and mouth disease vaccines consist of purified preparations of inactivated virions that induce antibodies almost exclusively to the structural proteins of the virus. Differentiation of infection from vaccination by detecting antibodies to NSP in infected ruminants has been described (Bergmann et al., 1989; De Diego et al. 1997; Haas 1997; Meyer et al. 1997; Silberstein et al. 1997; Sorensen et al. 1998b; Mackay et al. 1998a). To date, the detection by ELISA of an antibody response to the non-structural polyprotein 3ABC seems to be the most reliable indicator of a previous infection (Concerted action CT93 0909,1997). NSP ELISAs are simple to perform and are suited to large scale application by a routine serological laboratory. To date this test has been validated in cattle (refs. cited above). There is good data available for sheep but further work needs to be done in pigs.

Recently developed 3ABC-ELISAs show relatively high sensitivity and specificity. For infected animals at more than 8-15 days after infection the sensitivity is close to 100%. However, in the "worst case" scenario, when vaccinated animals have been exposed to virus and become infected without developing clinical signs, the sensitivity will be lower, probably around 90% (Haas, 1997). As a consequence, the 3ABC-ELISA should then be used for testing animals at the herd/flock level rather than the individual animal level. Furthermore, although the 3ABC-ELISA has been validated in some laboratories, additional technical improvements are required so that its use can be extended to regional laboratories, whose involvement will be essential for large scale campaigns⁶ (De Diego et al., 1997; Sorensen et al., 1998a; Berlinzani et al.,1998; Mackay et al., 1998a; Mackay et al., 1998b).

4.2.2 Further development of NSP tests

Additional work is necessary in order to complete the development of the NSP tests:

⁶ The test has to be offered as a complete, validated test kit which is easy to use and is compatible with pipetting robots. ELISA kits should be available to the National FMD reference laboratories and in addition could be stored in the vaccine banks.

1. The antigen used in NSP tests needs to be standardised.
2. A panel of positive and negative reference sera needs to be established which NSP tests must correctly identify before use is permitted. This panel should include sera from non infected animals vaccinated with highly potent vaccine and sera from animals that have been vaccinated and afterwards infected with FMD virus.
3. The specificity of the tests in field situations needs to be determined accurately. This is of crucial importance in defining a singleton (i.e. false positive) reactor and differentiating the herd from an infected herd (for example see Report of Scientific Committee on Animal Health and Animal Welfare of 10 August 1998 on Swine Vesicular disease – Annex II).

It should also be noted that there is a possibility that the use of high potency vaccines could influence the performance of NSP tests, in particular by reducing the specificity of the test. This aspect of the use of these test needs further research to determine the extent, if any, of this effect.

4.2.3 Current developments in other diagnostic tests

A range of additional laboratory diagnostic tests are currently under development:

- * assays for isotype-specific viral antibody in secretions (Archetti et al. 1995; Salt et al. 1996; Armstrong 1997);
- * analysis of nasal swabs by RT-PCR (Marquardt et al. 1994);
- * detection of PCR products by ELISA (Donini et al. 1992).

Further studies are necessary to validate these methods.

4.3 *Silent foot and mouth disease infection and FMDV carriers*

It is well known that vaccinated ruminants may become subclinically infected with FMDV and may excrete the virus following exposure. Therefore, it will be essential to consider vaccinated animals in the vaccination zone as potentially infected because they

have been at risk of exposure and hence a potential source of FMDV. In exceptional cases some ruminants may become carriers (Wittmann, 1990). However, the likelihood of carriers transmitting the infection under field conditions is not known.

As an adjunct to serological monitoring of vaccinated animals for antibodies to the non-structural proteins of FMD virus, it may be necessary to carry out tests for the detection of FMDV antigen to determine if vaccinated herds/flocks are subclinically infected. Tests can be carried on suitable samples (e.g. probang samples, blood, milk, nasal swabs) to detect the presence of live virus or viral RNA.

The culture of probang samples on bovine thyroid cells is considered a sensitive method to detect FMDV in non-vaccinated carrier ruminants. The sensitivity of virus detection tests, especially in vaccinated animals, is not known and may be a problem. The probang test suffers from some major constraints: (i) virus excretion in carrier animals is intermittent and (ii) false-negative results can be obtained due to virus inactivation during sampling and shipment to the laboratory. As a consequence, virus isolation from probang sampling cannot be considered to have a sensitivity of 100% for carrier animals. A combination of probang sampling with PCR may increase the sensitivity (Callens M and De Clercq C., 1997; Callens et al., 1998; Reid et al., 1998; Marquardt .1998; Forsyth et al., 1998.)

5. Criteria and factors affecting the decision to implement emergency vaccination

The rapid and objective assessment of the determining parameters is crucial to the decision to commence a vaccination programme.

If an analysis of parameters gives a result which supports a programme of protective emergency vaccination then the programme must be implemented without delay. It is emphasised that if decision-making and the required actions are delayed and as a consequence the initiative is lost and the disease becomes widespread, then the only remaining option may be a programme of either regional or national vaccination.

Several computer assisted models have been developed (De Jong and Diekmann 1992; Sanson 1995; Mackay 1997; Haydon and Woolhouse 1997; Donaldson et al. 1999), some of which are useful for strategic purposes e.g. operational planning, allocation of resources, whereas others are suitable for use in an epidemic e.g. to predict airborne spread of virus. These models are useful tools to assist in decision making and planning but for further development require the input of more data to refine their parameters and assumptions. It is essential that the necessary data (e.g. farm locations, stocking density) be collected and kept up to date in advance of an outbreak.

It is recommended that simulation models be further developed and used by Veterinary Services and experts to test the effects of variations in the quantitative elements referred to in Table 1. A list of criteria for or against the decision to implement a 'protective' emergency vaccination is presented in Table 1. When considering a decision to use emergency vaccination, these criteria should be assessed on a case by case basis.

Table 1 - List of criteria for consideration in decision-making related to 'protective' emergency vaccination

Criteria	For vaccination	Against vaccination
Population density of susceptible animals ⁷	High	Low
Clinically affected species	Significant number of pigs involved	Predominantly ruminants
Movement of potentially infected animals or products out of the protection zone ⁸	Evidence	No evidence
Predicted airborne spread of virus from infected premises	High	Low or absent
Suitable vaccine ⁹	Available	Not available
Origin of outbreaks (traceability)	Unknown	Known
Incidence slope of outbreaks ¹⁰	Rising rapidly	Shallow or slow rise
Distribution of outbreaks ⁷	Widespread	Restricted
Public reaction to total stamping out policy	Strong	Weak
Acceptance of regionalisation after vaccination	Yes	No

⁷ See Report of the Scientific Veterinary Committee of 14 November 1996 "The feasibility of identifying densely populated livestock areas in the Community that pose a particular high risk of major disease epidemics" doc ref VI/1986/96 final.

⁸ The presence of susceptible wildlife in the area should be taken into account.

⁹ High potency for all species and containing appropriate type/strain antigen.

¹⁰ An analytic expression (formula) which provides insight into the contribution of different parameters to the effectiveness of the control measures has been proposed (De Jong and Diekmann, 1992). The analysis is based on the 'basic reproduction ratio', R_0 (the average number of animals/herds infected by one infectious animal/herd), for which the following threshold condition holds: when $R_0 > 1$, the infection can spread through the population; when $R_0 < 1$, infection will eventually die out. 'Basic reproduction ratios' typical of foot and mouth disease epidemics in UK have been reported (Haydon et al. 1997).

6. Guidelines for the emergency vaccination programme

The National Contingency Plans of Member States (Council Directive 90/423/EEC, FAO 1993) should include all the provisions for the implementation of emergency foot and mouth disease vaccination.

The National Contingency Plans for emergency vaccination should provide an estimation of the total number of doses of foot and mouth disease vaccine required for the emergency vaccination (Commission Decision 91/42/EEC, Annex). This should be based on the most likely scenario and include the daily rate at which vaccine could be administered and the time over which the application of vaccination could be sustained.

The area of 'protective' emergency vaccination should be as small as possible, and its shape should be related to the geographical and meteorological situation. The inner boundary of the vaccination area should be clearly defined; on the basis of the available epidemiological data, it may include a part of the surveillance zone (i.e. an area 'at risk'), but not the protection zone. Provision of slaughter, milk collection and insemination services for vaccination zones must be considered in establishing the boundaries of restricted areas. Where such facilities are not contained in the zones, special controls are necessary if authorising transport from such zones to these facilities.

The usual disease control measures (including stamping out) as laid down e.g. in Council Directive 85/511/EEC should be continued irrespective of when vaccination commences.

Clinical inspections should always precede the administration of vaccine. Suspect signs must be reported. If a case of foot and mouth disease is encountered during the application of protective emergency vaccination, then vaccination must be suspended and measures taken.

Vaccine. An emergency vaccine should be a vaccine of high potency containing antigen of a strain which is antigenically appropriate. It should provide a sufficient level of protection after the application of a single dose. However, if the field strain is

antigenically different from the available vaccine strain and there is no alternative strain available it may be necessary to implement a second round of vaccination.

Cold chain facilities must be available for the storage and distribution of vaccine so that it is, at all times, kept under cool temperature conditions, as specified in the European Pharmacopoeia

Vaccination teams and equipment. A sufficient number of well trained vaccinators and the required equipment to ensure the rapid administration of vaccine to the animals must be immediately available according to prior contingency planning.

In the case of 'protective' emergency vaccination the first animals to be vaccinated should be those at the outer boundary of the zone. Vaccination should proceed inwards from those holdings towards the inner boundary. Personnel involved in vaccination should follow the zoo-sanitary measures specified in the National Contingency Plan to prevent the spread of infection between holdings.

In the case of 'dampening down' emergency vaccination within the infected area, the holdings should be selected for vaccination according to risk ranking with the highest priority being given to the vaccination of pigs, the species which has the greatest potential for the dispersion of plumes of airborne virus and environmental contamination downwind.

Identification and traceability of every vaccinated animal must be guaranteed (e.g. ear tagging or notching).

A *detailed report* at the end of a vaccination campaign must contain fundamental information about the number and the species of vaccinated animals, the holdings, if clinical signs were detected on holdings, the actions taken, and the number of doses of vaccine used.

7. Guidelines for the movement of animals and animal products within and out of an area which has been subjected to emergency vaccination.

7.1 Regionalisation

The concept of regionalisation in these circumstances has already been incorporated in Community law e.g. Council Directive 90/423/EEC (art. 2.3) amending Council Directive 64/432/EEC.

The Committee considers that there is no scientific reason to refuse a regionalisation policy for Member States which have used emergency vaccination under the following conditions:

- * the disease control measures laid down in Council Directive 85/511/EEC are fully implemented;
- * a detailed report giving up to date epidemiological information and full details of measures taken must be available;
- * the region is submitted to rigorous controls;
- * the control of movement of animals and animal products is effective.

Similar provisions should apply to third countries, according to OIE rules. In the context of emergency vaccination, international acceptance of regionalisation is essential.

7.2 Movement of vaccinated live animals within and out of the vaccination zone

The Committee notes that when a foot and mouth disease outbreak occurs in a free zone where prophylactic vaccination is not practised, there are two possible scenarios, in relation to the policy adopted:

- * **Policy 1: stamping out and surveillance.**

Taking into consideration Council Directive 85/511/EEC, free movement of live animals (ruminants and pigs) out of the restricted area (i.e. protection and surveillance zones) is permitted 30 days after the completion of stamping out in the last outbreak, provided

that adequate surveillance of the protection zone and cleaning and disinfection of the contaminated holdings have been carried out.

* ***Policy 2: stamping out, surveillance and emergency vaccination***

The OIE International Zoo-Sanitary Code (1997), Chapter 2.1.1., states that a vaccinated area can be considered free

* 1 year after cessation of the vaccination (Article 2.1.1.2; page 87), with documented evidence that an effective system of surveillance is in operation and that the regulatory measures for the prevention and control of FMD have been implemented,

or

* 3 months after slaughtering of the last vaccinated animal (Article 2.1.1.2; page 91), where stamping-out, serological surveillance and emergency vaccination are applied.

The OIE code does not state that free movement of vaccinated animals from free areas is permitted but this would be a logical conclusion.

In addition, the OIE rules do not take into account the new serological tests for FMDV-NSP, able to discriminate between vaccinated and infected herds. In spite of the uncertainties with regard to vaccinated herds, the Committee is of the opinion that the application of NSP-tests allows for an earlier lifting of the restrictions on the movement of vaccinated animals.

The Committee recommends that not less than 30 days¹¹ from the time of completion of vaccination, an adequate surveillance system (see 7.2.1 and 7.2.2 below) including serological tests for NSP in ruminants must be established in the vaccination area.

Restrictions could be lifted when the surveillance described below (paragraphs 7.2.1 to 7.2.3) for ruminants and swine has been completed with negative results. In the period from vaccination until lifting of restrictions, animals shall only be moved to a

¹¹ The 30 day period allows for 14 days needed for the development of complete protection plus a further 14 days as the maximum incubation period reported in the literature. (Roeder and Olechnowitz, 1980).

slaughterhouse preferably within the 'protective' vaccination zone, under the conditions detailed in section 7.3 of this report.

7.2.1 Surveillance to allow movement of ruminants

Free movement of vaccinated ruminants can only take place out of the vaccination zone when:

1. clinical inspection in all herds of the vaccination zone have provided no indication of FMD virus infection and;
2. the NSP-ELISA performed in all vaccinated animals has given a negative result and;
3. all the restrictions applied to protection and surveillance zones have been lifted in accordance with the Council Directive 85/511/EEC.

Cattle herds and sheep and goat flocks positive to NSP-test (i.e. herds with more than a singleton¹² reactor)¹³ shall be treated under the conditions detailed in the paragraph 7.2.3 of this report.

7.2.2 Surveillance to allow movement of swine

It is recognised that the NSP-tests are not yet validated for use in pigs. Until this is done, it is recommended to use tests for virus isolation in this species.

Free movement of vaccinated swine can only take place out of the vaccination zone when:

1- clinical inspection in all herds of the vaccination zone has provided no indication of FMD virus infection and;

2-the laboratory tests for virus isolation or genome or antigen detection, based on a statistically valid number of samples, have given negative results and;

¹² The precise definition of a singleton reactor needs to be addressed in the context of an accurate estimation of the specificity of the test in cases where high potency vaccines have been used.

3- all the restrictions applied to protection and surveillance zones have been lifted in accordance with the Council Directive 85/511/EEC.

Swine herds are considered 'infected' when FMD virus has been isolated or when genome or antigen has been detected in biological samples.

7.2.3 Action on positive results to surveillance

If there is any indication that in the premises with vaccinated animals:

* **virus is present** (clinical disease or virus isolation or genome or antigen detection), then the holding shall be treated as an outbreak (stamping out and restrictions);

* **virus has been present** (NSP-positive animals at numbers exceeding singleton levels) then the minimum actions should be:

- killing and destruction of the NSP-positive animals without delay;
- slaughter of the residual animals of susceptible species remaining on the holding, under controlled conditions; the products should be handled according to section 7.3 of this report;
- cleaning and disinfection of the holding;

7.3 Movement of animals for slaughter and products thereof within and out of the vaccination zone

7.3.1 Animals for slaughter

Movement of animals to slaughter in the 30 day period following the completion of vaccination should be limited to that absolutely necessary on welfare grounds. This is to permit the observation of any cases of disease in the zone.

¹³ Singleton reactors should be removed from the herd and destroyed. Samples should be taken from these animals for virus detection (isolation, PCR) and the NSP test repeated on all remaining animals in the herd.

Following this 30 day period until the lifting of all restrictions, animals may be moved to a slaughterhouse preferably within the 'protective' vaccination zone under the following conditions:

- * animals are accompanied by an official document certifying that all cloven hoofed animals in the holding of origin have been subjected to a clinical examination and have shown no clinical signs of foot and mouth disease;
- * animals have been transported directly from their holding of origin to an approved slaughterhouse preferably within the vaccination zone¹⁴, without passing through a market and without contact to other animals;
- * the transport vehicles have been cleaned and disinfected before loading and after the animals have been delivered;
- * animals have passed the ante-mortem health inspection at the slaughterhouse and have in particular been subject to a thorough examination of mouth and feet and have not shown signs of foot and mouth disease. Animals must be slaughtered without any delay on arrival at the slaughterhouse. This is particularly important in the case of pigs which might have encountered carrier cattle.

7.3.2 Beef and beef products (also mutton)

Beef from the above animals may be commercialised within and out of the vaccination zone provided that one of the following treatment has been applied and certified by the competent veterinary authorities:

- * maturation of carcasses at a temperature of more than +2°C for at least 24 hours and then the pH value in the middle of longissimus dorsi muscle has been recorded as less than 6.0, and deboning and removal of the main lymph nodes. Offal and heads should be destroyed or heat treated (Savi et al., 1962b).

or

¹⁴ Or as close as possible to the zone. Measures must be taken to avoid spread of infection.

* heat treatment to an FC-value of 3.00 or higher, i.e. autoclaving in tins (Council Directive 80/215/EEC), or alternative heat treatments such as those currently approved for pork (Council Directive 80/215/EEC), if also validated for beef.

7.3.3 Pork and pork products

Pork from animals slaughtered may be commercialised within and outside the vaccination zone as cured or heat-treated products. The treatment must be certified by the competent veterinary authority.

* *Heat treated products.*

Experiments have shown that adequate thermal processing (time-temperature combination) of pork prepared from FMD-infected animals has produced safe products (Savi et al. 1962 b). Council Directive 80/215/EEC prescribes thermal processing to core temperature of 70°C for 30 min.

* *Cured products.*

Pork products which are not heat treated owing to their particular characteristics (hams, salami, etc.), are cured and preserved by procedures such as salting, drying and smoking.

Hams. In hams, FMD virus is normally inactivated within 24-48 hours in the muscle, due to the drop of pH, but can persist longer in tissue such as bone marrow, lymph nodes or lard. The survival of FMD virus in typical Italian and Spanish hams has been studied by McKercher et al. (1987) and Mebus et al. (1993) respectively. The products, which were not deboned, were free of viable virus by days 170 and 168 respectively. According to the Council Directive 80/215/EEC deboned ham should be not be commercialised before 9 months have elapsed from the date of preparation.

Salami. The risk posed by salami (minced, cased and cured pork meat) can be considered negligible, provided these are manufactured industrially, according to the criteria given by the Scientific Veterinary Committee-Section Animal Health in 1995. In salami, FMD virus is normally inactivated in 24-48 hours in pig meat stored unfrozen after slaughter. In addition, the specific formulations used for salami production are able to eliminate any residual viral infectivity, mainly thanks to the low pH achieved in the mixture as a

consequence of the metabolism of the sugars by the starter microorganisms and the typical flora of salami (Savi et al. 1962 a & b, McKercher et al. 1975, Dhennin et al 1980 a & b, Panina et al. 1989).

7.3.4 Milk and dairy products

In accordance with the OIE Sanitary Code 1997, Appendix 4.3.2.3, page 541, milk produced within the vaccination zone in the period from the beginning of vaccination until the removal of all restrictions may be commercialised within or out of the vaccination zone provided that one of the following treatments has been applied in a plant preferably located in the vaccination zone and certified by the competent veterinary authorities:

* *if for animal consumption*, (a) double HTST pasteurisation (72°C for 15-17 sec), or (b) single HTST combined with another physical treatment, such as lowering the pH < 6 for at least one hour or additional heating to 72°C or more, combined with desiccation, or (c) single UHT pasteurisation (130°C for 2-3 sec) combined with another physical treatment referred to in (b) (Sellers 1969, Cunliffe et al, 1979; Scientific Veterinary Committee,1994; OIE International Zoo-Sanitary Code 1997).

* *if for human consumption only* , check the pH and (a) if 7.0 or over (abnormal), treat by double HTST or single UHT; or (b) if less than 7.0 then treat by HTST or UHT. (Scientific Veterinary Committee,1994; OIE International Zoo-Sanitary Code 1997).

No special ban should be enforced on *dairy products* produced during the period from the beginning of vaccination until the removal of all restrictions, provided that the raw milk has been previously treated as above.

Whey to be fed to pigs and produced from milk heat treated as above must be collected at least 16 hours after milk clotting and its pH must be recorded as <6.0 before transport to swine holdings within or out of the vaccination zone. Following a delivery to pig premises the vehicle must be cleaned and disinfected before it leaves.

7.3.5 Semen and Embryos

Production of semen and embryos in Artificial Insemination centres within the vaccination zone should be stopped during the period from the beginning of vaccination until all restrictions have been lifted. During that period, personnel at AI centres within the vaccination zone should not visit farms. If they are to be vaccinated, bulls or boars in AI centres must be checked for antibodies to FMDV before administration of vaccine in order to exclude that these centres may lead to spread of the disease (Amadori and Luini, 1995).

8. Conclusion and recommendations

In conclusion, the Scientific Committee on Animal Health and Animal Welfare having reviewed the scientific and technological progress made in the field of FMD diagnosis and vaccine production considers that emergency vaccination can be a useful tool in the control of FMD outbreaks with a risk or tendency towards uncontrolled spread. The text of this report sets out criteria leading to a decision to implement emergency vaccination against foot and mouth disease and establishes guidelines both for a vaccination programme and for the movement of animals and animal products within and out of the vaccination zone(s).

In particular, the Scientific Committee on Animal Health and Animal Welfare recommends:

The Community Reference Laboratory for foot and mouth disease should be established as a matter of urgency

The foot and mouth disease situation world-wide should be carefully monitored by the European Commission;

The antigens of recent highly contagious and significantly antigenically different FMD virus strains, particularly from regions neighbouring Europe, should be produced and stored in the EU or National antigen banks for production of emergency vaccines;

The quality of the antigens stored in the banks should be monitored by an Institute (Community Reference Laboratory) designated by the EU;

The suitability of the strains of antigens held in the banks should be kept continually under review;

Non structural proteins (e.g. 3ABC) should not be present in vaccines;

Computer assisted models should be further developed for strategic purposes (future planning, allocation of resources, operational use in epidemics);

The National Contingency Plans should consider the possibility of emergency vaccination and provide an estimate of all logistical requirements such as the number of vaccination teams required in different areas, in order to complete the task as rapidly as possible.

NSP tests should be optimised and further validated. The antigen used in these tests should be standardised. Regional laboratories should be trained in their practical use. An ELISA test kit, validated by an Institute designated by the EU, should be available at the national FMD laboratories.

In particular the specificity of NSP tests needs to be determined more accurately, especially when following the use of highly potent vaccine.

A panel of positive and negative sera should be established. Inter-laboratory comparison trials for diagnostic tests should be regularly carried out.

It is considered necessary for the Commission to pursue efforts to reach progress in negotiations within the framework of the World Trade Organisation for recognition of a regionalisation policy regarding trade restrictions for areas where FMD emergency vaccination has been applied, based on the principle of an acceptable risk level.

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10. Minority opinion Professor, Dr. Soren Alexandersen

Summary: The draft report on “Strategy for Emergency Vaccination against Foot-and-mouth disease (FMD)” have been discussed at two subcommittee meetings and I have on two occasions submitted written comments to the draft. Although the report has improved significantly, I still think it needs considerable improvement. Especially, because the safety inherent in the procedures is yet, in my opinion, not known in detail, and much more data is needed. So in conclusion, it is my opinion, that there is not enough data on the new tests to make the statements with any degree of precision. Therefore, it should be reworded to say, that earlier lifting of restrictions may be envisioned, when the full capacity of the tests is known (or may not be possible, if the tests have too many mistakes). Also, it still have to be shown, how these tests will work when used for screening thousands or millions of samples, and especially how precise they are when used as only diagnostic tool and on animals vaccinated in the field during an outbreak.

Specific remarks: The major issues missing or not dealt with properly are: a. When and how can restrictions be lifted, and what will the level of assurance be (compared to current regulations); b. Vaccinated animals should NOT be allowed to leave the area; c. Although almost no new information regarding potential importance of carrier animals in spread of disease is available, the current report apparently totally excludes the potential importance of carrier animals (state, that the sensitivity may in these situations only be 90%, meaning, that up to 10% of carrier animals may be negative against antibodies to NSP); d. Who decides to allow emergency vaccination in each case: PVC?; e. The details of post-vaccination surveillance is not detailed at all, this should be defined in detail in the report (however, data are most likely not yet available to detail this, because the prevalence of infection in vaccinated animals will be unknown); f. The sensitivity of the tests on animals vaccinated in the field and perhaps infected at/before/after vaccination, is not known in detail and may be a problem; g. The singleton reactor phenomenon mentioned in the report is not at all characterised for the NSP antibody test.

Regarding the period from vaccination to lifting of restrictions I do not agree with the report. At the current stage of knowledge, the period is set too short (not enough is known) and moreover, with the current knowledge, it would be necessary to sample ALL vaccinated animals or at least to sample large numbers of animals and rely potential lifting on a **full** epidemiological report. Thus, instead of a 30-day period after vaccination before screening, I would suggest a period of at least 60 days (to be on the safe side, when more data become available this period may be shortened). The opinion is based on a 14-day period for the vaccine to work and a 14-day period for the potential incubation period. However, in a biological system like this, these periods may work for the majority of the animals, however, as a safety margin (because nothing is known under field conditions) the period should, in my opinion, be

doubled (and thus at least 60 days after vaccination before start of NSP surveillance etc). It is mentioned in the report, that immunity can be induced by potent vaccines in a few days in both cattle and pigs. This may be true for most of the animals, however when many animals are vaccinated, some animals will be slower than others and some animals may react poorly and infection will thus depend on challenge dose. Secondly, piglets only respond when older than 2 weeks of age and also, two rounds of vaccination may be necessary to induce full protection for certain heterologous vaccines. Thus, the period before potential lifting of restrictions should have a wide safety margin.

Vaccination should in my opinion only be allowed OUTSIDE both the protection and the SURVEILLANCE zone. Otherwise, it will be impossible to estimate the potential infectious load in the area (based on clinical surveillance). However, if it is accepted, that no vaccinated animal can leave the zone except directly for slaughtering and processing, the vaccination in the surveillance zone could be accepted from a safety point of view.

In my opinion, vaccinated animals should not be allowed to leave the vaccination zone, except directly for slaughter and using the procedures described in section 7.3.2 and 7.3.3 of the report (after lifting of restrictions). All animals should go through this process.

CONCLUSION:

In conclusion, there are several weaknesses in the current report on emergency vaccination against FMD. The recommendations made will, with the current knowledge, represent a significant, and in my opinion intolerable, decrease in the safety of FMD control. The problems can be divided into two separate areas. The first area, which everything considered is a smaller problem, is the fact that the recommendations will result in vaccinated and thus seropositive (but NSP negative) animals being distributed from an outbreak near zone and out to all areas of the EU. This may for sure affect our status as non-vaccinating countries and furthermore, will present problems for export/import samples (which will react positive in the standard techniques). Having antibody positive animals in the region is in my opinion a scientific issue, because presence of a significant population of antibody positive animals may hide a potential FMD infection and may very well make clinical surveillance difficult and furthermore, put pressure on national laboratories for only using, or at least also using, the NSP tests instead of well known serological techniques.

The second problem is the major problem and can definitely not be ignored. It is a fact, that there may be an increased risk when allowing movement of vaccinated, potentially infected animals and products. It should be emphasised, that at the current stage of knowledge concerning the NSP techniques, these techniques are promising, however, not nearly enough is known to give any final recommendations. A potential scientific "safety level" may be reached, when we have more data, and provided, that any

recommendation or decision involving potential lifting of restrictions on vaccinated animals, should be based on a thorough, statistically highly significant, epidemiological surveillance for NSP antibodies and FMD virus isolation or genome/antigen detection. Thus, after vaccination in a zone (decided on the basis on thorough risk assessment) potential lifting of restrictions on herds/flocks can only be allowed after epidemiological analysis of the whole area and provided, that this analysis gives assurance for the absence of FMDV infection based on a high number of samples (statistically valid). However, vaccinated animals should not be removed from the zone except after lifting restrictions and then only directly for slaughtering and processing to remove potential FMD virus.

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