

# **EMERGENCY VACCINATION PROTOCOL**

1 April 2004

## Index

	<b><u>Executive Summary</u></b>	<b>Page 3</b>
1.	<b><u>Introduction</u></b>	<b>Page 3</b>
2.	<b><u>Purpose of Vaccination Protocol</u></b>	<b>Page 4</b>
3.	<b><u>Progress made on emergency vaccination since 2001</u></b>	<b>Page 4 - 5</b>
4.	<b><u>Legal framework</u></b>	<b>Page 5 - 6</b>
5.	<b><u>Emergency vaccination strategy</u></b>	<b>Page 6</b>
5.1	Species/area to be vaccinated	Page 6
5.2	Protective (to live) or suppressive (to kill) strategy	Page 6 – 7
5.3	Special Measures	Page 7 - 8
5.4	Dosage strategy	Page 8
5.5	Vaccination Surveillance Zone	Page 8 - 9
6.	<b><u>Operational requirements</u></b>	<b>Page 9</b>
6.1	Identification of the virus strain	Page 9
6.2	Provision and availability of suitable vaccines	Page 9
6.3	Marketing Authorisations	Page 9 - 10
6.4	Logistical arrangements for Vaccination	Page 10 - 11
6.5	Identification of vaccinated animals	Page 11
6.6	Lead-in time for emergency vaccination programme	Page 11 - 12
7.	<b><u>Post vaccination controls</u></b>	<b>Page 12</b>
7.1	3 phases of emergency vaccination campaign	Page 12
7.2	Controls over the movement of vaccinated animals	Page 12 - 13
7.3	Controls over milk and meat from vaccinated animals	Page 13 - 14
8.	<b><u>Exit Strategy</u></b>	<b>Page 14 - 15</b>
9.	<b><u>Glossary of terms</u></b>  See *	<b>Page 16</b>

# FMD EMERGENCY VACCINATION PROTOCOL

## Executive Summary

The Royal Society's Report on Infectious Diseases in Livestock recognised that there were a number of scientific and practical issues to be resolved before emergency vaccination could become a viable disease control option in the event of a future outbreak. This document sets out progress on these issues and outlines the factors which would need to be considered in the decision to use emergency vaccination. The Department will consider emergency vaccination as part of the control strategy from the start of any future outbreak of FMD. This is reflected in the new EU FMD Directive which will be transposed into domestic legislation during 2004. Substantial progress has been made on the testing and validation of Non Structural Protein (NSP) tests, especially for cattle, and although these are not yet at international recognition stage, this would not prevent us from vaccinating in the event of a future outbreak. We would, however, have to use a higher discriminatory test to demonstrate freedom from disease and this may result in a delay in regaining free status.

## 1. Introduction

"Emergency vaccination" is vaccination used in the face of an outbreak. It is to be distinguished from "prophylactic" (routine) vaccination which has been banned across the EU since 1992.

### Decision Tree

- The "Decision Tree", which forms part of the FMD Contingency Plan (see Annex B to the Contingency Plan), sets out the factors that the Government would take into account in deciding disease control strategy.. Since circumstances can vary widely, it is not possible to prescribe a detailed response in advance of an outbreak.
- The decision to adopt a particular control strategy will depend on a wide range of factors as indicated in the "Decision Tree", many of which cannot be determined until we have knowledge of the nature and extent of an outbreak. Veterinary and scientific advice and judgement remain vital in determining disease control strategy. This will, in turn be dependent on the quality of information available.

NB Terms marked \* are explained in the glossary at the end of this document

## **2. Purpose of vaccination protocol**

The purpose of this document is to clarify what factors would need to be considered in the decision to use emergency vaccination as a possible disease control measure in a future FMD outbreak. It is not possible to place deadlines or timescales on when decisions on disease control policy would be taken. Decisions would be made as quickly as possible given the particular set of circumstances and would be reviewed repeatedly as circumstances changed and more information became available.

## **3. Progress made on emergency vaccination since 2001**

Whilst there is still work to be done, much progress has been made towards resolving the issues surrounding an emergency vaccination policy since the 2001 outbreak of FMD. There is more detail on this in the relevant sections below, but progress to date can be summarised as follows:

- The UK holds vaccines which are suitable for use in an emergency vaccinate-to-live strategy (the Government's preferred vaccination policy).
- We are continuing to work with stakeholders to gain their acceptance of products from vaccinated animals entering the food chain as normal.
- The UK's independent supply of antigens are all suitable for use with NSP\* tests.
- Defra is continuing to work with the EU and the OIE\* to achieve an internationally validated NSP test.
- Defra is continuing to fund research into a confirmatory discriminatory test as an adjunct to current NSP tests.
- During negotiations on the new EU FMD Directive, the UK worked hard to strike the right balance in the controls imposed on products from vaccinated animals. The Directive allows the sale on the domestic market of untreated products from vaccinated animals after the completion of the survey to check for infected animals amongst the vaccinated population, but before FMD free status has been regained. In addition, during this period (known as Phase 3), untreated meat from vaccinated pigs can be exported, to another Member State, at their request; such meat would have to bear a special mark.
- The Government has published, as part of the FMD Contingency Plan, a "Decision Tree" which sets out the factors which the Government would take into account in deciding on disease control strategy.
- We have commissioned a Cost Benefit Analysis on Disease Control Strategies, which will consider a number of core scenarios and provide additional evidence for future decision making on disease control strategy.

Results from the Cost Benefit Analysis are expected towards the end of 2004.

- The UK has its own stocks of FMD antigens held, on its behalf by a commercial supplier and the EU Vaccine Bank also holds a range of antigens for emergency use.
- Defra has arrangements in place with an external contractor to implement an emergency vaccination programme. The contractor has trained a first response team made up of sufficient lay vaccinators and support staff for 50 teams and recruited 25 vets to support them. The contractor can ramp-up this level of response to meet any reasonable disease scenario within four to five days of notification. This is GB wide contract and the contractor will, at all times, be working under the control and direction of the State Veterinary Service.
- Vaccination teams can be operationally ready to vaccinate by day 5 of any outbreak. Strain identification of the virus and vaccine formulation might take a little longer. Vaccine could be formulated for despatch to the regional vaccination centres within 3 to 4 days once the strain is known. In practice, it is unlikely that vaccination would commence on this timescale as it will take time to collect the epidemiological data to support vaccination decisions.

#### 4. Legal framework

- A new **EU Directive (2003/85/EC) on measures to control foot-and-mouth disease** was adopted at Agriculture Council on 29 September. Transposition into domestic legislation will be achieved through a new FMD Order 2004 for England and parallel legislation in Wales, Scotland and Northern Ireland. The FMD Contingency Plan and Veterinary Instructions will also be updated to reflect such requirements in the new Directive.
- The EU Directive maintains the ban on **prophylactic** (routine) vaccination, which has been in place across the EU since 1992. This is in line with the recommendation of the UK Inquiry Reports into the 2001 outbreak and the report of the European Parliament Temporary Committee of Inquiry. This allows EU Member States to maintain the highest FMD status under international (OIE) rules of “countries free from foot-and-mouth disease without vaccination” which the UK is keen to retain.
- The **basic disease control policy** required under the new EU Directive remains the **slaughter of all susceptible animals on premises infected with FMD and those identified as “dangerous contacts”**.<sup>\*</sup> However, the Directive gives greater prominence to the potential use of emergency vaccination in the event of an outbreak as an adjunct to this basic slaughter policy. Article 14 of the Directive places a duty on Member States “to prepare all arrangements necessary for emergency vaccination

in an area at least the size of the Surveillance Zone” as soon as the first case of FMD is confirmed. The Directive does not detail exactly what these arrangements should be but requires that any vaccination should “ be carried out swiftly and in conformity with the rules of hygiene and biosecurity so as to avoid the spread of FMD virus”. Defra’s arrangements are set out in Annex D of the Foot and Mouth Disease Contingency Plan, which covers accommodation, equipment, personnel, vaccine supplies and emergency vaccination arrangements.

- The Government will consider emergency vaccination as a disease control option from the start of any outbreak of FMD, on the basis of **vaccinate to live**, wherever possible. This is in line with the recommendations of the main FMD Inquiries.
- Other relevant legislation is the **Animal Health Act 1981**, as amended (in respect of England & Wales only), by the 2002 Act. Section 14B of the amended Act requires the Secretary of State (SoS) to consider the most appropriate means of preventing the spread of disease, particularly the use of emergency vaccination. In addition, if measures additional to slaughter of animals on infected premises and those identified as dangerous contacts are required, the SoS has to publish reasons for using her preventive slaughter powers and explain why emergency vaccination is not used.

## 5. Emergency vaccination strategy

### 5.1 Species/area to be vaccinated

- **Article 14 of the new EU FMD Directive** requires a Member State to prepare all arrangements deemed necessary for emergency vaccination in an area at least the size of the Surveillance Zone (10km centred on an outbreak) immediately the first outbreak is confirmed.
- In advance of an outbreak, it is not possible to identify **how large the vaccination zone would be**. The decision on which species would be vaccinated and the size and shape of the vaccination zone would be determined by veterinary/epidemiological judgement. Other factors such as the availability of vaccine; the virulence of the strain; its tendency to airborne transmission; and how long the disease had been undetected, facilitating its spread, would all need to be taken into account. Seasonal farm management factors may also need to be taken into account.

### 5.2 Protective (to live) or suppressive vaccination (to kill) strategy

- The Government believes that if emergency vaccination is used, it should be on the basis of **vaccinate to live** wherever possible.

Protective vaccination (vaccination to live) would be considered:

- where veterinary and scientific advice is that an outbreak cannot be contained i.e. it threatens to become extensive, by culling susceptible animals on infected premises and dangerous contacts alone;
- where a defined category of animals can be identified for protection, either in geographical or species terms; this could include pet or sanctuary animals within a vaccination zone;
- to protect, where appropriate, zoo animals and rare breed collections.

Suppressive vaccination (vaccinate to kill) could be considered where the number of animals to be culled is likely to exceed the immediately available disposal capacity. In those instances, animals in defined areas would be vaccinated first and slaughtered only as disposal capacity became available. It could also be used where there is an urgent need to reduce the amount of virus circulating in an area and reduce the risk of spread beyond that area.

### 5.3 Special measures

- Article 15 of the Directive allows special measures to be applied for the conservation of “**farm animal genetic resources**” in the event of an FMD outbreak on premises that are identified in advance. The Directive places a responsibility on Member States to establish lists of holdings where animals are kept for purposes related to the conservation of animals that are indispensable for the survival of that breed (Farm Animal Genetic Resources).
- Depending on the circumstances, and veterinary and epidemiological advice at the time, the registered breeding nucleus may benefit from special provisions, providing that the highest levels of biosecurity were implemented to prevent the spread of disease. Special measures include derogations from the killing of susceptible animals subject to certain pre-conditions, if the premises becomes infected, and emergency vaccination.
- Following a consultation exercise, which closed in November 2003, the list of susceptible “rare breeds” has now been agreed (available on Defra’s website) and the following definition for a “breeding nucleus” for each species:

Cattle: 8 cows + bull (or AI)  
 Goats: 6 females + male  
 Pigs: 3 sows + boar (or AI)  
 Sheep: 16 ewes + ram

- Based on these criteria we will be able to compile a register of holdings which contain breeding nuclei of genetically valuable stock which may qualify for special measures in the event of an outbreak. Information on the registration process will be publicised on the website, later this year, once arrangements have been finalised.
- Arrangements for **zoos and wildlife parks** are slightly different. They can also qualify for the special measures under Article 15 of the Directive but

there is no requirement in the Directive for pre-registration of such premises. However, the Royal Society Report “Infectious Diseases in Livestock” recommended that a list of zoos be drawn up so that they can easily be located in the event of a future outbreak. Defra’s Global Wildlife Division are working on this register in conjunction with Local Authorities.

- Animals in laboratories and fenced areas or in bodies, institutes, or centres keeping animals for scientific purposes may also qualify for special measures.

#### 5.4 Dosage Strategy

- To comply with the UK Marketing Authorisation for FMD vaccines, a second dose would be required 3-4 weeks after the first dose and boosters required every 6 months (and every 4 weeks for pigs). However, the need for a second inoculation or booster will depend on the weight of disease challenge. NSP testing can start 30 days after vaccination has been completed within the vaccination zone.

#### 5.5 Vaccination Surveillance Zone

- Under the EU FMD Directive strict controls would apply to vaccinated animals (see Section 7 below). In addition, there would have to be a **vaccination surveillance zone** of not less than 10km wide surrounding the vaccination zone. Within the vaccination surveillance zone, movements restrictions would apply, animals could not be vaccinated and there would be enhanced disease surveillance.
- The perimeters of both the Vaccination zone and its surrounding surveillance zone would have to be clearly defined to ensure livestock keepers were in no doubt about the zone they were in. The zone would be defined by using obvious geographical boundaries such as roads, rivers and other natural features which may pose a natural barrier to the spread of disease e.g. a large abutting area of woodland which was livestock free.
- Given the surveillance requirements in the EU Directive (blood sampling and serological testing), it would be appropriate to limit the size of any vaccination zone to the minimum necessary to control disease based on an epidemiological assessment taking account of , amongst others, the following factors :
  - Natural barriers to the spread of disease;
  - The number of cases in the area, their geographical disposition and estimated area of future spread;
  - The numbers and type of livestock affected and the duration of that infection;
  - The predominant livestock species in the area and its density;
  - The type of husbandry
  - The standards of biosecurity

- Any prevailing climatic conditions that might predispose to the spread of disease
- Animals are at greatest risk of infection within 3 kilometres of an existing outbreak.

## 6. **Operational requirements (see also Annex D of FMD Contingency Plan)**

### 6.1 Identification of the virus strain

- Identification of the particular strain of virus and assessment of the protective effect of the available vaccine against the strain could take two days or longer.

### 6.2 Provision and availability of suitable vaccines

- The UK has its own stocks of 8 different FMD antigen strains held, on its behalf, by a commercial supplier. These independent supplies have over 10 million doses of FMD antigen at a potency suitable for emergency use.
- The number of doses available would need to be taken into account and this would vary according to the strain. Defra annually takes advice from the Institute of Animal Health at Pirbright, on those strains of FMD which present the greatest risk to the UK and reviews the strains and quantities held in the light of that advice.
- In addition, the UK has access to 30 million doses of a wider range of strains in the EU Vaccine Bank for emergency use.
- Once the strain of virus has been identified, it would take 3 days to formulate water-based vaccine and 4 days for oil based vaccine.

### 6.3 Marketing Authorisations

- Emergency vaccination strategies must be acceptable to stakeholders who will want assurances that the vaccines to be used at the very least meet regulatory requirements. Council Directive 2001/82/EC requires that no veterinary medicinal product may be placed on the market of an EU Member State unless a Marketing Authorisation (MA) has been issued by the competent authorities of that Member State in accordance with the Directive's provisions. The existence of an MA indicates that an independent assessment of compliance with European Pharmacopoeia (EP) standards has been carried out. Compliance with EP standards represent minimum legal requirements. The existence of an MA confirms that the vaccine is safe in terms of animal and human health and that it works.
- It is, therefore, desirable, that vaccines, including those held in international banks, such as the EU Bank, have MAs.

- Under current arrangements, MAs issued in one EU Member State are not applicable in others except where they have been through mutual recognition procedure as provided for under Directive 2001/82/EC
- The UK has purchased stocks of antigen that have UK MAs issued by the UK regulatory authority which confirm that the vaccines meet the safety and quality criteria i.e. are safe in terms of animal and human health. In order to meet the requirements of Directive 2001/82/EC they also need to be challenge tested so that they can be released as authorised products. Challenge testing of FMD vaccines provides veterinary services and stakeholders with assurances regarding the efficacy of the vaccines to be used. Such vaccines could thus be released onto the UK market as authorised products in the event of a future FMD outbreak. A programme of challenge testing is underway.
- In an emergency, Article 8 of Directive 2001/82/EC would allow the use of FMD vaccines which do not have full UK MAs because they had not yet been challenge tested and after informing the Commission of the detailed conditions of use. Such vaccines would be safe and quality assured.
- The Food Standards Agency have issued a statement which confirms that there are no risks to human health from consuming products from animals which have been vaccinated against FMD with an approved vaccine.

#### 6.4 Logistical arrangements for vaccination

- During the 2001 FMD outbreak, ADAS were commissioned to develop a programme for the emergency vaccination of cattle in parts of Cumbria and Devon. ADAS has since been retained to provide operational support for emergency FMD vaccination (vets and vaccination teams working under State Veterinary Service direction) until such time as Defra is able to let a formal contract to cover this operation, expected shortly.
- Vaccine would be distributed to field vaccination teams via regional vaccination centres.
- Consultation on a proposal to amend legislation to allow lay vaccination of livestock in the event of a future outbreak of FMD closed on 19 March 2004. This would allow vaccine to be supplied to and administered by lay vaccinators in the event of the use of emergency vaccination in a future outbreak. This approach would relieve pressure on veterinary surgeons during any future outbreaks of FMD, when it is likely that they would be fully occupied on other essential disease control duties. The proposed amendment to the Veterinary Surgeons Act 1966 would allow non-veterinarians to administer FMD vaccine, provided they were over 18 years of age, acting under the direction of a veterinary surgeon and deemed competent by the directing veterinary surgeon. An amendment to the Medicines Act 1968 would allow supply of FMD vaccines to and by

Defra appointed officers, contractors, volunteers and lay vaccinators in the event of a future outbreak.

- Arrangements to enable emergency vaccination will form part of a series of desktop exercises being conducted through the course of 2004 and beyond.
- Defra is seeking, through its FMD communications strategy, to ensure that all those likely to be affected by an emergency vaccination programme will know, in advance, what the process is likely to involve.

#### 6.5 Identification of vaccinated animals

- Additional, permanent and indelible marking of vaccinated livestock is required under Article 47 of the new FMD Directive to ensure that all vaccinated animals are killed or products from vaccinates are correctly treated. Vaccinated animals would have to have markings which were permanent and indelible, but not unique, so we intend to identify each vaccinated animal with a specific tag. Stocks of these ear-tags have been ordered and arrangements are in place to increase supplies if required in the event of an outbreak. Where animals do have individual numbers, such as in the case of statutory ear tags for cattle or flock marks for other animals, our procedures will require that number to be recorded when the animals are vaccinated. Each vaccination team of 3 people will include support staff for recording ear tag numbers.

#### 6.6 Lead in time for emergency vaccination programme

- Without knowing the specific circumstances of a particular outbreak, it is not possible to place a precise timescale on this in advance.
- The contractor is currently on a 5-day standby to implement a vaccination programme from the time of confirmation of disease. Within the 5-day time period, the particular strain of the FMD virus would need to be identified and the vaccine would need to be formulated ready for dispatch to the vaccination centres. Formulation could take up to 3 days for a water-based vaccine or 4 days for an oil-based vaccine.
- Veterinary advice to Ministers would be based on epidemiological evidence. However, it is probable that due to a lack of epidemiological data at the outset and the time necessary for its acquisition and veterinary assessment it would be unlikely that vaccination would start five days after positive confirmation of the first outbreak.
- Estimates have been made on how quickly the most densely populated livestock areas could be vaccinated. Assuming 10km vaccination zones, it is estimated that it would take just over 4 days for 50 vaccination teams to vaccinate cattle only in a cattle dense area, just under 6 days to vaccinate sheep only in a sheep dense area and just under 3 days to vaccinate pigs only in a pig dense area.

- Whilst it is important to complete a vaccination campaign as quickly as possible, the speed at which this could be achieved would depend on a range of factors such as the number and species of animals on each holding, handling facilities, available daylight hours, travel time from vaccination centre to farm, weather conditions and so on.

## 7. **Post vaccination controls**

### 7.1 There are 3 phases of an emergency vaccination campaign:

- Phase 1 – During emergency vaccination and until 30 days after completion of vaccination
- Phase 2 – Post vaccination and prior to completion of NSP survey
- Phase 3 – After completion of survey and before FMD free status regained

Details of the controls applicable during each Phase are outlined below.

### 7.2 Controls over the movement of vaccinated animals

- It should be noted that, under the EU FMD Directive, restrictions would apply in the Protection Zone (minimum 3km radius centred on an outbreak) and Surveillance Zone (minimum 10km radius centred on an outbreak). In the Protection Zone (PZ), movement of susceptible animals from and between holdings would be prohibited except under licence for emergency slaughter. In the Surveillance Zone (SZ), movement of susceptible animals from holdings would be prohibited except under licence to slaughter and for leading to pasture under certain conditions.
- Specific restrictions would also apply to the movement of animals within the vaccination zone and products from vaccinated animals as set out below. If a vaccination zone overlaps with a PZ or a SZ then the stricter regulations would apply.
- **During emergency vaccination and until 30 days after completion of vaccination (Phase 1)**, no movement of live susceptible animals between holdings within the vaccination zone or out of the vaccination zone would be permitted except, after clinical inspection of the herd, for direct transport for immediate slaughter to a slaughterhouse within, or in exceptional circumstances, close to the vaccination zone.
- **Post vaccination and prior to completion of NSP survey (Phase 2)** no movement of live susceptible animals between holdings within the vaccination zone or out of the vaccination zone would be permitted. However, direct transport for immediate slaughter to a slaughterhouse could be authorised subject to the animals not coming into contact with other susceptible animals during transport and in the slaughterhouse; all animals in the herd of origin, or all vaccinated animals in the vaccination

zone, undergo clinical inspection and NSP testing; and pass an ante mortem inspection at the slaughterhouse during the 24 hours before slaughter and show no signs of FMD.

- **After completion of survey and before FMD free status regained (Phase 3)**, movements to slaughter would be as in Phase 2. Movement of live susceptible animals between holdings in the vaccination zone would be permitted, subject to licence.

### 7.3 Controls over milk and meat from vaccinated animals:

- **During emergency vaccination and until 30 days after completion of vaccination (Phase 1)**, fresh **milk** would have to be treated\* at a dairy either within the vaccination zone or transported outside the zone for treatment subject to strict biosecurity and transport rules. **Meat** from vaccinated animals would have to be cross-stamped, transported in sealed containers and then treated (heat treated or naturally fermented and matured). Once the meat had been treated, the resulting product would be given the health mark, thus enabling it to enter intra Community trade. Consumers would not see cross-stamped meat.
- **Post vaccination and prior to completion of NSP survey (Phase 2)**, fresh **milk** would have to be pasteurised at a dairy either within the vaccination zone or transported outside the zone for treatment subject to strict biosecurity and transport rules. **Fresh meat from vaccinated pigs** would continue to require heat treatment before it could be placed on the market. However, **fresh meat** (excluding offal) **from vaccinated ruminants** (i.e. sheep and cattle), would be subject to deboning and maturation so that it could bear an oval health mark to enable it to enter intra Community trade. Indications from the industry are that such treatments would be uneconomic for sheepmeat production.
- **After completion of survey and before FMD free status regained (Phase 3)** fresh **milk** would have to be pasteurised at a dairy either within the vaccination zone or transported outside the zone for treatment subject to strict biosecurity and transport rules. **Fresh meat from ruminants** would still be subject to deboning and maturation as in Phase 2 but derogation exists which would permit **untreated meat from vaccinated cattle and sheep to be marketed freely on the domestic market** (i.e. within the Member State), and therefore approach more normal market conditions for livestock producers. **Likewise fresh meat from vaccinated pigs** would still have to be treated as in Phase 1 but a derogation allows for untreated meat from vaccinated pigs to be placed on the domestic market and may, if requested by another Member State, be exported to them with a special mark.
- It should be noted that, under the EU FMD Directive, meat and meat products from animals in the Protection Zone and Surveillance Zone and meat and meat products produced in these Zones are also subject to treatment similar to that from vaccinated animals for at least 30 days after

these zones have been applied. After 30 days derogation may be granted by SCOFCAH for untreated products to be allowed from the PZ and SZ

- There would be no compensation for loss of value of vaccinated animals as there is no reason why their products could not be sold as normal.
- The Food Standards Agency have confirmed that there is no risk to human health from consuming products from vaccinated animals and products would not have to be labelled as such.

## 8. Exit strategy

- Trading partners would be concerned about the risks of importing disease via live animals, animal products or food products from a country which had suffered an outbreak of FMD. A clear strategy to demonstrate absence of disease is essential, whether emergency vaccination is used or not, to ensure normal trading can be resumed as quickly as possible following an outbreak.
- The role of **vaccinated carrier animals** (i.e. where persistent infection is present beyond 28 days) is an important one in terms of exit strategy. At present we are unable to determine the level of risk posed by carrier animals and, under OIE rules, we have to assume that there is a risk until we are in a position to prove otherwise. Research into the role of carrier animals in spreading disease is on-going.
- The OIE Code sets down rules for recovery of FMD free status. Disease free status can be recovered three months after the last case where vaccination is not used or after the slaughter of all vaccinated animals if stamping out and “suppressive” vaccination to kill is used. Serological surveillance would be required to demonstrate the absence of infection before disease free status could be granted. Where a policy of stamping out and “protective” vaccination to live is used, disease free status can be recovered after six months following completion of serological surveillance which demonstrates the absence of infection in the remaining vaccinated population. The serological survey would be based on the detection of antibodies to the nonstructural proteins of FMD virus to distinguish vaccinated from infected animals.
- There is not yet an **internationally accepted NSP test** for use in any species of livestock. The OIE has established an ad-hoc group to evaluate the NSP tests for FMD. Validation of tests in the field needs to be carried out for all species, as this is the key to developing agreed testing regimes for the control of FMD where emergency vaccination is used as part of the control strategy.
- The principle of using NSP testing for serosurveillance to distinguish herds that have been vaccinated against FMD from those that have been infected has been agreed by the OIE Standards Commission but the

sampling level necessary to demonstrate this is still under consideration. There are currently two NSP serological tests for FMD NSPs described in the OIE manual but as these are not sufficiently reliable on an individual animal basis, they cannot be accepted as prescribed tests for the purposes of international trade. Nevertheless, the OIE FMD and Exotic Diseases Commission and the OIE Code Commission have accepted the principle of herd based NSP serosurveillance as a basis for countries regaining FMD free status.

- A number of commercially produced NSP tests exist with differing levels of validation and work has been published about the validation and use of these tests in the field. The main limiting factor for the validation of NSP tests is the availability of suitable panels of sera, especially from vaccinated and then challenged animals. Full validation requires panels of seven FMD serotypes in at least three target species. Testing has to be carried out in high security accommodation. There is also a need for thorough trials where vaccination and exposure to virus occur.
- There are currently several research projects in the UK, Europe and America. There is a European Concerted Action project on FMD diagnosis. Defra is supporting research in this area.
- In summary, quite substantial progress has been made on the testing and validation of NSP tests but these are not yet at international recognition stage. However, the absence of an internationally validated NSP test would not prevent Defra from using vaccination in the event of a future outbreak. Defra would perform a herd-based test on a statistical basis and, where positive results were found we would use a higher discriminatory test (Probang). This may result in a delay in demonstrating freedom from disease and it therefore remains vital that an internationally validated test is available as soon as possible.

9. **Glossary of terms**

<b>“dangerous contacts”</b>	These are animals of susceptible species which are believed to have been exposed to infection.
<b>NSP (Non structural protein) tests</b>	Antibody tests which can differentiate between animals which have been vaccinated and those that have been vaccinated and exposed to the FMD virus, or may still be infected.
<b>“pre-emptive” or “preventive slaughter”; “firebreak” cull</b>	This involves the culling of animals which are not on infected premises nor are dangerous contacts or necessarily exposed to the disease, in order to prevent the wider spread of disease outwith an area. Use of this power is described by a Disease Control (Slaughter) Protocol as required by the Animal Health Act 1981, as amended.
<b>OIE</b>	Organisation International des Epizooties – the international animal health standard setting body
<b>Milk treatment</b>	Where the pH of the milk is below 7.0 : High Temperature Short Time (HTST) pasteurisation at 72° for at least 15 seconds or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test. Where the pH of the milk is above 7.0 : This treatment has to be applied twice or combined with another heat treatment. NB The pH of milk is normally 6.6 so single pasteurisation would generally apply.

**AMED, Defra  
26 March 2004**