www.defra.gov.uk

Exotic Animal Disease Generic Contingency Plan
2006 Draft Consultation Version- July 2006

Version 1.2 (replacing version 1.1)

Covering Foot & Mouth Disease, Avian Influenza, Newcastle Disease, Classical Swine Fever, African Swine Fever & Swine Vesicular Disease

Volume 2- Foot & Mouth Disease

defra
Department for Environment
Food and Rural Affairs

Department for Environment, Food and Rural Affairs
Nobel House
17 Smith Square
London SW1P 3JR
Telephone 020 7238 6000
Website: www.defra.gov.uk

© Crown copyright 2006
Copyright in the typographical arrangement and design rests with the Crown.

This publication (excluding the royal arms and departmental logos) may be re-used free of charge in any format or medium provided that it is re-used accurately and not used in a misleading context. The material must be acknowledged as crown copyright and the title of the publication specified.

Information about this publication and further copies are available from:

SVS HQ – Contingency Planning
Room 805
Defra
1a Page Street
London SW1P 4PQ
Email address: svshqcontingencyplanning@svs.gsi.gov.uk

Tel: 020 7904 8604

This document is also available on the Defra website.

PUBLISHED BY THE DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

CONTENTS

Note: See Volume 1: Generic Annex K for **Glossary**

SECTION 1. Foot and Mouth Disease (FMD)

1.1. FMD is a highly infectious viral disease affecting cloven-hoofed animals, in particular cattle, sheep, pigs, goats and deer. Other susceptible animals include camelids and some wild animals such as coypu, deer and zoo animals including elephants.

1.2. Fever is followed by the development of vesicles or blisters - chiefly in the mouth or on the feet. There are 7 main types of virus, which produce similar clinical signs and which can only be differentiated in the laboratory.

1.3. FMD can spread by direct or indirect contact with infected animals. Infected animals begin excreting the virus a few days before signs of the disease develop. Pigs in particular produce large numbers of virus particles. The disease is spread mechanically by the movement of animals, persons, vehicles and other things, which have been contaminated by the virus. Airborne spread of the disease can also take place. The prevailing meteorological conditions and local topography determine the distance that the disease can travel and this may be considerable.

1.4. Meat from the carcases of animals infected with FMD at the time of slaughter can transmit the virus. In the past, outbreaks of the disease have been linked with the importation of infected meat and meat products.

1.5. Advice from the Department of Health is that it is very rare for humans to be affected by FMD. There has only been one recorded case of FMD in a human being in Great Britain in 1966. The general effects of the disease in that case were similar to influenza with some blisters. The Food Standards Agency has advised that the disease has no implications for the human food chain.

1.6. The FMD virus can be destroyed by heat, low humidity, or certain disinfectants, but it may remain active for a varying time in a suitable medium such as the frozen or chilled carcase of an infected animal and on contaminated objects.

1.7. Good biosecurity is required to stop onward spread.

1.8. The prompt detection and reporting of the initial outbreak of disease are crucial in limiting the ultimate scale of the emergency, and arrangements to enhance surveillance are being taken forward under the Veterinary Surveillance Strategy which was launched in October 2003. Part of this strategy aims to upgrade the use of information on the numbers and location of livestock, which will be important in the smooth operation of this contingency plan in the event of an outbreak. Management of the outbreak will also depend upon the availability of geographical information systems and expertise, which is being developed with this plan.

1.9. An updated illegal imports action plan for 2003-2004 was published in June 2003, which consolidates and builds upon progress made since March 2002. Since 1 January 2003 the import of meat, milk and their products into the United Kingdom (UK) from most non-European Union countries for personal use has been prohibited. There are also restrictions on other products of animal origin. The concession, which provides for small quantities of controlled plants and plant products to be imported by travellers from outside the EU for personal use is currently under review.

1.10. To improve effectiveness of border controls, all anti-smuggling activity was transferred to Her Majesty's Revenue and Customs on 11 April 2003 and this is proving successful. It also means that more stringent penalties for smuggling prohibited or restricted items of up to seven years' imprisonment and/or unlimited fines, could be applied through prosecution under the Customs and Excise Management Act. All Customs officers have powers to seize illegal imports.

1.11. HM Customs has four mobile strike teams dedicated to the enforcement of restrictions on products of animal origin (POAO). They have also increased the number of detector dogs teams trained to tackle smuggling of POAO. This enforcement activity will be further enhanced over the coming financial year.

1.12. A leaflet setting out in detail the rules on personal imports is being distributed via HM Customs, who have taken over responsibility for publicity at our ports and airports. Revised posters are on display in more prominent positions at ports and airports.

SECTION 2. General Legislation – FMD

Animal Health Act 1981

2.1. The Animal Health Act 1981 provides the powers for the control of FMD.

2.2. The 1981 Act, together with the FMD (England) Order 2006, which is made under it provides for the following measures:

- Power of entry to premises for the purpose of veterinary inquiry;
- slaughter of affected, suspected or exposed animals;
- seizure and control of affected carcases and things;
- cleansing and disinfection of premises, vehicles and people;
- movement controls on people, animals and vehicles;
- slaughter (and payment of compensation) of animals on welfare grounds arising as a result of movement controls;
- other controls in a number of control zones.

Animal Health Act 2002

2.3. The Animal Health Act 2002 amended the Animal Health Act 1981 and supplemented its existing powers by allowing animals to be slaughtered wherever this is necessary to prevent the spread of disease.

2.4. However, the 2002 Act amendments require the Secretary of State to publish the reasons for using this preventive slaughter power, prior to exercising it. Emergency vaccination would have to be considered prior to any preventive slaughter powers, and, if not used, the reasons would have to be published.

2.5. The 2002 Act amendments allow vaccinated animals to be slaughtered and require compensation at the market value for such animals to be paid. They also provided for the publication and annual review of this Contingency Plan and required the publication of Biosecurity guidance. They strengthen enforcement powers, including improved powers of entry to farms; require reasonable assistance for the purposes of slaughter, vaccination and testing; and increase penalties.

European Union (EU) Legislation

2.6. In 2001, the legal basis for the control of FMD across the EU was Council Directive 85/511. However, this was replaced by Council Directive 2003/85/EC, adopted in September 2003. This Directive updates measures contained in previous Directives, taking into account scientific progress and experience gained in eradicating the disease in the EU in 2001. It sets out minimum control measures Member States must take against FMD and allows

stricter measures to be taken if the disease situation requires it. It requires rapid action to be taken as soon as disease is suspected, including movement controls.

2.7. The ban on prophylactic (routine) vaccination, which has been in place across the EU since 1992, is maintained in the new Directive, though emergency vaccination is moved to the forefront of our control strategies in the event of an outbreak. However, under both Directive 85/511 and Directive 2003/85 the required basic disease control policy is the slaughter of all susceptible animals on premises infected with FMD and those identified as "dangerous contacts".

2.8. Other features of Directive 2003/85 include:

- provision for the adoption of "special measures" (including possible protective emergency vaccination and derogation from slaughter) to be applied in premises including laboratories, zoos, and wildlife parks and to allow the conservation of "farm animal genetic resources"

the requirement for 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.

- details of the treatment required for animal health reasons for meat and meat products and milk and milk products from animals from the Protection, Surveillance and Vaccination Zones. Such treatments include heat treatment or deboning and maturation of meat and pasteurisation of milk.

Secondary Legislation

Council Directive 2003/85 was transposed into domestic legislation in late 2005/early 2006 by the introduction of three separate pieces of secondary legislation:

- ***The Animal Health Act 1981 (Amendment) Regulations 2005*.** These Regulations take account of the Directive by making a minor technical amendment to the Animal Health Act 1981 to change the Secretary of State's previous discretion to slaughter susceptible animals on infected premises to a duty to slaughter on infected premises only. This does not represent any change to policy but is merely to bring the 1981 Act into line with the Directive. The amendments made by the Regulations also allow certain exceptions to this duty to slaughter in laboratories, zoos, wildlife parks, for rare breeds and separate production units.
- ***The Foot and Mouth Disease (Control of Vaccination) (England) Regulations 2006.*** These transpose the vaccination provisions of the Directive. The Regulations move the potential use of emergency vaccination to the forefront of disease control, as an adjunct to the basic slaughter policy. The Regulations ban vaccination except under

licence by the Secretary of State and also ban the export of vaccinated animals to other EU or EEA states. The Regulations also similarly provide for zones of control, both for where vaccination takes place and where it is expressly prohibited, and introduces treatments for meat and other animal products from vaccinated animals.

- ***Foot and Mouth Disease (England) Order 2006.*** This transposes the bulk of the FMD Directive, as well as some additional provisions preserved from the FMD Order 1983 (which is repealed). Under the Order, the slaughter of susceptible animals on infected premises remains the principal tool for tackling an FMD outbreak. The Order sets out the procedures and controls required on suspicion and confirmation of FMD and provides for a number of zones of different levels of control. In particular, the Order introduces a number of treatments, such as heat treatment (cooking) and deboning and maturation, that have to be applied to meat and other animal products from infected areas.

2.9. The table below indicates the local veterinary action to be taken in relation to the level of suspicion.

SUMMARY OF INITIAL ACTION ON SUSPECT CASES

Level	**FMD**
0	All restrictions on premises lifted no further action.
1	Suspect animal(s) left alive and observed. Samples submitted for laboratory diagnosis. Premises restrictions imposed. Impose temporary control zone (Form C)
2	Suspect animal(s) showing typical lesions are killed. Samples submitted for laboratory diagnosis. Premises restrictions imposed. Impose temporary control zone (Form C)
3	All susceptible livestock on the premises are pre-emptively slaughtered. Samples submitted for laboratory diagnosis. Premises restrictions imposed. Impose temporary control zone (Form C)
4	Disease confirmed on clinical grounds only without awaiting laboratory results. Samples submitted for laboratory diagnosis. Premises restrictions imposed. Area restrictions imposed All susceptible livestock on the premises slaughtered. Dangerous contacts traced and slaughtered depending on veterinary assessment.

SECTION 3. Disease Control Strategy

3.1. The disease control strategy adopted will be consistent with the UK's EU obligations and in line with the new FMD legislation which transposed Directive 2003/85. The Government's objective in tackling any fresh outbreaks of FMD will be to eradicate the disease as quickly as possible and to maintain the UK's disease-free status. In doing so, the Government will seek to select a control strategy which:

- causes the least possible disruption to the food, farming and tourism industries, to visitors to the countryside, and to rural communities and the wider economy;
- minimises the number of animals which need to be slaughtered, either to control the disease or on welfare grounds, and which keeps animal welfare problems to a minimum;
- minimises damage to the environment and protects public health;
- minimises the burden on taxpayers and the public at large.

Control Policies

3.2. The following policies will be applied on confirmation of FMD:
(Note: The first case will be confirmed by the CVO following Laboratory diagnosis)

- A GB wide national movement ban of susceptible species will be put in place immediately through the declaration of a Supplementary Movement Control Zone throughout the whole country around a Temporary Control Zone – which would be the area immediately surrounding a suspect premises.
- Export health certificates for animals and animal products will be withdrawn. Exports from GB of susceptible animals during the risk period will be identified and notified to the importing countries.
- Diseased and other susceptible animals on infected premises will be culled with a target of within 24 hours of report. Those identified as dangerous contacts will be culled with a target of within 48 hours of report.
- Emergency Vaccination will immediately be considered as an option based upon emerging epidemiological and logistical factors. If emergency vaccination is used it would be on the basis of vaccinate-to-live wherever possible.
- A Protection Zone will be imposed with a minimum radius of 3km around the Infected Premises and a Surveillance Zone with a minimum radius of 10km. In the Protection Zone no animal movements will be allowed except for movement to emergency slaughter. In both the Protection and Surveillance Zones, there will be requirements for increased levels of biosecurity on farms, cleansing and disinfection (C&D) of vehicles, people and machinery moving

on/off farms. Movement of animals, animal products, feed and bedding will be prohibited, except under licence. Products from animals in these zones will be subject to treatment to ensure destruction of the FMD virus. This is an animal health measure rather than a public health measure. Such treatments include the pasteurisation of milk (normal process for most milk produced in the UK), heat treatment or de-boning and maturation of meat in certain circumstances.

- Disposal by incineration will be implemented immediately with rendering as the next option and other disposal routes being available as an additional resource subject to environmental, land use planning and public health considerations.
- Footpaths will only be closed on Infected Premises and within the 3km Protection Zone, (A Veterinary Risk Assessment and Protocol for Rights of Way closure is at Volume 1: Generic Plan, Annex G

3.3. Additional control strategies which might be employed include:

- culling of other susceptible livestock exposed to the disease (e.g. premises under virus plumes, premises adjoining the infected premises); and
- pre-emptive or 'firebreak' culling of animals not on infected premises, not dangerous contacts or not necessarily exposed to the disease, in order to prevent the wider spread of the disease outwith an area.

3.4. A Disease Control (Slaughter) Protocol setting out the requirements that must be followed in the event of a pre-emptive cull is at Volume 2: FMD, Annex C.

3.5. Further action will depend on the circumstances of a particular outbreak and on scientific and veterinary advice. The Decision Tree for FMD control strategies (Volume 2: FMD Annex A & B) will be followed in deciding what action to take. This sets out the factors the Government will take into account in deciding which strategy to adopt in order to control and eradicate the disease. The Animal Health Act 1981, as amended by the **Animal Health Act 2002**, lays a duty on the Secretary of State to consider vaccination as a means of preventing the spread of the disease. Wherever possible this would be on the basis of emergency vaccinate-to-live. If a decision not to vaccinate were taken the reasons would be explained before further measures were introduced.
Consultation with interested parties, to address outstanding technical, commercial and communications issues on emergency vaccination is continuing.

Vaccination Communications

3.6. A paper on FMD Control Policy and Communications Strategy is on the Defra Website. The paper is aimed at planning for: -

- communications in advance of a future outbreak;
- communications during a future outbreak, by contributing an 'emergency vaccination' element for inclusion in Defra's FMD Contingency Plan

The Strategy paper should be read alongside the "Communications" section in the Contingency Plan

Emergency Vaccination

Introduction

3.7. There are various factors which must be taken into account before reaching a decision on whether or not to adopt an emergency vaccination strategy against the exotic animal diseases covered by this plan, and if so whether the animals should subsequently be killed or not. The Department's preferred approach is that emergency vaccination should be on the basis of 'vaccinate to live' wherever possible. As soon as the FMD strain has been identified the Department will make arrangements for a suitable antigen to be made up into vaccine.

3.8. The full range of options and the factors that the Department will take into consideration in the event of a future outbreak are contained in full in the Decision Tree and reflected in the Foot and Mouth (Control of Vaccination)(England) Regulations 2006. An Illustration of how these factors will be taken into account is given in Vaccination Scenario at Volume 2: FMD, Annex E. This covers how we will deal with rare breeds and zoo animals.

Vaccination Operations

3.9. Genus PLC have been appointed to implement any future vaccination programme under the direction of the SVS. Under the terms of the contract, 50 teams (150 staff) have been trained by Genus to be operationally ready to implement a programme of emergency vaccination within 5 days of an outbreak, if requested. In addition, 61 veterinary surgeons will be provided to support these teams to check for disease prior to vaccination and to direct the work of lay teams in the field. We also have a provision to require Genus to ramp up the level of response to meet any reasonable disease scenario at 4 to 5 days' notice. See Volume 2: FMD, Section 4 for Emergency Vaccination arrangements.

Vaccination Teams

3.10. Upon confirmation of FMD the contractor responsible for emergency FMD vaccination will be notified by the Director Contingency Planning Division to set its plans in action to establish the required structures and organisation, numbers of vets and team members within the agreed time.

3.11. The vaccination contractor will notify its pre-appointed and trained vets, team leaders and vaccination members of the situation, brief them of the current situation, and provide refresher training on bio-security measures and on-farm vaccination. Specialist training covering vaccination, tagging and data recording will also be provided. All external contractors will be required to make themselves familiar with all Health and Safety requirements and will be provided with Biosecurity Protocols. All local recruits to vaccination teams must meet, and confirm in writing that they comply with, specified criteria including no contact with susceptible livestock for 3 days prior to starting the programme, during the programme and for 3 days after completion.

Further Action

3.12. Once FMD is confirmed the main elements of this plan are brought into action.

- Volume 1: Generic Plan, Section 3 outlines emergency preparedness & mobilisation
- Volume 1: Generic Plan, Section 4 describes outbreak management
- Volume 1: Generic Plan, Section 5 sets out the main elements of the Communications Plan;
- Volume 1: Generic Plan, Section 6 describes the strategic, tactical and operational organisations and structures.

These last two are augmented by the SVS instructions and the local office contingency plans.

SECTION 4. Outbreak Management – FMD

Human Welfare

4.1. For guidance on health and safety and staff welfare refer to Volume 1: Generic Plan, Section 3.

Biosecurity Guidance

4.2. Anyone coming into contact with livestock or their waste runs the risk of spreading animal diseases. Biosecurity is the prevention of disease causing agents entering or leaving a livestock premises. It involves a number of measures and protocols designed to prevent potential disease causing agents being spread from one premises to another.

4.3. Biosecurity guidance to prevent the spread of animal diseases has been developed (in accordance with legislation[1]) This guide, for anyone who comes into contact with animals, can be found at Volume 1: Generic Plan, Annex H of this Plan and on the Defra website at:

http://www.defra.gov.uk/animalh/diseases/pdf/biosecurity_guidance.pdf

Animal Welfare

4.4. There is a responsibility on all involved with the keeping of livestock to anticipate problems and to take steps to mitigate the effects. Guidance will be issued by Defra to farmers in advance of, or in the early stages of, movement restrictions being put in place. If welfare problems arise which cannot be alleviated by management or husbandry practices, farmers will be given the opportunity to move their animals under licence. Such movements will include movement to slaughter for the food chain or to more suitable land or buildings. If it is more appropriate fodder may be taken to the stock and Defra may assist in facilitating access to fodder and bedding.

4.5. If it is considered appropriate and to prevent deterioration in welfare standards, Defra will arrange the slaughter and disposal of animals via a Livestock Welfare Disposal Scheme. Animals will be slaughtered in abattoirs or purpose built killing plants. On farm slaughter will only take place when animals cannot be licensed off the farm or when the animals cannot be transported because they are unfit for transport e.g. heavily pregnant animals or newly born calves, piglets and lambs. Each case will be evaluated to ensure that welfare standards are maintained. There will be no payment made to farmers for animals slaughtered under such a scheme. This is in line with the policy set out in the Government's response to the FMD Inquiries (November 2002). This states that "*experience has shown that payments to farmers under such schemes can provide a disincentive for them to take*

---

1 Animal Health Act 1981 as amended by the Animal Health Act 2002,

responsibility for looking after their animals, and may also create a false market".

4.6. The Head ofStrategic Farming Businesses Division/ Livestock Products Division, in consultation with the Heads of Animal Welfare Division, and Exotic Disease Prevention and Control Division will draw up a contingency plan for such measures and will consult stakeholders on it.

Conservation of "Farm Animal Genetic Resources"

4.7. Under the Animal Health Act 1981 (as amended by the Animal Health Act 1981 (Amendment) Regulations 2006 special measures can be applied for the conservation of "farm animal genetic resources" (rare breeds) on premises that are identified in advance, in the event of an FMD outbreak. There are agreed definitions for such groups of animals and a registration process has been developed, which is publicised on the Defra website. Providing the highest levels of biosecurity are implemented to prevent the spread of disease, premises holding the registered breeding nucleus may qualify for derogations from killing all susceptible animals if the premise becomes infected, and consideration will be given to the use of emergency vaccination if the premises falls within a vaccination zone, but did not meet the criteria for vaccination. The derogation from slaughter would only be applied for the rare breed animals and not for any "commercially" kept animals on the same premises. The use of any of the measures would only be available in exceptional cases and the message about the registration of animals is being carefully managed to ensure that producers have realistic expectations about the possibility of rare breed animals being spared from slaughter.

Conservation of Zoo Animals

Derogation for Zoos and Wildlife Parks

4.8. Species of animals susceptible to foot and mouth (FMD) are defined by the FMD (England) Order 2006 as a cow, bull, sheep, goat, deer, camel, llama, alpaca, guanaco, vicuna, any other ruminant, and any swine (that is, a member of the suborder Suina of the order Artiodactyla), elephants and rodents (excluding pet rodents).

4.9. An amendment to the AHA 1981 (under the Animal Health Act 1981 (Amendment) Regulations 2005) allows for an exemption from the duty of slaughter on infected premises (although still subject to a discretion to slaughter) to be applied to certain types of premises where susceptible species are present. These include zoos and wildlife parks in addition to laboratories and certain premises where animals are kept for scientific purposes or for the conservation of animals that are indispensable for the survival of that species/breed. We would also consider the use of emergency vaccination.

4.10. As recommended by the Royal Society Report, individual zoos or owners of rare breeds would be responsible for applying for permission to vaccinate animals of susceptible species.

4.11. The decision to vaccinate would be informed by the legal requirements of the Animal Health Act 1981 (as amended) and the FMD (Control of Vaccination) (England) Regulations 2006, and considered in line with veterinary and epidemiological advice at the time of an outbreak. Such a decision would take into account biosecurity measures employed at the premises, including restriction of access.

4.12. The arrangements for the vaccination of zoo animals have yet to be finalised, however consideration is being given to the most appropriate personnel to undertake it.

4.13. There is no requirement for zoo animals to be pre-registered to enable them to qualify for special measures under the FMD legislation. However, the Royal Society Report recommended that a list of zoos be drawn up so that they can be easily located in the event of an outbreak. Defra's Global Wildlife Division has developed a database for England and is currently populating this with information received from Local Authorities.

Operational Procedures

Initial Investigation

4.14. For details on operational procedures to be followed at the initial investigation stage refer to Volume 1: Generic Plan, Section 3.

Valuation

4.15. A list of valuers who are approved to undertake livestock valuation on behalf of Defra for exotic disease control is maintained by the SVS and reviewed annually. Each valuer has instructions for carrying out valuations. In the event of an outbreak of FMD, Defra will contact these valuers and confirm their eligibility and wish to remain on the list. They will also be provided with the latest version of the Instructions to Valuers.

4.16. Where livestock are required to be valued the Field Operations Team in the LDCC will contact a valuer from the list. If necessary, more than one valuer may be appointed if the nature of the stock is beyond the expertise of one valuer and to ensure valuation and hence slaughter is undertaken as rapidly as possible. Only valuers from the approved list may be used. If appropriate, clerical assistance to facilitate the rapid valuation may be available.

4.17. In the event of an animal disease outbreak, the Department will call upon the services of Monitor Valuers who have been appointed (these appointments will be reviewed regularly). Initially the Monitor Valuers will attend Defra offices in London to advise on further instruction and guidance to issue to valuers (reflecting species affected, area etc.) to ensure uniformity in

valuations and fairness to both livestock owners and taxpayers. Depending on the extent of the outbreak the Monitor Valuers could be situated in London and in/near LDCCs.

Compensation

4.18. A review of all the animal disease compensation arrangements is being undertaken with a view to rationalisation and simplification. Part of this process will be to look at the case for compulsory standard valuation. This would remove the need for individual valuation in many or most cases. Such a system would help speed up the slaughtering process which is necessary to further reduce the risk of disease spread and would ensure a greater degree of uniformity in animal valuation.

Slaughter

4.19. The policy in the event of an outbreak of FMD is governed by the Foot and Mouth Disease (England) Order 2006 and is to slaughter susceptible animals on infected premises and those identified as dangerous contacts. See Volume 2: FMD, Section 3 and Annex C for further details on Disease Control Strategy and Disease Control Slaughter Protocol.

Disposal

4.20. See Volume 1: Generic Plan, Section 3 for details on disposal options

Cleansing and Disinfection of Affected Premises

4.21. Preliminary C & D will remain the responsibility of Defra and will be undertaken and paid for by Defra. Government funding of secondary cleansing and disinfection on farm premises will be subject to review and separate consultation as part of the consideration of the future funding of disease control measures.

Restricted Zone

4.22. A restricted zone is an area where restrictions are imposed around protection and surveillance zones and which can extend to cover the whole of the country (and would do so at least in the early stages of an outbreak although it might subsequently be shrunk to cover only part of the country to allow regionalisation and freedom from control for areas that are free of disease).

Immediate Ban on Moving Livestock – Controlled Area

4.23. All livestock movements from any farm premises are **prohibited** once disease has been confirmed and a Declaratory Order made. Movements within farm premises (e.g. from field to field) may continue to take place. This will apply nationally if the disease is FMD.

4.24. These restrictions will apply until the extent of the disease has been assessed and the risk of further spread is minimised. The movement of infected livestock poses the greatest risk of a disease spread.

4.25. Livestock in transit at the time disease is confirmed will be allowed to continue to its destination or to return to the premises of departure. Stock at markets, collecting centres and assembly centres should remain there for up to 21 days, unless their owner or new owner wishes to send them to slaughter (once the abattoirs are operating) or back to the premises from which they were consigned. Premises which receive/take live animals (excluding abattoirs) in these circumstances would be subject to restrictions for at least 21 days.

4.26. As the disease situation becomes clearer, certain types of movements will be permitted subject to certain conditions. The first movement is likely to be movements of livestock to slaughterhouses. The condition applied will depend upon the type of restrictions the premises or area is under. It will be some time before movements of livestock to other farms will be permitted, especially if the recipient farm has resident livestock. Likewise it will be some time before movements of livestock to livestock markets or shows will be permitted.

4.27. In a few circumstances it may be necessary to move livestock in an emergency situation e.g. straying stock; livestock at risk of rising water levels; emergency veterinary treatment etc. These exceptional circumstances will be dealt with locally on a case by case basis taking into consideration the welfare of the livestock and the disease risk.

Surveillance

4.28. Those carrying out clinical examinations or serological sampling will do so in accordance with the FMD (England) Order 2006 in transposing the requirements of Annex III of Directive 2003/85/EC (which may be varied by decisions of the European Commission).

Serology

4.29. The Institute for Animal Health (IAH) Pirbright and the Veterinary Laboratories Agency at Weybridge provides the diagnostic testing service for FMD. It also carries out additional tests (i.e. VNT) on positive or inconclusive serology samples submitted by VLA.

4.30. IAH Pirbright offers an immediate serology capacity of up to 8,000 samples per week. Defra has an agreement with the VLA that they will provide serological testing capacity for FMD on a contingency basis of 120,000 samples per week at three laboratories. The first laboratory would be ready to start testing within three weeks of notification with an initial capacity of 7,000 tests per week, 20,000 tests in the second week and reaching full capacity of 40,000 in the third week. The second laboratory would be operational within 6 weeks and a third laboratory within 8 weeks with the

same capacity build up. Full capacity of 120,000 tests per week would be reached by the tenth week.

4.31. Personnel required to undertake blood sampling will be recruited and trained under the co-ordination of Human Resources Services Division. Personnel could be drawn from veterinary/agricultural students and from local Job Centres.

4.32. In a vaccination zone surveillance will be carried out, after a minimum of 30 days have elapsed since vaccination was completed, to establish whether any vaccinated herd or flock has become infected with virus.

4.33. Diagnostic testing will be carried out in accordance with the requirements of Annex XIII of Directive 2003/85/EC (which may be varied by Decisions of the European Commission).

Transport of Samples

4.34. DVMs will ensure they have access to the best means of transporting blood samples during an animal disease outbreak as set out in SVS operational instructions.

Emergency Vaccination Arrangements

Accommodation

4.35. For vaccination, the contractor will provide 3 portable forward vaccination centres capable of being relocated to areas of the country where vaccination services are required, to enable a vaccination programme to commence on day 5 of an outbreak. Each forward vaccination centre comprises of:

- a transportable 'office' equipped to accommodate up to 12 staff to be involved with the control scheduling and reporting of vaccination activity and the provision of necessary supplies;
- a transportable 'mess room' providing basis facilities (rest room and canteen) for staff and for use for meetings. The Mess Room will also be the operational centre for a small team of reserve Vaccinators responsible for control, cleaning, disinfection and distribution of handling equipment;
- a secure equipment storage facility, consisting of hired containers;
- a secure location for clinical waste.

4.36. Additionally, a range of suitable sites are currently being investigated for use as vaccination centres. In doing so, consideration will be given to the following factors:

- good road access to the target area(s) and to any satellite centres - where possible, within the target area;

- appropriate security systems (day and night);
- parking;
- office accommodation for management and administrative staff;
- appropriate IT and telecoms facilities;
- secure refrigerated storage facilities for vaccine;
- storage facilities for equipment (vaccination kits, personal protection equipment, footbaths, buckets, tagging and inspection equipment, etc.;
- facilities for mixing, storage and safe disposal of disinfectant;
- suitable area for plunge disinfection of Personal Protective Equipment (PPE) and subsequent drying;
- suitable area for vaccination team dispatch.

Equipment

4.37. The Vaccination Contractor is required to supply, store and distribute the necessary equipment to support a vaccination programme and to replace items as they reach the end of their shelf life or have been found to deteriorate. The Contractor will appoint Stores Managers to maintain these stores - which will hold enough equipment to supply 50 vaccination teams and veterinary surgeons for at least the first 5 days of a vaccination programme - and will have in place contracts for the replenishment of those stocks within 48 hours.

4.38. Defra will remain responsible for the maintenance of call of contracts for disinfectant, ear tags and applicators, mobile handling facilities and vehicles to tow mobile facilities complete with disinfectant containers and power washers and call off contracts are currently being put in place for this purpose.

Personnel

4.39. The vaccination contractor is in a position of being operationally capable of vaccinating on day 5 following confirmation of disease. To arrive at this state of readiness sufficient vaccinators and support staff have been trained to provide 50 teams and some 60 vets have been recruited to support this first response team. Working under the overall control of the SVS, the role of these vets will be to conduct pre-vaccination farm visits, to check for any overt signs of disease, and also to be responsible for the veterinary direction of vaccination teams in the field. The vaccination contractor also has the capability to ramp up the number of vaccination teams to meet any reasonable disease scenario within 4/5 days of notification.

4.40. A Health and Safety Team will be established by the vaccination contractor as part of the management of operational aspects. This will consist of a Manager and 2 other trained H&S consultants. This team will produce

risk assessments for pre-vaccination visits by vets, for farm vaccinators, on handling facilities and maintain the necessary documentation to accompany this. The vaccination contractor will comply with best practice and all relevant provisions whether statutory or otherwise, relating to health and safety at work and shall ensure that employees and sub-contractors also comply and shall produce evidence of such compliance if asked to do so.

4.41. All external contractors will be provided with, and will make themselves familiar with, Biosecurity Protocols.

4.42. To ensure that emergency vaccination could be implemented without delays in any future outbreak, the Veterinary Surgeons Act 1966 and the Medicines Act 1968 have been amended. This allows non-veterinary personnel to handle and administer FMD vaccine and in particular will allow vaccine to be supplied and administered by lay vaccinators who:

- Are 18 years of age or over
- Are acting under the direction of a veterinary surgeon, and
- Have obtained a certificate of competence from a veterinary surgeon

4.43. All casual staff recruited by the contractor must meet specified criteria, including no contact with susceptible livestock for 3 days prior to starting the programme, during the programme and for 3 days after completion. They must sign to say that they comply.

4.44. Defra will convey the scope and policy of the project to the vaccination contractor, and confirm the approach to be taken. This will involve providing vaccine delivery arrangements. Defra will also keep the vaccination contractor informed of all suspect and confirmed cases as they occur and will keep the vaccination contractor informed of current policy and changes which may affect field operations.

Vaccine Supplies and Emergency Vaccination Arrangements

4.45. The UK has its own stocks of 9 different strains of FMD antigen, adding up to over 20 million doses held on its behalf by a commercial supplier. In addition, the EU Vaccine Bank holds a wide range of antigens for emergency use. The number of doses available and strains is kept under review, including taking advice from IAH Pirbright on those strains of FMD which present the greatest risk to the UK. As soon as the FMD strain responsible for the outbreak is identified and it has been confirmed that one of the antigens held in the UK bank will afford protection, the supplier will be instructed to formulate vaccine. Vaccine formulation by the designated external contractor takes 4 days.

4.46. A call-off contract is in place with the external contractor for the delivery of vaccine (stored at the correct temperature) to the vaccination centre.

4.47. When an vaccination zone is set up, a vaccination surveillance zone of at least 10 km width surrounding the vaccination zone must be designated.

4.48. Upon establishment of the emergency vaccination zone, the vaccination contractor will then produce a complete list of holdings within selected parishes (or other agreed area to be targeted) in the Vaccination Control Zone and identify those with animals that require vaccination as advised by Defra. This information will be drawn together from the following sources, which Defra will provide access to, where appropriate:-

- Defra Census Data;
- The Rural Payments Agency (RPA);
- Cattle Tracing System (CTS);
- Integrated Administration and Control (IACS) data;
- Defra's Disease Control System (DCS) on Infected Premises and Dangerous Contacts;
- Contextual datasets, such as Ordnance Survey (OS), Boundary Line (to produce parish and county boundaries), and OS raster map products.
- List of holdings containing a breeding nucleus of animal genetic resources (rare breeds).

4.49. The vaccination contractor will then contact farmers to arrange visits (giving 3 days notice where possible) and check animal handling facilities.

4.50. Pre-vaccination visits by veterinary surgeons appointed by the vaccination contractor will be arranged to carry out inspections which will detect suspected FMD and to exclude these from the vaccination programme.

4.51. Teams will be withdrawn from farms where clinical signs of FMD have been discovered. In doing so, biosecurity protocols must be followed (i.e. remove traces of organic matter from clothing, equipment, disinfect and remove any protective clothing at gate, wash wellingtons, waterproofs and equipment (inc. vehicles) with an approved disinfectant, and place all items for disposal into a clinical waste bag, which should then be sealed for disposal. Teams would be redeployed after suitable biosecurity protocols have been followed and a 72 hour break.

4.52. Where FMD is not found, vaccination teams will be deployed to carry out vaccination, record animal numbers, collect and return records. Vaccinated animals will be ear-tagged in a manner outlined in the FMD (Control of Vaccination) (England) Regulations 2006 and advised by Defra. For identification purposes, vaccinated cattle will also have their details recorded on the cattle passport and, for all animals, on the Defra disease control database. However, in an outbreak situation where the disease has been rapidly brought under control it will not be necessary to administer booster doses.

4.53. Under the current UK Marketing Authorisation conditions, FMD vaccine is authorised for use as a multi dose vaccine i.e. the initial vaccine is followed by a second 3-4 weeks later, and a further booster after six months (or every 4 weeks after the initial vaccine is administered in the case of pigs.) However in an outbreak situation where the disease has been rapidly brought under control it will not be necessary to administer booster doses.

4.54. The vaccination contractor will also provide progress reports and ad hoc management information to NDCC at Page Street by 18.00 hours daily.

Timing

4.55. The vaccination contractor is required to be operationally capable of vaccinating on day 5 of an outbreak with at least 17 vets (although a reserve of over 60 vets has been recruited) and sufficient trained vaccinators and support staff for 50 teams. Working under the overall control of the SVS, the role of these vets will be to conduct pre-vaccination farm visits, to check for any overt signs of disease, and also to be responsible for the veterinary direction of vaccination teams in the field. As emergency vaccination is to be considered as an option from the start of any future FMD outbreak, the vaccination contractor will be placed on standby by the Contingency Planning Director as soon as disease is confirmed. The particular strain of the FMD virus would need to be identified and the vaccine would need to be formulated before vaccination could begin.

4.56. Veterinary advice to Ministers will be bases on epidemiological evidence and it is unlikely to be immediately available. It is probable that gathering epidemiological data, veterinary assessment of this epidemiological data, the use of the Decision Tree and the development of advice on the strategic deployment of vaccination made it unlikely that vaccination could begin until more than five days after the first confirmed case.

Expert Group

An FMD Expert Group has been established, to maintain an expertise in order to assist in ensuring preparedness against a disease outbreak.

4.57. The FMD Directive requires the establishment of a permanently operational expert group comprised of epidemiologists, veterinary scientists and virologists, to maintain an expertise in order to assist the competent authority in ensuring preparedness against an outbreak of FMD. The Directive also sets down the functions this group would be expected to fulfill if an outbreak occurred.

4.58. Pre-outbreak the FMD Expert Group will meet on at least a six monthly basis.

4.59. In the event of an outbreak, the FMD Expert Group in some form will

meet on a daily basis.

The FMD Expert Group will comprise:

Chair: Defra CVO/DCVO

FMD advice/consultation on clinical disease recognition	IAH Pirbright
FMD virologist/diagnosis	IAH Pirbright
FMD pathogenesis/pathology	IAH Pirbright
FMD Vaccination	IAH Pirbright
FMD Epidemiology	Defra's Consultant Epidemiologist
Meteorologist	Met Office/IAH Pirbright
Serology	VLA
Observer/link to Science Advisory Council	Head of Veterinary Research Division, Defra
Epidemiologists	SVS (HQ) Vets and other staff responsible for field epidemiology
Modelling representatives	
Veterinary representatives of the devolved administrations	

4.60. The expert group will be a strategic/tactical level group of specialists whose role will be to provide advice to senior management on surveillance programmes, analyse information and advise on control strategies. They will report to and be directed by the ADPG. In an outbreak the Expert Group will also have close links with the NEEG, the NDCC and the SAC-ED through its nominated member.

National Emergencies Epidemiology Group

4.61. A group of people will be established who have skills and technical knowledge of clinical science and epidemiology of FMD and the methods of prevention and eradication of an outbreak of the disease. In the event of an outbreak this group will become the national emergencies epidemiology group providing advice and information to the centre and to the policy group.

- This group will comprise of five teams with expertise drawn from the AHWDG, SVS, VLA, IAH and Met office as appropriate. The teams will be responsible for:
  - Descriptive epidemiology

- Analytical epidemiology to include data analysis, data release, GIS and involvement with surveillance strategy for disease and disease freedom
- Modelling to include interspread, development of models and liaison with other modelling groups
- Providing epidemiological information from the field (National Field Epidemiology Team)
- Risk assessment to update the existing risk assessments from the 2001 outbreak

[This page is left intentionally blank]

FMD Annexes

Decision Tree for Disease Control Strategies against FMD – FMD ANNEX A

Disease Control Strategies: FMD Decision Tree

Introduction

1. This paper outlines the measures that may be taken to slaughter or vaccinate animals in the event of an outbreak of FMD. It sets out the factors the Government will take into account in deciding which strategy to adopt in order to control and eradicate the disease in the future.

2. The Animal Health Act 1981 as amended, requires slaughter of all susceptible animals on infected premises, and provides for culling of susceptible animals on epidemiologically linked holdings (known as dangerous contacts). This reflects the EU's policy of adopting "FMD free without vaccination" status for all Member States, and is provided for in Defra's FMD Contingency plan.

3. Beyond this basic strategy, which will apply in all cases, there are a range of additional options and strategies potentially available depending on the circumstances of a particular outbreak and on the scientific and veterinary advice. Section 14B of the Animal Health Act 1981 requires the Secretary of State to consider what is the most appropriate means of preventing the spread of disease, in particular the use of vaccination. The FMD (Control of Vaccination) (England) Regulations 2006 place emergency vaccination at the forefront of disease control strategies. The range of options includes: -

- culling of other livestock exposed to the disease (e.g. premises under virus plumes, contiguous premises); and,
- emergency vaccination (either to live or to kill; within an area or in a ring around an area);
- pre-emptive or 'firebreak' culling of animals which are not on infected premises nor are dangerous contacts nor are necessarily exposed to the disease, in order to prevent the wider spread of the disease within an area.

4. Since each disease outbreak is different and each has to be tackled at speed and – inevitably – with imperfect information it is not possible to prescribe in detail which strategy will be followed in advance of knowing the circumstances of a particular outbreak. This calls for a flexible approach, which recognises that different approaches may be needed in different geographical areas or to deal with different species. Nevertheless, there is clear advantage in reaching a view on the likely options for response in advance. Accordingly, this paper and the enclosed "decision tree" seeks to set out:

- The factors that would be taken into account in deciding whether to use emergency vaccination and if so whether to vaccinate to live or kill.
- The factors that would be taken into account in deciding slaughter policy.

5. The Government's objective in tackling any fresh outbreaks of FMD will be to eradicate the disease as quickly as possible and to maintain the UK's disease-free status. In doing so, the Government will seek to select a control strategy which:

- causes the least possible disruption to the food, farming and tourism industries, to visitors to the countryside, and to rural communities and the wider economy;
- minimises the number of animals which need to be slaughtered, either to control the disease or on welfare grounds, and which keeps animal welfare problems to a minimum;
- minimises damage to the environment and protects public health;
- minimises the burden on taxpayers and the public at large.

See Volume 2: FMD, Annex D & E – Vaccination Protocol & Scenario

Vaccination Policy

6. In responding to the FMD Inquiries the Government has made clear that where measures additional to the culling of infected animals and dangerous contacts are needed, emergency vaccination will be considered as part of the control strategy. The legal basis for such a strategy has been transposed from EU legislation and incorporated into the FMD (England) Order 2006 and the FMD (Control of Vaccination)(England) Regulations 2006. The Government accepts that if emergency vaccination is used it should be on the basis of vaccinate-to-live wherever possible.

7. The legislation allows for the use of emergency vaccination in circumstances where an outbreak of FMD threatens to become extensive in the Member State concerned; where other Member States are at risk due to the geographical situation or prevailing meteorological conditions; where other Member States are at risk due to epidemiologically relevant contacts; and in Member States at risk due to geographical situation or meteorological conditions in a neighbouring third country. The legislation also 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.

8. The decision to introduce emergency vaccination is normally taken by the European Commission in consultation with Member States in the Standing Committee on the Food Chain and Animal Health, although Member States can vaccinate and then seek the EU's agreement later. Two types of vaccination strategy are envisaged and are reflected in UK legislation:

(i) "Protective Vaccination" (Vaccination to live)
(ii) "Suppressive Vaccination" (Vaccination to kill)

9. The Government is committed to being in a position to trigger an emergency vaccination campaign should the need arise. It is essential to have stakeholder support and the Government has engaged in dialogue with a wide range of stakeholders in order to achieve, so far as possible, a shared understanding in advance of an outbreak of the factors which influence the choice of control options. The Decision Tree is intended to assist this process.

Protective Vaccination (Vaccination to live)

10. This strategy would be considered:-

where veterinary and scientific advice is that an outbreak could not be contained by stamping out of Infected Premises and Dangerous Contacts alone; where a defined category of animals could 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 breeds collections as recommended by the Royal Society Inquiry and provided for under the Vaccination Regulations 2005. These Regulations also extend special measures to animals in wildlife parks and laboratories.

11. The FMD (Control of Vaccination) (England) Regulations 2006 outline factors to be considered and the conditions under which emergency vaccination should be carried out. Criteria to be taken into account when a Member State is considering using emergency vaccination include:

- the risk of an outbreak in the UK becoming widespread in any part of the country;
- the risk of an outbreak spreading to and from England in susceptible animals, carcases or other things liable to transmit disease;
- spread of disease from prevailing meteorological conditions;
- the threat of disease to laboratories, zoos, wildlife parks or other premises which keep and display animals principally for educational purposes;
- the threat of disease to premises keeping animals for research, conservation, display and education of the public and conservation of species or farm animal genetic resource;
- the availability of vaccine and resources to conduct a vaccination programme;

- the criteria in Annex X of the FMD Directive.

The guidelines also indicate that emergency vaccination should be considered if it is foreseeable that the targets of culling infected animals within 24 hours of confirmation and dangerous contacts within 48 hours cannot be met for two consecutive days.

Such criteria can only ever be indicative rather than prescriptive. 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. Veterinary/epidemiological judgement will remain a key factor in determining the most effective disease control policy in any set of circumstances.

Suppressive Vaccination (Vaccinate to Kill)

12. This strategy could be considered where the number of animals to be culled is likely to exceed the 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. The Vaccination Regulations require that suppressive vaccination is only carried out within a Protection Zone that is normally within 3km of an infected premises. This requirement does not mean that all vaccinated animals in a PZ will be slaughtered; it may only be some within this area.

Stamping Out Policy

13. The Animal Health Act 1981 requires slaughter of all susceptible animals on infected premises, and provides for culling of susceptible animals on epidemiologically linked holdings, as well as culling of susceptible animals on holdings where FMD is suspected.

14. The Act also provides for slaughter of:

- Animals affected or suspected of being affected with FMD.
- Animals in the same place or in contact with animals affected or suspected of being affected with FMD.
- Animals which are believed to have been exposed to FMD infection.
- Animals to prevent the spread of FMD e.g. a 'firebreak' cull.

Animals Affected or Suspected of Being Affected

15. When the SVS is made aware of suspicion of foot and mouth disease in animals they will arrange for a veterinary investigation to be undertaken.

16. The decision to slaughter will be based either on the results of laboratory tests carried out on samples arising from animals suspected of being affected with disease, or on clinical evidence of disease. In an area

considered to be free of disease, except in exceptional circumstances, it is likely that disease will be confirmed on laboratory results. However, once disease has become established in an area it is likely that cases will be confirmed on clinical grounds alone in order to ensure animals are slaughtered quickly. However, samples will be taken to aid the epidemiological inquiries. All susceptible animals on an infected premises are required to be slaughtered under the Animal Health Act.

Animals Which Are Believed to Have Been Exposed to Infection

17. Animals may be slaughtered if they are believed to have been exposed to infection. In these cases, animals will be subject to a veterinary inquiry to determine if, in the opinion of the Veterinary Inspector, they have been exposed. In making this judgement the Veterinary Inspector may take account of national information from experts that animals in certain areas have been exposed.

18. Animals that are believed, based on veterinary judgement, to have been exposed to infection are known as Dangerous Contacts. This can include animals on contiguous premises. As virus can be excreted by such animals prior to the development of obvious and identifiable clinical signs, it is important that they are culled as soon as possible to stop virus production and hence spread of disease. A decision to slaughter will be taken by the veterinary inspector based on information gathered during the inquiry (e.g. geographical, epidemiological) and account will be taken of levels of biosecurity. The action that taken will depend on a risk assessment. Where it is believed that the likelihood is that exposed animals are at a high risk of becoming diseased they will be slaughtered. Where that risk is lower and there are the resources to observe the animals, they will be restricted and observed. Any action taken depends not only on the degree of risk but the ability to mitigate the risk by having available the necessary resources to observe animals regularly and the ability to detect early disease in exposed animals and take immediate action should disease occur.

19. Animals can be exposed to infection by many routes. The following list is not exhaustive and the relative importance of each will depend on a number of factors:

a. Direct contact with infected animals
b. Airborne Spread
c. Movement of a live animal
d. Movement of a person
e. Movement of vehicles
f. Movement of equipment or other materials
g. Movement of animal products
h. Movement of feedstuffs or bedding
i. Movement by wildlife or non-susceptible vector

To Prevent the Spread of Disease

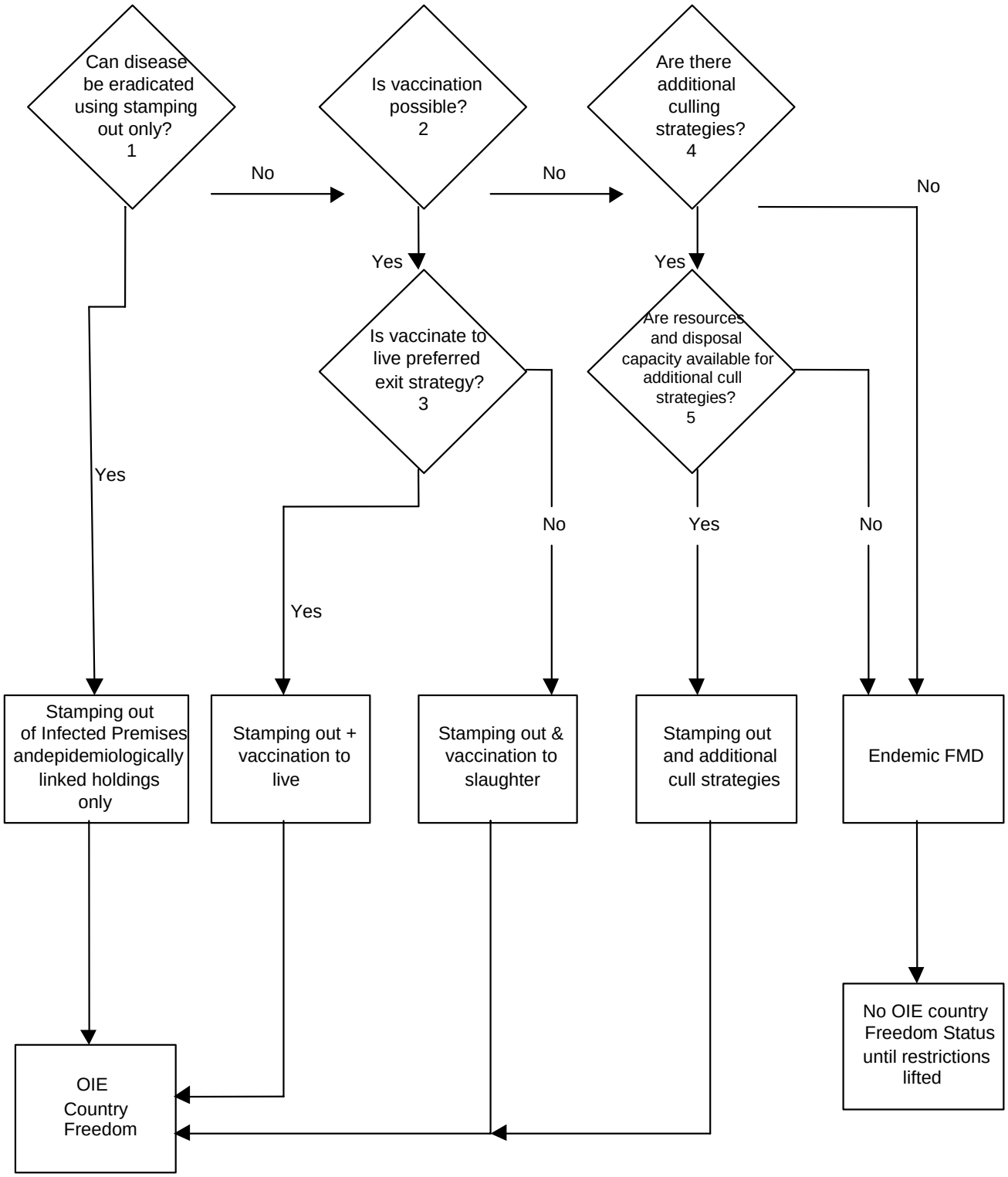
20. A third type of slaughter policy is "to prevent the spread of disease", e.g. to create a 'firebreak'. Such a cull might be required in order to protect areas of high livestock density, either as an addition to emergency vaccination or, in some cases, instead of it. The species and geographical area of the cull would have to be carefully assessed. Use of this power is described by a Disease Control (Slaughter) Protocol as required by the Animal Health Act 1981 as amended. The Protocol identifies the criteria to be considered and procedures to be followed should it be considered necessary to call on this power.

21. The Government intends to use the new slaughter powers only where this is justified by the level of risk of the disease spreading and on the basis of sound veterinary, epidemiological and scientific advice. Vaccination would have been considered first and if not used the reasons would be published.

22. Any decision to use these wider powers of slaughter would be taken in the light of an overall assessment of the risks, costs and benefits in a given situation. This could include not only risks of transmission but also social and economic risks that would arise if effective and timely action were not taken. The Government would justify its decision to use the slaughter powers, explaining the veterinary, epidemiological and other relevant factors that had been taken into account.

Decision Tree for Control Strategies for FMD – FMD ANNEX B

Note: Start at top left decision - diamond box



FMD Decision Tree – Factors to Be Considered

Each decision on the tree is taken on the basis of a number of factors. The decision matrix has been based on a USDA paper but has been adapted to take account of the fact that any disease control strategy in the UK must take account of the relevant EU and domestic legal framework.

In using the decision tree, the following factors should be taken into account at each decision point. Modelling – economic & epidemiological – will be used to assist in identifying trigger points. The Government accepted the recommendation of the UK Lessons Learned Inquiry to undertake a cost-benefit analysis of different FMD control strategies. The results from this were published in May 2005 and will help inform decisions concerning disease control strategies in a future outbreak.

Decision Box 1: Can disease be eradicated by stamping out alone (of Infected Premises and Dangerous Contacts)?

All outbreak and mitigation factors need to be considered at this point in deciding whether stamping out alone will eradicate the disease. However at the start of an outbreak information on many of these factors will be incomplete and this may not be available until well into the outbreak. Decisions may need to be revisited as more information becomes available.

1. **Outbreak factors**

- Time from introduction of infection to detection (epidemiology);
- Contact rate: type of farms; direct and indirect movement and distance of movement; efficacy of movement controls;
- Host or species affected – the species affected and species at risk (manifestation of clinical signs leading to early recognition): domestic livestock only – whether disease is in pigs, cattle or sheep; game farms/zoos – how effective would isolation methods be; wildlife.
- Status of outbreak – estimation of the extent of the geographical distribution of FMD and duration of epidemic: number of affected herds; number of foci of infection; rate of spread. Use of epidemiological models.
- Environmental: livestock density and distribution; livestock management; standards of biosecurity; casual access – network of roads, etc; physical barriers.
- Climate – does it favour airborne spread?

Mitigation factors:

- Physical resources: slaughter capacity; transportation capacity; disposal capacity. Incineration - max 1500 tonnes per week. Rendering - max 15,000 tonnes per week (Combined weekly capacity before licensed landfill or on-farm disposal options would need to be

considered is 16,500 tonnes which is equivalent to approximately 33,000 cattle, or 330,000 sheep or 165,000 pigs).

- Human resources: emergency response system i.e. are there sufficiently trained staff for stamping out and to maintain movement controls; what are the epidemic projections? Defra's Contingency Plan identifies the resources needed to deal with an outbreak of FMD.
- Socio-political factors: The Animal Health Act requires slaughter of all susceptible animals on Infected Premises and provides for culling of susceptible animals on epidemiologically linked holdings (known as Dangerous Contacts); public opinion; industry acceptance; other affected sectors e.g. tourism.
- Economic considerations: compensation; value of exports and value of other affected sectors e.g. tourism.

Decision Box 2: Is emergency vaccination possible?

2. **Physical resources** to be considered:

- Vaccine strain availability – Is there a vaccine available? The UK has its own stocks of 9 different FMD antigen strains held, on its behalf, by a commercial supplier. In addition, the EU Vaccine Bank holds a range of antigens for emergency use.
- Numbers of vaccine doses available – Doses available vary depending on the strains. (Defra is keeping the availability of strains and quantities under review).
- Emergency vaccination strategy i.e. ring or firebreak vaccination – the strategy would depend on factors such as the virulence of the strain, number of foci of infection, density and species of livestock in likely vaccination zone, etc. Arrangements for a process of prior registration of zoos and rare breeds for possible emergency vaccination in a future outbreak are currently being developed.
- Vaccination logistics – this will be covered by the SVS operational field instructions. To comply with the UK Marketing Authorisation for FMD vaccines, a second dose would be required 3-4 weeks after the first dose. However, the need for a second inoculation or a booster will depend on the length of time that active disease is present. Where the policy is vaccinate-to-slaughter a 1-dose strategy is more likely to be used. (In an emergency, Article 8 of Directive 2001/82 /EC would provisionally allow the use of FMD vaccines which do not have UK Marketing Authorisations (MAs) in the absence of a suitable medicinal product and after informing the Commission of the detailed conditions of use.)
- Vaccine distribution – vaccine would be procured centrally and distributed to field vaccination teams via regional vaccination centres.
- Laboratory capacity/ability to distinguish vaccinates from infected – Laboratory capacity exists to undertake testing. 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.
- Time – Whether there would be enough time for vaccination to be completed before spread of infection would depend on the epidemiological projections during the outbreak. Need for modelling input.
- Progress made since 2001 – there has been much progress made towards resolving the issues surrounding emergency vaccination policy since the 2001 outbreak of FMD. These are detailed at section 3 of the FMD Emergency Vaccination Protocol

3. **Human resources** to be considered:

- Emergency response system – need to have sufficient numbers of vaccinators available. At present there are 50 fully trained vaccination teams (each consisting of 1 vaccinator, 1 ear tag reader and 1 recorder) available and operationally capable of vaccinating on day 5 of an outbreak. Some 25 vets have also been recruited to support this initial response team. Current arrangements also provide for these numbers to be ramped up within 4/5 days of notification to meet the needs of any reasonable disease scenario. There are also human resource implications in carrying out NSP testing of all vaccinated herds/flocks and in the establishment of a vaccination surveillance area.
- Movement controls are a recognised part of any UK control strategy. Specific restrictions will apply on movement of vaccinated animals and products from vaccinated animals within the vaccination zone as laid down by the Vaccination Regulations There will be welfare considerations in establishing a vaccination zone. Need sufficient staff to monitor movement controls. There will also be a vaccination surveillance zone of at least 10km around a vaccination zone.
- Epidemic projections – different for each outbreak.
- The Institute for Animal Health (IAH) Pirbright and the Veterinary Laboratories Agency at Weybridge provides the diagnostic testing service for FMD. It also carries out additional tests (i.e. VNT) on positive or inconclusive serology samples submitted by VLA.
- IAH Pirbright offers an immediate serology capacity of up to 8,000 samples per week. Defra has an agreement with the VLA that they will provide serological testing capacity for FMD on a contingency basis of 120,000 samples per week at three laboratories. The first laboratory would be ready to start testing within three weeks of notification with an initial capacity of 7,000 tests per week, 20,000 tests in the second week and reaching full capacity of 40,000 in the third week. The second laboratory would be operational within 6 weeks and a third laboratory within 8 weeks with the same capacity build up. Full capacity of 120,000 tests per week would be reached by the 10^{th} week.
- Personnel required to undertake blood sampling will be recruited and trained under the co-ordination of Human Resources Services Division. Personnel could be drawn from veterinary/agricultural students and from local Job Centres.
- In a vaccination zone surveillance will be carried out, after a minimum of 30 days have elapsed since vaccination was completed, to establish whether any vaccinated herd or flock has become infected with virus.

4. **Socio-political factors** to be considered:

- Stakeholders – a communications plan is in place. Active engagement with stakeholders has highlighted the role of the FSA advice on safety.
- Available legislation – Powers to vaccinate against FMD are contained in the FMD (Control of Vaccination) (England) Regulations 2006. The Animal Health Act 1981 as amended by the Animal Health Act 2002 provides enhanced powers of entry for emergency vaccination of susceptible animals. Any decision to carry out emergency vaccination would have to be agreed by the EU. Parallel OIE rules need also to be considered.
- Industry opinion – Stakeholders to be kept involved in developments connected with the issue of vaccination i.e. the Vaccination Regulations , changes to the OIE Code, implications for the resumption of trade. Stakeholder involvement (should be all-inclusive) and agreement would be important in any decision to vaccinate.

5. **Economic considerations** to be considered:

- Cost of vaccination – as part of its contingency planning, against a future outbreak of FMD, the UK has purchased a range of antigens. Additional costs would be those of formulating the vaccine from the antigen, or of acquiring vaccine if the strain was not one held. The cost of vaccination equipment, training and employing staff as part of a vaccination campaign also needs to be costed into the equation.
- Economic losses – whether it is foreseeable that a control strategy without emergency vaccination would lead to significantly higher economic losses in the agricultural and non-agricultural sectors. The Cost Benefit Analysis (CBA) of FMD control strategies shows that vaccination can be an appropriate policy, particularly in the largest outbreaks
- Regionalisation – would be required under the FMD Directive and is reflected in the FMD Order where the outbreak threatens to become extensive or if emergency vaccination is used. The FMD Order sets out the controls that would apply within a regionalised zone by creating a Restricted Zone which could apply to the whole of England or a smaller area.

Decision Box 3: Is the exit strategy "vaccinate to live"?

6. **Physical resources** to be considered:

- Slaughter capacity – vaccinate to live is likely to reduce pressure on slaughter capacity whereas vaccinate to slaughter might lead to higher numbers for slaughter than a stamping out policy (the Dutch experience). Capacity would need to be able to cope with slaughter of vaccinates and slaughter of infected livestock in a vaccinate-to-slaughter scenario.

- Disposal capacity – The higher numbers generated by a vaccinate to slaughter policy may result in disposal becoming a limiting factor. A vaccinate to live policy would help alleviate disposal problems.
- Controls on products from vaccinated animals - Under the Vaccination Regulations, products from vaccinates would need to be kept separate from non-vaccinates. The Regulations set out the post vaccination controls that would be required following emergency vaccination. However during phase 3 of the vaccination campaign, the UK would seek a derogation from the European Commission for untreated meat from vaccinated cattle and sheep to be placed on the domestic market. Untreated meat from vaccinated pigs can also be placed on the domestic market in certain circumstances and in addition exported to other member states if requested by them.
- Time – If a vaccinate to slaughter policy was followed it would be more cost-effective to cull after the first inoculation. See Box 2 criteria on physical resources.
- Identification: ear-tagging of vaccinated livestock is required under the Vaccination Regulations to ensure that products from vaccinates are correctly treated (in the case of a vaccinate-to-live policy) or all vaccinates are killed (in the event of a vaccinate to kill policy being implemented). Call-off contracts are in place for plastic button ear tags to identify vaccinated animals.

7. **Human resources** to be considered:

- Emergency response system – Current and future arrangements for delivery of a vaccination programme take account of the need to implement a vaccinate to live strategy which, by implication, may require 2 or more doses to be administered. For a vaccinate to slaughter policy, we would need to consider whether we had the necessary staff i.e. slaughtermen. Intensified surveillance will be carried out in the 10km area (vaccination surveillance zone) surrounding the vaccination zone.
- Epidemic projections. As above.

8. **Socio-political factors** to be considered:

- Available legislation – The AHA and the Vaccination Regulations allow for emergency vaccination. The AHA allows for the slaughter of vaccinates and for payment of compensation for vaccinated animals which are compulsorily slaughtered. The Vaccination Regulations explicitly provides for the option of suppressive vaccination i.e. vaccination to kill, as well as protective vaccination i.e. vaccination to live. The Government has made clear its preference for protective vaccination.
- Public opinion – Public are likely to support a vaccinate to live policy and this would be in line with FMD Inquiry recommendations. Food Standards Agency advice is that labelling of products from vaccinated animals would not be required. A shared statement on the use of

vaccination as part of FMD control strategies has been produced in partnership with consumer organisations.

- Industry acceptance –possible pressure from trade, and other Member States, to slaughter vaccinates to regain FMD free status. Currently engaging with industry stakeholders to clarify the effect of the treatments for meat and other animal products from vaccinated animals and the likely market impact and agreeing supportive statements with consumer group and major retailers.

9. **Economic considerations** to be considered:

- Cost of vaccination to slaughter – include the costs of vaccination (Box 4) plus the cost of slaughter and disposal of all vaccinates.
- FMD free status – this can be regained 3 months earlier where suppressive vaccination is used. However, there are other economic considerations that will need to be taken into account in a full cost benefit analysis (see earlier decision boxes).
- Compensation – Cost of compensation for slaughtered vaccinates would substantially increase overall costs of epidemic.
- The value of export markets lost until disease free status is regained versus the benefit of reduced disruption to the wider rural economy.
- Regionalisation – As for Box 2.

Decision Box 4: Are there additional culling strategies that are appropriate to the circumstances?

In some circumstances culling additional to DCs and IPs may be the optimal solution based on a risk assessment. This culling could take a number of forms – contiguous premises (where these are judged to have been exposed to infection) or preventive culling where scientific and veterinary advice is that this will prevent further spread of disease outside the area. In choosing between these and other additional forms of culling a number of factors will need to be taken into account:

10. **Socio-political factors** to be considered:

- Available legislation – The Animal Health Act 1981 (as amended) provides the necessary powers including the power to slaughter pre-emptively in order to stop the spread of the disease. The AHA places a duty on the Secretary of State to consider emergency vaccination before using the pre-emptive slaughter powers. The FMD Directive also provides for a preventive cull.
- Public & industry opinion - contiguous and 3km culls were controversial aspects of the control of FMD during 2001.

11. **Economic considerations** to be considered:

- compensation – additional culling may significantly increase the amount paid in compensation.

- value of exports & other economic costs particularly in the wider countryside and for tourism. There are extra costs involved in additional culling.
- Regionalisation

Decision Box 5: Are resources available for additional culling strategies?

A limiting factor is whether adequate resources exist to accommodate the anticipated number of additional livestock in addition to those slaughtered under stamping out.

12. **Physical resources** to be considered:

- slaughter capacity – does the capacity exist to slaughter animals both under the stamping out policy and additional culling;
- transportation capacity – does the transport capacity exist to remove animals from farm for disposal under an additional culling scenario;
- disposal capacity - does the capacity exist to dispose of animals under the stamping out policy and additional culling in environmentally acceptable and welfare friendly ways;
- time i.e. are there sufficient resources to accommodate additional culling before such livestock develop FMD; identification of all premises included in an additional cull.

13. **Human resources** to be considered:

- emergency response system i.e. are there sufficiently trained staff to carry out an additional culling policy without adversely impacting on other key control policies i.e. enforcing movement controls, etc;
- what are the epidemic projections – epidemiological modelling of high risk groups.
- Identification of all premises included in an additional cull.

SOME OF THE ROUTES BY WHICH ANIMALS CAN BE EXPOSED TO INFECTION

a. *Direct Contact with Infected Animals*

1. Infection is rapidly and efficiently passed from an infected animal to an uninfected, susceptible animal by direct contact between the animals. When establishing if animals have been exposed to infection following direct contact with an infected live animal, the following factors will be taken into account:

i. Physical nature of barrier between infected animal and susceptible uninfected animal.
ii. Distance between animals.
iii. Nature of the contact between animals.
iv. Amount of virus excretion.

b. *Airborne Spread*

2. Virus can be exhaled by an infected animal. The virus may be carried on air currents to susceptible, uninfected stock. The greatest risk of infection will be to stock on premises that are close to an IP though under certain circumstances more distant premises, possibly some distance away, may also be considered to have been exposed by such a route. (This is different to the culling to prevent the spread of disease that is covered in paragraph 25). When establishing if animals have been exposed to infection following airborne spread of virus the following factors will be taken into account:

i. Species of infected animals.
ii. Species of uninfected, susceptible animals.
iii. Pathogenicity and virulence of the viral strain.
iv. Prevailing wind direction during the period when animals on the IP are considered to have been excreting virus in exhaled air.
v. Distance between the infected and uninfected animals.
vi. Environmental conditions that could contribute to virus survival, e.g. temperature and humidity.
vii. Likelihood of release of airborne virus, e.g. nature of housing or measures to control air outlets from housed livestock.
viii. Likelihood of exposure to the airborne virus. e.g. nature of housing or measures to control air supply to livestock.

c. *Movement of a Live Animal*

3. Before disease is suspected and subsequently confirmed on a premises it is possible that an animal could, quite legitimately, have moved off that premises. Although disease had not been suspected, it is possible that disease was present when that animal moved off the premises. If that animal was itself infected it could infect other susceptible livestock at any time after leaving the premises.

4. When establishing if animals have been exposed to infection following the movement of a live animal, the following factors will be taken into account:

i. Likelihood the animal could have taken infection from the IP.
ii. Nature of contact with susceptible uninfected animals. (See (a) above.)

d. ***Movement of a Person***

5. A person moving from a premises where infection was present could transmit infective material on their skin, hair, clothes or footwear. When establishing if animals have been exposed to infection following the movement of a person, the following factors will be taken into account:

i. Likelihood that the person could have taken infection from the IP.
ii. Nature of biosecurity measures on leaving the IP and before any contact with susceptible uninfected animals.
iii. Likelihood the person could have introduced infection to susceptible uninfected animals.

e. ***Movement of Vehicles***

6. Vehicles could carry infection from a premises where infection was present to other premises where susceptible livestock are present. Such vehicles could include:

i. Livestock transports.
ii. Vehicle moving between livestock under the same ownership.
iii. Vehicles collecting agricultural products, e.g. milk, wool etc.
iv. Vehicle delivering agricultural products e.g. feed, fertiliser, fuel etc.
v. Vehicle delivering non-agricultural products, e.g. post.
vi. Vehicle bringing persons etc for working on the premises.

7. The infective material could be carried anywhere on or in the vehicle. When establishing if animals have been exposed to infection following a vehicle movement, the following factors will be taken into account:

i. The nature of the contact with infected animals or materials from infected animals.
ii. Whether there was any cleansing and disinfection of the vehicle after contact with infected animals or materials and before contact with uninfected susceptible livestock.
iii. Whether the conditions during the journey would have rendered the virus non-viable.
iv. The nature of the contact with susceptible uninfected animals.

f. Movement of Equipment or Other Materials

8. Equipment or other materials used on a premises where infection was present could carry infective material to susceptible, uninfected animals. Such equipment could range widely, from large feed mixers to thermometers. In establishing if animals have been exposed to infection following movement of equipment the following factors will be taken into account:

i. The nature of the contact between the item and infected animals.
ii. The nature of the contact between the item and susceptible, uninfected animals.
iii. Whether there was any cleansing and disinfection of the item.

g. Movement of Animal Products

9. Products from infected animals could contain viable virus that could infect susceptible, uninfected animals. Such products include milk, slurry, manure, meat, carcases (see also scavenging at (j) below). When establishing if animals have been exposed to infection following any movement of animal products the following factors will be taken into account:

i. Likelihood that the product contains viable virus.
ii. Effectiveness of any treatment undertaken before it leaves the IP or before it comes into contact with uninfected susceptible animals.
iii. Interval between removal of product and contact with the susceptible, uninfected animals.

h. Movement of Feedstuffs or Bedding

10. Products from infected animals could contaminate forages, feedstuffs and bedding materials with viable virus that could infect susceptible, uninfected animals. Such products include hay, silage, straw, materials used to contain or transport such products. In establishing if animals have been exposed to infection following movement of these products the following factors will be taken into account:

i. Likelihood that the product contains viable virus.
ii. Effectiveness of any treatment undertaken before it leaves the IP or comes into contact with uninfected susceptible animals.
iii. Interval between removal of product and contact with the susceptible, uninfected animals.

i. Movement by Wildlife or Non-susceptible Vector

11. This is when a species of animal that is not susceptible to infection carries infective material from an IP either inadvertently or during scavenging. It is difficult to prevent this though good husbandry should reduce the levels of vermin that are attracted to a premises and rodent control on IPs is required under the FMD Order. Once the animals are slaughtered, and if there is likely

to be any delay in disposal, then measures, e.g. rodent control, covering and spraying carcases, etc will be taken by the National Wildlife Management Team, SVS and others to minimise this risk.

Disease Control (Slaughter) Protocol – FMD ANNEX C

Introduction

1. The Lessons Learned Inquiry on the 2001 FMD outbreak recommended that provision should be made for the possible application of pre-emptive culling policies, if justified by well-informed veterinary and scientific advice, and judged to be appropriate to the circumstances. Such powers for pre-emptive (or preventive or "firebreak") culling of animals not exposed to FMD infection are provided for by the Animal Health Act 1981 (as amended). It adds to the armoury the Government has to fight FMD by getting ahead of the disease and stopping it spreading.

2. Section 32B of the Animal Health Act 1981, as amended by the Animal Health Act 2002, requires the Secretary of State to have a disease control (slaughter) protocol for the use of the new slaughter power in the Act (Schedule 3, paragraph 3(c)) to prevent the spread of FMD. This would be a pre-emptive or "firebreak" cull.

3. This power cannot be used unless the protocol has been published and vaccination has first been considered to prevent the spread of disease (Sections 14A and 14B of the Animal Health Act 1981, as amended). The reasons for not using vaccination would be published. The factors to be considered in deciding on the measures to be used to tackle an outbreak of FMD are set out in a separate document - FMD Disease Control Strategies, referred to as the FMD Decision Tree. The purpose of this disease control (slaughter) protocol is to identify criteria to be considered and procedures to be followed should it be considered necessary to call on this new slaughter power.

Purpose for which the power would be used

4. This power would be used only where this is justified by the circumstances of the possibility of disease spreading and on the basis of sound veterinary, epidemiological and scientific advice. Emergency vaccination would have been considered first and if not used the reasons would be published.

The principal factors to be taken into account

5. A major factor will be to get ahead of the disease. It could apply in particular to protect areas of dense livestock population. The cull would include those animals which, should they become affected, would present a significant risk to the farming and livestock community more generally by contributing to onward spread. It is in such circumstances that effective preventative action may be necessary to safeguard the wider public interest. Species, geographical area and, if appropriate, type of farming would be relevant. Any decision to use the wider powers of slaughter would be taken in the light of an overall assessment of the risks, costs and benefits in a given

situation. This could include not only risks of transmission but also social and economic risks that would arise if effective and timely action were not taken.

The procedure to be followed in reaching a decision

6. Such a decision could not be made until the use of emergency vaccination had been considered and, if not used, the reasons published.

7. The steps to be taken would then comprise:

(a) the identification of a group of animals that are likely to contribute to spread of disease, based on epidemiological modelling, veterinary advice and local factors;

(b) the determination of which species are involved;

(c) consideration of exemptions on the basis of husbandry or other criteria, for example, rare breeds or genetic value;

(d) the determination of the geographical area involved;

(e) the determination of the rules for inclusion or exclusion of animals at the boundary of that area;

(f) analysis of risks, costs and benefits;

(g) the publication of an outline of the reasons why such a cull is needed.

The procedure by which animals on a premises will be deemed to be included in a slaughter

8. Premises believed to contain animals to be slaughtered to prevent the spread of disease would be identified. A Veterinary Inspector would visit and ascertain if animals meet the criteria and are to be slaughtered.

9. The Veterinary Inspector would be required to explain the reasons to the owner and give him an opportunity to provide evidence if he believed the animals should be exempted. To ensure the reason for slaughter is clear to the owner a slaughter notice would be issued. The slaughter notice would state the powers under which slaughter is required and the reason why the owner's stock is included (with reference to the criteria for slaughter to prevent the spread of disease).

The means by which a particular decision to slaughter can be reviewed

10. Both as part of the slaughter notice and during explanations the owner must be made aware that they can ask the DVM to review the decision that their stock meet the criteria for the cull and be advised how and by when this can be done.

11. The DVM, or a suitable alternative, must be available to hear such reviews. The following action would be taken:

(a) they will consider the views of the owner as to why they believe the decision is wrong;

(b) they must ensure that the veterinary inspector has carried out a full and fair inquiry to establish if the animals meet the appropriate criteria.

Emergency Vaccination Protocol – FMD ANNEX D

Index

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 FMD (Control of Vaccination)(England) Regulations 2006. 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 Volume 2: FMD, Annex A & B), 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/maintain 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 EU FMD Directive of 2003, the UK worked hard to strike the right balance in the controls imposed on products from vaccinated animals. A summary of the controls on vaccinated animals and their products can be found on the Defra website at:
- http://www.defra.gov.uk/footandmouth/disease/strategies/movement.htm
- 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 produced a Cost Benefit Analysis on Disease Control Strategies, which was published in May 2005. This considers a number of core scenarios and provides additional evidence for future decision making on disease control strategy. This shows that vaccination can be an appropriate policy particularly in the largest outbreaks. The study is on the Defra website at:

  http://www.defra.gov.uk/footandmouth/disease/index.htm
- 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 SVS.

- 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 **Directive (2003/85/EC) on measures to control FMD** was adopted at Agriculture Council on 29 September 2003 and has now been transposed into domestic legislation and is contained within:
The FMD (England) Order 2006
The FMD (Control of Vaccination) (England) (Regulations 2006 and
The Animal Health Act 1981 (Amendment) Regulations 2005, as outlined in Section 2. However, many of the Directive's requirements have already been met by administrative means and in the updated FMD Contingency Plan and Veterinary Instructions.

- The new legislation 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 FMD legislation remains the **slaughter of all susceptible animals on premises infected with FMD and those identified as "dangerous contacts**".* However, the legislation 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 EU 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 Volume 2: FMD, Section 4 of the 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 and by the Animal Health Act 1981 (Amendment) Regulations 2005. The Amendment Regulations amend the Secretary of State's previous discretion to slaughter to a duty to slaughter susceptible animals on infected premises only, with exceptions under certain conditions for laboratories, zoo, and rare breeds amongst others. Section 14B of the amended Act also 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 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 possibly include pet or sanctuary animals within a vaccination zone;
- to possibly 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. The use of any of the measures would only be available in exceptional cases and the message about the registration of animals is being carefully managed to ensure that producers have realistic expectations about the possibility rare breed animals being spared from slaughter.
- Following a consultation exercise, 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 was publicised on the website in December 2005.
- Arrangements for zoos and wildlife parks are slightly different. They can also possibly qualify for the special measures under the Animal

Health Act 1981 (Amendment) Regulations 2005, but there is no requirement 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 has developed a database of English Zoos.

- Animals in laboratories and fenced areas or in bodies, institutes, or centres keeping animals for scientific purposes may also possibly 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 Vaccination Regulations 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, movement 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 Vaccination Regulations (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

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 9 different FMD antigen strains held, on its behalf, by a commercial supplier. These independent supplies have over 20 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 represents 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 as 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. A similar statement has been issued by the BEUC, the European consumers organisation and in partnership with Defra UK consumer organisations have produced a statement on the role of vaccination as part of FMD control strategies.

6.4 Logistical Arrangements for Vaccination

- Genus Plc have been appointed to provide trained staff to support any proposed emergency vaccination programme in England, Scotland and Wales. This contract provides for pre-trained vaccination teams to conduct emergency vaccination of susceptible farm livestock – as instructed by the State Veterinary Service. Vaccination teams, which will act under the direction of a veterinary surgeon and will typically consist of 3 members, will be responsible for vaccination, animal handling, marking of vaccinated animals and record keeping. Arrangements are also in place to increase the vaccination resource, including veterinary suregeons, to meet a range of disease control situations within 5 days of notification.
- Vaccine would be distributed to field vaccination teams via regional vaccination centres.
- The Veterinary Surgeons Act of 1966 and the Medicines Act of 1968 permits lay vaccination of livestock to free up the limited veterinary resource during an outbreak. This will 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.

- Arrangements to enable emergency vaccination formed part of a series of desktop exercises conducted in the lead up to a national exercise – Exercise Hornbeam - which took place on 29/30 June 2004. In the exercise, Ministers, senior officials and vets from both the Department and across Government played out Days 7 and 8 of an outbreak scenario which was designed to test the Government's preparedness as set out in the published contingency plans. Plans are also in hand to test the vaccination contractor's operational state of readiness.
- 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

- Eartagging of vaccinated livestock is required under the Vaccination Regulations to ensure that all vaccinated animals are killed or products from vaccinates are correctly treated. 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 FMD Order, 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 within or outside the VZ 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 bio-security 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 heat treatment or deboning and maturation so that it could bear an oval health mark to enable it to enter intra Community trade.
- **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 heat treatment or 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 FMD Order, 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 the same as that from vaccinated animals for at least 30 days after these zones have been applied [*I cannot immediately find this time limit re meat in the FMD Order*]. After 30 days derogation may be granted by Standing Committee on the Food Chain and Animal Health (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 FSA 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 non-structural proteins of FMD virus to distinguish vaccinated from infected animals.

9. Glossary of Terms Used in Vaccination Protocol

NSP (Non structural protein) tests	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.
"pre-emptive" or "preventive slaughter"; "firebreak" cull	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.
Milk treatment	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.

Vaccination Scenarios - FMD ANNEX E

The Role of Vaccination in a Future Outbreak of FMD

Introduction

1. FMD is a highly infectious disease which is serious for animal health and for the economics of the livestock industry. As a result there are international trade rules and disease control legislation which influence the options available to the Government in controlling the disease. In the event of an outbreak, the overriding aim is to prevent the production and spread of the virus which causes the disease.

Why Vaccinate?

2. Vaccination can play a major role in controlling FMD by:

- preventing or reducing the incidence of clinical disease when the animal is exposed to virus;
- preventing or reducing the amount of virus produced by an infected animal, thus reducing the likelihood of spread to other animals; and thus
- reducing the number of animals killed during an outbreak.

3. Routine, preventative vaccination is banned under EU law, thus allowing the EU to maintain the highest FMD status under international trade rules of "countries free from foot-and-mouth disease without vaccination".

4. However, the Government recognises the potential value of emergency vaccination as a disease control measure. In its report following the 2001 outbreak, the Royal Society Report took the view that:

> "rapid culling of infected premises and known dangerous contacts, combined with movement control and rapid diagnosis, will remain essential to controlling FMD and most other highly infectious diseases" but " in many cases this will not be sufficient guarantee that the outbreak does not develop into an epidemic". It also accepted that, although much work remained to be done on what the potential of vaccination might be "emergency vaccination should now be considered as part of the control strategy from the start of any outbreak of FMD".

5. The Vaccination Regulations moves vaccination to the forefront of any disease control strategy. There are 3 phases to an emergency vaccination campaign laid down in the new Vaccination Regualtions:

- Phase 1 – During emergency vaccination and until 30 days after completion of vaccination
- Phase 2 – Post vaccination and prior to completion of survey to detect vaccinated animals from those which have been vaccinated and

subsequently exposed to the virus (the latter would have to be culled as infected animals)

– Phase 3 – After completion of the survey (required in Phase 2) but before FMD free status is regained (as outlined in para 8).

So Where Are We Now?

6. The Government accepted the recommendation made by the Royal Society Report and this is clearly reflected in the Government's published contingency plan. This makes it clear that if we are in any doubt about the ability of culling of IPs and DCs to control the outbreak quickly, then vaccination to live will be among the disease control options to be considered. This is supported by new FMD legislation which requires arrangements for emergency vaccination to be put in place as soon as the first outbreak is confirmed.

7. Since the 2001 outbreak there has been major progress in resolving the issues surrounding an emergency vaccination policy including:

- the purchase of vaccines suitable for use in an emergency vaccinate to- live strategy;
- the Institute of Animal Health at Pirbright has carried out an evaluation of NSP tests (these seek to distinguish vaccinated from infected animals);
- we have put in place the operational capability to be ready to vaccinate 5 days into an outbreak;
- re-confirmation from the FSA that it is safe to consume products from vaccinated animals;
- negotiating new EU legislation, which ensures a more ready market for such products. Under the Vaccination Regulations, products from vaccinates would need to be kept separate from non-vaccinates. The Regulations also set out the post vaccination controls that would be required following emergency vaccination. However during phase 3 of the vaccination campaign a derogation can be sought for untreated meat from vaccinated cattle and sheep can be placed on the domestic market . Untreated meat from vaccinated pigs can also be placed on the domestic market in certain circumstances and in addition exported to other member states if requested by them.
- we have been working with representatives of retailers, the food industry and the NFU to ensure a common understanding of the role of vaccination and its implications;
- working with a wider group of stakeholders to gain their acceptance of products from vaccinated animals entering the food chain as normal;
- we have published a shared statement on the use of vaccination as part of FMD control strategies, produced in partnership with consumer organizations;

- we have published a vaccination protocol setting out the logistical and scientific implications of vaccination and how we would operate the criteria for the decision on vaccination in an outbreak; and • we have consulted on and published a FMD contingency plan (including a decision tree) enshrining the Government's policy on vaccination.

8. In addition, international trade rules have been revised so that disease free status can be regained more quickly after emergency vaccination has been used: only 3 months longer than if vaccination is not used. Many of the past barriers to emergency vaccination have therefore been addressed to ensure it is a real disease control option in any future outbreak.

Future Use of Vaccination

9. In any future outbreak, when deciding the role of vaccination there will be many uncertainties about the behaviour and characteristics of the virus, its origin, the length of time it has been present, the degree of geographical spread and the number of undisclosed foci of infection as a result of secondary spread. In the face of such uncertainties any decision taken by Ministers to vaccinate will need to take account of veterinary and epidemiological advice in an area where difficult judgements have to be made. Ministers would also need to balance a range of other important factors including stakeholder views, the effects on tourism and rural businesses, animal welfare and the costs and benefits to the economy generally before final decisions were made.

10. This document explains how the FMD Decision Tree and Vaccination Protocol would be used to develop the veterinary advice on when to vaccinate in any future outbreak of FMD. It includes specific scenarios illustrating what the veterinary advice would be on how vaccination might be used in different circumstances in future.

Speed of Detection of Disease

11. One of the key factors which influence the eventual size of any foot and mouth disease epidemic is the time from introduction of infection to the initial detection of disease. (Decision box 1 – Outbreak factors – FMD Decision Tree). Any delay in detection will give an opportunity for disease to spread, perhaps quite widely, making control very difficult by stretching the immediate resources available to control it. In Europe, FMD has been detected, on average, 21 days after its introduction. Although surveillance for exotic diseases may have improved, it is perhaps not surprising that in 2001 there was delay of around three weeks between introduction of infection in Northumberland and the initial detection of disease in pigs sent to a slaughterhouse in Essex. During that period disease spread silently with movements of sheep through markets and dealers such that, by the time the presence of disease was confirmed, at least 57 premises in 16 counties from southwest Scotland to the southwest of England were infected.

12. At the start of an outbreak it is often difficult to establish how long a delay in detection there has been. It might therefore take a considerable time to determine where infection had first been introduced, how long it had been there and the extent of spread in the meantime. Where there had been a delay in detection, other factors would need to be considered in determining whether vaccination should be used in areas where disease had spread.

13. Vaccination is ideally suited for an area where there was FMD in a part of the country and there had not been rapid detection of disease and there was indication of lateral spread. Other epidemiological factors would also need to be taken into account. For example, if the mode of spread to the new area suggested that other herds in the area may have become infected by the same route, or the density of livestock and type of husbandry suggested that there might be rapid dissemination of disease in the area, despite rapid detection, then emergency vaccination might be recommended. Where there was evidence that there had been little or no delay in the detection of disease then it would probably be unnecessary to use emergency vaccination in order to control and eliminate the disease.

Development of FMD in Different Species

14. Foot and mouth disease develops differently in different species of livestock (Decision box 1 – Outbreak factors – FMD Decision Tree). In broad terms, pigs are infected primarily by ingestion (for routes of infection see Decision Tree) whereas sheep and cattle are primarily infected by inhalation. Once infected, generally, pigs excrete most virus, cattle much less than pigs and sheep even less than cattle.

15. The way in which FMD develops in a livestock population will also depend on the strain of FMD virus involved and new strains of FMD continue to emerge. It may not be possible to determine the detailed behavioral characteristics of any particular strain of FMD virus for a number of weeks, especially if experimental infections were required. Where the origin of infection is unknown there will always be initial uncertainty about how the disease will behave in any new outbreak.

16. In the event of an outbreak, particularly in pigs, it is normal practice to model the potential for windborne dissemination of disease from infected premises, using the prevailing meteorological data. Without detailed knowledge of the characteristics of the virus in the early stages of an outbreak it would be wise to assume that pigs would excrete extremely large amounts of virus and use this parameter in the meteorological dispersion model. Where the plume was predicted to have the potential to infect cattle (see scenario below) emergency vaccination might be undertaken in the area under the plume. Subsequent work, taking several weeks, may show that pigs did not excrete the large amounts of virus assumed as a parameter in the model and that vaccination was unnecessary but, given the uncertainty, emergency vaccination would have been a wise precaution.

Disease in Cattle

17. Cattle are susceptible to infection by inhalation and once infected may also generate infectious aerosols of virus. Cattle may therefore become infected by either local aerosol spread, over a relatively short distance or, if there are very exceptional weather conditions, infectious aerosols may carry quite large distances on the wind.

18. During phase 1 of a vaccination campaign, meat from vaccinated cattle would have to be heat-treated. It is economically viable to debone and mature beef. Milk may be marketed after normal pasteurisation. But both require the infrastructure needed to apply and enforce official controls and the availability of these must be a factor in the decision making process. During phase 2 of a vaccination campaign meat from vaccinated cattle would again have to be heat-treated or deboned and matured before placing on the market. During phase 3 of a vaccination campaign we will seek a derogation for untreated meat from vaccinated cattle to be placed on the domestic market.

19. Vaccination of cattle in certain cases may be valuable in controlling disease. Where cattle are the main generators of the FMD virus, the overall cattle density in an area, the size and proximity of herds and standards of biosecurity (influenced by the type of husbandry) would all affect the decision. For example, if there were delay in detecting disease in a pig herd that had excreted large amounts of virus and meteorological conditions were such that there was a wide angle plume of virus over an area of dense cattle population, and herds were becoming infected leading to a heavy weight of infection in an area, then vaccination might be likely. Infectious aerosol spreading over a wide area in certain meteorological conditions might also be generated from cattle herds, with high prevalence of diseased animals, and this is a further scenario where vaccination might be likely.

20. Vaccination of cattle in an area where sheep farming is the principal activity is less likely than in areas of intensive cattle or pig farming but, nevertheless, cannot be ruled out and would depend on the particular local epidemiological conditions, for example, where there was poor biosecurity and evidence of lateral spread of disease. Indeed, vaccination in cattle in Cumbria in this sort of scenario was recommended on veterinary grounds in 2001 but did not take place because of lack of stakeholder support.

21. Vaccination may possibly be used in registered rare breed herds, which are considered to be under direct threat of infection, for example, within 3km of an infected premises.

Disease in Pigs

22. Pigs are normally infected by ingestion and not by inhalation. Once pigs become infected they may pose the greatest risk to surrounding cattle because, of all species, they normally produce the most viruses once infected. Virus is normally excreted as an aerosol when the pig exhales. Cattle are the species most susceptible to infection by inhalation.

23. The origin of the 2001 outbreak of FMD was the illegal feeding to pigs of unprocessed waste food containing imported infected meat or meat product. All waste food feeding is now banned, but the illegal or accidental feeding of pigs with infected imported meat or meat products remains the most likely method of introduction of disease into the country.

24. If vaccination is used in pigs, until it has been proven by surveillance testing that virus is no longer circulating in an area, meat from vaccinated pigs will have to be heat treated before it can be traded with an EC health mark. There will also be implications for integrated multi-site production where it may not be possible to move vaccinated pigs reared in the vaccination zone to finishing units outside the vaccination zone. During phase 1 of a vaccination campaign, meat from vaccinated pigs would have to be heat-treated. During phase 2 of a vaccination campaign meat from vaccinated pigs would again have to be heat-treated before placing on the market. During phase 3 of the vaccination campaign untreated meat from vaccinated pigs can be placed on the domestic market and in addition exported to other member states if requested by them. The provision for placing untreated meat on the domestic market or exporting to other member states is however conditional upon the UK having obtained the necessary derogation from the EU Commission, the possibility for which is provided for in the EU FMD Directive."

25. For the reasons in paragraph 21 above, the FMD Directive says that vaccination should be considered where pigs are the principal species clinically affected by disease. In such a situation, we would need to consider the risk from aerosol/windborne infection and assess:

- how recently the pigs had become infected;
- whether, as a result of a breakdown in biosecurity, there was a risk that disease had been spread to other pig herds thereby increasing the amounts of virus being excreted;
- the susceptibility of the livestock population in the area to infection by the inhalation route; and
- weather patterns in the period since the initial infection.

Such factors would determine how many farms with livestock were potentially at risk from aerosol/windborne spread of disease and whether there was a risk that relying on the slaughter of IPs and DCs might not be enough to control the outbreak.

26. In general, pigs are the species least susceptible to infection by the aerosol route. In the pig industry, standards of biosecurity are good and 20-day standstill movement controls are in place. Computer modelling carried out during the 2001 epidemic also showed that disease was unlikely to spread in areas of predominantly intensive pig production. It is therefore unlikely that it would be necessary to vaccinate such pig herds in an outbreak. Nevertheless, where standards of biosecurity were poor and there was not

early detection of disease in any pig herd it might be necessary to vaccinate pigs in order to control disease.

27. Vaccination may possibly be used in registered rare breed herds, which are considered to be under direct threat of infection, for example, within 3km of an infected premises.

Disease in Sheep

28. If disease is discovered in sheep and there is good biosecurity, it should be possible to control the disease by the rapid slaughter required by law of infected sheep flocks and slaughter of Dangerous Contacts. (Decision point 1 of the Decision Tree).

29. If vaccination were to be used in sheep, then the Directive requires that, before the meat from vaccinated animals can be traded with an EC health mark, it should either be heat treated or, from Phase 2 of a vaccination programme, - deboned and matured until the country's FMD-free status is established. There are concerns about whether it would be economically viable to debone and mature sheep meat. This could be critical in determining whether emergency vaccination to live would deliver the expected benefits. During phase 1 of a vaccination campaign, meat from vaccinated sheep would have to be heat-treated. During phase 2 of a vaccination campaign meat from vaccinated sheep would again have to be heat-treated or deboned and matured before placing on the market. During phase 3 of a vaccination campaign untreated meat from vaccinated sheep can be placed on the domestic market. The provision for placing untreated meat on the domestic market is however conditional upon the UK having obtained the necessary derogation from the EU Commission, the possibility for which is provided for in the EU FMD Directive.

30. Once a sheep flock on extensive grazing is infected the disease tends to move very slowly through it because of the low level of virus excretion. In very extensive sheep, because of low contact rates, an infected flock will pose much less of a risk to neighbouring animals than infected cattle or pigs. Gathering sheep for vaccination might perversely increase the numbers of sheep that subsequently become infected in extensive systems. It is, therefore, very unlikely that vaccination will be used in grazed commercial sheep flocks or in areas where grazed sheep are the predominant livestock.

31. For the reasons given above, if disease were discovered in a sheep flock in a predominantly pig or cattle producing area, it is probable that vaccination would not be used in either pigs or cattle in that area, unless local epidemiological conditions indicated a higher risk (see para 19).

32. Vaccination may be used in registered rare breed flocks which are considered to be under direct threat of infection, for example, within 3km of an outbreak of FMD.

Size of Vaccination Zone

33. Under the Vaccination Regulations, strict controls would have to operate over vaccinated animals. In addition, there would have to be a vaccination surveillance zone of not less than 10km in depth surrounding a vaccination zone. Within the vaccination surveillance zone there would be movement restrictions; it would not be permitted to vaccinate any susceptible animals and there would be enhanced surveillance in this area to detect disease. The perimeters of both the vaccination zone and the vaccination surveillance zone would have to be clearly defined so that livestock keepers were in no doubt about the area they were in. This would be done by using obvious geographical boundaries such as roads, rivers and other natural features, for example, a large abutting area of woodland, which was livestock free, which may pose a natural barrier to the spread of disease.

34. Given the clinical and serological surveillance required under the FMD legislation, it would be sensible to limit the size of any vaccination zone to the minimum necessary to control disease based on an epidemiological assessment. This would take account of factors in the following list, which is not exhaustive: -

- 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;
- the prevailing climatic conditions that might predispose to the spread of disease;
- animals being at greatest risk of infection within 3 kilometres of an existing outbreak.

Exit Strategy

35. As soon as a FMD outbreak is confirmed, a country loses its international trading status of "free from foot-and-mouth disease without vaccination". How quickly a country regains its FMD free status depends partly upon how long it takes to eradicate the disease and partly on the disease control strategies used. The international rules governing FMD free status have changed since 2001 and the use of emergency vaccination no longer carries the same trade "penalty" as previously.

36. The OIE (Organisation International des Epizooties – the international animal health standard setting body) sets down rules for recovery of FMD free status. Disease free status can be recovered:

- three months after the last case where culling of animals on infected premises and dangerous contacts ("stamping out") and surveillance are applied;
- three months after the slaughter of the last vaccinated animal where stamping out, serological surveillance and emergency ("suppressive") vaccination is used;
- six months after the last case or the last vaccination (whichever is latest) where stamping out and "protective vaccination" to live is used, provided that serological surveillance based on the detection of FMD non-structural proteins demonstrates the absence of infection in the remaining vaccinated population.

Controls on Products from Vaccinated Animals

37. In the 3 phases of the vaccination campaign specific controls would apply on products from vaccinated animals.

38. Phase 1. Fresh milk would have to be treated (single HTST pasteurisation) at a dairy within the vaccination zone or transported outside the zone for treatment, subject to strict biosecurity and transport rules. Fresh meat from vaccinated animals would then have to be cross-stamped, transported in sealed containers and then treated (heat treated or naturally fermented or deboned 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.

39. 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 heat treatment or deboning and maturation so that it could bear an oval mark to enable it to enter intra Community trade.

40. 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 vaccinated ruminants would still be subject to heat treatment or 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 heat treated as in Phase 1, but a derogation allows for untreated meat from vaccinated pigs to be placed on the domestic market, and may be exported to another Member State if requested by them. Such meat would have to carry a special mark.

41. It should be noted that, under the FMD Order , meat and meat products from animals in the Protection 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 [*I cannot immediately find this time limit re meat in the FMD Order*]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.

42. The treatments required for meat are complicated; this is why we have produced 2 papers to explain these to stakeholders in detail:

- A guide for livestock keepers – Sending livestock to an abattoir for slaughter during an outbreak of foot-and-mouth disease in Great Britain.
- What are the implications of an outbreak of FMD for the meat industry in Great Britain?

Serological Surveillance

43. During Phase 2 of a Vaccination campaign, a serological survey has to be carried out to differentiate between those animals which have been vaccinated and those which have been vaccinated and subsequently exposed to the FMD virus, or may still be infected. The antibody tests used for this are Non Structural Protein (NSP) tests.

44. At present there are no internationally recognised NSP tests for use in any species of livestock. The OIE has agreed the principle of using NSP tests for serosurveillance to distinguish herds that have been vaccinated against FMD from those that have been infected but the sampling level to demonstrate this is still under consideration. There are currently two NSP tests for FMD 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 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.

45. **However, the absence of an internationally validated test would not prevent the use of vaccination in the event of a future outbreak.** We would use a herd based test on a statistical basis and, where positive results were found, we would use a higher discriminatory test (Probang). Where the presence of FMD virus is confirmed, then the premises will be confirmed as infected premises. Where the survey shows that at least one animal has been infected, through previous contact with the virus, but where further testing of the animals on the holding confirm no FMD virus is present then the animals on the premises are either all culled (and disposed of) or classified according to the tests, and some culled and others slaughtered i.e. can enter the food chain depending on whether it is believed that virus no longer circulating and the interpretation of the tests applied to the herd.

46. Where testing on the premises rules out past or present infection with FMD virus, the premises will become subject to phase 3 controls until FMD free status is regained (see paragraph 36).

47. For unvaccinated animals in a surveillance zone serological surveillance would also have to be carried out. This would use a serological test that would detect antibodies to FMD virus but it would not be an NSP test. The sampling protocols are set out in the EU Directive and are similar to those used in 2001. It is very likely that a vaccination zone may partly or wholly cover a surveillance zone. The tests used and the sampling protocol used in the overlapping zones would depend on whether or not the animals were vaccinated.

Export of Live Animals Post Vaccination

48. Once vaccinated, animals cannot be exported, even after FMD free status is regained.

Illustrative Scenarios

49. These scenarios have been developed to illustrate mainly the veterinary and epidemiological judgements to be made, rather than to take into account the wider economic and social dimensions of the decision.

No Vaccination Scenario

50. In an urban fringe area, animals on a city farm have become infected. There is negligible contact either direct or indirect with any other livestock farm. There is a very low level of livestock keeping in the county that borders the urban fringe. Computer modelling has confirmed that disease is unlikely to spread in the area because of the low stocking density and that vaccination would not bring any control or economic benefits. It is not necessary to vaccinate in this scenario.

Windborne Spread

51. A pig-finishing unit with 900 pigs has become infected and there has been a delay in reporting disease. Some 250 pigs on the unit are showing clinical signs of disease. The affected pigs are generating a large amount of virus which is aerosolised in their breath. Computer modelling, using the Meteorological Office's modelling, shows that the prevailing weather conditions have predisposed an area some 30 kilometres in length from the pig unit and 15 kilometres wide at its widest point, to infection from large highly concentrated virus plume.

52. The area under the plume is a mixed livestock area with sheep and cattle but the predominant enterprise is dairying. Cattle under the plume are most susceptible to infection by inhalation. Other computer modelling has shown that the area is one in which there is likely to be significant lateral spread of disease because of the concentration of livestock in the area and the size of

enterprise with individual units close to one another. The modelling has shown that vaccination would be an effective aid to control and would be likely to bring economic benefits. The virus strain has been identified and there is a reserve of antigen in the vaccine bank, from which an effective vaccine can be formulated, which has been tested for safety, efficacy and potency.

53. A vaccination zone, the size and shape of the predicted plume of infection, is declared and all cattle in the zone are vaccinated. The vaccination policy is one of protection with the intention that vaccinated animals that do not become infected will live out their productive lives. Sheep and pigs in the zone will not be vaccinated, other than registered rare breeds of sheep and pigs.

Multiple Insertions of Infected Animals into an Area

54. Disease has been introduced into the Country and into an outdoor pig unit by a member of the public throwing a sandwich containing an illegal personal import of meat. Disease initially goes unnoticed and an aerosol plume from an affected pig reaches rams in a neighboring field. The rams become infected but initially show no obvious signs of disease. They are moved to a large ram sale where a large number of rams in adjoining pens become infected. Several batches of infected rams which are showing no obvious signs of disease are moved to an area of the country of predominantly permanent pasture with lowland cattle and sheep in a valley floor some 50 km long and 20 km wide.

55. Throughout this area there have been several outbreaks of FMD in cattle and sheep as a result of movement of infected rams onto holdings. Holdings are fragmented with rented grazings. Biosecurity is poor with movements of livestock keepers between their parcels of land giving opportunity for lateral spread of disease by the movement of people and vehicles. The occurrence of cattle cases gives rise to a heavy weight of infection in the area.

56. Computer modelling has confirmed that the area is one in which there is likely to be significant lateral spread of disease for the reasons given above. The modelling has shown that vaccination would be an effective aid to control. The virus strain has been identified and there is a reserve of antigen in the vaccine bank, from which an effective vaccine can be formulated, which has been tested for safety, efficacy and potency. A vaccination zone the size and shape of the valley is declared and all cattle in the zone are vaccinated. The vaccination policy is one of protection with the intention that vaccinated animals that do not become infected will live out their productive lives. Sheep and pigs in the zone will not be vaccinated, other than registered rare breeds of sheep and pigs.

Downland Outdoor Pigs

57. There is a large area of downland particularly suited to outdoor pig keeping and there are many outdoor pig units close to one another. Biosecurity is poor with frequent movements of personnel between units. Disease is introduced into this area and there have been several outbreaks in

the area. Spread has been by the movement of people and vehicles. Computer modelling has confirmed that disease is likely to spread in this downland area. The modelling has shown that vaccination would be an effective aid to control. The virus strain has been identified and there is a reserve of antigen in the vaccine bank from which an effective vaccine can be formulated, which has been tested for safety efficacy and potency. A vaccination zone the size and shape of the downland pig keeping area is declared and all pigs and cattle in the zone are vaccinated. The vaccination policy is one of protection with the intention that vaccinated animals that do not become infected will live out their productive lives. Sheep in the zone will not be vaccinated, other than registered rare breeds.

Veterinary Exotic Diseases Division
16 June 2004

Veterinary Risk Assessment and Protocol for Rights of Way Closure – FMD ANNEX F

Veterinary Risk Assessment

In the event of an outbreak of FMD, what is the risk of causing further outbreaks if rights of way are open to the public?

1. Summary of Risk Assessment

Great Britain is classified as FMD free, in the event of a new introduction of disease, there is a risk that persons using rights of way could cause further outbreaks. Infection may result from contaminated persons or accompanying animals arriving at the right of way and subsequently passing on infection to livestock or by persons or accompanying animals becoming contaminated while using the right of way and passing infection to livestock then or at a later time.

The factors considered to be most responsible for increasing this risk are:

- contact with infected premises or premises where animals have been exposed to the risk of infection prior to arrival at a right of way
- contact with livestock prior to arrival at a right of way
- failure to disinfect footwear prior to arrival at a right of way
- proximity of rights of way to livestock areas, including infected premises and premises where animals have been exposed to the risk of infection
- presence of accompanying animals
- failure to limit access for persons or accompanying animals from rights of way to livestock areas failure to limit access by livestock to rights of way, resulting in deposits of faeces, urine, milk etc.
- contact with livestock while in locality of a right of way
- contact with surroundings (including pasture and foliage) while in locality of a right of way
- meteorological and environment conditions which influence virus survival
- failure to disinfect footwear after leaving locality of a right of way
- contact with livestock after leaving locality of a right of way
- contact with surroundings (including pasture and foliage) after leaving locality of a right of way

Of these, the major factors are:

- proximity of rights of way to livestock areas, including infected premises and premises where animals have been exposed to the risk of infection
- contact with livestock prior to arrival at a right of way
- contact with livestock while in locality of a right of way
- contact with livestock after leaving locality of a right of way
- failure to limit access for livestock to rights of way, resulting in deposits of faeces, urine, milk etc.

2. Summary of Risk Management options and rationale

This section identifies ways in which the risks which have been identified can be managed, taking no account of whether the management options are practical or proportionate to the level of risk. Theoretical risk management options include:-

i. Closing all rights of way over land which may be grazed by livestock, making public access a criminal offence.

ii. Closing rights of way only in areas where the risk of FMD virus being present is greatest

iii. Preventing or discouraging access by those who keep or handle susceptible livestock in the course of their work, and so are most likely to have been exposed to and contaminated by FMD virus.

iv. Permitting access but encouraging the public

- to wear clean clothing and footwear so that they do not introduce infection to an area;
- to avoid walking amongst livestock, and, in particular, NEVER to handle or touch animals, and
- to use any disinfectant footbaths or pads which the landowner may choose to provide.

Regulating access in accordance with the likelihood that infected animals or their products may be encountered. The risks are greatest on Form A and Form D premises, but entry and exit to and from these are already controlled by statute. Elsewhere the risk diminishes with distance as follows: -

- within the protection zone, normally an area of 3km radius around any Infected Premises in an Infected Area
- within an Infected Area outside any protection zone
- within a Controlled Area
- where no FMD controls are in force.

In addition to geographical factors, risk may diminish with time. Virus viability on pasture is limited and is dependent on meteorological conditions. Virus survival during the summer months is limited by warmer, drier weather. Meteorological conditions will be more favourable to virus survival on pasture during the winter months.

3. Recommended action

i. FMD virus may be introduced to previously uninfected premises in many ways: by airborne spread; by the movement of infected animals, feed or bedding; and by the movement of people, vehicles or equipment contaminated with the virus. Transmission by people has been recorded on many occasions, but those responsible have generally had close contact with animals on infected, and then on uninfected, premises. It is theoretically possible that persons using rights of way who had not had direct contact with infected animals could carry infection to previously uninfected animals, although there is no evidence that this has actually happened and the risk, if any, is small in comparison to other transmission risks.

ii. Even small risks can be further diminished by appropriate action, but the cost may outweigh the benefit. There is a balance to be struck between the need to control FMD and the damage that controls do to other important industries, such as tourism. Draconian action may be unnecessary and inappropriate, particularly if universally applied.

iii. There is no veterinary justification for closing all rights of way and preventing all public access to land. A more measured response, which takes account of both public perception and of the real risk, is required. The latter is the product of many factors, including the prevalence of infection in an area, the presence or absence of susceptible livestock, and the density of the livestock if present.

iv. Viable virus is most likely to be picked up on premises which have been recently infected or exposed to the risk of infection by human, animal, or animal product movement, or by proximity. Premises on which infection is suspected or has been confirmed, or on which animals have been exposed to the risk of infection, are subject to restrictions which prohibit entry or exit except under licence. Restrictions on individual premises may remain in force for many months, particularly on premises where full cleansing and disinfection is not carried out for any reason. The risk that persons using rights of way will come into contact with FMD virus on premises on which final cleansing and disinfection has been completed is very small, and even on premises where it has not, there is virtually no risk from walking on the land (as opposed to through yards or buildings) after a sufficient period of time has elapsed.

v. Even on premises that are not subject to Form A or Form D restrictions, infection may be present but unrecognised. The risk is greatest in premises situated in the PZ of an Infected Area, less in Infected Areas outside PZs, much less in Controlled Areas, and least where there are no restrictions or where restrictions have been lifted.

vi. Whatever the status of an area there is only a very small risk that persons using rights of way who have not recently handled or been in direct contact with susceptible livestock will introduce infection from elsewhere, or spread infection from one premises to another. The risk is greatest on land close to an Infected Premises on which FMD has recently been confirmed and diminishes with time. A high density of livestock increases the likelihood of contact between persons using rights of way and animals, and so increases any risk of transmission.

vii. The single most effective method of reducing any risk posed by persons using rights of way is to ensure that they have not handled or been in contact with susceptible livestock before or during their visit. Enforcement of such a condition is not practicable but it is reasonable to suppose that most people using rights of way will respect the interests of the community at large by taking precautions, which will minimise the risk of spreading FMD.

viii**.** It is extremely unlikely that people using rights of way will come into contact with viable FMD virus. The risk of transmission by these persons from one farm to another is therefore very small. The following action can be justified:

- Allow public access to all paths and rights of way, but publicise and seek the co-operation of persons using rights of way in observing the following precautions intended to protect the disease - free status of the area:
- start your walk wearing clean footwear and clothing;
- do not approach, touch or handle livestock;
- keep dogs on a lead wherever there are livestock;
- take any waste, including food, home; and
- use any disinfectant footpads or baths which the landowner provides.

ix. Even when area restrictions are lifted, individual premises may remain under restriction for much longer than is necessary to control the risk that persons using rights of way may come into contact with viable virus and carry infection to other premises. Virus survival on land at any time of the year is unlikely to extend beyond the date when final cleansing and disinfection of the premises is completed or more than three months from the date of preliminary cleansing and disinfection if this is sooner.

x. Entry to and exit from restricted premises is normally permissible only under licence but there is statutory provision for this requirement to be discontinued or modified. It is therefore feasible to allow rights of way on restricted premises to reopen whilst other restrictions (such as that which prevents restocking) remain in force.

xi. It is therefore recommended that:

- In the event of an outbreak, rights of way should be closed within the Protection Zone, normally the area within a 3km radius of an infected place. In exceptional circumstances, following a veterinary risk assessment, the area may be larger than this in order to control the spread of disease. Such circumstances might arise, for example, where it is believed that conditions have allowed windborne dissemination of virus in high concentration over a large area. Rights of way should remain closed until the protection zone restrictions have been lifted. This will normally be when the Infected Area restrictions are lifted.
- Rights of way which only cross the land of restricted premises should be reopened as soon as the completion of final cleansing and disinfection has been certified. However, rights of way which pass through farmyards and buildings should be temporarily diverted, but if this cannot be done, they should remain closed until supervised restocking has been completed and restrictions lifted.
- If full cleansing and disinfection is being undertaken but has been delayed then rights of way which cross the land only may be reopened 3 months after the preliminary cleansing and disinfection. However, rights of way which pass through farmyards and buildings should be temporarily diverted, but if this cannot be done, they should remain closed until supervised restocking has been completed and restrictions lifted.
- If full cleansing and disinfection is not being undertaken at all then rights of way which cross the land only may be opened 3 months after the preliminary cleansing and disinfection. However, rights of way which pass through farmyards and buildings should be temporarily diverted, but if this cannot be done, they should remain closed until the restrictions are lifted.