Summary
Towards the end of the 2001 Foot and Mouth epidemic, the Royal Society was commissioned by the Government (Department for Environment, Food and Rural Affairs (Defra) and the Office of Science and Technology) to undertake a review of the scientific aspects of the control of infectious diseases in livestock. This was one of three commissioned investigations, the others being the “Lessons Learned” inquiry undertaken by Sir Iain Anderson and the Policy Commission on the Future of Farming and Food, chaired by Sir Donald Curry. The Royal Society’s inquiry was undertaken by a committee chaired by Sir Brian Follett FRS, and was explicitly charged with looking to future developments. It reported in July 2002 (RS 2002) – The IDL Report.

This follow-up review highlights some particular issues and concerns identified in a more detailed review of progress on the various recommendations in the IDL report, which is attached at annex A¹. Sir Brian and several members of the original committee have been involved in the process of following up the IDL recommendations and in producing this review, which has been endorsed by the Society’s Council. We also shared a late draft of the annexes with Defra officials, who had the opportunity to comment on the factual accuracy.

Since July 2002 there have been a number of important developments at European and domestic level:

• Defra’s response to the IDL report and the Lessons Learned Inquiry in November 2002 (Defra 2002), and the issuing of a route map for the implementation of commitments in the response (Defra 2003a); with the latter being updated in July 2003 (Defra 2003b);

• The UK Animal Health Act 2002;

• The adoption on 29 September 2003 of a revised EU Directive for the handling of an outbreak of Foot and Mouth Disease (FMD), which will be transposed into domestic UK legislation;

• The laying before Parliament on 31 March 2004 of a revised contingency plan for handling an outbreak of FMD, after consultation with stakeholders;

• The testing of the contingency plan by a real-time national exercise (Exercise Hornbeam) at the end of June 2004.

The EU Directive on FMD gives a comprehensive set of guidelines for member states for both the prevention and the control of FMD in the event of an outbreak. In response, the United Kingdom, through Defra, published an updated contingency plan and the Animal Health and Welfare Strategy for Great Britain (Defra2004f) along with its associated 2004 Implementation Plan. The strategy and its implementation plan encourage the development of improved animal health and welfare in the UK, as well as arrangements for countering exotic infectious diseases.

¹ References to sections in this report are in ( ) and references in { } are to paragraphs in annex A.
We welcome the detailed work that Defra has undertaken on many aspects of our recommendations. We acknowledge that some aspects will require longer to implement than the two years since the publication of our report, and provide below, as bullet points, some areas that require further attention, largely building on work already in progress¹.

- The surveillance arrangements. (1)
- The arrangements for active Parliamentary scrutiny of the contingency plans, possibly by the Environment, Food and Rural Affair Select Committee. (2)
- The arrangements for a wider interim review of arrangements for handling infectious diseases in livestock. (2)
- The capture and handling of data during an outbreak. (3)
- The completion of the various projects analysing the data from the 2001 outbreak and other research to inform the decision making process on whether pre-emptive action beyond the culling of infected premises and dangerous contacts is required to control the outbreak. (4)
- The structure of technical input into the handling of an outbreak of an infectious disease. (4)
- Further action to ensure that emergency vaccination is a viable option for pre-emptive action, including the validation of Non Structural Protein (NSP) tests and a better understanding of the implications of vaccination by all stakeholders. (4, 5)
- The development of portable RT-PCR diagnostic equipment that can be used in the field and sensitive enough to detect virus in pre-clinical cases. (5)
- The need to ensure that animal health research is given the support it requires and is co-ordinated with support provided by research councils. (7)
- Training, especially of farm workers and an increase in the overall number of large animal veterinarians. (6,8)

Defra has undertaken a considerable amount of work since the publication of the two inquiry reports, has consulted on many issues with stakeholders and published many of the key documents on its website in a welcome increase in transparency. Apart from some fundamental work that still remains to be done, summarised in the bullets above, the crucial challenge for Defra is to ensure that it has brought together the many strands of its work on infectious diseases in livestock into a coherent structure, in particular ensuring that the command structure and the information flow arrangements designed to combat an outbreak are fully fit for purpose. The report on Exercise Hornbeam and knowledge gained during the exercise should provide helpful feedback in this regard.

### Detailed Points

#### 1. Surveillance

Defra has defined a sophisticated surveillance information system – RADAR (4.1) - which will be developed in a number of phases leading to a fully populated, comprehensive range of data sources by 2013. It is critical that the choice of the data sources is made in consultation with the user community, to ensure that researchers are able to make best use of the system. Plans must be put in place to address the reduced surveillance capacity during the development phase and, more fundamentally, it needs to be made clear how the completed system will enhance the surveillance or early diagnosis of non-endemic diseases. Government has to ensure that at all times the means of delivering rapid diagnosis are available and that provisions to ensure that delays will not occur are in place.

Current and future animal tracking systems will need to provide correct and up-to-date information in the event of an outbreak. Concerns have been raised by, amongst others, the National Audit Office that there are errors and gaps in the data in the current system (NAO 2003). **We hope that the careful management of the proposed new tracking system is maintained so that the new animal tracking system can be implemented on time and within budget.** In addition, we note that procedures for the IDL report’s recommendation that registration of all keepers of livestock have not been implemented (4.5).

The control of illegal imports is still of concern despite a recent action plan from Defra and funding from Government (4.4). There remains some confusion over the roles of Defra, HM Customs and Excise, and the Food Standards Agency in reducing the risk to animal and plant health posed by illegal imports.

#### 2. Contingency Planning

The IDL report stressed the importance of; developing, in advance, detailed arrangements to counter an outbreak of an exotic animal disease epidemic; ensuring that these arrangements were known to the various stakeholders and where possible accepted by them; and regularly reviewing whether the arrangements were still relevant in terms of the ongoing technological developments and the known threats.

a. Parliamentary scrutiny

The IDL report recommended that the contingency plan should be brought before Parliament for debate. This recommendation aimed to ensure broad acceptance within the farming and livestock industry, and the general public, of an agreed set of procedures in the event of a future outbreak, many of which were bound to be contentious to one party or another. So far there has been no active Parliamentary scrutiny (3.1), and it remains unclear whether the consultation process has provided the Government with

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¹ References to sections in this report are in ( ) and references in { } are to paragraphs in annex A.
political empowerment supported by the farming community and the general public, rather than just a legal and administrative framework to operate in the case of any outbreak scenario. The Environment, Food and Rural Affairs Select Committee may wish to consider if it could take responsibility for the scrutiny of the contingency plan.

b. Reviewing

The Animal Heath Act 2002 requires the contingency plan to be reviewed at least once a year. However, it is critical for a more extensive review to be undertaken every few years in which the wider context is considered, and actions are taken to ensure that the contingency plan is evolving in step with scientific, farming and societal changes. We therefore welcome the recently published Animal Health and Welfare Strategy and the commitment to review the Implementation Plan, a key part of the strategy, on an annual basis along with a formal five-year review of the ten year vision (3.5). This strategy goes some way to satisfying the IDL recommendation that the Prime Minister establish a formal three yearly review procedure for diseases in livestock. However, we note with some concern that there is a five year gap between reviews. It is important that careful consideration is given to the time period between reviews so that the Animal Health and Welfare Strategy and the contingency planning can keep pace with scientific, farming and societal changes.

c. Fire-drills

Defra organised a testing of the contingency arrangements culminating in a final exercise (Hornbeam) in June 2004. The real-time Hornbeam exercise was a welcome development to ensure all involved in an outbreak scenario are up to date with current procedures (7.3). Such testing should continue on a regular basis because any one exercise is only committed to a single major scenario. The outbreak in 2001 was propagated by transport and sheep and so involved scenarios that were very different from those of the 1967 outbreak which involved wind and cattle.

We note that the outcome of the exercise has been studied by Defra’s Science Advisory Council and its epidemic diseases sub-group, who have recently issued their recommendations (Defra 2004k). We look forward to publication by Defra of a full report on the outcomes from the exercise and encourage the Department to seek comments from stakeholders.

d. Involvement of stakeholders

Defra has worked well to engage stakeholder groups in drawing up the contingency plan. There have been open consultations and a clear timeline for discussion and implementation of the updated contingency plan (3.1). The engagement of stakeholders should ensure the contingency plan is kept up to date and relevant to the user communities that have to buy-in to the objectives and practical aims.

3. Basic control

a. Movement controls

A considerable amount of planning has been undertaken by Defra to put in place controls on livestock movements in the event of an outbreak (6.1). An essential aspect of these controls will be the provision of an early warning system that can identify movement risk and initiate increased vigilance at the first indication of an outbreak. Both the EU Directive and Defra’s Contingency Plan appear to provide a clear chain of command once an outbreak is confirmed. Further work is required to ensure that a system is put in place that can quickly reduce movements in the event of an outbreak. The issue of movement control has become more important in recent years with the closure of many local slaughter houses resulting in increasingly longer journeys for animals to travel to slaughter and the increased risks of disease spread.

b. Biosecurity

The original IDL report recognised the role of disinfection during an outbreak and identified the need to ensure that people, vehicles and premises are adequately disinfected to minimise as far as possible further transmission of the disease (7.11). The contingency plan specifies the biosecurity measures that should be implemented. However, the IDL report also stressed that the term biosecurity should encompass wider issues such as controls on all movements within specified risk areas, prudent sourcing of stock, quarantine, vaccination and testing in order to move away from the thinking that disinfection is the only ‘barrier’ that should be considered. Further research developments involving biosecurity measures should have an impact on future control measures, and the measures specified in the contingency plan will need to be updated to reflect this.

c. Culling infected premises and dangerous contacts

The IDL report recommended the culling of infected premises and dangerous contacts (DC’s) and the use of emergency vaccination if further pre-emptive action was required. While the policy of culling of infected premises is clear, work still needs to continue to establish a soundly based method for the identification of DC’s. Identification of DC’s will be informed from an epidemiological investigation of the data from previous outbreaks. Recent scientific publications have begun to make use of the data collected during the 2001 outbreak and forthcoming analysis may further elucidate the effect of culling on the progress of the disease (7.12).

d. Data collection

Some work remains to be carried out on the capture, transmission, storage, processing and use of background and disease dependent information (9.1) for management of the disease control process. The use of geographical information systems (GIS) will be important in clearly identifying infected premises during an outbreak.
4. Further, pre-emptive, control measures

a. Identification of need for additional pre-emptive action

The IDL report stressed the need to examine the 2001 data for further information on the transmission characteristics and associated control methods in order to inform the decision as to whether more extensive pre-emptive control measures are required in a particular outbreak. To undertake this analysis a number of research contracts/grants have been awarded by the Wellcome Trust and public sources to explore the epidemiological information in the 2001 data and to develop modelling techniques. Some of the first analyses of this work have recently been published (Honhold 2004a; Honhold 2004b). These have indicated that, for the strain of the virus involved with the 2001 epidemic, the rapid culling of IP’s and DC’s and the imposition of strict biosecurity measures were the key control mechanism. It will however be some time before a significant proportion of the analytical results are published. Furthermore modelling will be required to explore sensitivity to different virus characteristics. It is important for policy makers to keep in touch with this work.

b. Decision making during outbreak

While many of the individual components within the contingency plans are in place, concern remains about some of the decision-making processes within Defra during an outbreak of an exotic infectious disease; in particular about testing the robustness of the criteria that would be used in the decision tree to determine whether to employ extended pre-emptive action and if so whether this should involve emergency vaccination or slaughter (7.2).

We also remain concerned both about the effectiveness of arrangements for securing independent expert advice from outside Defra during an outbreak and about the mechanisms whereby this advice is then fed into decision making (3.9; 3.10). We await the full report of Exercise Hornbeam to assess the expert advice requested and the impact of the decision making process in a large-scale fire drill.

c. Diagnostics

The key to the use of emergency vaccination, discussed fully in the next section, is the validation of Non-Structural Protein (NSP) tests. It is essential for NSP tests in cattle to be validated. In particular, issues of sensitivity and of identification of false positives need to be resolved so that a recognised diagnostic test can be used Europe-wide.

The other priority is the development of sensitive rapid tests that can be used outside of reference laboratories, to aid rapid diagnosis during an outbreak. Ideally these tests should be applicable in the field. Commercially used equipment is already available which, with appropriate reagents, can rapidly detect very small amounts of FMD virus in preclinical cases. More generally, there is still scope in this area for veterinary practice to make more use of developments in the medicinal area (8.3).

5. Emergency vaccination

Although the IDL report recognised that rapid culling of infected premises and of epidemiologically determined dangerous contacts was the appropriate approach for the control of exotic diseases, it stressed that it was becoming increasingly unacceptable across Europe to cull and destroy large number of animals, as occurred in the 2001 outbreak, either as part of wider pre-emptive disease control or for welfare purposes. It is therefore imperative to find approaches whereby emergency vaccination can be employed in situations where pre-emptive action is required. Use of such vaccination procedures must be coupled with arrangements to ensure that the animals subsequently enter the food chain (7.7). If there are problems associated with a non-slaughter approach then these need to be resolved.

Defra has put a great deal of effort into putting in place contingency arrangements for securing and delivering emergency vaccination in the event of an outbreak of FMD. These include securing derogations within the EU Directive (7.7) that will ease the exit strategies after the use of emergency vaccination. More work is required to promulgate to stakeholders and the general public the exit strategies. In addition clear explanations of meat treatments required in a FMD outbreak must be provided. The drafting of Defra’s recent publication ‘The role of vaccination in a future outbreak of FMD’ (Defra2004d) was not sufficiently clear in this respect (7.7). Failure to clarify both the exit strategies and meat treatment protocols will undermine Defra’s sterling work in securing these derogations when the Directive was being drafted.

The contingency arrangements outline the scale of the delivery of emergency vaccination. Further information is required to assess whether the arrangements for scaling up vaccination capacity would meet the EU Directive requirements for a worse case scenario (7.5). A consultation by Defra on the use of lay vaccinators was completed at the end of March (Defra2004j) resulting in two orders recently being laid before Parliament to allow trained personnel to handle and administer vaccine during an outbreak (Defra2004l).

The delay in obtaining validation of the NSP tests required to secure regaining of disease free status under a vaccination to live strategy remains a concern (8.2). However, the recent Defra publication ‘The role of vaccination in a future outbreak of FMD’ (Defra2004d) states that “the absence of an internationally validated test would not prevent the use of vaccination in the event of a future outbreak”.

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6. Resources

a. State Veterinary Service (SVS)

The recent review of the SVS and its future role will potentially have a large impact on the delivery of the Animal Health and Welfare Strategy in the UK. The final shape and function of the service must ensure that it is fit for its purpose and of an adequate size. In particular there should be adequate coverage to manage the additional temporary veterinary support recruited in the event of an outbreak (10.5, 10.6).

b. Vets and other skilled workers

Expertise that resides within private sector veterinary services and the veterinary schools is an essential resource during an outbreak. However, a shortage of the number of large animal veterinarians and the need for a critical mass to undertake the roles required of them will become an increasing problem unless action is taken to reduce the decline in recruitment to the profession (10.7).

The provision of emergency vaccination during an outbreak is contracted out to Genus Plc, but the processes involved in provision of qualified teams still requires further planning. The amendment of the Veterinary Surgeons Act (1966) to allow the use of lay vaccinators will help resource any large scale emergency vaccination programme, but the overall veterinary management of the process will require careful planning (7.6). The resources required for culling of animals also need to be considered carefully to ensure culling can take place within the guideline times.

7. Research

Defra has reviewed all of their research programmes into exotic diseases (Defra 2003c), and issued a joint call for proposals in this field with the Scottish Executive and BBSRC. It is to be hoped that the Science Advisory Council (SAC) will review the research programmes to identify missing elements. In addition the findings from relevant research world wide should be reviewed to inform future advice on research needs and if necessary updates of contingency arrangements. The proposal for five research institutes to develop better vaccines and anti-viral compounds should be a priority for the animal health research programme (5.2). With Defra’s other significant responsibilities for sustainable development and climate change, its research budget is likely to be under severe pressure. It is essential that relevant animal health research is given a sufficient degree of priority. At the time of going to press we note with concern reports of a reduction in size of the Institute of Animal Health. It is important to ensure that this does not result in a reduced overall research capability. The IDL report recommended an expansion of this capability.

8. Education and training

The IDL report recommended that many areas of further education provision for education and training should be improved, across the range from farm workers through to veterinary surgeons (10.5). We have noted the positive comments by the Chief Veterinary Officer (CVO 2004) and the extra resource being made available to veterinary colleges. Increased levels of co-ordination and training, particularly of farm workers, are still required to ensure a higher standard of disease prevention.
Progress:

1.1 A range of measures have been implemented at both the EU and UK level in the wake of the Foot and Mouth outbreak in the UK. The fundamental documents are the revised EU Foot and Mouth Directive (2003/85/EC) (EU 2003) and the Animal Health Act 2002 (AHA 2002). Defra has published a completely updated Foot and Mouth Disease Contingency Plan (Version 4.0) (Defra 2004a), Slaughter and Emergency Vaccination Protocols, and several additional documents e.g. on communications (Defra 2004e), surveillance (Defra 2003e) and the role of vaccination (Defra2004d). Defra has also circulated other draft documents to stakeholders on issues such as the treatment of products of vaccinated animals (Defra 2004d). A full list of relevant Defra publications is at annex C; these documents cover prevention, diagnosis and containment of Foot and Mouth disease by bringing together prevention and control mechanisms. In general, policy developments have made advances on all fronts but, as discussed below some recommendations have yet to be fully implemented.

1.2 In addition a draft Animal Health and Welfare Strategy (Defra 2003d) was published for consultation in December 2003 followed by the full strategy in June 2004 (Defra 2004f). This document outlines five strategic outcomes with the broad aim of improving the health and welfare of animals and protecting society, the economy and environment against the impact of animal diseases.

Main Recommendation 1: The overall objective of policy must be to minimise the risk of a disease entering the country and, if it does enter, to ensure the outbreak is localised and does not develop into an epidemic.

R1.4 Providing the level of international threat does not increase; there are improved import controls; and there is a demonstrable improvement in the arrangements for handling disease outbreaks, the UK should not adopt a policy of routine vaccination, and should retain the internationally recognised status of “disease-free without vaccination”. (p6)

Progress:

2.1 Maintaining disease-free status without routine vaccination is the underlying principle of EU and UK policy. The lack of a satisfactory prophylactic vaccine makes maintenance of the disease-free state without vaccination the only option at present.

Main Recommendation 3: Better contingency planning is vital. The Government must be empowered to act decisively during an outbreak. This requires prior debate about the control measures to be adopted. The Government's Contingency Plans should therefore be brought before Parliament for debate and approval. The Plans should be subject to a practical rehearsal each year and should be formally reviewed triennially to ensure that they take account of: the latest information about the scale of international disease threat; changes in farming practice; scientific and technological developments; regulatory developments at national, EU and global level; and the country’s state of preparedness.

Maintaining disease-free status

R1.3 The UK should continue to strive for “disease-free” status against highly infectious diseases such as those listed in the OIE’s List A. (p5)
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R1.2 The Prime Minister should establish a formal procedure to review at three-yearly intervals:
- the level of threat from imported animal diseases of livestock
- changes in livestock farming practices that could affect vulnerability to disease
- scientific and therapeutic advances that could affect policy options
- the UK’s and Europe’s state of preparedness. (p1)

3.2 As part of planning and training, over 50 regional training events have taken place with the first full ‘fire-drill’ at the end of June 2004, Exercise Hornbeam. This exercise played out the strategic, tactical and operational responses to suspicion and confirmation of FMD and its spread. It involved operational partners, including other Government departments and agencies, devolved administrations, local authorities, and police forces, playing out Days 7 and 8 of an outbreak scenario in order to test the Government’s preparedness as set out in its published Contingency Plan.

3.3 On a wider scale, an umbrella plan for matters common to all diseases has not yet been actioned, with individual contingency plans being prepared for list A diseases from which the UK is at risk (Classical Swine Fever, Bluetongue, Newcastle Disease and Avian Flu). Wherever possible, common policy should be produced for matters common to all diseases to reduce unnecessary administration and to be as helpful as possible to the end users of the documents. Although this approach was accepted in the Government’s response to the report, much of the current planning appears to be at individual disease level without, as yet, the extraction of common principles.

3.4 As part of the on-going process of revising the contingency plans, Defra announced in January 2004 that it was funding a year-long cost benefit analysis contract to inform future FMD Control Strategies. The aim is to inform the decisions over different disease control policies by taking into account the wider economic costs of four scenarios including the use of vaccination.

3.5 The Government is still considering a formal three-yearly review process that would examine the threats from all diseases in livestock. The arrangements for dealing with these threats have been outlined in Animal Health and Welfare Strategy (Defra 2004f), including the management of the strategy through a science group and a strategy steering board. The strategy will be reviewed mid way through its 10 year programme with an annual review of the Implementation Plan. The only formal process is the annual review of the contingency plan, which requires publication and presentation before Parliament as a requirement of the Animal Health Act 2002.

3.6 Equally, no formal review process exists at the EU Level, although the ‘Standing Committee on the Food Chain and Animal Health Section: Animal Health and Animal Welfare’ assists the European Commission in its development of new measures. The committee is made up of representatives of Member States and chaired by a European Commission representative.

Technical input to the decision making process

3.7 Although not reflected in the numbered recommendations, the IDL report expressed concern (paragraph 9.20) that early drafts of the contingency plan did not appear to be taking sufficient account of the need to involve at the strategic level the Defra Chief Scientific Advisor (CSA), and strongly recommended the creation of a high level technical advisory committee chaired by the Department’s CSA. The input of expert advice is also reflected in the EU FMD Directive (Article 78), which requires Member States to create a permanently operational balanced expert group to ensure preparedness against an outbreak.

3.8 The establishment of a FMD Expert Group has been included in the latest version of Defra’s Contingency Plan to bring it in line with the EU Directive. The Group has a clearly defined membership for ‘peacetime’ and an enhanced membership in the event of an outbreak. We note, however, that the core and enhanced membership of the Expert Group are currently made up of staff from Defra, the Veterinary Laboratories Agency and the Institute of Animal Health, with no independent members. While this meets the letter of the EU Directive (Article 78 (1)), it is not clear that it contains all the expertise that would be required during an outbreak.

3.9 The contingency plan recognises the role of the Science Advisory Council and its sub-groups during an outbreak, and provides for cross representation at official level to the expert group to challenge policy decisions.

3.10 One of the first actions of the SAC was to establish an epidemic diseases sub-group to review the science underpinning Defra’s FMD contingency plan, and this...
sub-group included co-opted members with expertise in veterinary and social science. The roles of the expert group and the SAC FMD group were rehearsed during exercise Hornbeam, a report on which is expected shortly. This sub-group has also reviewed the outcome of Exercise Hornbeam, and its views should input into the next review of the contingency plan and more generally to the FMD Expert Group.

Main Recommendation 4: As a result of globalisation, the risk of invasion by exotic (i.e. non- endemic) animal diseases has increased. It is essential that the UK, and the EU, strengthen their early warning systems and ensure that warnings are acted upon. This requires an EU risk and surveillance unit; better funding for the OIE reference laboratories to track disease spread and type the strains; heightened animal disease surveillance on farms; and greater interaction between farmers and veterinarians to improve the effectiveness of national surveillance. Import controls over meat products require tightening.

Surveillance of infectious diseases

R3.1 Defra should undertake a systematic analysis of the information available on the relative threats to the UK from the range of diseases covered here (and other significant diseases such as TSEs and TB), taking account of the impact of globalisation and climate change, in order to set priorities for the national strategy for animal disease and surveillance. (p35)

R5.1 Defra should propose an EU-wide risk assessment unit and centralised database on surveillance and disease data, and a review of the bodies that provide early warning of animal disease threats. (p54)

Progress:

4.1 The UK Veterinary Surveillance Strategy (launched in October 2003) is a ten-year programme seeking to address highlighted surveillance issues. A key part is a strategic goal to derive better value from surveillance information and activities. Currently, data comes from a range of sources including veterinary laboratories, abattoirs, private vets and livestock producers. An information management system called RADAR (Rapid Analysis and Detection of Animal-related Risks) is currently being implemented. A prototype has recently been completed with the various phases/milestones due for completion from April 2006 with the fully populated system implemented by March 2013. During the current development phase data sources are being selected and loaded, with several further phases until completion in 2013. The first phase of the data loading is expected by autumn 2005.

4.2 When notified of a new disease incident in an EU Member State, a country on the border of the EU or a third party trading partner, Defra undertakes a qualitative risk assessment and publishes it on its website. 21 such reports have been published over the past 12 months. The OIE also provides surveillance information as well as the collection, analysis and dissemination of veterinary scientific information.

4.3 The OIE reference laboratory is currently funded through annual contributions and additional voluntary donations from member countries, which is a matter for international discussion and decision. Defra has stated that adequate funding would be provided to the UK reference laboratories to enable them to fulfil their national commitments (also paragraph 8.1).

Import control

R5.2 Defra should promote the speedy implementation of the Action Plan on illegal importing and of a much more coordinated approach at all levels by all bodies concerned with import control. (p54)

Progress:

4.4 A revised Action Plan, published in June 2003, updated the original plan released in March 2002. There are several other bodies, each with their own role in import control, that work with Defra on different aspects. Government made available £6 million in 2003-04 to tackle illegal imports, which will be primarily delivered through Defra, HM Customs and Excise, and the Food Standards Agency working in partnership with other interested parties. Controls at airports for flights originating outside the EU are still very low key compared with some countries. There is, for example, scope for use of surveillance equipment to monitor luggage coming in from high risk countries.

Registering, monitoring and managing livestock

R5.4 Defra should ensure that all keepers of livestock (including that not kept for food production) are properly registered and submit to Defra each year the name of their nominated private veterinary surgeon and a health plan approved by the same veterinary surgeon. (p54)

Progress:

4.5 The Government’s response indicated that further consideration was being given to the setting up of a register to ensure that all keepers of livestock have submitted the name of their veterinary surgeon and a health plan that would allow effective monitoring and management of livestock. While this is clearly an additional burden on the keepers of animals, this has to be weighed against the costs if there is an outbreak of an infectious disease.
Vaccination and disease-free status

R8.1 The Government should take the lead in developing an international research programme aimed at an improved vaccine that would permit routine and global vaccination of livestock against FMD and other List A diseases. (p105)

Progress:
5.1 Under current legislation, “disease-free status without routine vaccination” is the Government’s position though contingency plans for FMD, Classical Swine Fever, Newcastle disease and Avian Flu allow for emergency vaccination. At the international level, the European Commission for the Control of Foot-and-Mouth Disease (EUFMD) (established under the auspices of the Food and Agriculture Organisation of the United Nations (FAO)) promotes foot and mouth research and coordinates national programmes at the EU level. It has a research group of the standing technical committee that co-ordinates information gathering on developments of vaccination technology. The Institute of Animal Health represents the UK on this committee.

5.2 There has been increased investment in basic research programmes by several funding organisations, including for example a £3 million increase in Defra's Disease Prevention research programme since 2002. This has led to the initiation of new research studies, including the developments of improved diagnostic tests and vector-borne diseases. Research is focusing on the underlying biology, where many gaps in knowledge exist, however there remains a lack of a coordinated research programme to develop a routine vaccine for FMD and other List A diseases. In correspondence from Defra we understand a global partnership of five research institutes, including the IAH, are putting together a proposal for a research programme to develop better vaccines and anti-viral compounds. It should be a priority that funding for this project should be found.

Main Recommendation 5: Routine vaccination against some of the OIE List A diseases is possible. While there are no overwhelming scientific or economic reasons against this approach being adopted we believe that, at present, the considerable technical problems and the trade implications argue against changing current arrangements. Nevertheless it is clear that the long-term solution is to develop a vaccine against FMD (and other diseases such as classical swine fever) that confers lifelong sterile immunity against all strains of the virus. An international research effort is required to develop such a vaccine.

Main Recommendation 6: The precautionary principle should be adopted more widely to ensure that any disease outbreak cannot develop into an epidemic. One of the most effective means of achieving this is to minimise animal movements at all times. The Government should consider a system whereby early warning of infection triggers significantly enhanced precautionary measures.

Animal movements

R5.3 Defra should investigate all the issues connected with reducing animal movements and come forward with practicable solutions that strike the right balance between the legitimate interests of livestock owners, market systems and long-term disease control. (p54)

Progress:
6.1 The current Defra arrangements for tracking animal movements have been the subject of a recent NAO report (NAO 2003). Although positive in principle about the long term ‘Livestock Identification and Tracing Programme’, which aims to bring together data into a single Livestock Register, the report was critical of the current livestock identification systems. The current system involves the Cattle Tracing System and the Animal Movements and Licensing System (sheep and pig movements with cattle movements reported via a link to the Cattle Tracing System), with both systems still based around extensive postal notification. The NAO report highlighted the high levels of errors and gaps in the data and the subsequent cost in terms of staff time, additional postage and European Commission penalties.

6.2 Currently a six-day standstill period operates for the movement of livestock with exceptions for some breeding animals and for animals in shows where the six-day standstill is not triggered. Both exemptions require that the animal has met the agreed isolation requirements in a Defra approved isolation facility. Defra believes that the restrictions strike a balance between the needs of business and disease prevention. There is provision for this standstill period to be increased up to 20 days should early-warning triggers suggest a disease threat. Options are covered extensively in both the EU Directive and the UK Contingency Plan. However a question remains as to whether an early warning system is in place that can quickly trigger reduced movements. The severity of the 2001 epidemic was exacerbated by the fact that it took place during the peak sale season.
Main Recommendation 7: 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. In many cases this will not be sufficient to guarantee that the outbreak does not develop into an epidemic. Given recent advances in vaccine science and improved trading regulations, emergency vaccination should now be considered as part of the control strategy from the start of any outbreak of FMD. By this we mean vaccination-to-live, under which meat and meat products from animals vaccinated and subsequently found to be uninfected may enter the normal human food chain. The Government should prepare the regulatory framework and practical arrangements (e.g. validation of tests, and the supply of vaccines) that would allow this. There must at the outset be an exit strategy agreed among the main stakeholders to allow the country to return to the preferred ‘disease-free without vaccination’ status.

Emergency vaccination

R8.2 Emergency vaccination should be seen as a major tool of first resort, along with culling of infected premises and known dangerous contacts, for controlling FMD outbreaks. This policy should be vaccine-to-live, which necessitates acceptance that meat and meat products from vaccinated animals enter the food chain normally. (p105)

R8.3 In determining the arrangements for deploying emergency vaccination, Defra should:
- take account of the urgent need to achieve validation for field use of the tests that discriminate infected from vaccinated animals;
- develop emergency vaccination strategies that integrate theoretical and empirical epidemiology and the logistics of delivery of vaccine cover;
- establish an exit strategy that takes account of the need for on-going surveillance, safeguards for those involved and agreement that products from vaccinated animals can enter the normal human food chain;  (p105)

R8.4 Defra should explore with the EU and OIE what improvements to vaccines and surveillance tests are required to allow disease free status to be based entirely on surveillance results without the requirement for a minimum waiting period. (p105)

Progress:
7.1 The EU Directive (September 2003) outlines the FMD control strategy, which includes the provision of emergency vaccination. Arrangements for the possible use of emergency vaccination have to be put in place by each Member State. The Directive takes account of new OIE rules, which enable disease free status to be applied for after six rather than 12 months. This is only three months longer than the situation if no vaccination had been used, and goes a long way to making ‘vaccination to live’ a more feasible option.

7.2 The option to deploy pre-emptive emergency vaccination as a ‘firebreak’ has been incorporated into the contingency plan. The latest version of the plan include the draft Emergency Vaccination Protocol published in April 2004, coupled with a decision tree to determine if pre-emptive action is appropriate and if so whether emergency vaccination should be used. The Animal Health act specifies that if the Secretary of State rejects emergency vaccination the reasons for this decision must be published before using pre-emptive slaughter. The contingency plan provides some background to the decision points in the decision tree, and these are set out in more detail in a further publication ‘The role of vaccination in a future outbreak of FMD’ (Defra2004d).

7.3 The recent national exercise, Exercise Hornbeam, was designed to test Defra’s contingency planning in the event of an outbreak of FMD. We understand that emergency vaccination was deployed and that the public report of the exercise and details of how emergency vaccination was used during an outbreak scenario will be published shortly.

7.4 Ben Bradshaw’s letter of November 2003 (Annex B) stated that the use of vaccination as a control policy had to be coupled with validated Non Structural Protein (NSP) tests, but paragraph 45 of the contingency plan (Defra2004a) states that “the absence of an internationally validated test would not prevent the use of vaccination in the event of a future outbreak”. A herd based test would be used and where there was a positive result a higher discriminatory (probing) test would be used. The development and validation of NSP tests is discussed further under Recommendation 8.

7.5 The contingency plan outlines the scale of the delivery of emergency vaccination in terms of manpower in the event of an outbreak. The contract at the outset allows 50 vaccination teams to be ready with provision to scale them up to 150 teams (450 staff) within the first 5 days. The contractor is on 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 have to be identified and the vaccine 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. With the closure of the International Vaccine Bank, previously maintained at the IAH Pirbright, vaccines will now be provided through a commercial contract with Merial and access to the EU Vaccine Bank. However, in order to increase the pool of personnel available to undertake the vaccination, the Veterinary Surgeons Act (1966) has been amended by secondary legislation to allow the handling and administering of vaccination by lay vaccinators (Defra2004i).
7.6 The EU Directive requires a Member State to prepare all arrangements deemed necessary for emergency vaccination in an area at least 10km centred on an outbreak immediately the FMD outbreak is confirmed. The IDL report discusses the delivery of vaccine required in an outbreak (RS 2002; paragraphs 9.57 – 9.61). The IDL Report set out the manpower requirements for vaccination teams, should a widespread outbreak occur. It is not clear how the Defra arrangements for vaccination could be deployed at sufficient levels over the critical timescale.

7.7 The creation of a satisfactory exit strategy after emergency vaccination is crucial, and it is important that all stakeholders understand exactly what is involved. During the consultation phase of the development of the EU Directive, Defra worked with EU officials and colleagues in other Member States to obtain derogations to the provisions in the period between the completion of surveillance testing and obtaining disease free status for a particular area. This ensures that meat and milk from vaccinated animals can be sold on the domestic market without having to undertake costly deboning or heat treatment [Articles 25-27, EU Directive (EU 2003)]. The recent publication on the role of vaccination (Defra2004d) does not mention these derogations in the sections dealing with each of the various animal species (cattle paragraph 17, pigs paragraph 23 and sheep paragraph 28) although they are described later in the document. This has caused some confusion, for example the front page of the Veterinary Times (VT 2004) entitled “Vaccinate to live in debt?” Defra is consulting on notes on the treatment of products from vaccinated animals which were designed to inform the relevant stakeholders. Furthermore we understand that Defra are currently preparing a paper to explain the meat treatments required in a FMD outbreak.

Use of anti-viral agents

7.8 The IDL report suggested that the fast growing field of anti-viral agents in human diseases should be periodically reviewed for possible spin-offs for animal diseases (RS 2002; paragraphs 1.18 and 10.15). In particular there is potential for providing rapid short term protection until the vaccines take effect. Some research is being undertaken at Pirbright and in the United States in this area.

Rare breeds and zoos

R9.2 As a matter of urgency, Defra should draw up arrangements for a process for the prior registration for vaccination of zoos and rare breed collections. (p125)

Progress:

7.9 The contingency plan and emergency vaccination protocol accept the recommendation for separate consideration of rare breeds and zoological collections. A prior registration scheme is being developed to allow rapid protection for those groups of animals identified in advance.

Handling an outbreak

R9.1 The main objective in dealing with an outbreak must be to ensure that it does not develop into an epidemic. This requires the following basic measures:

i. on suspicion of an outbreak, immediate imposition of strict local movement restrictions and biosecurity measures including culling the animal with clinical signs;

ii. on confirmation by an OIE Reference laboratory of an outbreak:

- mobilisation of the full emergency arrangements including all the additional logistic resources and the interdepartmental co-ordination and scientific advisory structure;
- imposition of a total country-wide ban on animal movement with unambiguous and widely publicised advice on the fate of any animals in transit;
- rapid culling of all infected premises;
- identification and rapid culling of all premises where there is a high risk of the disease where these measures are insufficient to guarantee that the outbreak will be contained, we recommend in addition the early deployment of emergency vaccination. (p125)

R3.3 Defra should carry out urgent research into local transmission of FMD that will improve biosecurity in the field. (p35)

Progress:

7.10 The EU Directive and the contingency plan set a course of action when an outbreak is confirmed. This involves an amber and red warning system, the former being deployed on the suspicion of an outbreak and the latter following subsequent confirmation. These warning systems include the rapid diagnosis, movement restrictions and establishment of a control centre as outlined in the recommendations.

7.11 The Government’s response (HMG2002) accepted that there was a need to research local transmission, and pointed to the extensive epidemiological field data that was available. The response also indicated that good biosecurity was of critical importance and stressed that the use of “Blue Box” restricted infected areas had reduced the local spread of infection. However, it is essential that more quantitative research is undertaken in this area, and checked by the relevant science community through publications and parallel investigations using different analyses. The findings must then be drawn together to inform the decision making processes, including the arrangements for identifying “dangerous contacts”.
7.12 The contingency plan provides for rapid culling of infected farms and all premises where there is a high risk of the disease as defined in Article 2 of the EU Directive. At this stage, a decision has to be made on whether further pre-emptive action is also required. This decision is the responsibility of the Secretary of State, who has to explain the reason for the use of culling rather than emergency vaccination (Contingency Plan Section 2.22). The IDL report recognised that much more work was necessary on the decision making process as to whether this wider pre-emptive action was required. The 2001 records are a valuable resource and a number of teams are examining the data (Section 9.7). So far only one group has reported its findings (Honhold 2004a; Honhold 2004b; Taylor 2004). It is also important to explore the dependence of the results on the characteristics of the strain of the FMD virus associated with the 2001 epidemic, and the sensitivity of the findings to the range of characteristics for the FMD virus.

Vaccinating for other diseases

R7.5 Defra should consider the benefits of bringing responsibility for all list A diseases under a single organisation. (p84)

R9.3 Defra should review its arrangements for other diseases, and in particular the developments required to enable emergency vaccination. (p125)

Progress:

7.13 Division still exists between the responsibility for exotic diseases (Institute of Animal Health) and endemic diseases (Veterinary Laboratories Agency). If such a division is to continue, it is essential that not only for there to be close cooperation between the two organisations, but also that there are formal arrangements during an outbreak for coordinating their activities on a day-to-day basis.

7.14 The arrangements for other diseases have been detailed in contingency plans for Classical Swine Fever, Bluetongue, Newcastle Disease and Avian Flu, which cover the major notifiable diseases in the UK.

Main Recommendation 8: The first suspected case in an outbreak must be diagnosed in an approved OIE reference laboratory. Thereafter, modern diagnostic methods – including pen-side tests – need to be developed that can shift the burden of diagnosis to veterinarians on the farm. Rapid diagnosis, particularly before clinical signs appear, would limit the size of any epidemic and improve strategic deployment of resources. Such diagnostic methods must be linked by modern telecommunications to central headquarters.

Diagnostic testing and reference laboratories

R7.1 Defra should consult with other member states to ensure that the OIE is appropriately constituted to validate new diagnostic techniques and reagents as rapidly as possible; and that OIE reference laboratories are supported politically and financially so they can better undertake their national and international obligations, including the development of diagnostic tests. (p84)

R7.2 Defra should ensure that sufficiently specific and sensitive pen-side antigen detection ELISAs are developed for FMD and other major diseases, are validated as quickly as possible, and are available on a large scale for use in the field, and that a similar ELISA is developed especially for detecting antibodies in sheep. (p84)

R7.3 Defra should explore the potential for portable RT-PCR machines for use in the field or at regional laboratories. (p84)

Progress:

8.1 OIE Reference laboratories have a funding formula which supports their activities. This is derived mainly from annual and voluntary contributions from Member Countries (see also paragraph 4.2).

8.2 The OIE chapter on FMD was reviewed post 2001 outbreak. The use of serosurveillance based on NSP tests to demonstrate the absence of potential carrier animals is recommended by the OIE. The availability of an internationally validated NSP test that distinguishes between vaccinated and infected animals is important to the acceptability of vaccination as a control policy. Despite the Defra announcement (Defra 2004d) that full validation is not required to deploy emergency vaccination, there remain concerns that the necessary screening and confirmatory tests have not been fully validated in all of the target species, nor has a statistical sampling framework been established. The OIE has established an ad-hoc group to evaluate the guidelines for FMD surveillance and NSP tests for FMD. Defra is funding a three-year research project on FMD sampling strategies, including evaluating currently available NSP serological methods. The validation of NSP tests in cattle across the EU was due to have been completed by the end of 2003 that would subsequently be validated by the OIE. Progress has been made towards validation of NSP tests at the last OIE meeting in September 2004, but questions still remain over sensitivity and the identification of false positives. The validation of a NSP test for use in sheep and pigs is still at an early stage.

8.3 There is significant development work being undertaken on the development of portable tests to aid rapid diagnosis in the field, much of it in the United States as part of the anti-terrorist activities. Hence it is important for Defra to engage in regular information exchange. These RT-PCR devices offer not only more rapid results, but also are sufficiently sensitive to detect virus before
clinical signs are apparent. Despite this progress in veterinary tests, it is not clear that full regard is being taken of advances in the medical field.

Communications

R7.4 Defra should develop advanced telecommunications between the field and central control. (p84)

Progress:
8.4 The UK contingency plan and the EU FMD Directive contain detailed information about the communication arrangements in the event of an outbreak (discussed under Recommendation 7). A chain of command is established to involve all parties in the process to allow information to feed into the system. Developments in advanced telecommunications and enhanced central and regional information management systems should be investigated as part of the evolution of the plans.

Data collection, availability and quality

R3.2 Defra should undertake a comprehensive review of the available information on FMD and develop a consistent and coherent database of the basic information that would be required during an outbreak. (p35)

R6.1 Defra should establish a review to determine the data required for informing policy both before and during epidemics of infectious diseases. This review should involve all those likely to be involved in disease control, including modelling teams, and cover:
- information to be collected on a routine basis, and how this can be kept up to date;
- information to be collected during an outbreak;
- incorporation of the data into a central database;
- use of modern techniques for real time data capture and verification. (p72)

R6.4 Defra should ensure that the data from the 2001 epidemic are checked and then made widely available, while ensuring that any data protection issues are resolved. (p72)

Progress:
9.1 Significant work remains to be done in creating a database and an associated management information system of up-to-date information on FMD, farm locations and animal population that can be immediately available to officials at all levels and in an appropriate form in the event of an outbreak.

9.2 The European Commission has introduced TRACES (Trade Control and Expert System), an IT system designed to improve the management of animal movements both from outside the EU and within the EU. TRACES is a single central database tracking the movement of animals and certain types of products both within the EU and from outside the EU. The system came online in April 2004 and will run in parallel with the old system (ANIMO) until December 2004.

9.3 The contingency plan lists the information that has to be collected during an outbreak. The real time data capture details under Section 5 of the contingency plan (5.1 -5.4) make it a requirement for data capture as soon as practicably possible. It gives five outline data requirements under 5.4: animals slaughtered; performance against 24 hour slaughter target (if farm is an infected premise); animals disposed; disposal route and cleansing and disinfection - when primary cleansing and disinfection is complete. Under the section there is no requirement to collect vaccination data if and when emergency vaccination is deployed.

9.4 During the 2001 epidemic, a number of mistakes were reported on the map references of infected premises. The use of modern GIS equipment as part of a real time data collection system should eliminate this problem.

9.5 The incorporation of surveillance data into an on-line disease control database that can inform officials at all levels, and the development of a user friendly management information system should be considered.

9.6 In June 2003 Defra released an online database of the statistical data from the 2001 outbreak aimed at the research community to allow researchers to explore the epidemiology of the 2001 Foot and Mouth outbreak. The future direction for the analysis of data will focus on the epidemiology and development of new models (see paragraphs 7.11 and 7.12).

Disease modelling

R6.2 Defra should commission research to improve the methodology used to identify dangerous contacts. (p72)
Main Recommendation 10: A national strategy for animal disease research should be developed. The overall costs of animal diseases to the UK over the last fifteen years may well have exceeded £15 billion: research is the only rational means available of improving animal health and diminishing disease. The strategy should be delivered through a ‘virtual national centre' for animal disease research and surveillance involving the Institute for Animal Health, the Veterinary Laboratories Agency and research groups in universities. It should also involve private research institutes and publicly funded animal disease research being undertaken in Northern Ireland and Scotland.

Developing and funding a research strategy

R5.5 Defra should establish an Applied Research Unit on Livestock Management Practices that will undertake or commission research leading to (i) the design of effective biosecurity measures against infectious animal diseases, and (ii) the design of livestock management structures and practices that improve animal health in terms of infectious diseases. (p55)

R10.1 The Government should undertake a thorough overhaul of research into animal disease, and in particular develop a national strategy for research in animal disease and surveillance. (p136)

R10.2 The Government should draw together the current research funding in infectious diseases of animals (both endemic and exotic) within England into a single joint arrangement, the funds being made available to implement the National Strategy; (p136)

R10.3 The Government should create a virtual National Centre for Animal Disease Research and Surveillance, the Board of which would be responsible for delivering the National Strategy; (p136)

R10.4 The Government should increase investment in animal disease research and development by the order of £250M over the next 10 years. (p136)

Progress:

10.1 The co-ordination of a research strategy has been taken forward by an Applied Research Forum, established by Defra in September 2003, which aims to coordinate and support research in farming and food. The coordination of research has also been discussed as part of the recent Animal Health and Welfare Strategy to inform priorities for scientific research.

10.2 Defra directly funds several research projects, some in collaboration with other funding bodies such as the Wellcome Trust and BBSRC. There has been commitment from Defra for increased funding in animal disease
research but only broad plans where research priorities will be in the medium to long term and no target level of expenditure. Defra has a number of research contracts with the Institute of Animal Health, and the Institute produces a yearly update paper on developments in FMD.

10.3 A virtual National Centre or some form of co-ordination model has yet to be implemented. The Animal Health and Welfare strategy recognises the need to coordinate research and claims that Government is in the best place to do this.

10.4 As for as specific research topics, a number of areas have already been identified in this report, including analysis of the 2001 data, developing models and in vivo aspects of diagnosis. In addition, there is a need for further work on biosecurity including basic work on transmission of the virus within the environment, and also on the degree of infectivity of carrier animals.

Education and training

R10.5 Defra should take rapid action to investigate and improve:
  • the continuous professional development of farmers and stock keepers;
  • postgraduate training in livestock health and welfare;
  • the attractiveness of careers within the State Veterinary Service
  • the training of TVIs and LVIs by Defra, with the RCVS, the BVA and its species divisions, investigating the feasibility of the BCVA proposals. (p138)

Progress:
10.5 The Animal Health and Welfare Strategy comments on training, education and skills and how these can be delivered at all levels from veterinary surgeons through to stockmen. Several meetings have taken place but as yet there are no definite training courses on offer.

10.6 Defra established a review of the State Veterinary Service (Defra 2003h) and issued consultation documents on the future arrangements of Local Veterinary Inspectors (LVIs) (Defra 2003g) and the establishment of the SVS as an Executive Agency (Defra 2004h). In parallel, the Environment, Food and Rural Affairs Committee conducted a review on Vets and Veterinary Services and published its report in October 2003 (EFRA 2003), to which the Government responded in July 2004 (EFRA 2004). The Government announced in November 2004 that the SVS would be established as an executive agency from April 2005.

10.7 One of the important points raised by the Select Committee was the growing shortage of large animal veterinarians. This was also a concern of the IDL Committee. Although a review of the situation conducted by Defra late in 2003 indicated that there was no shortage of veterinary students and that many had indicated that they “would be willing to give large animal work a try as part of a mixed practice as part of their first job”, the Department concedes that there is a problem of retaining vets in this area. In part this is due to the difficult economic position of much of livestock farming.

10.8 Defra has recently launched the Veterinary Training Research Initiative (Defra 2004i) in partnership with HEFCE and SHEFC to fill the “knowledge gap” in veterinary research in Britain. Funding of £21.5 Million has been made available for the five research and training programmes, spread between Scottish and English veterinary schools, over the next five years. The programme is anticipated to cover a wide range of research topics.
Sir Brian Follett,
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From the Minister for Nature Conservation and Fisheries
Ben Bradshaw MP

Dear Sir Brian

Your letter of 4 February to Lord Whitty indicated that the Royal Society would be expecting to see an update on the outcome of the various recommendations in the Infectious Diseases in Livestock Report around now. Moreover, in the synopsis of the Royal Society’s Report it was stated that Defra should be able to resolve a number of issues by the end of 2003. The points highlighted in the synopsis were: the trade implications of vaccination; the need to gain stakeholder buy-in for emergency vaccination; the validation of marker vaccines; vaccination strategies including threshold criteria; and the practical issues concerned with a vaccination programme. The purpose of this letter is to bring you up-to-date on progress on all these issues.

One of the main achievements of this year has been to negotiate a new EU Directive on foot-and-mouth disease (FMD) control, which meets the recommendations of the various inquiries and takes into account the changes in the OIE Code since 2001. The basic disease control policy required under the new EU Directive remains the slaughter of all susceptible animals on premises infected with FMD and “dangerous contacts”. However, the Directive gives greater prominence to the potential use of emergency vaccination as an adjunct to this basic slaughter policy. In addition, Article 14 of the Directive places a duty on Member States “to prepare all arrangements necessary for emergency vaccination in an area at least the size of the Surveillance Zone” as soon as the first case of FMD is confirmed.

Following publication of the first draft of the EU Directive on FMD, last December, we have been engaging with stakeholders to discuss the various controls outlined in the Directive. The Directive will form the legislative basis for disease control in a future outbreak and was adopted at the end of September 2003. Transposition into national legislation is required by 30 June 2004 and formal, written consultation on the FMD Order will start in early 2004.

Under the new Directive any products from vaccinated animals would be subject to treatment, ie. heat treatment or deboning and maturation of meat. Nevertheless, the Directive does allow the sale on the domestic market of untreated products from vaccinated sheep, cattle and pigs during Phase 3 of a vaccination campaign (after completion of the NSP survey and before FMD free status is regained). In addition, during phase 3, untreated meat from vaccinated pigs can also be exported to another Member State at their request. Moreover, in the early stages of an outbreak, meat from unvaccinated animals in the area around an infected premises would also need to be treated.

During negotiations on the Directive, the UK worked hard to strike the right balance, especially in the treatments required for products from vaccinated animals, so that emergency vaccination gains the necessary support from the farming and food industries to make it a workable option in the event of a future outbreak. A meeting of retail stakeholders confirmed that, providing the Food Standards Agency re-issued their statement about the safety to human health of products from vaccinated animals (which they did to coincide with the agreement of the Directive) and that no special labelling was required, such products could enter the food chain as normal. We are close to finalising, with input from stakeholders, a communications strategy which will seek to convey the message about the safety of products from vaccinated animals. This strategy and what action we will take to implement it will be discussed with stakeholders at the next meeting on 5 December.

As you know the Government stated, in its Response to the Royal Society and Lessons Learned Report, that vaccinate-to-live would be the preferred vaccination policy in a future outbreak. I can assure you that the vaccines held by the UK could be used for protective vaccination as they are all suitable for use with NSP tests. The UK’s stocks of 8 different FMD antigen strains are held, on its behalf, by a commercial supplier. The number of doses and availability of strains are kept under review.
Under the new EU Directive, recovery of FMD-free status post-vaccination is dependent on completion of a serological survey based on NSP testing to demonstrate the absence of infection in vaccinated animals. This is in line with the OIE rules. Of course, this means that availability of an internationally validated NSP test is important to the acceptability of vaccination as a control policy and we will continue to work with the EU and OIE to achieve this aim. There is also a need to develop and validate a confirmatory discriminatory test as an adjunct to current NSP tests. Defra is continuing to fund research in this area. However, there are a limited number of facilities within Europe that are equipped to carry out such research and so this work is going to take some years to come to fruition.

Defra have commissioned the IAH, Pirbright, to write an annual report on developments in FMD science especially relating to rapid diagnostics and vaccinology. The first report was published this summer and was submitted to the Environment, Food and Rural Affairs Select Committee. Whilst the report is commissioned from IAH, the review of the science takes a global perspective.

The Royal Society Report suggested that precise vaccination strategies to be employed in a future outbreak, including threshold criteria, should be agreed and that modelling would have a role here. With respect to threshold criteria for emergency vaccination, you will wish to note that Annex X of the EU Directive details criteria to be taken into account when a Member State is considering introducing protective vaccination and guidelines for emergency vaccination programmes. Modelling was used to good effect during the 2001 epidemic and has a role both during epidemics and in the development of disease control strategies. Following on from the FMD Modelling Workshop hosted by Defra last year, a project to "Review the use of epidemiological models in informing disease control policy" at Reading University has been completed. This report will help guide Defra in identifying areas where additional research is needed. We are currently commissioning a Cost Benefit Analysis on Disease Control Strategies which will consider a number of core scenarios and provide additional evidence for future decision making on disease control strategy. Results of the Cost Benefit Analysis are expected towards the end of 2004.

Since circumstances can vary widely, it is not possible to prescribe a detailed response in advance of an outbreak. This is why 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 disease control strategy. 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 the nature and extent of an outbreak is understood. Veterinary and scientific advice and judgement remain vital in determining disease control strategy. The decision tree is in the process of being updated to reflect changes brought about by the new FMD Directive and we are also considering what further work on scenarios could help with the decision-making process and aid transparency.

Finally, many of the logistical and operational arrangements for a vaccination programme have now been put in place. Strains of vaccine have been identified and stocks purchased; the equipment needed by vaccination teams in the event of an outbreak is either in store or available on a call-off contract basis; and we are currently making arrangements, subject to public consultation, for the use of lay vaccinators to be permitted, so saving scarce veterinary resource, by amending the Veterinary Surgeons Act 1966 and the Medicines Act 1968. An interim contract is in place to deliver the vaccination operation and we aim to have a long term contract agreed in the New Year.

Under this interim contract we are operationally capable of vaccinating on day 5 of an outbreak. To arrive at this state of readiness, sufficient vets, lay vaccinators and support staff have been recruited and trained to provide 50 first response teams. Working under the overall control of the SVS, the role of the team veterinary surgeons vets will be to conduct pre-vaccination farm visits and to be responsible for the veterinary direction of vaccination teams in the field. Our contractor also has the capability to ramp this number up to meet any reasonable disease scenario within 4/5 days of notification.

In conclusion, I hope the above will assure you that progress has been made, and will continue, on all the issues highlighted in the Royal Society Report.

With best wishes

BEN BRADSHAW
Annex C

List of relevant UK government documents since the IDL report (by year):

2002

**AHA2002** Animal Health Act 2002

**HMG 2002** Response to the Reports of the Foot and Mouth Inquiries Cm 5637 November 2002

2003

**Defra 2003a** Route Map for implementation of commitments; January 2003

**Defra 2003b** Route map for implementation of commitments:
Defra progress report; July 2003

**Defra 2003c** Review of Statutory and Exotic Diseases Programme (excluding Brucellosis, Rabies and TB),
Post-meeting report; June 2003

**Defra 2003d** Outline Animal Health and Welfare Strategy
http://www.defra.gov.uk/animalh/ahws/default.htm

**Defra 2003e** Strategy for enhancing veterinary surveillance in the UK

**EFRA2003** Environment, Food and Rural Affairs Committee: Vets and veterinary services

**NAO 2003** Identifying and Tracking Livestock in England
http://www.nao.org.uk/publications/nao_reports/02-03/02031144.pdf

2004

**Defra2004a** Foot and Mouth Disease Contingency Plan (Version 4.0)
http://www.defra.gov.uk/footandmouth/contingency/index.htm

**Defra2004b** Emergency Vaccination Protocol

**Defra2004c** Disease Control (Slaughter) Protocol
http://www.defra.gov.uk/footandmouth/pdf/slaughterprotocol.PDF

**Defra2004d** The role of vaccination in a future outbreak of FMD

**Defra2004e** Foot and Mouth Disease Control Policy Communications Strategy

**Defra2004f** Animal Health and Welfare Strategy for Great Britain, UK Government, the Scottish Executive and the National Assembly for Wales. Comprising:
- Animal health and welfare strategy
- Evidence Base and Regulatory Impact Assessment
- Implementation Plan

**Defra2004g** Review of the Local Veterinary Inspector System

**Defra2004h** Delivering animal health and welfare: A review of the delivery of veterinary services

**Defra2004i** Veterinary Training Research Initiative (VTRI)
http://www.defra.gov.uk/animalh/vtri/

**Defra2004j** Consultation on amendments to legislation to allow lay vaccination of livestock in the event of a future outbreak of Foot and Mouth disease

**Defra2004k** Review of the Foot and Mouth Disease contingency plan, including Exercise Hornbeam:
recommendations of the Science Advisory Council

**Defra2004l** New orders in parliament increase flexibility for handling & vaccinating in the event of an outbreak of foot and mouth disease.
EFRA2004 Vets and veterinary services: Government reply to the committee’s report

Other References

EU2003 EU Directive on Community measures for the control of foot-and-mouth disease; September 2003


RS 2002 Royal Society Infectious Diseases in Livestock report, July 2002
http://www.royalsoc.ac.uk/inquiry/


VEERU2003 Veterinary Epidemiology and Economics Research Unit Modelling Report, May 2003
The Royal Society

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