The role of vaccination in a future outbreak of FMD

Introduction

1. Foot and Mouth Disease (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".

So where are we now?

5. 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 EU legislation which requires arrangements for emergency vaccination to be put in place as soon as the first outbreak is confirmed.

6. 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 Food Standards Agency that it is safe to consume products from vaccinated animals;
    - negotiating new EU legislation, which ensures a more ready market for such products;
    - 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 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.

7. 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

8. 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.

9. 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 foot and mouth disease. 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

10. One of the key factors which influences 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.

11. 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.

12. Vaccination is ideally suited for an area where there was FMD in a part of the country and there had not 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

13. 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.

14. 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 behavioural 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.

15. In the event of an outbreak, particularly in pigs, it is normal practice to model the potential for windborne dissemination of disease from an 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 may 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

16. 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.

17. During the first stage of a vaccination campaign, meat from vaccinated cattle would have to be heat-treated. Once it has been shown that virus is no

longer circulating, meat from vaccinated cattle may be marketed with an EC health mark after deboning and maturation. 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.

18. 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.

19. 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.

20. Vaccination may 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

21. 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 virus once infected. Virus is normally excreted as an aerosol when the pig exhales. Cattle are the species most susceptible to infection by inhalation.

22. 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.

23. 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.

24. For the reasons in paragraph 21 above, the new EU Directive on FMD 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.

25. 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.

26. Vaccination may 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

27. 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).

28. 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 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.

29. 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.

30. 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).

31. 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

32. Under the Directive, 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.

33. Given the clinical and serological surveillance required under the EU Directive, 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

34. 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.

35. 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

36. There are 3 phases to an emergency vaccination campaign laid down in the new EU Directive on FMD control:

- 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 7 above).

37. In each of these phases, 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 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 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 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 EU FMD Directive, 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 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 foot-and-mouth disease 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 an 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 35).

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 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.

<u>No Vaccination Scenario</u>

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.

<u>Windborne Spread</u>

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 neighbouring 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
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