www.defra.gov.uk

# Vaccination as a Control Tool for Exotic Animal Disease

Key Considerations

March 2010



Department for Environment, Food and Rural Affairs Nobel House 17 Smith Square London SW1P 3JR

Tel: 020 7238 6000 Website: <u>www.defra.gov.uk</u>

© Crown copyright 2010 Copyright in the typographical arrangement and design rests with the Crown.

This publication (excluding the Royal Arms and departmental logos) may be re-used free of charge in any format or medium for research for non-commercial purposes, private study or for internal circulation within an organisation. This is subject to it being re-used accurately and not used in a misleading context. The material must be acknowledged as Crown copyright and the title of the publication specified.

For any other use of this material please apply for a <u>*Click-Use PSI Licence*</u> or by writing to:

Office of Public Sector Information Information Policy Team Kew Richmond Surrey TW9 4DU

e-mail: licensing@opsi.gsi.gov.uk

Information about this publication and copies are available from:

Exotic Disease Policy Programme Defra Nobel House 17 Smith Square London SW1P 3JR

This document is available on the Defra website:

Published by the Department for Environment, Food and Rural Affairs

# Vaccination as a Control Tool for Exotic Animal Disease Key Considerations

Introduction	4
Using Vaccination against an Exotic Animal Disease: Implications	5
and Considerations	
Veterinary and Technical Considerations	5
Whether vaccination is the most appropriate disease control tool	5
Box A: A disease for which vaccination is not used.	5
Specificity, timeline for immunity and types of vaccines available	6
Box B: Live and dead vaccine use	6
To what end would we use vaccination	7
Box C: Vaccination to prevent disease spread	7
Box D: Suppressive vaccination	7
Whether further action would be needed for vaccinated animals	8
Whether vaccination impedes disease surveillance and exit strategies	9
Box E: DIVA vaccines	9
Wider Economic, Social and Welfare Considerations	9
Effects on trade	10
Box F: Vaccination and trade	10
Industry and stakeholder views and input	10
Vaccine licensing and food standards	11
Public opinion	11
Likelihood of success	12
Domestic, European and international coordination	12
Working and delivering with others	12
Practicalities of vaccination	13
Supply of vaccine	13
Quantities required	13
Obtaining and distributing vaccine	13
Box G: Vaccine and antigen banks	13
Level of compulsion on keepers to use vaccine	14
Administration of vaccine	14
Target animals to be vaccinated	14
Box H: Vaccination of wild animals	15
Cost of vaccine and who pays	15
Box I: Meeting the costs of vaccination against avian diseases	16
Reviewing vaccination and emerging evidence	16
Box J: Defra's vaccine research programme	16

### **Introduction**

The control of exotic animal disease forms part of Defra's work to implement the Animal Health and Welfare Strategy for Great Britain. It strives to make a lasting and continuous improvement in the health and welfare of kept animals whilst protecting society, the economy, public health and the environment from the effects of animal diseases.

In delivering protection from exotic animal diseases on each of these counts, vaccination may be considered an effective disease control tool as part of wider disease control strategies. This can help move towards the overall goal of eradicating the disease where it is practical to do so, and the full benefits outweigh the wider costs. In the short term vaccination can help slow, reduce and potentially prevent disease spread. At the same time however, vaccination can carry with it significant costs for industry and Government, while having wider implications for other factors such as the effective monitoring of disease spread, trade and movements. Vaccination as a disease control measure therefore requires careful consideration.

This document aims to bring together and highlight some of the significant factors that Defra takes into account when considering vaccination as a disease control measure for an exotic animal disease.

The list is neither exhaustive nor prescriptive; the varying characteristics of different exotic diseases and the varying circumstances in which vaccination may be employed, do not tend towards a single overarching vaccination policy for all exotic diseases.

This paper simply aims to highlight some of the pertinent issues considered by Defra and its delivery and industry partners and other consultees, from the point at which vaccination is first considered as a potential disease control tool, to the point at which vaccine is ultimately administered.

It should be noted that vaccines are not available for all exotic notifiable diseases. In the UK there are even fewer diseases which have vaccines with a full Marketing Authorisation that would allow for their immediate deployment in the event of an emergency.

The paper considers only exotic notifiable diseases: those which are not normally present in animals in the UK and which are subject to statutory controls.

This paper outlines Defra's framework for vaccination in England, but we continue to work closely with relevant departments in Scotland, Wales and Northern Ireland to ensure a coherent response to disease control across the UK.

For detailed information on the control policies for specific diseases, please refer to the disease-specific pages on the Defra website.

# Using Vaccination against an Exotic Animal Disease: Implications and Considerations

A range of different factors will need to be taken into account at various stages of deciding whether to use vaccine to control disease. In the preliminary stages, a range of technical issues need to be considered to establish whether it is possible, appropriate or effective from a veterinary point of view, to use vaccination as a disease control tool. The wider social, legal, welfare, public health, economic, international and practical issues then need to be factored in to the decision, which will balance these costs and benefits. In reality of course these issues may all be discussed in parallel. The following sections detail some of the pertinent issues Defra will consider.

# Veterinary and Technical Considerations

Expert opinion and scientific evidence that vaccination would prove a credible and effective disease control tool is key to determining whether or not to pursue vaccination as part of a disease control strategy. There is often much uncertainty about the extent to which vaccination would be effective given the number of dependencies there are in making it a success. The role of experts, and often modelling, is therefore crucial in determining the ultimate effectiveness of any vaccine, and experts will be consulted by Defra on the use of available vaccines in a wide range of scenarios, and in light of any emerging science. Experts may be asked to provide advice on a number of key issues, including the following:

#### 1. Whether vaccination is the most appropriate disease control tool

It may be that other preventive measures such as maintaining biosecurity standards, carrying out surveillance, restricting movements and slaughter, are more effective at preventing disease or controlling an outbreak compared with vaccination, (and may also be used alongside vaccination). Experts will be able to advise on which methods are most likely to be effective and compatible with the aims of the disease control policy, and these will need to be balanced against their costs. The Department's <u>Contingency Plan for Exotic Animal Diseases</u> sets out some other disease control measures in more detail.

**Box A: A disease for which vaccination is not used.** Rinderpest is an example of a disease where it is extremely unlikely that vaccination would be used to control an outbreak in the UK. Vaccination has been used effectively in developing countries, where there is frequent contact with wildlife reservoirs of Rinderpest. However, in the UK, the disease was successfully eradicated in 1877 by the imposition of movement controls and killing out infected farms. There is no reason why this strategy would not continue to be successful in dealing with an outbreak in this country, should it occur again. Coupled with the fact that there is no approved vaccine for Rinderpest in UK, we would not be likely to use vaccine against it in the UK.

#### 2. Specificity, timeline for immunity, and types of vaccines available

Experts are asked for advice on whether the vaccines available actually provide a useful level of protection against the disease in question. Where several strains of disease exist, it will be necessary to know how closely vaccines match the field strains and whether there are any risks associated with their use. The time taken to build immunity, and the length of protection offered, must also be considered. For example, if several doses of a particular vaccine are required to provide immunity, and it takes several weeks following the final dose to offer protection against disease, it may be that such a vaccine would not be appropriate for use in an emergency situation.

When considering whether to vaccinate, there is also a question over whether the vaccine available is 'live' or 'dead'. Dead ('killed' or 'inactivated') vaccines are made from virus or bacterial cultures which are inactivated, generally by heat or chemical treatment, during the manufacturing process. These vaccines are often given with an adjuvant (or stimulant) which induces a better immune response in the animal. In contrast, live vaccines are made from a weakened or an attenuated form of the virus or bacterium. All live vaccines mimic the disease process in the animal in exactly the same way as the original disease. The best attenuated vaccines do not cause any clinical signs of the disease. They require much smaller quantities of the virus/ bacterium to be cultured and can in some cases be administered without injecting every individual animal and therefore tend to be cheaper. For example, chicks may be inoculated *via* the conjunctiva at the hatchery for some diseases. The benefits of a live versus dead vaccine in various different situations, and any associated risks, will need to be gauged.

#### Box B: Live and dead vaccine use

In the UK we currently use an inactivated monovalent vaccine (i.e. against only one serotype) for bluetongue, whereas some countries, such as South Africa use live vaccines, often multivalent (which protect against number of different serotypes of bluetongue) but which carry wider risks.

For Newcastle disease both live and inactivated vaccines are used routinely. Most poultry vaccines are administered via other routes than injection (i.e. spray or in drinking water) in order to reach a large number of birds quickly.

For African Horse Sickness, live vaccine was used in Spain for a certain period of time in an outbreak when no other vaccine was available.

#### 3. To what end would we use vaccination

It is important to be clear, before deploying vaccine, what its use is ultimately aiming to achieve. There are two main ends to which vaccine is generally used:

#### a. To prevent disease establishment and spread.

Before exotic disease arrives in the country, vaccination may be used to protect susceptible animals, thereby reducing the possibility of the disease establishing and spreading should it arrive. Such a strategy is likely to be employed if there is an imminent or sustained threat of the disease arriving.

**Box C: Vaccination to prevent disease spread.** Newcastle Disease, a disease affecting birds, is an example where preventive vaccination is permitted on a routine basis. Because the presence of the disease in wild birds presents a continuing threat to domesticated birds and poultry, keepers are permitted to vaccinate their animals as they see fit, following the advice of their private veterinarian.

Consideration will also need to be given to what proportion of the susceptible population is vaccinated. This would broadly depend on the epidemiology of a disease (e.g. highly contagious disease, vector borne disease).

#### b. <u>Vaccination to slow the spread of disease.</u>

Once exotic disease has arrived, vaccination may be undertaken in an attempt to prevent more animals becoming infected, thereby slowing or stopping the geographic spread of the disease. Thought needs to be given as to how best to target the vaccination, especially if there are limited supplies of vaccine to permit blanket coverage. Depending upon the epidemiological advice, susceptible animals most at risk of the disease could be vaccinated first, which may or may not mean vaccinating animals geographically close to known infected premises. Advice is sought from experts on what the priority areas are in light of the risk situation and how quickly a specified vaccination, experts may advise targeting vaccination in one of several ways:

*Ring vaccination* – animals surrounding an infected farm are vaccinated

*Barrier vaccination* – animals are vaccinated in an area in which the disease is spreading

Suppressive vaccination – animals within whole regions are vaccinated

**Box D: Suppressive vaccination**. An example of suppressive vaccination was seen in 2008 when inactivated vaccine for Bluetongue serotype 8 (BTV-8) was prioritised to keepers of susceptible animals within the regions in which disease was first identified.

#### 4. Whether further action would be needed for vaccinated animals

In some instances, it may be the case that even where a vaccination campaign has been successful in controlling disease, vaccinated animals may need to be culled at a later date. Reasons to adopt a "vaccinate to cull" approach may include the following:

- a) <u>Difficulty in confirming whether a vaccinated animal is infected or not</u> vaccination may suppress the development of clinical signs of disease and not prevent infection or spread of virus, therefore making it difficult to detect infected animals, hindering disease surveillance and slowing disease eradication and demonstration of Country Freedom. However, the use of DIVA-vaccines, where available could help to resolve this issue (see point 5 below).
- b) <u>Trade issues</u> the presence of vaccinated animals may delay the resumption of normal trade in animals and animal products (including a wide range of human foods, and by-products such as hides and skins). Foot and Mouth disease is an example where the costs of culling vaccinated animals may, in some circumstances, be found to be outweighed by the benefits of allowing trade with overseas markets to resume. This is discussed in more detail at point 6.
- c) <u>Vaccinated animals not allowed to enter food chain</u> vaccinated animals or their products may be ineligible to enter the food chain, or products need specific treatments which may mean they have limited long term value. This issue may arise where legislation (e.g. for CSF or FMD) puts restrictions on products from vaccinated animals. Alternatively, it is possible a vaccine used under an emergency authorisation in an outbreak may leave the animal products unsuitable for human consumption. (This is unlikely, and the Veterinary Medicines Directorate would provide advice to the CVO on this matter on a case by case basis.)
- d) Insufficient capacity to cull or insufficient capacity for carcase disposal In the event of a very large outbreak the availability of suitable trained and licensed slaughtermen may limit the speed with which animals can be humanely culled on-farm. It is also recognised that there is a finite capacity for the disposal of carcases using rendering and incineration and it may be preferable to vaccinate animals to slow down or stop disease spread rather than resort to alternative forms of disposal such as the use of mass pyres. This option would be used to 'buy time' under circumstances where animals cannot be culled and/or removed quickly enough to prevent the disease spreading. In such circumstances, animals may be vaccinated to stop disease spreading before they are eventually culled.

#### 5. Whether vaccination impedes disease surveillance and exit strategies

If a large proportion of the population is vaccinated, then surveillance for the disease could be made more difficult. Straightforward serological surveys to monitor disease spread, (where blood samples are tested for disease antibodies), may not be possible if tests do not distinguish between antibodies produced by vaccination and those which have developed naturally because the animal was infected. For some vaccines, it is possible to mitigate this problem through the use of a 'differentiating infected from vaccinated animals' (DIVA) strategy, though for many diseases such DIVA tests or 'marker' vaccines are not available or are prohibitively expensive.

Robust surveillance is an important part of an exit strategy from disease. Following a period without confirmed outbreaks after vaccination has been deployed, supplemented with surveillance using DIVA strategies when these are available, it may be shown that vaccination has been successful in eradicating infection. The vaccine programme could be phased out, with vaccinated animals allowed to complete their production cycle with the eventual establishment of an uninfected, unvaccinated population. Northern Ireland is currently considering moving to this stage with Aujeszky's disease. Experts will therefore also advise on what suitable surveillance should entail.

**Box E: DIVA vaccines.** A commercially available DIVA vaccine is available for Aujeszky's disease. In this case, a segment of the gene has been deleted from the vaccine virus. Under the testing strategy, the detection of that deleted segment means that the animal must have been infected with a field virus, rather than having been vaccinated.

DIVA vaccines are also available for Classical Swine Fever but in this case, are far less effective at stimulating a rapid and effective immune response in vaccinated pigs, than the more conventional 'C strain' vaccines. However, there is no current DIVA test for the 'C Strain' vaccines so there will be trade-offs to consider in using either of these vaccines.

DIVA tests are also being developed for Foot-and-Mouth Disease. These are based on the detection of antibodies to Non-Structural Proteins which are only produced in infected animals, but are not present in vaccinated animals

## Wider Economic, Social and Welfare Considerations

Whilst the primary driver for vaccination will be as a disease control tool, the use of vaccine against exotic animal disease can have wide-ranging implications, both positive and negative, for a number of areas over and above the control of the disease itself. In addition to the direct costs of vaccine and its administration, decisions on a vaccination programme may have significant impacts on animal keepers, other sectors of the economy and the wider population. The decision to use vaccine therefore needs to be considered against a broader context, incorporating the full costs and benefits of vaccination, including factors such as the following:

#### 6. Effects on trade

Vaccination programmes can impact both positively and negatively on trade, depending on the disease in question and corresponding trade rules for that disease. For some diseases, vaccination permits freer movement of livestock than might otherwise be permitted, e.g. the movement of animals vaccinated against rabies to another Member State. Vaccination decisions may therefore be influenced, to some degree, by other countries' vaccination policies.

On the other hand, the vaccination of animals for some diseases is only permitted in areas where disease is present. Vaccinating pre-emptively in such circumstances to protect animals in advance of a potential outbreak may present trade barriers with free areas in other Member States. This is not restricted to trade between Member States, and can also impact domestically where disease, and thus vaccination, may be contained in a particular part of the country. Careful consideration is therefore given to the impacts of a vaccination programme on trade and any wider economic impacts this might have.

**Box F: Vaccination and trade.** Routine (or prophylactic) vaccination against some diseases (e.g. Newcastle disease) is already the norm in the UK and does not affect trade. For example, vaccinated animals for Newcastle disease are accepted for trade on the basis the vaccination status is clearly indicated in accompanying certification, if required, or accompanied certification that animals have protected immunity following testing, if required.

However, use of vaccines for some diseases, e.g. Classical Swine Fever and Foot and Mouth Disease, could, in practice, have a significant impact on the UK trading ability. This is because the time required to re-gain disease free status by trading partners, which enables the freest form of trade between member states, may be extended beyond the period stipulated by European Community or World Organisation for Animal Health (OIE), than it would be normally if vaccination did not take place. This extension may be up to 3 months for Classical Swine Fever, and up to 6 months for Foot and Mouth Disease, following the last case of confirmed disease, and only if other measures are followed (i.e. surveillance), including the slaughter of vaccinated animals.

A vaccination programme may also have implications for tracing and recording throughout the food processing and distribution chain. It is important to take full account of all these impacts in deciding whether the benefits of vaccination are likely to exceed the costs.

#### 7. Industry and stakeholder views and input

Stakeholder views are essential in helping policy-makers design a programme that works for livestock keepers, is effective, and takes into account the practical and logistical issues on the ground. Stakeholders can also advise on the appetite among industry to vaccinate at all and whether they prefer a hands-on or hands-off approach and so on. By regularly sharing information with stakeholders, we are able to make more effective decisions and policies, and ensure that the split of roles and responsibilities between Government and owners, both in preventing and responding to disease, are clear and understood.

#### 8. Vaccine licensing and food standards

All licensed veterinary medicines to be used in the UK, including vaccines, must be assessed and approved for safety for the target species. There is also need to ensure that meat and milk are safe for human consumption after observing withdrawal period, if any, if the target animal is destined for the human food chain. Manufacturers are required to supply the results of studies to the appropriate regulatory authority. In the UK, the Veterinary Medicines Directorate (VMD) assess the data to establish the safety, quality and efficacy of the products. The VMD will use the data to set any necessary withdrawal period.

Beyond initial licensing, the VMD continue to monitor the safety and efficacy of vaccines through 'pharmacovigilance', where manufacturers, animal keepers and veterinarians report to them any suspected adverse reactions to vaccine use to identify trends that may require a change to the way the product is used. Defra maintains close relationships with the VMD on such issues to ensure vaccination campaigns take account of any new information. The Food Standards Agency (FSA) can advise on whether foods from vaccinated animals meet the standards required for human consumption.

In an emergency situation, it may be the case that the use of a vaccine is permitted which is not yet authorised for use in the UK because the necessary trials have not been completed. Such use of unauthorised vaccines would only be considered in exceptional circumstances, and the use would need to be balanced against the implications of doing so. In general, these vaccines may be considered safe to be used in food producing animals. However, whether the products from these animals can be used for human consumption will depend on the make-up of the vaccine and an individual decision will be made by experts.

#### 9. Public opinion

The use of vaccination for a variety of diseases of food animals is already widespread and generally accepted. However, even if animals are vaccinated against a disease using licensed vaccines, and the required withdrawal periods are observed, it cannot be excluded that a certain proportion of public may not want to consume meat from vaccinated animals. In such a case, industry may suffer losses from vaccination, perhaps more so than from infection from disease. On the other hand, some people may find it more acceptable to vaccinate where possible rather than to cull in the event of an outbreak. It will be important to ensure that the public has the relevant information to enable them to make informed choices. These considerations will need to be balanced against the disease control benefits of vaccinating.

#### 10. Likelihood of success

The likelihood of success needs to be carefully considered before beginning a vaccination campaign. Vaccination campaigns may fail to meet their objectives for a variety of technical and socio-economic reasons. For example, although unlikely, vaccine batches may fail quality control so delivery is delayed; the 'cold chain' (when vaccines need to be stored at a certain temperature) may be broken rendering the vaccine ineffective (this tends to be discovered only after the vaccination has failed to control disease); or animal keepers may resist even compulsory vaccination. Efforts will be made to identify potential risks to success, and contingency plans put in place.

#### 11. Domestic, European and international coordination

Animal disease control is a devolved matter in the UK. However, Defra works extremely closely with Devolved Administrations officials to coordinate policies. Defra also works with other European Member States on the preferred and long-term solution to preventing and dealing with exotic animal disease across the EU. This is crucial to ensure a more joined up approach and to share best practice. Communication is achieved through a variety of organisations including European Working Groups, the World Organisation for Animal Health (OIE, which is the intergovernmental organisation responsible for improving animal health worldwide), the Food and Agriculture Organisation of the United Nations (FAO, which leads international efforts to defeat hunger), and directly with third countries and through disease specific initiatives.

#### 12. Working and delivering with others

Defra works closely and consults with a number of stakeholders and organisations in considering, establishing and implementing a vaccination programme for an exotic disease. These include, but are not restricted to:

- Animal Health (Defra's delivery agency)
- Devolved Administrations
- European Commission
- Food and Environment Research Agency
- Food Standards Agency
- Industry organisations and representative bodies
- Institute of Animal Health at Pirbright and Compton (primary research bodies for exotic diseases)
- Meat Hygiene Service
- Natural England

- Other European Member States
- Private contractors
- Royal College of Veterinary Surgeons
- The Veterinary Laboratories Agency (primary research body for exotic diseases)
- Vaccine manufacturers
- Veterinary Medicines Directorate (which licenses vaccines)
- Veterinary practices
- Veterinary wholesalers

# Practicalities of vaccination

If, when all the issues detailed above have been considered, and it is found that vaccination presents an effective disease control tool, and the benefits are found to outweigh the costs, attention will need to be paid to the design of a vaccination campaign. The following considerations will be included in designing a campaign.

#### 13. Supply of vaccine

Vaccines can take varying amounts of time to produce and establish protection. If vaccine is considered an appropriate disease control tool in an outbreak situation, any dependencies in getting vaccine produced to the required timescales will need to be accounted for in advance, if considered necessary. Early discussions will be held with relevant manufacturers to discuss their production capabilities and timelines.

#### 14. Quantities required

Experts may be asked to provide advice on the minimum level of protection that is needed within a susceptible population to provide a sufficient level of protective immunity to prevent onward spread. Experts will therefore need to advise on what quantities may be needed in certain situations over a specified period of time.

#### 15. Obtaining and distributing vaccine

Depending on the nature of the vaccination programme, vaccine might be supplied to keepers in different ways. It might, for example, be supplied through the normal veterinary wholesale route as for other veterinary medicines, or supplied by Government through other channels.

Defra may chose to purchase vaccine on a 'call-off' contract, under which vaccine is only produced when needed and within a specified time frame. Alternatively, if large quantities of vaccine are needed rapidly in the event of an outbreak, or if it is necessary to secure supply of vaccine that is not readily available, a vaccine bank may be considered, either domestically or in collaboration with other countries.

Where an emergency vaccine bank is considered necessary, attention is also given to how stock can be maintained when vaccine expires or is used. Whether the action going forward is to re-tender for new stock, or to seek shelf life extensions to that existing, consideration needs to be given to the timescales and costs required to complete the chosen course of action.

**Box G: Vaccine and antigen banks.** For some diseases it may be advantageous for the EU and/or a country to hold a vaccine or antigen bank. This may be the case when control strategies rely on rapid sourcing of large quantities of vaccine; where an unusual vaccine is needed that is not commonly available on the market; or where particular species or individual animals need to be protected e.g. for conservation reasons. In such circumstances, a vaccine or antigen bank can offer some assurance that vaccine will be available at short notice if needed.

However, any vaccine or antigen stored in a bank will have a 'shelf life', so if there are no disease outbreaks in a given period, these will expire and will need to be replenished. Furthermore, a bank can never fully guarantee that there will be the right type of vaccine available. There are often a variety of strains of any one disease, and the cost of keeping sufficient vaccine of them all to counter all possible outbreaks may be prohibitive.

Therefore a number of factors will need to be taken into account when considering whether to hold a vaccine bank, and what should be in that bank. When considering stocking vaccine banks, bank owners will have regard to the expert advice as to the likely risks and impacts that the various strains pose at any time.

For example, the EU has a vaccine banks for Classical Swine Fever (marker vaccine for domestic pigs, C-strain for wild boar). The UK and other Member States contribute to the funding of this bank, and can all utilise this bank if needed. Indeed Germany has recently used this bank to successfully vaccinate herds in their country during a recent outbreak. The EU also has a bank of high priority Foot and Mouth antigens. These antigens can be used to quickly make up vaccine when needed, and the antigens have the advantage of having a longer shelf life than the vaccine itself, thereby prolonging the life of the bank.

#### 16. Level of compulsion on keepers to use vaccine

This will depend on a wide variety of factors, ranging from the severity of the disease, stakeholder views, costs, practicality of administration, time frames, likely success and the disease situation, both domestically and in Europe. If a compulsory programme is decided upon, consideration will be given to additional factors including, but not limited to, how compliance is monitored and what the sanctions are for non-compliance. Where a programme is voluntary, consideration will need to be given to factors including how uptake is monitored.

#### 17. Administration of vaccine

Depending on the nature of vaccine and the level of control required over a vaccination programme, vaccination may be carried out by Animal Health (Defra's delivery agency) staff, local private veterinarians, lay vaccinators, by keepers with supervision, or by keepers without supervision. The urgency of vaccination and the certainty required in different circumstances will usually dictate the level of supervision required on a case-by-case basis. In the event of compulsory vaccination, the training of staff to administer vaccine will also be considered.

#### 18. Target animals to be vaccinated

The feasibility of vaccinating the target species, including whether they are domesticated or wild, will be a key and early consideration. If disease is shown to be in wild animals, and the wild population presents a challenge to domestic disease control, then it may be considered whether vaccination would be a feasible option. Vaccination in wildlife, such as for rabies, is done to prevent wildlife becoming infected, and hence reduce the rate of transmission within and between populations of animals / humans.

There are a number of factors that limit the use of vaccination in wild species. Firstly, vaccine suitability – whether the vaccine available is effective in wild species, which are often not the species the vaccine was originally developed and intended for. Secondly, is whether there is a delivery mechanism which results in a high enough proportion of the wild population receiving vaccine to be effective. The actual proportion of the population that must receive vaccine depends on many factors including the nature of transmission, population density and the rate of turnover in the population (how quickly animals die and are born). The most successful method of mass vaccination of wild species is through the use of vaccine bait in food. This is not without its difficulties however as the vaccine must be formulated so that it confers immunity via the oral route without being inactivated by the digestive process. The technique may also raise wider safety concerns if the bait is distributed within an environment where it is available to non-target species.

**Box H: Vaccination of wild animals.** The successful vaccination of foxes in Europe against rabies was achieved through the aerial dispersal of edible bait containing rabies vaccine. The vaccine bait also contained a tetracycline antibiotic marker that, when ingested by the fox, produced a fluorescent mark on the teeth. By examining their dentition the level of vaccine uptake by the fox population could be monitored.

#### **19. Costs of vaccine and who pays**

Government may meet the full cost of vaccine and administration, it may underwrite supply of vaccine or subsidise its use, or it may allow or require vaccination paid for by animal keepers themselves. The Government's cost and responsibility sharing agenda is establishing new principles and mechanisms for sharing the cost of programmes to prevent and control exotic animal disease. This broader policy will govern the approach to vaccination costs.

Decisions on who pays for vaccination are discussed in full with stakeholders and made on a case-by-case basis. These decisions are closely related to whether a vaccination programme is to be compulsory or voluntary. Important factors are the severity of the disease, whether it has public health implications or major economic impacts for the UK livestock sector, the availability of vaccine, and whether the benefits of vaccination to the individual animal keeper are enough to generate an appropriate level of coverage.

In some circumstances, funds may be available from the European Union to meet some of the costs of emergency or preventive vaccination. In deciding whether to seek European funding for domestic programmes, we will duly consider any conditions attached to such funding and the impact of the UK's budget rebate on the net value of the funds. **Box I: Meeting the costs of vaccination against avian diseases.** For avian diseases a variety of methods have been used. For Newcastle disease vaccine is readily available and keepers already vaccinate widely, purchasing vaccine on the free market through their veterinarian. For Avian Influenza, Government has purchased a small stock of vaccine for the H5 strain which is held in a bank for potential use during an outbreak. In addition to use during an emergency, the bank can also be called upon by licensed zoo's wishing to vaccinate birds such as penguins and parrots, for conservation purposes. In these circumstances vaccine is purchased from the bank by private veterinarians.

# **Reviewing Vaccination and Emerging Evidence**

Regular reviews of the science behind vaccination are key to ensuring that vaccination remains a suitable and effective disease control tool. The frequencies with which these reviews occur depend on how established the use of vaccine is for a particular disease, as well as the emergence of any new challenging evidence and stakeholder views. A long-established disease/vaccine for example, is likely to require fewer reviews as substantial bodies of evidence have built up, yet for newer diseases and/or vaccines where new evidence is becoming available regularly, reviews will be more frequent. Regular contact between Defra and experts ensures that policy-makers are kept aware of changes in the science and that policies can be reviewed as appropriate.

Defra has an ongoing commitment to fund research into new and improved vaccines, strategies and surveillance techniques where Government involvement is justified. There is an extensive programme of research in place aimed at ensuring current vaccines are used in the most effective way, and the development of novel vaccines to further improve our ability to control disease. This research is co-ordinated with other research funders, including other European Member States and institutions, as well as the vaccine manufacturers themselves who run their own research programmes.

**Box J: Defra's vaccine research programme.** Defra supports a large programme of research to support objectives for the control and prevention of exotic and notifiable diseases. The current level of funding (£7.5million per annum), provides a broad platform which is both disease specific and cross cutting in nature. Scientific research is supported that builds our knowledge of disease processes and control mechanisms, and is essential to taking forward studies on the development of vaccines.

The department is currently funding a number of projects that aim to develop new vaccines (and supporting diagnostic tests) for diseases including Foot and Mouth Disease and African Swine Fever, whilst also supporting more applied studies that make sure we are able to use currently available vaccines in the most effective manner. The Veterinary Laboratories Agency and the Institute of Animal Health are the main providers of this research, although collaboration is encouraged with other institutes and industry where possible.

This Vaccination Framework will be reviewed and revised as appropriate as disease conditions change and new information becomes available.