

EXPLANATORY MEMORANDUM TO
THE AVIAN INFLUENZA (FEES FOR THE LICENSED VACCINATION OF
BIRDS) (ENGLAND) REGULATIONS 2007

2007 No.954

1. This Explanatory Memorandum has been prepared by Defra and is laid before Parliament by Command of Her Majesty.
 - 1.1 This Memorandum contains information for the Joint Committee on Statutory Instruments.
2. **Description**
 - 2.1 The Regulations will enable the Department to recover certain costs that it may incur in relation to allowing zoos and other bird keepers to vaccinate their birds against avian influenza.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 This legislation does not need to come into force on the Common Commencement Date. It introduces measures relating to European Community legislation on the prevention of avian influenza.
4. **Legislative background**
 - 4.1 Under the Avian Influenza (Preventive Measures) (England) Regulations 2006 (S.I. 2006/2701), the Secretary of State can issue the occupier of a zoo with a licence allowing him to vaccinate birds against avian influenza.
 - 4.2 Under the Avian Influenza (Vaccination) (England) Regulations 2006 (S.I. 2006/2703), the Secretary of State can issue the owner of poultry or other captive birds outside zoos with a licence allowing him to vaccinate his birds against avian influenza. Under both pieces of legislation, the Secretary of State can also issue licences authorising the movement of vaccinated birds.
 - 4.3 These Fees Regulations will enable the Department to recover any costs incurred in issuing such licences, ensuring the applicant complies with their conditions and other associated costs.
5. **Extent**
 - 5.1 This instrument applies in England only.
6. **European Convention on Human Rights**
 - 6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- 7.1 Avian influenza is a highly infectious and contagious disease of birds. It affects many species, including commercial, wild and pet birds. There are many strains of avian influenza viruses which vary in their ability to cause severe disease.
- 7.2 As part of its contingency planning, the Department has obtained a supply of avian influenza vaccine. Since January 2007, licensed zoos have been permitted to voluntarily vaccinate their birds, providing they meet certain eligibility criteria, because of the vital role they play in global conservation and their high standards of biosecurity and veterinary surveillance which mean they can contain the risks of available vaccines in terms of potentially masking disease spread. However, due to these limitations, birds outside zoos are not currently permitted to be vaccinated in advance of an avian influenza outbreak, nor as an *immediate* disease control response.
- 7.3 The costs of the on-going vaccination of zoo birds (e.g. purchasing vaccine, administration and record-keeping) are currently incurred directly by the zoo through their private veterinary surgeon. However, there may be circumstances of higher risk in the future where the Department may have to incur costs which it wishes to recover (e.g. carrying out surveillance and testing samples from vaccinated birds to ensure they are not carrying the virus). Although birds outside zoos cannot be vaccinated so no costs are incurred at present, the Department wishes to put in place all the necessary provisions to allow vaccination against the disease (including cost recovery where vaccination is on a voluntary basis) to ensure full preparedness. The Department will not seek to recover costs where vaccination is compulsory. The Department will also not seek to recover its administrative and salary costs in planning a vaccination programme.
- 7.4 This legislation is designed to share the costs with those who may benefit from a policy to voluntarily allow bird keepers to vaccinate their birds. This is in line with the principles of joint responsibility and cost-sharing for disease prevention and control set out in the Department's Animal Health and Welfare Strategy.

8. Impact

A Regulatory Impact Assessment has been carried out and is attached.

9. Contact

Philip Reed at the Department for Environment, Food and Rural Affairs Tel: 020 7904 6946 or email: philip.reed@defra.gsi.gov.uk can answer any queries regarding the instrument.

REGULATORY IMPACT ASSESSMENT

1. Title

The Avian Influenza (Fees For The Licensed Vaccination Of Birds) (England) Regulations 2007.

2. Purpose and intended effect

a) Objective

To enable the Department to recover certain costs that it may incur in relation to licensing zoos and other bird owners to vaccinate their birds against avian influenza, and in licensing the movement and release of vaccinated birds.

This legislation applies in England only.

b) Background

As part of its contingency planning, Defra has obtained a supply of avian influenza vaccine, to be distributed to zoos and certain bird keepers to vaccinate their birds in the event that we were to decide to permit such vaccination. It would not be practical to allow bird keepers to source and purchase their vaccine individually because avian influenza is a highly infectious and contagious disease with potential human health risks, so the Department would therefore need to exercise a level of control over the distribution of any vaccine against it to remain consistent with its disease control policies. It would also be uneconomical for the manufacturer to produce the vaccine in small quantities and bird keepers can therefore benefit from the economies of scale of the Department buying the vaccine in bulk.

Since January 2007, licensed zoos have been permitted to voluntarily vaccinate their birds, providing they meet certain eligibility criteria, because of the vital role they play in global conservation and their high standards of biosecurity and veterinary surveillance which mean they can contain the risks of available vaccines in terms of potentially masking disease spread. However, due to these limitations, birds outside zoos are not currently permitted to be vaccinated in advance of an avian influenza outbreak, nor as an *immediate* disease control response.

The costs of the on-going vaccination of zoo birds (e.g. purchasing vaccine, administration and record-keeping) are currently incurred directly by the zoo through their private veterinary surgeon. However, there may be circumstances of higher risk in the future where the Department may have to incur costs which it wishes to recover (e.g. carrying out surveillance and testing samples from vaccinated birds to ensure they are not carrying the virus).

Although birds outside zoos cannot be vaccinated so no costs are incurred at present, the Department wishes to put in place all the necessary provisions to allow vaccination against the disease (including cost recovery where vaccination is on a voluntary basis) to ensure full preparedness. The Department will not seek to recover costs where vaccination is compulsory. The Department will also not seek to recover its administrative and salary costs in planning a vaccination programme.

The Regulations will enable the Department to recover a range of costs in relation to vaccination, including those incurred in:

- i) issuing, amending or renewing a vaccination licence
- ii) ensuring the licence holder complies with its conditions
- iii) providing and disposing of vaccine
- iv) supplying and applying identification
- v) monitoring, surveillance, sampling and testing.

c) Rationale for government intervention

Without any intervention, many of the costs of allowing bird owners to preventively vaccinate their birds would fall on the taxpayer.

These Regulations are designed to share the costs of allowing keepers to vaccinate with those who may benefit from voluntary vaccination, the bird owners. This is in line with the principles of joint responsibility and cost-sharing for disease prevention and control set out in Defra's Animal Health and Welfare Strategy.

3. Consultation

External stakeholders have been informally consulted on the likely costs of vaccination and the intention to recover some of those costs. Those consulted represent the broad interests of all sectors of bird keepers, from large-scale commercial production to small hobby flocks, and include:

Aviagen Limited
British & Irish Association of Zoos and Aquariums
British Egg Industry Council
British Free Range Egg Producers Association
British Poultry Council
British Veterinary Association
British Waterfowl Association
Country Land and Business Association
Domestic Waterfowl Club
Elm Farm Research
Game Conservatory Trust
Henkeepers Association
Local Authorities Coordinators of Regulatory Services
National Farmers Union
Royal Pigeon Racing Association

Royal Society for the Prevention of Cruelty to Animals
Soil Association
Turkey Club UK
Wildfowl & Wetland Trust

The Devolved Administrations and HM Treasury have also been consulted.

The Department does not intend to issue a formal, 12 week written consultation. The above external stakeholders were informally consulted on this process and no objections to the principle of cost-recovery for voluntary vaccination were raised. Further, due to the risk from avian influenza, it is important to put in place all the necessary provisions to allow vaccination against the disease (including cost recovery) to ensure full preparedness.

4. Options

Option 1: Do nothing. In which case, any costs incurred by government of allowing bird owners to voluntarily vaccinate their birds would fall on the taxpayer.

Option 2: Introduce this legislation. This will allow the Department to recover the costs it reasonably incurs in relation to permitting vaccination from people who benefit from this policy, the bird keepers.

5. Sectors and groups affected

The legislation will affect keepers of birds who choose to vaccinate them against avian influenza if they are permitted to do so. These keepers include private individuals keeping hobby or pet birds, zoos and poultry farmers, and may also include charities that, for example, house birds at rescue centres. The number of charities affected is unknown. To date, seven zoos have currently taken advantage of the permission to vaccinate their birds and a further 50 have expressed an interest in doing so. Although the Department has not yet incurred any costs in relation to vaccination of zoo birds which it currently wishes to recover, this may change in the future depending on the risk situation. The number of keepers outside zoos who will actually be affected will depend on how many of them are allowed to, and choose to, vaccinate their birds and is therefore unknown.

This proposal has been considered against the Race Relations Act 1976 (as amended by the Race Relations (Amendment) Act 2000) and there is no evidence that this proposal has a differential impact on different racial groups.

6. Costs

Option 1:

Under this option all the costs incurred by the government of allowing owners to vaccinate their birds will remain with the taxpayer.

Option 2:

Under this option some of the costs incurred by the government of allowing owners to vaccinate their birds will be transferred from the taxpayer to bird owners who choose to vaccinate. These costs will depend on the disease and vaccination situation at the time and will only apply to those bird owners that choose to vaccinate their birds.

The most likely costs to be recovered would be the cost of supplying vaccine for two doses of vaccine per bird (approximately £35 for a 1,000 dose bottle and approximately £5 for a 40 dose bottle), auditing and disposing of any vaccine left over (approximately £25 per premises) and the costs of any surveillance and testing required. The cost of any testing and surveillance would depend on the risk at the time, but each test occasion is currently estimated to cost £28 per bird tested. The number of birds that would need to be tested would depend on flock size and be determined by statistical sampling principles, with a maximum of 59 birds tested from any one flock so the costs would be proportionately higher, the smaller the flock.

There will also be some costs incurred by government in transferring the costs of allowing vaccination to keepers. These include the administrative costs of calculating the amount to be recovered, notifying keepers and collecting the money. These administration costs are unknown and will depend on the number of bird keepers who choose to vaccinate, and how often the costs are recovered. As an example, if each recovery took half an hour of Administrative Officer time per licence, then the cost would be approximately £25 per licence.

However, the Department will not seek to recover costs where vaccination is compulsory. The Department will also not seek to recover its administrative and salary costs in planning a vaccination programme.

Worked examples of costs recovered under Option 2:

The total annual costs to keepers will depend on how much testing and surveillance is required, which will in turn depend on the risk situation at the time. Therefore it is not possible to give a final figure for total costs. However, some illustrative examples of possible situations are given below.

Example 1: a hobby keeper with ten birds who chooses to vaccinate

Two 40 dose bottles of vaccine	2 x £5
Auditing and disposal of vaccine	£25
Four test occasions (all 10 birds would need to be tested)	4 x £28 x 10
Total annual cost to keeper under example 1	£1,195
Per bird cost to keeper	£120
Total government cost	£25

Example 2: a commercial poultry unit with 10,000 birds who chooses to vaccinate

Twenty 1,000 dose bottles of vaccine	20 x £35
Auditing and disposal of vaccine	£25
Four test occasions (59 birds would need to be tested)	4 x £28 x 59
Total annual cost to keeper under example 2	£7,333
Per bird cost to keeper	£0.73
Total government cost	£25

7. Benefits

Option 1:

The benefits are unchanged from the current situation.

Option 2:

Under this option the person benefiting from vaccinating birds, the bird keeper, also bears the costs. Therefore the keeper must take into account the full costs of vaccination when deciding whether or not to vaccinate his birds, and therefore his decision will more fully reflect the true costs and benefits of vaccination. Under this option the costs incurred by taxpayers are also reduced.

8. Small Firms Impact Test

Most of the bird keepers affected will be either private individuals or small firms such as zoos and farms, although there are a few large companies in the poultry sector who may also be affected. Costs will only be recovered if voluntary vaccination is pursued by a bird keeper, and therefore the bird keeper has a choice as to whether or not to incur such costs.

The costs per bird may be higher for those keepers with a small number of birds as, if surveillance and testing was required, they would need to test a larger proportion of their birds than those with large flocks. This higher proportion is required to ensure that enough birds are tested to detect any avian influenza present in a flock.

Small businesses are represented by some of the organisations informally consulted (see section 3).

9. Competition assessment

On the basis of the competition filter test, a detailed competition assessment is deemed not to be required. Those affected by the measure will be bird keepers, including private individuals, zoos and poultry farmers. The costs are

not expected to penalise new entrants or result in changes to market structures. The sectors affected are not subject to high levels of technological change, and the measures are not expected to restrict a firm's ability to choose the location, price, quality or range of its products.

10. Enforcement, sanctions and monitoring

As stated in Section 6, one of the most likely costs involved would be those incurred in supplying vaccine and auditing and disposing of any vaccine left over. The cost of supplying vaccine will be charged by the manufacturer through the normal wholesale to private vet route, and then refunded to Defra under the terms of the Department's contract with the manufacturer. The private vet conducting the vaccination will be responsible for disposing of any vaccine left over and will have to sign a declaration to confirm that the vaccine and equipment used has been disposed of correctly. For auditing purposes, this declaration will be checked by the State Veterinary Service on behalf of the Department but currently the costs of auditing the process are too low to justify the costs of collection and processing.

In the event of an outbreak or increased risk, surveillance and testing may also be required. Depending on the circumstances, sampling would be carried out by the private vet, and sent to the Veterinary Laboratories Agency (VLA) for testing on behalf of the Department. The costs of these laboratory tests will be recovered from the vaccinating premises by the VLA, via the private vet who conducted the sampling.

These processes of cost recovery have been designed to minimise the burden of administration.

11. Implementation

This legislation does not need to come into force on the Common Commencement Date as it introduces measures relating to European Community legislation on the prevention of avian influenza.

12. Summary and recommendation

Two options have been identified. The second, to introduce legislation to allow the Government to recover the costs it reasonably incurs in relation to permitting vaccination from the bird keepers who benefit from this policy, is recommended. This option reduces the costs incurred by the taxpayer and is in line with the principles of joint responsibility and cost-sharing for disease prevention and control set out in Defra's Animal Health and Welfare Strategy. It also requires the bird keeper to take into account the full costs of vaccination when deciding whether or not to vaccinate his birds, and therefore makes his decision more fully reflect the true costs and benefits of vaccination.

13. Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

SignedBen Bradshaw.....

Date.....8th March 2007.....

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