EXECUTIVE NOTE

THE AVIAN INFLUENZA and INFLUENZA of AVIAN ORIGIN in MAMMALS (SCOTLAND) ORDER 2006 (SSI 2006/336)

Introduction

The above Order is made by Scottish Ministers under the Animal Health Act 1981. It is not subject to parliamentary procedures.

Policy Objective

The **Avian Influenza and Influenza of Avian Origin (Scotland) Order 2006 (SSI 2006/336)** transposes the major part of the EU Avian Influenza Directive 2005/94/EC to provide powers to respond to any future outbreak of Avian Influenza (AI) in Scotland. The remainder of the Directive, specifically those provisions relating to slaughter and to vaccination are transposed via the companion SSI, the Avian Influenza (Slaughter and Vaccination) (Scotland) Regulations 2006. In addition to transposing European legislation, the effect of these measures is reinforce existing controls on Highly Pathogenic Avian Influenza on a risk basis, and to require control measures for Low Pathogenic Avian Influenza for the first time.

Background

Avian Influenza (AI) is a serious disease of poultry and other birds. It exists in two main forms, the more serious being Highly Pathogenic Avian Influenza (HPAI) which is a notifiable disease causing high and rapid mortality in birds and entailing serious economic consequences. Although it does not transmit easily to humans, fatalities have been recorded, usually in people living in close contact with infected birds. The less serious form, Low Pathogenic Avian Influenza (LPAI) is, owing to its tendency to mutate into the HP form, subject to controls for the first time in the Directive.

The AI Order sets out the procedures and controls required on suspicion and confirmation of HPAI and LPAI and provides for a number of zones of different levels of control, principally on movements of poultry and poultry products. The slaughter of susceptible birds on infected premises remains the principal tool for tackling an AI outbreak, and powers for this are taken in the companion SSI, the Avian Influenza (Slaughter and Vaccination) (Scotland) Regulations 2006.

Further new measures consist of:

- surveillance for LPAI and controls following outbreaks of LPAI on holdings.
- the option to impose a temporary national, regional or local movement restriction on suspicion or confirmation of disease.
- the ability for competent authorities to derogate from certain control measures following a veterinary risk assessment and where they will not endanger disease control.
- extending controls to captive birds (already in domestic legislation).

- introducing measures for pigs and other animals.
- a requirement for a database of commercial poultry holdings (already a requirement of European food hygiene legislation and in domestic legislation).
- provision for recognition of officially registered rare breeds of poultry and other captive birds so that these sectors have the possibility of taking advantage of derogations within the proposal.

Consultation

The draft SSI was made available for public consultation for eight weeks from March to May 2006. During that time a meeting of key Scottish stakeholders was held to explain and discuss the main points of the legislation and to elicit responses. This process was complicated to some extent by the finding of an AI virus in a swan carcase found in Fife, which necessitated the rapid introduction of legislation to implement Commission Decision 2006/115/EC. Stakeholder interest was focused on the response to the disease finding, and this has influenced their views on the SSI.

In general stakeholders are supportive of the thrust of the Executive's proposals. The poultry industry encouraged the Executive to move ahead as fast as possible with transposition and the associated administrative measures such as designation of slaughterhouses, hatcheries etc, so that the industry could continue to operate safely if an outbreak occurred. However, given the complexity of some of the movement requirements, there was emphasis on the need to communicate them effectively. Game interests felt that the game industry had not been given sufficient prominence, and while this will not affect the transposition of the Directive as such, these observations are welcomed for their input to policy development.

Impact

A draft Regulatory Impact Assessment, covering both this Order and the Avian Influenza (Slaughter and Vaccination) (Scotland) Regulations 2006 was published for consultation in March 2006. Responses to the consultation indicated support for Option 3 (transposition of the Directive plus other measures founds to be effective in disease control.)

A full Regulatory Impact Assessment is included with these Regulations.

Key points are:

- Options examined are (1) to use current legislation, (2) transpose Directive exactly, (3) include extra measures to enhance disease control
- Costs depend on location, size and duration of outbreak
- Difficult to estimate costs for a disease not yet suffered
- Benefits of disease control measures accrue from costs avoided

SCOTTISH EXECUTIVE ENVIRONMENT AND RURAL AFFAIRS DEPARTMENT
May 2006

Full Regulatory Impact Assessment

1. Title of proposal

Transposition of Council Directive 2005/94/EC on measures for the control of avian influenza.

Transposition will be carried out by the following two separate Scottish Statutory Instruments (SSIs):

- Avian Influenza and Influenza of Avian Origin in Mammals Order (Scotland) 2006
- Avian Influenza (Slaughter and Vaccination) (Scotland) Regulations 2006

2. Purpose and intended effect

Objectives

The objective of these measures is to provide an up to date and appropriate regulatory framework for the control of avian influenza. This will be achieved by transposing Council Directive 2005/94/EC of 20 December 2005 on Community measures to be taken should avian influenza be suspected or confirmed in EU territory. The Directive also includes provision for ongoing surveillance measures. The legislation amends previous measures to control and eradicate avian influenza to incorporate lessons learned from the outbreaks of avian influenza in the Netherlands and Italy and the most recent scientific knowledge.

Principally legislation will only be used in the event that avian influenza is suspected or confirmed with the only ongoing impact being surveillance provisions allowing for early detection and avoidance of disease. However, it is imperative that in the event of an avian influenza outbreak, disease control and eradication are achieved as quickly as possible, thus safeguarding animal health and welfare and minimising impacts on industries and rural communities. The central purpose of this Order is to create a legislative base from which this can accomplished.

Background

Previous community measures for the control of avian influenza were laid down in Directive 92/40/EEC. The current Order, which dates from 2003, requires updating in the light of the advances made in disease control, and experience gained from recent outbreaks. New legislation is required which fulfils our EU obligation and provides an up to date and comprehensive legislative basis for monitoring disease and eradicating any future outbreak quickly and effectively.

In terms of Highly Pathogenic Avian Influenza (HPAI), the Directive does not significantly change the terms of the disease control response but adds a new level of detail, particularly in terms of movement restrictions. It also provides greater ability for some restrictions to be lifted on the basis of a veterinary risk assessment.

The particular novelty in the Directive relates to the new provisions for Low Pathogenic Avian Influenza (LPAI). For the last 3 years a survey of domestic poultry for H5 or H7 LPAI has been undertaken. This now becomes an annual obligation. More significantly it makes

LPAI in domestic poultry a notifiable disease requiring a stamping out policy on infected premises. Restrictions are also required to be imposed over an area of 1 km around infected premises. These new provisions relating to LPAI will benefit the industry by helping to keep holdings free from disease and eradicating disease which has the potential to mutate into the more serious highly pathogenic form.

This legislation is due to be in place by July 2007 across the EU but in the UK we are working to have it transposed into domestic legislation by summer 2006. This approach reflects the increased flexibility which the new Directive provides in support of disease control response.

This Order will also support the implementation of the Scottish Avian Influenza and Newcastle Disease Contingency Plan:
http://www.scotland.gov.uk/Publications/2006/02/03103441/0

Rationale for government intervention

The rationale for government intervention is based on the need to mitigate the serious risk to animal health and welfare which would be caused by an outbreak of avian influenza. Avian influenza is one of a number of exotic animal diseases which are internationally recognised as causing severe damage to the industry. In addition, avian influenza has zoonotic potential, sometimes causing mild infections but occasionally death. There is concern that the virus may mutate to emerge as a new virus that is easily transmissible between people and capable of causing disease in people, birds and other animals. Influenza A viruses occur worldwide in man and a wide range of mammals.

Avian influenza is a highly infectious disease caused by an Influenza type A virus that normally infects birds. The disease in birds can manifest itself in a number of different forms ranging from relatively mild to severe. Certain wild birds, particularly waterfowl, commonly carry the milder forms. There are many different sub-types of avian influenza, grouped into a less serious - low pathogenic - form (LPAI) and a more serious - highly pathogenic - form (HPAI). The viruses are described by their major antigen determinants, H (for haemagglutinin) and N (neuraminidase). The current strain of concern is a high pathogenic H5N1. While LPAI is the less serious form of the disease, it is known that the LPAI H5 and H7 virus subtypes can mutate into the high pathogenic form. The high pathogenic form of the disease can cause high and rapid mortality in many poultry species. Outbreaks have to be notified to the OIE (the world organisation for animal health) and other countries refuse to accept any exports that might pose a risk of disease spreading. International standards require the elimination of the disease and country freedom is not recognised until this has been achieved.

The UK has had five outbreaks of HPAI since the late 1950s, the last being in 1991 in a flock of turkeys in Norfolk. It was thought to have been triggered by the mutation of LPAI virus into an HPAI virus in the poultry house. All the outbreaks were confined to a single holding, were contained by stamping out and did not spread.

There have been a number of far more serious outbreaks of HPAI in countries around the world in recent years, including the Netherlands, Italy and SE Asia, with devastating effect (the outbreak that occurred in the Netherlands in 2003, resulted in the slaughter of 30.7 million birds and heavy financial losses to the poultry industry). In 2005 China, Russia,

Mongolia, Kazakhstan, Turkey, Romania and Croatia confirmed outbreaks and there has been increased global concern on the risk posed by migrating wild birds. In 2006 we have seen incursions of the virus into EU territory with HPAI being confirmed in a number of Member States including Scotland.

Under the Scotland Act (1998) we are required to fully implement EU legislation; not fulfilling this obligation could lead to infraction proceedings and ultimately European Court of Justice action. The existing legislation does not allow full implementation. More importantly, not implementing (and ignoring lessons learned as well as the scientific advances in disease control) would be to forego the ability the Directive offers to implement controls in an effective and proportionate way.

3. Consultation

The consultation exercise was undertaken within Government as well as with the wider public.

Within Government

Within Government we have worked closely with the Scottish Executive Health Department, Health Protection Scotland, Food Standards Agency (Scotland), the other UK administrations and the State Veterinary Service in preparing the legislation.

Public Consultation

Following the adoption of the Directive, a full written public consultation package gave stakeholders the opportunity to comment on the proposed legislation. The consultation period ran from 13 March 2006 to 7 May 2006. The standard 12 week consultation period was reduced in agreement with key industry stakeholders in order to complete early transposition into domestic legislation by summer 2006. We continue to meet with industry on a regular basis and bilateral meetings have been offered to discuss the industry perspective in more detail. A summary of consultation responses is available on the Scottish Executive website.[1]

4. Options

Option 1: Do nothing

This approach continues to rely upon present controls in the Diseases of Poultry (Scotland) Order 2003. It is included to provide a baseline for the costs of controlling an outbreak using the existing powers but is not in itself a viable option as it does not provide the range of measures required by the Directive.

Option 2: Transpose the Directive exactly, using the minimum measures

This option is a 'least action' approach. It fulfils the requirements of the Directive but provides only the minimum complement of powers to do so. The provisions of the Directive retain the basic principles of disease control contained in previous legislation but introduce

[1] http://www.scotland.gov.uk/Publications/2006/03/13154600/AIconsult

key new measures. The important additional requirements in the Directive are summarised in Table A below.

Table A – New requirements of the 2005 Directive
• surveillance for low pathogenicity avian influenza (LPAI) and controls following outbreaks of LPAI on holdings.
• the option to impose a temporary national, regional or local movement restriction on suspicion or confirmation of disease.
• the ability for competent authorities to derogate from certain control measures following a veterinary risk assessment and where they will not endanger disease control.
• extending controls to captive birds (already in domestic legislation).
• introducing measures for pigs and other animals.
• new provisions for preventive vaccination.
• a requirement for a database of commercial poultry holdings (already a requirement of European food hygiene legislation and in domestic legislation).
• provision for recognition of officially registered rare breeds of poultry and other captive birds so that these sectors have the possibility of taking advantage of derogations within the proposal.

Option 3: As option 2, with additional measures as set out below

The Directive sets down minimum measures but specifically allows, in Article 1, for Member States to take more stringent action. Option 3 goes further than the Directive in a limited number of areas, based on veterinary advice. These additional provisions are set out in Table B below.

Table B – Additional measures
• powers to introduce preventive measures including separating poultry from wild birds if a risk assessment shows that those birds pose a significant risk of the spread of disease and the power to ban gatherings of birds, subject to risk assessment and a licensing system.
• a requirement for those who notify the suspicion of disease not to move anything from the premises concerned that might pose a risk of the spread of disease pending the arrival of the Veterinary Officer to investigate the suspicion.
• The power to close footpaths if a veterinary risk assessment shows this is necessary to reduce the risk of spread of disease.

5. Costs and benefits

Sectors and groups affected

The types of businesses affected or potentially affected by the Directive are principally the commercial poultry sector and related industries (egg packing, egg products, poultry meat

and meat products etc). The Scottish poultry sector has an annual gross output of around £90 million – representing 5 percent of the total agricultural industry's output. In 2003, employment in the sector was 1300 – just over 3 per cent of the food manufacturing sector's employment. Although there are around 1800 holdings registered with poultry, as much as 80 percent of the industry's chicken output comes from only 3 percent of these holdings. This indicates that the direct impact of a national avian influenza outbreak is likely to be concentrated among a few relatively big businesses in the sector. Recently, the industry has had to cope with a decline in producer prices which has been fuelled by cheap imports from EU countries that have been affected by recent outbreaks. An outbreak in Scotland is therefore likely to have a significantly adverse effect on the sector.

Other industries which could be affected include the game rearing and shooting industry, which is estimated to be worth £1 bn per annum (UK-wide). Over 4 million pheasants are being reared in Scotland, mostly to supply the game meat and shooting industry. Businesses connected with birds of prey may also be affected if disease control requirements such as a requirement to house birds were introduced. In the event of a disease outbreak the epidemiological situation may require measures to be adopted which result in wider impacts on other rural industries such as tourism, particularly if it is necessary to close footpaths. However, closures are likely to be confined to the immediate area of an outbreak hence restricting the scope of possible impacts on tourism.

In the event of disease suspicion or confirmation, the number of businesses affected is dependant on the epidemiology of the disease. At one end of the scale an outbreak may be only on a single holding and one infected area be declared with its associated movement restrictions lasting for at least 30 days. Past evidence suggests that this could be the most likely scenario in the UK. All outbreaks since the late 1950's have been contained before they had an opportunity to spread. Poultry densities in the UK are such that large scale diffusion of an avian influenza virus, such as took place during the Netherlands outbreak of 2003, is unlikely.

Benefits

Overview of benefits:

The benefits (under all three options) accrue from reducing the severity of an outbreak, and thus reducing or avoiding the associated costs. Work to assess the economic benefits of preventing an outbreak is still ongoing. It has already however shown that benefits in terms of government, stakeholder and wider economy costs averted increases linearly with the number of poultry premises that are saved from an outbreak. Until an outbreak occurs, benefits are not accrued while low level costs associated with surveillance measures are incurred.

Benefits of option 1:

This option requires no regulatory changes to be made, which would have a benefit (in the sense of costs avoided) of lack of disturbance to well understood work practices.

Benefits of option 2 (transpose exactly):

The Directive benefits the poultry industry by specifically addressing the lessons learned from recent outbreaks of avian influenza and latest scientific knowledge. The key additional elements are summarised in Table A above.

The risk of an outbreak of HPAI should reduce (although cannot be eliminated), as the new measures for surveillance and control of LPAI will reduce the likelihood of undiscovered LPAI viruses mutating to HPAI. Control options for outbreaks of LPAI are based on risk of disease spreading, assessed at the time of the outbreak, and allow for the production cycle and trade to continue unless high risk is indicated. As major epidemics of HPAI in other countries have led to severe direct and indirect losses to the industry, for which they receive no compensation, the Directive will have a favourable economic impact on the poultry sector in terms of costs avoided. The 2003 and 2004 HPAI outbreaks in Asia led to 15 – 20 percent loss of the poultry population in Vietnam (44 million birds) and Thailand (29 million birds). Assessments of the outbreaks show that the veterinary services in these countries had not been properly equipped to deal with the outbreaks, which resulted in the disease spreading widely and in some cases recurring.

Expanding the controls in the event that an outbreak of avian influenza occurs also offers significant benefits. The ability to impose national, regional or local movement controls on suspicion or confirmation of disease allows the extent of potential disease spread to be assessed whilst preventing it spreading any further. The need to impose these controls would be assessed on a case-by-case basis. The measures provide the potential for easier containment of the disease, fewer birds to be slaughtered and fewer premises to be placed under restriction. The Directive also allows derogation from some controls, where veterinary advice is that there is no risk of disease spread, to allow industry to continue operating during an outbreak.

The requirement for a database of commercial poultry holdings significantly improves government's ability to monitor disease outbreaks and prevent further spread of disease. This requirement has therefore been implemented in advance by means of the Avian Influenza (Preventive Measures) (Scotland) Regulations 2005. The consolidated data will help to identify holdings most at risk and will aid in making risk assessments. The data will also make it easier and less costly to trace contacts, will aid decisions with regard movement restrictions in the infected zone and will better inform decisions on the need for culls.

There is likely to be a positive impact on zoos, pet shops and premises which contain pet birds and rare breeds of birds, etc. due both to the reduced risk of HPAI outbreaks and the distinction between non-commercial holdings (e.g. zoos) and commercial holdings which allows for less stringent action in non-commercial holdings if there is no threat to disease control. The registration of rare breeds will provide benefits for keepers as they will be eligible for the application of derogations, again, providing that disease control is not at risk.

Social and environmental benefits

Benefits are measured in terms of costs saved. These may include a decrease in the risk of poultry and other birds contracting HPAI, which will significantly reduce the public health risks posed by avian influenza viruses. Outbreaks of HPAI would cause considerable stress to farmers, others in the poultry industry and the staff they employ, not least the concerns over their own and their families health. The welfare of birds on restricted premises could also be an issue, particularly if staff are reluctant to carry out their normal duties. The main

environmental benefits from the Directive would be the reduced impact of culling and disposal, as more effective control would potentially reduce the number of infected premises, the duration of the outbreak and therefore the number of birds slaughtered.

Benefits of option 3 (additional measures):

The benefits of these controls are very similar to those for Option 2. However, veterinary advice is that the imposition of a limited number of additional controls (see Table B) to those found in the Directive are necessary. These controls could provide additional benefits in leading to a reduction in the overall size and duration of an outbreak and thereby limiting its economic, environmental and social costs.

The requirement not to move anything on or off the farm between notification and investigation of suspected disease will prevent the movement of contaminated materials that could spread disease and is a very small burden on the business concerned.

Powers to close footpaths in a protection zone will increase the ability to contain disease. The movement of people in areas where disease is present can pose a veterinary risk, especially where walkers on footpaths may come into contact with poultry. The closures would be limited to the protection zone, a minimum of 3 km around an infected premises unless extended further where justified by risk. It is unlikely that this power would be needed beyond the infected premise itself but there may be circumstances where a veterinary risk assessment concludes that wider closure is necessary. Government policy is to keep the countryside open for business as far as possible during a disease outbreak.

The power to introduce preventive measures such as separating poultry from wild birds where veterinary risk assessment shows that those birds pose a significant risk will provide benefits in allowing early action to reduce the risk of disease entering the national flock.

Costs

Overview of costs:

As with the benefits (above), most of the costs associated with this proposed legislation are incurred only when an outbreak happens. They are however, real costs where they do occur. As the severity of an outbreak depends on several variables, including location and timing, it is difficult to estimate them in advance with any accuracy; however the following analysis examines the potential impact of each option.

Costs of option 1:

Option 1 is regarded as the "base case" for each of the scenarios. Associated costs with this option could include the presence of LPAI going undetected and mutating into HPAI leading to a disease outbreak. However, as Option 1 does not fulfil our obligation to implement EU legislation, there may be further costs relating to infraction proceedings and fines imposed by the European Court of Justice, which are impossible to estimate in advance but would be expected to be substantial.

Costs of option 2:

Provisions for surveillance will require commercial holdings to register their birds and a sample of commercial holdings will be selected at random to provide statistically based evidence of the presence of disease. In both cases the cost to business is small. The registration of rare breeds will require keepers to complete a form, however registration will be voluntary.

Current legislation already imposes costs on businesses in the event of a suspected or confirmed case of HPAI and these would continue under the Directive. The Directive introduces control measures for LPAI cases. Costs are difficult to quantify for both types of the disease and depend very much on the nature of the outbreak. As well as the cost of the loss of birds if disease is confirmed and the restriction on movements, there may be costs in housing and isolating free range birds, cleansing and disinfecting holdings and additional requirements for biosecurity of vehicles. Controls over a suspect case would be of limited duration but may nevertheless have some cost impact. The range of different scenarios for a confirmed case of disease is wide. A confirmed case of HPAI contained on one holding would impose restrictions on poultry and bird premises in a 10 km zone for 30 days after the infected holding had undertaken preliminary cleansing and disinfection. A similar scenario in a confirmed case of LPAI would impose restrictions in a 1 km zone for 21 days. At the other end of the scale would be rapid spread of HPAI across the country with multiple infected areas and associated controls.

Compensation is payable under the Animal Health Act 1981 for birds that are compulsorily slaughtered for avian influenza disease control purposes. It is not payable for consequential losses or indirect losses to business during an outbreak. For example, the British and Irish Association of Zoos and Aquariums (BIAZA) has pointed out that zoos rely almost entirely upon the revenue generated by visitors to sustain them. There would be serious financial implications if a zoo was closed (although the more likely scenario would be restriction of access to the aviary concerned) or visitor numbers reduced.

The Directive introduces the possibility of a national or regional temporary control zone on suspicion or confirmation of disease. Temporary movement restrictions may have considerable impact on some sectors of the industry, e.g. hatcheries that are highly mechanised and subject to tight timetables. Movement controls have the potential to impact on producer profits because of increased costs associated with keeping or losing excess stock and suboptimal marketing leading to lower prices. However, the Directive allows the State Veterinary Service to derogate from some control measures in the controlled zone as long as disease control is not threatened. This new flexibility will allow the industry to function as far as possible although there will be increased biosecurity requirements. The benefits of this will significantly outweigh any costs.

The proposals will impact on farms where both pigs and poultry are kept and poultry are confirmed with avian influenza. Establishments such as zoos may also fall into this category and may be subject to restrictions that impact on their revenue. Where movements are restricted but disease is not confirmed, farmers can expect some consequential losses particularly where the pigs were due to be marketed, in terms of extra food, labour and deterioration of the pig's optimum marketing weight. However, such restrictions are unlikely to last longer than around 13 days. As noted, UK Government policy is to pay compensation for animals that it requires to be slaughtered.

The costs of vaccination will be considered as part of the Scottish Executive's review of options for vaccination. There is ongoing work to enhance the possible use of vaccination in a disease control response.

Social and environmental costs

There would be costs in disposing of carcases and other contaminated materials and treating waste waters.

Costs of option 3:

All costs associated with option 2 above also apply here. There are net benefits in terms of disease avoidance for industry where preventive measures are utilised under the threat of disease from wild birds. Costs will only become high where suitable buildings for the housing of birds are unavailable or if controls are imposed for more than 12 weeks and free range status is lost. Game farmers may have to install nipple drinkers to prevent wild birds accessing drinking water. The cost of this is £35 per drinker with each drinker accommodating about 100 birds. There will be costs associated with closing footpaths around an infected premises (or if risk dictated in the protection zone) although these would be offset by containing a disease outbreak. The cost to those notifying suspicion of disease of not moving anything on or off the farm for a short time pending official investigation is insignificant.

6. Small/micro firms impact test

In the event of a suspected or confirmed outbreak of avian influenza, the proposal will affect small businesses, predominantly poultry keepers but also other businesses such as zoos. Consultation was carried out with representative groups that represent the interests of small as well as large businesses during the negotiation of the Directive (including British Poultry Council, British Egg Industry Council, NFU Scotland, BIAZA, Poultry Club of Great Britain, Pet Care Trust and the Game Conservancy Trust). Through the coverage of these organisations feedback was received from a range of businesses, both small and large. In the main feedback took the form of acknowledgements to the proposed changes in legislation. However, there was recognition that associated costs were not high relative to current legislation and most respondents were happy that derogations could allow for the early relaxation of movement controls. The consultation process for transposition of the legislation will further develop the relationship with business representatives.

7. Test run of business forms

The business forms required by this legislation are revised versions of forms which have been tested in use over a long period. Those forms which are new have been tested by the SVS, who will be the main users of the forms.

8. Competition assessment

The proposals are unlikely to have negative impacts on competition unless disease is confirmed (and even then it will have minimal impact on consumers). The majority of the proposals apply equally to all new and existing businesses and are similar to existing requirements for other serious diseases of livestock.

9. Enforcement, sanctions and monitoring

In the event of an outbreak in Scotland, the proposed measures will be implemented by the State Veterinary Service Agency, as under existing EU and national law. Local Authorities will assist in enforcement.

The sanctions available for non compliance with the provisions of the Order are as laid down in the Animal Health Act 1981, with the amendment that on summary conviction the fine is at level 5 (currently £5,000). For offences against the Regulations the maximum penalty is imprisonment for 3 months. These penalties apply to bodies corporate as well as to individuals.

The European Commission has responsibility for monitoring enforcement by Member States in order to ensure uniform application of EU legislation.

Monitoring of the effectiveness of the Regulations will arise from regular Contingency Plan Exercises.

10. Implementation and Delivery Plan

The measures in this legislation will only be implemented in the event of an outbreak of disease in Scotland. Delivery of the measures will be as set out in the Scottish Avian Influenza and Newcastle Disease Contingency Plan, which clarifies the respective roles of the SVS, local authority and other public and industry stakeholders.

11. Post Implementation Review

This legislation will only be implemented in the event of a disease outbreak. However, the contingency planning arrangements for which it provides the legal base are kept under review and subject to regular exercises.

12. Summary and recommendation

Three main policy options for the transposition of the EU Avian Influenza Directive are examined in this Regulatory Impact Assessment. The analysis of the three options shows that Option 2 provides significant benefits in terms of the potential costs avoided. Option 3 builds on the measures offered under Option 2 and for a relatively low cost provides net benefits to industry in terms of disease avoidance.

Option 3 is therefore recommended as offering a complete transposition of the EU Directive and a cost effective set of additional measures which could help to minimise disease incursion, thereby limiting potential costs associated with an avian influenza outbreak.

Declaration

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister:

Ross Finnie, Minister for Environment and Rural Development

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Date: .....……

Contact: Neil Ritchie
Animal Health and Welfare Division

June 2006