EXECUTIVE NOTE TO

THE PRODUCTS OF ANIMAL ORIGIN (DISEASE CONTROL) (SCOTLAND) ORDER 2008 SSI 2008/158

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 objective of this Order is to implement in Scotland Council Directive 2002/99/EC which requires control of meat for human consumption during an outbreak of specified exotic animal diseases and Commission Decision 2007/118/EC laying down detailed rules in relation to marking and supply of poultry meat during an outbreak of Newcastle Disease (a disease of birds).

Background

Directive 2002/99/EC is a consolidation of other European Directives which had already been implemented in Scotland. However, previous domestic legislation complying with the Directive was repealed in January 2006 when new measures in respect of food hygiene were introduced by the Food Standards Agency. This left a gap in the transposition of Articles 3 and 4 of Directive 2002/99/EC.

The Order implements in Scotland, in relation to the control of meat for human consumption, Article 3 and 4 of Directive 2002/99/EC including the derogations available and implements Decision 2007/118/EC. It provides for the control of meat intended for human consumption in the event of an outbreak of the following diseases:

- classical swine fever;
- African swine fever;
- swine vesicular disease;
- rinderpest;
- sheep and goat plague;
- Newcastle disease.

The Order includes:

- a prohibition on the sale of meat from animals originating from protection and surveillance zones declared during an outbreak of exotic disease until such time that the meat is treated with an approved treatment;
- requirements for premises handling such meat prior to treatment to be designated under the Order, keep such meat separate from other meat and retain records;
- during an outbreak of Newcastle Disease a derogation from the requirement to treat such poultry meat and certain other requirements where the poultry meat is intended for domestic consumption and will not be exported. This implements Commission Decision 2007/118/EC.

This policy ensures meat will be traceable, handled safely and treated correctly thus providing confidence in the system of controls to minimise the risk of disease spread. In doing this the Order is designed to require the minimum of Scottish Government interventions in day-to-day meat production.

The obligations for specific treatments of meat and milk during a Foot and Mouth Disease outbreak are principally covered by separate legislation¹. Directive 2002/99/EC does not recognise any treatments for milk in an outbreak of Rinderpest or Sheep and Goat Plague. We have not therefore made provision to prohibit movement/sale of milk during an outbreak of these diseases, but are looking at this issue separately and will make an amendment to the legislation when policy in this area is more fully developed.

Consultation and financial effects

A Regulatory Impact Assessment has been prepared for this instrument. A copy is attached. The changes made reflect EU requirements.

The impact assessment compares the option of retaining the status quo to the preferred option of fully transposing the prohibitions of Article 3 and the derogations of Article 4 of the Directive.

The impact on the public sector is not significant. The public sector will approve applications by food business operators to operate as a designated premise should they wish to handle restricted meat during a disease outbreak. The public sector will also undertake inspections of some premise handling restricted meat during a disease outbreak and take enforcement action as necessary.

Scottish Government Rural Directorate April 2008

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¹ The Foot and Mouth Disease (Scotland) Order 2006 as amended

FINAL REGULATORY IMPACT ASSESSMENT

1. Title of proposal

Transposition of articles 3 and 4 of Council Directive 2002/99/EC (known as Hygiene 4 or H4)

Transposition of these articles, to the extent they have not already been transposed by other secondary legislation will be carried out by the following Scottish Statutory Instrument (SSI):

The Products of Animal Origin (Disease Control) (Scotland) Order 2008.

2. Purpose and intended effect

Objectives

- To control the movement of products of animal origin produced from animals originating from holdings near infected premises, and therefore in areas subject to animal health restrictions, for certain specified exotic animal diseases.
- To ensure treatment of meat to make it safe from an animal health perspective before it is passed to other livestock and enters the human food chain. These animal health rules apply in addition to the Food Hygiene Order which safeguard public health².
- The ultimate outcome of placing controls on such products will be to minimise the risk of disease spreading to other animals. There is no risk to human health from the diseases covered by the Directive. Furthermore, the testing, treatment, control, culling and disposal of animals from infected premises (IPs) are covered in separate legislation.

Background

Legislation relating to public and animal health matters was revoked on 1 January 2006 by the Food Standards Agency (FSA) to be replaced by the transposition into UK law of new EU legislation. This suite of legislation relates to public health with the exception of the fourth measure (Hygiene 4 or H4) which relates to animal health and is therefore the responsibility of Rural Directorate to transpose.

The H4 Directive includes European Community measures covering both domestic trade and export. The animal diseases covered by the Directive are Foot and Mouth Disease, Classical Swine Fever, Swine Vesicular Disease, African Swine Fever, Rinderpest (cattle plague), Peste des Petit Ruminants (Sheep and Goat Plague); Avian Influenza and Newcastle Disease and aquaculture diseases.

The above Order excludes Avian Influenza which is already transposed in separate legislation³. The obligations for Foot and Mouth Disease are principally covered by

² The Official Feed and Food Controls (Scotland) Regulations 2007

The Food Hygiene (Scotland) Regulations 2006 as amended

³ The Avian Influenza and Influenza of Avian Origin in Mammals (Scotland) Order 2006

separate legislation which specifies treatments for meat. Following the experience of FMD in Great Britain in 2007, any outstanding obligations for this disease are intended to be addressed in an amendment to the FMD legislation.

The animal diseases covered by the Directive have had varying impacts on GB livestock -

- Foot and Mouth Disease (FMD) was most recently found in the UK in 2001, involving over 2,000 separate outbreaks and the infection or culling of over 4 million animals; and in a smaller outbreak in 2007 involving 8 IPs in the south of England. It is a disease with significant economic consequences: although Scotland had no cases of FMD, the effect of movement restrictions placed a burden of approximately £28.5m on the sheep sector. FMD affects cattle, sheep, goats and pigs. The virus remains infectious in muscles (meat) until rigor mortis sets in and much longer in tissues which do not go through the pH change of rigor mortis.
- The most recent outbreak of Classical Swine Fever (CSF) was in 2000 in England and involved 16 separate cases with almost 75,000 animals in total. CSF is widely distributed in the carcase of an infected animal and is capable of surviving for extended periods in some meat and other foods containing uncooked meat.
- The last outbreak of Swine Vesicular Disease in GB was in 1982, when 10,000 animals were affected in total. However, the feeding of meat scraps and swill from infected pigs are still a significant factor in the spread of this disease. It is resistant to many standard food preparation processes and can survive in hams and sausage for over 6 months.
- Rinderpest (cattle plague) had its last occurrence in GB in 1877.
- No UK outbreak of African Swine Fever has ever been recorded. However, the feeding of meat scraps and swill from infected animals are a significant factor of transmission, as for Swine Vesicular Disease.
- No Sheep and goat plague (Peste des Petits ruminants) outbreak has ever been recorded in the UK.
- There have been isolated cases of Newcastle disease in GB, the most recent case being in Scotland in 2006.

H4 controls apply only to raw meat and other foods containing raw meat produced from animals originating from Protection or Surveillance Zones (PZs and SZs) around Infected Premises (IPs). (Meat from suspect premises must be detained until its safety is assured; that from infected premises must be destroyed.) When disease is first confirmed, measures to contain and severely limit any disease spread will be implemented immediately in an area not less than 10 km surrounding the IP. This area will comprise a PZ of a minimum radius 3 km and a SZ of a minimum radius 10 km. Zones will be expanded as necessary to control disease.

Fresh meat from the PZ and SZ cannot be marketed internally, traded with other Member States or be exported from the EU unless it has undergone heat treatment as specified in the Directive (except in the case of Newcastle Disease where poultry meat may be placed on the domestic market if specially marked). Controls will only cease when meat has been made safe from an animal health perspective.

The requirements of H4 would be something new for the industry in terms of separation of meat from restricted animals when slaughtering, transporting, storing and undertaking the specified heat treatments before marketing meat or meat products.

Rationale for government intervention

Transposition of the 2002/99 Directive would ensure that there are clear disease control measures governing products of animal origin for human consumption. These controls are necessary as the meat from animals which are on farms near disease outbreak sites could contain the virus responsible for the disease and if fed to other livestock could cause a further outbreak in livestock. Other animal health controls such as the ban on swill feeding have also been applied to mitigate this risk of transmission. (The FMD outbreak in 2001 was associated with the illegal feeding of catering waste or swill to pigs and there is now a ban on feeding such material to livestock which is important in preventing future disease outbreaks.) However, further control measures are needed to address the risk of disease transmission which arises from meat produced from animals infected with an exotic viral disease in the early stage of the disease when clinical signs are not evident.

Transposition of the Directive in every EU country will confer continued protection against outbreaks of potentially damaging diseases which have not yet entered the UK, as well as controlling disease spread within countries when outbreaks do occur. These rules also apply to the importation of any meat, or foodstuffs containing meat, into the European Union. HM Customs and Excise do surveillance work at ports to detect illegal imports of such meat or other foods containing meat.

Non implementation of control measures would not only mean the non fulfilment of the UK's Community obligations, but could lead to infraction proceedings and ultimately European Court of Justice action. Equally, failure to implement would forego the opportunity to implement controls in an effective and proportionate way.

3. Consultation

A partial Regulatory Impact Assessment formed part of the consultation package. The final draft of the Order and this final RIA have been informed by stakeholder responses and also draw on internal discussions within the Scottish Government and with other UK administrations.

In general respondents to the consultation favoured Option 2. Industry bodies expressed concern over the proportionality of the controls and the lack of suitable heat treatment facilities in Scotland, which they felt would materially reduce the value of carcases. This has been factored into the calculations.

4. Options

Option 1: Do nothing

To continue with previous animal health rules on meat and meat products is not possible because they have largely been repealed by the Food Standards Agency to be replaced by the transposition into UK law of new EU legislation. Currently there are, therefore, insufficient control measures in place to deal with meat and animal products during a disease outbreak.

This option is included to provide a baseline for the potential costs of a disease outbreak where there are no control measures for meat and animal products, but does not provide the range of measures as required by the Directive.

Option 2: Transpose the Directive. Bring in the control measures for products of animal origin from the PZ and SZ and invoke the derogations

The Directive prohibits the movement of products of animal origin from PZs and SZs, however option 2 allows for derogations as specified by the Directive in Article 4.

The derogations require keeping separate the meat from restricted animals when slaughtering, transporting and storing and undertaking specified treatments before marketing meat or meat products, either in the UK or for export.

The application of the unique health mark (crossed stamp, or "beermat" shaped mark in the case of Newcastle disease poultry) to the fresh meat from animals from the PZ or SZ will ensure it is readily identifiable. Compliance with these controls, under appropriate enforcement measures, should restrict trade in untreated products from PZs and SZs.

These measures would prevent the spread of disease while allowing for products of animal origin produced from animals originating from sites near infected premises to be manufactured under the specified conditions.

This option would minimise the risk of disease spread during a disease outbreak, whilst still providing opportunities for the industry to function and the meat from animals in PZs and SZs to be used for its intended purpose i.e. enter the human food chain.

Option 3: Transpose the Directive exactly. Bring in the control measures for products of animal origin from PZ and SZ

Article 3 of Council Directive 2002/99/EC requires the introduction of specific measures at all stages of the production, processing and distribution of products of animal origin from restricted zones to prevent the spread of diseases transmissible to animals. This means animal products are prohibited from being obtained from farms in areas subject to animal health restrictions i.e. PZs and SZs.

Option 3 ensures that products of animal origin from within PZs and SZs do not cause the spread of those diseases to other livestock. It also prevents the meat

industry from processing these animal products in any way as this option does not invoke the derogations which allow for this (see option 2). This could create serious welfare problems if the PZs and SZs are in place for some time as it does not allow the movement of animals to slaughter when they are ready.

5. Costs and benefits

In evaluating costs and benefits it is important to remember that the circumstances of a disease outbreak may vary widely in its impact, depending on the nature of the disease, the geographical location, the time of year, and the effectiveness of control measures. In general the costs of a disease outbreak are real, while the benefits accrue as a result of further costs being avoided. It is therefore useful to examine an illustrative scenario - the more credible the better – to see where the main costs arise.

Illustrative Scenario

To evaluate the costs and benefits of the options above, Classical Swine Fever (CSF) has been used as an illustrative scenario. Of the diseases covered by the Directive, CSF has the highest likelihood of occurring (apart from FMD, controls for which have been subject to a separate RIA and legislation⁴). CSF also carries a high risk of disease spread through products of animal origin with studies having shown that the virus is capable of surviving for extended periods in some meat and meat products.

In our illustrative scenario we have used an estimate of 32,000 pigs in the SZ and PZ being affected. This example will be used to examine the cost to industry and Government of larger scale and longer lasting outbreaks (option 1) and compare these with the moderate costs of placing controls on meat which allow the outbreak to be contained (option 2). The costs of a total ban on the production, processing and distribution of meat from controlled zones will also be considered (option 3).

Cost of H4 controls (using Option 1 as a baseline)	Option 2	Option 3
To farmer	£0.8 m	£1.7 m
To Government	£30,000	£30,000
TOTAL COST	£0.8 million	£1.7 million

The benefit of H4 controls is that they reduce the likelihood of disease spread. Under option 1 the absence of those specific controls leads to disease spread with the estimated cost between £3 million and £3.9 million, depending on the size of the export ban. Therefore the costs of H4 controls can be seen as an insurance against potentially very large costs in the unlikely event of an outbreak spreading. This insurance is achieved at a lower cost under option 2.

The Foot and Mouth Disease (Scotland) Order 2006 (SSI 2006/44)

The Foot and Mouth Disease (Slaughter and Vaccination) (Scotland) Regulations 2006 (SSI 2006/45)

⁴ The Foot and Mouth Disease (Scotland) Order 2006 (SSI 2006/44)

Sectors and groups affected

In the event of a disease outbreak, any or all of the livestock and export industry in the UK with susceptible animals from the PZ and SZ and beyond would be affected, either by the disease itself or, more likely, through national movement restrictions which are uncompensated. This RIA considers the costs and benefits to industry and Government.

Statistical data⁵ shows livestock numbers in Scotland as:

- 1,929,990 cattle
- 7,608,100 sheep
- 463,000 pigs
- 4,130 goats

Although farmers may incur many of the costs of the proposed legislation, they may also benefit from a reduced risk of disease spread, and hence may avoid costs associated with disease control. Reducing the risk of disease spread also reduces the likely length of an export ban which would be of benefit to farmers in terms of costs avoided.

Under the proposed legislation, a disease outbreak would have an impact on industries such as the meat trade, including slaughterhouses, food processors and specialist road hauliers as a result of the control measures imposed.

Slaughterhouses that received these animals would need to be designated to operate under this Order. Slaughterhouses would be required to slaughter animals from restricted zones separately from animals from other areas. Veterinary advice is that there is no need for physical separation of slaughter areas, as long as the areas used are cleansed and disinfected as normal before being re-used for unrestricted animals. Products originating from restricted zones are required to be identified by health marks (crossed stamp) applied to the meat or its packaging. This is thought to be a small impact as, in the scenario considered, the PZ and SZ will not be large and supplies of pigs will be available from unrestricted areas and imports.

Slaughterhouses that do not wish to meet the costs of compliance with the legislation or who feel that dealing with meat from PZs and SZs will have an adverse effect on their business will simply choose not to be designated, and hence will incur no designation costs. They may however experience problems finding suitable pigs to slaughter in the event of a larger scale outbreak, which may mean they have to pay higher prices and hence lose some profit margin.

An outbreak of disease would also greatly impact on those involved in the export business of fresh meat and meat products. Exports of fresh meat to third countries may stop and exports to the EU may be severely restricted. In 2005 the UK exported 88,000 tonnes of pork and 10,000 tonnes of bacon and ham⁶. This represents 13% of pork and 5% of bacon and ham produced in the UK in 2005.

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⁵ June 2006 Agricultural Census: Scotland

⁶ From "Agriculture in the United Kingdom"

Approximately 64,000 live pigs are also exported annually (out of a UK population of more than five million).

Benefits

Overview of benefits

The benefits (under all three options) accrue from reducing the risk of disease spread and thus reducing or avoiding the associated costs. Until an outbreak occurs, benefits are not accrued while low level costs associated with slaughterhouse designation are incurred.

Benefits of option 1: Do nothing

Under option 1, there would be no change, so there would be no benefits over the current situation. Benefits of other options, where controls are introduced, are compared to this baseline.

Option 2: Transpose the Directive. Bring in the control measures for products of animal origin from the PZ and SZ and invoke the derogations

The benefit of this option is that the control measures reduce the risk of incurring the costs of disease spread. If disease spread from the original outbreak this would result in additional costs - costs to animal health from disease incidence, costs to government from taking action on IPs beyond the original IP (including the costs of culling animals) and costs to industry in terms of lost production (including lost production due to diseased animals being less productive and due to reduced numbers of animals for production due to culling controls).

In terms of international trade in both live pigs and pig meat, controls would remove the risk of disease spread from the PZ and SZ which could result in a longer outbreak, and therefore a longer ban on exports of live pigs and pig meat. The cost of an export ban would be that uncooked pig meat and live pigs would have to be sold at an estimated price reduction of 50% on the domestic market. A longer ban (resulting from disease spread) would therefore result in larger costs to industry as they would have to sell their meat at a reduced cost for longer. The size of the export ban is currently uncertain. A UK wide ban would have large costs, whereas the costs of a ban only on pigs and pig products from the PZ and SZ would be very small.

If disease did spread, and there was a UK wide export ban the total cost in the illustrative example would be approximately £3.9 million – of which £3 million would be the costs of disease and £0.9 million would be the costs of a longer export ban. If the export ban was restricted to the PZ and SZ, the cost of the ban would be approximately £6,000.

The benefit of option 2 is that the small risk of incurring the cost of disease spread is reduced. We do not have an estimate of what this reduction in risk might be.

Social and environmental benefits

Benefits are measured in terms of costs saved. These may include a decrease in the risk of disease spread, which will significantly reduce welfare concerns as farmers will be able to move animals when they are ready for slaughter. Controlling the disease spread will also limit the levels of stress which farmers and others in the industry may be subject to. The main environmental benefit from the Directive would be the reduced impact of culling and disposal, as more effective control would potentially reduce the number of IPs, the duration of the outbreak and therefore the number of animals culled.

Option 3: Transpose the Directive exactly. Bring in the control measures for products of animal origin from PZ and SZ

In the event of an outbreak the total ban on the production, processing and distribution of products of animal origin from PZs and SZs reduces the risk of disease spreading to other parts of the country – which would cost £3 million in the illustrative example. Disease spread would also result in a longer export ban, giving a further cost of up to £0.9 million, depending on the size of the ban. Total benefit would therefore be a reduction in the risk of incurring costs of between £3 million and £3.9 million.

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. 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: Do nothing

Failure to impose official controls during a disease outbreak might result in significant costs to the entire UK pig industry as the European Commission may close our borders to all exports and possibly our internal movements of pigs. Also, failure to implement EU legislation may result in costs, including fines, arising from infraction proceedings.

Option 2: Transpose the Directive. Bring in the control measures for products of animal origin from the PZ and SZ and invoke the derogations

The implementation and provisions of this Directive will cause additional burdens for the industry. There is the need to obtain additional licenses (specific licence) for the movement of the animals to the slaughterhouse. The specific licence would require having the adequate facilities and resources for treatments and control measures (such as separation of fresh meat products). There would also be administrative requirements in terms of reporting every movement of fresh meat/products from the consignor to consignee. Additional costs to government are in terms of checks and enforcement of control measures.

In the event of an outbreak, restrictions are placed on movements of animals from the PZ and SZ, including restrictions on movement to slaughter. Farmers with holdings within the PZ or SZ could withhold their animals (that is, no animals would leave the holding for the duration of the outbreak while restrictions were in place). However, this is not practical for the farmer and is very expensive due to the reduced value of the pig once it has gone past its optimal finishing date. Furthermore, pig units tend not to have the space and facilities to retain animals and this approach could cause welfare problems.

When farmers continue to sell and move their animals while the PZ and SZ is still in place, a number of costs are incurred. These include Animal Health agency inspections of the premises and licenses for the animals to be moved. These costs are incurred regardless of whether H4 legislation is implemented and are met by Government.

The greatest cost to farmers would be the reduction in price per head, which would decrease by between 30% and 50%. This is because H4 controls would require licenses and checks for hauliers, slaughterhouses, cutting plants, meat processors, cold stores and at export points. As a result these businesses would incur costs which they would then pass on to farmers in the form of lower prices. Further to this, most meat is sold fresh so cooked meat would have limited uses, and would therefore have a reduced price compared to fresh. High value cuts of pig meat e.g. fillet cannot be sold in the normal way i.e. raw and there is no established market for cooked pig fillet. Many food producers would not be interested in promoting such products for a short space of time.

Slaughterhouses and processing plants would have to apply for designation in advance, would be required to separate animals and products from restricted and non restricted areas, and would have to stamp meat coming from a PZ or SZ with the unique (crossed stamp) health mark. Processing plants would have to keep uncooked meat from PZs and SZs separate until such time as the raw meat had irreversibly entered the cooking process. There would also be a series of movement notifications required each time the animal or untreated meat was moved. Initial estimates suggest this could cost industry approximately £10 each time (there will be additional costs to government from processing these notifications, and these are included below). Meat from PZs and SZs will, in general, not be allowed to be kept in cold storage and will only be able to go to a cutting plant if it was located with the slaughterhouse – which may cause inconvenience and some additional costs to the industry. The majority of these costs would be passed back to the farmers through lower prices. Total costs are estimated at £0.8 million in the illustrative example.

The additional costs of inspection would be small because supervision is routine at slaughterhouses, cutting plants, meat processing and cold storage, although during an outbreak some additional activity would be required. There would also be costs incurred by Government in processing movement notifications and designating slaughterhouses. In total costs incurred by inspection bodies are estimated to be £30,000.

The total economic cost to the State and industry when farmers continue to sell their animals under option 2 is estimated to be £0.8 million with the majority of this cost being met by farmers through lower prices.

Social and environmental costs

There would be costs in disposing of carcasses and other contaminated materials and treating waste waters should farmers be unable to move their animals to slaughter. Public perception of welfare problems can also be regarded as a societal cost, although it is difficult to estimate the magnitude of this.

Option 3: Transpose the Directive exactly. Bring in the control measures for products of animal origin from PZ and SZ

The cost of option 3 to farmers will be that those located in a PZ or SZ will be unable to sell their animals during the outbreak. Therefore, in the illustrative example, it is assumed they will lose between 90% and 100% of the value of those animals, as the pigs will either have to be culled on site and disposed of (which will also incur costs) or they will have to be withheld from sale until after the outbreak, by which time they will have lost 90% of their value as they will not be of optimal age or weight. Assuming farmers choose the cheapest option for them the cost will be approximately £1.7 million. These costs may be less in the case of other diseases and species as pigs lose value particularly quickly.

The cost to the Government would be the cost of enforcing the ban on moving pigs or pig meat out of the SZ and PZ. The enforcement regime is currently uncertain and therefore costs cannot be accurately estimated at this time. Currently enforcement costs are assumed to be £30,000.

6. Small/micro firms business test

This legislation would only have an impact in the event of a confirmed disease outbreak. The small number of farmers in PZs and SZs (almost all farms are classified as small businesses) would primarily bear the costs which have been covered above. There may also be a small number of specialist firms, for example market stalls trading in local organic pork, which may suffer if their suppliers were all located in the PZ or SZ.

During consultation on the FMD Directive in 2003, our normal stakeholder consultation arrangements included small medium enterprises (SMEs) from all parts of the meat supply chain across Scotland. The H4 Directive impacts on similar businesses and requires heat treatments specified in the FMD Directive. SMEs have been able to make representations on the measures and their effect on the businesses. They are fully aware that the impact of a disease outbreak will depend on its location, scale and timing. Further comments from all stakeholders are still welcomed.

7. Test run of business forms

Business forms will be piloted and tested by Animal Health agency who will be the main user.

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. Implementation and delivery plan (enforcement/ sanctions/ monitoring)

In the event of disease outbreak in Scotland, the proposed measures will be implemented by the Animal Health 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. On summary conviction the fine is at level 5 (currently £5,000). For offences against the Order 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 Order will arise from regular Contingency Plan Exercises.

10. Legal Aid Impact Test

No impact on legal aid is envisaged. The conditions within the order would only apply during an outbreak of a specific exotic notifiable animal disease, and even then only within a protection or surveillance zone.

11. Post-implementation Review

This legislation has effect during an outbreak of exotic diseases. A lessons learnt exercise is undertaken after any outbreak, including a review of the effectiveness of legislation.

12. Summary and recommendation

There are compelling reasons for implementing Articles 3 and 4 of Council Directive 2002/99/EC, and Directive 2007/118/EC into domestic legislation under The Products of Animal Origin (Disease Control) (Scotland) Order 2008. This Order makes an important contribution to our preparedness to control outbreak of disease. Controls in this Order would only come into play when there is an outbreak of disease, and then only affect meat from Protection and Surveillance Zones. The controls reduce the risk of disease spread from these zones, and should offer a significant benefit by providing assurance to trading partners that meat from the rest of the country can be traded without additional restrictions. In the light of the public consultation, it is our recommendation that we transpose Directive 2002/99/EC by implementing Option 2.

The Order implements the preferred option by:

- placing obligations on all food business operators;
- prohibiting the trade of meat from premises that are infected or suspected of being infected;
- defining the areas subject to animal health restrictions as being Protection Zones and Surveillance Zones declared in disease control legislation (or the equivalent Infected Area declared in some legislation). A protection zone covers a minimum area of 3km radius from the infected premises, and the surveillance zone 10km:
- controlling meat products from susceptible animals originating in protection or surveillance zones or infected areas;
- requiring any premises handling such meat to be designated and to comply with any conditions of designation to reduce the risk of disease spread. Such premises will be able to apply for designation in advance in readiness to respond to any disease outbreak;
- requiring such meat to be obtained, handled, transported and stored separately or at different times from products produced from animals which are not subject to restrictions;
- requiring such meat to be identified by the application of a special mark on meat or packaging;
- applying a prescribed a treatment to such meat prior to sale, primarily heat treatment, to eliminate any animal health risk
- requiring records of the handling of such meat
- The Order provides for meat produced during an outbreak of Newcastle Disease to be traded on the Domestic market (not for export) without treatment subject to the use of an alternative meat mark. Only slaughterhouses need be designated, although all premises processing such meat will be required to retain records.

13. Declaration

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

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Richard Lochhead Cabinet Secretary for Rural Affairs and the Environment

17 April 2008

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