

EXPLANATORY MEMORANDUM TO
THE PRODUCTS OF ANIMAL ORIGIN (DISEASE CONTROL) (ENGLAND)
REGULATIONS 2008

2008 No. 465

1. This explanatory memorandum has been prepared by Department for Environment, Food, and Rural Affairs and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

In this memorandum, the following abbreviations are used:

- “The Regulations” is used to refer to the Products of Animal Origin (Disease Control) Regulations 2008;
- “The Directive” is used to refer to Council Directive 2002/99/EC laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption;
- “The Decision” is used to refer to Commission Decision 2007/118/EC laying down detailed rules in relation to an alternative identification mark pursuant to Council Directive 2002/99/EC.

2. **Description**

2.1 The Regulations implements in England articles 3 and 4 of the Directive which seek to reduce the risk of spread of certain exotic diseases transmissible to animals via products of animal origin intended for human consumption by setting out general animal health requirements and optional derogations from those requirements.

2.2 The Regulations also implements the Decision insofar as this relates to the control of poultry meat during an outbreak of Newcastle Disease.

2.3 This legislation is concerned with reducing the risk to animal not human health.

3. **Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 None

4. **Legislative Background**

4.1 This legislation is made to comply with the Government’s obligations under both the Directive insofar as it deals with control of meat and milk for human consumption during an outbreak of specified exotic diseases and the Decision insofar as it applies to marking and supply of meat during an outbreak of Newcastle Disease.

- 4.2 The Directive was a consolidation of other European directives which had already been implemented into English law. However, previous domestic legislation complying with the Directive was repealed in January 2006 when new measures in respect of food hygiene were introduced by the Food Standards Agency.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 the Directive and both legal and operational risk to the control of meat during a disease outbreak.
- 4.3 A Transposition Note is annexed. The approach to transposition has been to fully implement Article 3 and 4 of the Directive including the derogations available. Subsequent to consultation, the Regulations have been simplified and unnecessary government interventions replaced by simple obligations on industry designed to minimise the risk of spread of animal disease.
- 4.4 The requirements of articles 3.3(c) and 4.2 of the Directive apply to aquaculture and are already transposed in Statutory Instrument 1881/97.
- 4.5 This Directive came forward from the EU Council Proposal 10427/00 of 19 July 2000 which included a package of proposals on food hygiene and animal health. This was initially considered by the Select Committee on European Scrutiny in 2000/2001. Measures were subsequently debated in the European Standing Committee C in April 2002. The Committee took note of these measures and supported the Government's aim of securing effective proportionate legislation throughout the food chain.

5. Territorial Extent and Application

- 5.1 This instrument applies to England.
- 5.2 Separate and similar instruments are being prepared in Scotland, Wales and Northern Ireland.

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 Defra's objective in making the Regulations is to reduce the risk of transmission of disease to animals via products of animal origin intended for human consumption during an outbreak of certain exotic diseases.
- 7.2 To mitigate this risk, and to transpose article 3 & 4 of the Directive, the Regulations include:-
- 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 Regulations, keep such meat separate from other meat and retain records;

- during an outbreak of Newcastle Disease (a disease of birds) 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;
- 7.3 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 Regulations are designed to require the minimum of Government interventions in day-to-day meat production.
- 7.4 The Regulations provide powers for the control of milk and milk products in the event of an outbreak of Rinderpest or Sheep and Goat Plague, these diseases being of very low likelihood to occur in the UK. The Regulations are drafted to allow the controls required by the Directive, or some less onerous regime agreed with the EU at the time, to be implemented during any such outbreak. We are discussing with the milk industry the implications of this prohibition and practical steps to minimise the impact on the dairy industry whilst ensuring effective control of these diseases.

8. Impact

- 8.1 An Impact Assessment is attached to this memorandum.
- 8.2 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.
- 8.3 A third option was consulted upon and assessed in the partial RIA. This considered implementing only article 3 of the Directive and not adopting any of the optional derogations available in article 4. This was rejected by consultees and has not been carried through in to the final Impact Assessment.
- 8.4 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.

9. Contact

- 9.1 Andy C Smith at the Department for Environment, Food, and Rural Affairs Tel: 0207 238 6132 or e-mail: andy.c.smith@defra.gsi.gov.uk can answer any queries regarding the instrument.

ANNEX I: Transposition Note

Council Directive 2002/99/EC laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption

TABLE SHOWING TRANSPOSITION OF THE DIRECTIVE BY THE PRODUCTS OF ANIMAL ORIGIN (DISEASE CONTROL) (ENGLAND) REGULATIONS 2008

These Regulations implement, in England, articles 3 and 4 of EC Directive 2002/99/EC and European Commission Decision 2007/118/EC in respect of Newcastle disease.

Article	Objective	Regulation
3.1, 3.2, and Annex 1	By imposing the requirements of article 3, Member States must ensure food business operators do not cause the spread of classical swine fever, African swine fever, swine vesicular disease, rinderpest, sheep and goat plague, foot-and-mouth disease, avian influenza or Newcastle disease in the production, processing and distribution of products of animal origin (“products”). Products must come from animals which fulfil animal health conditions laid down in other relevant Community legislation.	General proposition.
3.3(a) and (b)	Unless article 4 derogations are provided for by the Member State, products must not come from animals from: (i) premises or areas subject to animal health restrictions under Community disease control legislation ¹ ; or (ii) from a slaughterhouse where disease is suspected or confirmed in the case of meat and meat products.	Derogations provided for (see below).
3.3(c)	Aquaculture is implemented in SI 1881/97.	Not applicable
4.1, Annex II and Annex III	Member States may derogate from the requirements of Article 3(a) and (b) ² except in the case of products from infected holdings provided: (i) products subject to restrictions are kept separate from other products; (ii) conditions for movement out of a restricted area under disease control legislation are approved by the competent authority ³ ; (iii) identified products are treated (in accordance with Annex II treatment) at an establishment approved by the competent authority. European Commission Decision 2007/118/EC in respect of Newcastle disease provides for untreated poultry meat that is marked according to that Decision to be traded on the domestic market only.	Regulation 3 provides for the concept of restricted meat, enabling requirements in respect of meat from areas subject to restrictions to be imposed. Regulation 7(3) prevents meat and meat products (“meat” in this document) from an

¹ Transposed in England in disease control legislation specific to each disease.

² Provision in respect of eggs and egg products are provided for in existing legislation in England.

³ Licensing regimes to control movements between areas are provided for in disease specific legislation in England.

		<p>infected holding entering the production and distribution chain.</p> <p>Regulation 7(1) requires meat to be detained when there is suspicion of disease at premises.</p> <p>Regulations 10(2) – 10(3), 10(4) and 12(2) transpose the separation requirements.</p> <p>Regulation 13 and Schedule 3 provide for meat marking.</p> <p>Regulations 3(8) and 5 mean that meat must be treated at an approved (designated) treatment centre before it can be placed on the market. Schedule 2 details the treatment required.</p> <p>Regulation 9(1) prevents meat that has not been treated going onto the market. Regulation 9(2) implements European Commission Decision 2007/118/EC for poultry meat.</p> <p>Regulations 10(1), 11(1), 12(1) and 14 ensure that movements of products are</p>
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		<p>between designated premises only.</p> <p>Regulation 16 provides for requirements in respect of milk and milk products to be declared by the Secretary of State.</p> <p>Other provisions in the Regulations relate to compliance and enforcement.</p>
4.2	Provides for derogations for aquaculture (see article 3.3(c))	Not applicable
4.3	Provides for additional derogations to be implemented via European Commission procedures	Not applicable

ANNEX II – Impact Assessment

Summary: Intervention & Options

Department /Agency: Defra	Title: Impact Assessment of The Products of Animal Origin (Disease Control) (England) Regulations 2008	
Stage: final	Version: 1.0	Date: 21.02.08
Related Publications: The above Regulations were formerly known as "The Meat (Disease Control) (England) Regulations" during its consultation in January 2007.		

Available to view or download at:

<http://www.defra.gov.uk/animalh/diseases/control/mhcd.htm>

Contact for enquiries: **Andy C Smith**

Telephone: **0207 238 6132**

What is the problem under consideration? Why is government intervention necessary?

During an exotic animal disease outbreak, there is the potential for meat to spread disease to other animals with significant costs for Government and industry in managing the outbreak and in lost markets. Following other domestic legislative changes, the UK needs to re-implement certain provisions of EC Directive 2002/99/EC, which gives powers to control meat produced from animals from protection and surveillance zones during exotic disease outbreaks.

Intervention is required to minimise the risk of disease spread, ensure compliance with EC law and to provide appropriate assurances to permit trade in meat during an exotic disease outbreak.

What are the policy objectives and the intended effects?

To prevent the spread of exotic disease to animals through meat or milk whilst minimising the impact on trade.

A clear regime which will enable industry and Government to prepare and minimise the impact of future outbreaks.

What policy options have been considered? Please justify any preferred option.

1. Retain the status quo would not reduce the risk of disease spread and is likely to attract infraction proceedings for under-implementing the Directive 2002/99/EC.
2. The preferred option transposes both the prohibitions of article 3 prohibiting trade in animal products from areas subject to animal health restrictions whilst enabling restricted trade in meat from such animals by implementing the optional derogations available in article 4.
3. Transpose only the prohibitions in article 3. This reduces the risk of animal disease spread but would prohibit trade in meat in areas subject to animal health restrictions.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? 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.

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impacts of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister:

Jeff Rooker

.....Date: 21st February 2008

Summary: Analysis & Evidence

Policy Option: Preferred option	Description: Implementation of article 3 and derogations of article 4 of Council Directive 2002/99/EC (illustrative analysis only)
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COSTS	ANNUAL COSTS		<p style="color: #008080; font-weight: bold;">Description and scale of key monetised costs by 'main affected groups' Illustrative one-off costs for an example involving an outbreak of classical swine fever.</p> <p>Cost to farmers (reduced sale price of heat treated meat): £890,000</p> <p>Cost to govt (inspections): £4000</p> <p>One-off cost to meat processors pre outbreak: £3000</p> <p style="text-align: right;">Total Cost (PV) £ 0.9m</p>
	One-off (Transition)	Yrs	
	£ 0.9m	1	
	Average Annual Cost (excluding one-off)		
£ N/A			

Other key non-monetised costs by 'main affected groups'

BENEFITS	ANNUAL BENEFITS		<p style="color: #008080; font-weight: bold;">Description and scale of key monetised benefits by 'main affected groups' Illustrative one-off benefits for the same example involving an outbreak of classical swine fever are:</p> <p>Benefit to farmers from lighter export restrictions: £4,020,000</p> <p style="text-align: right;">Total Benefit (PV) £ 4.0m</p>
	One-off	Yrs	
	£ 4.0m	1	
	Average Annual Benefit (excluding one-off)		
£N/A			

Other key non-monetised benefits by 'main affected groups' Implementing the Regulations will reduce the risk of disease spread. Estimated benefits of £3.6M are based on a possible disease scenario. In practice the pattern of disease spread will be different in every outbreak; therefore these indicative benefits have not been included in the monetised benefits.

Key Assumptions/Sensitivities/Risks Scenario modelled on a Classical Swine Fever outbreak with a 67% chance of a 32 day outbreak with 1 infected premises and a 33% chance of a 47 day outbreak with 23 infected premises. We have assumed 32,000 pigs in the surveillance zones and a 30-50% discount on the price farmers receive for potentially infected meat which needs heat treatment.

Price Base Year 2005	Time Period Years 1	Net Benefit Range (NPV) £ 2.9 - 3.3m	NET BENEFIT (NPV Best estimate) £ 3.1m
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What is the geographic coverage of the policy/option?			England		
On what date will the policy be implemented?			April 2008		
Which organisation(s) will enforce the policy?			MHS, LA, Defra		
What is the total annual cost of enforcement for these organisations?			£ 4000 (one-off)		
Does enforcement comply with Hampton principles?			Yes		
Will implementation go beyond minimum EU requirements?			No		
What is the value of the proposed offsetting measure per year?			£ 0		
What is the value of changes in greenhouse gas emissions?			£ 0		
Will the proposal have a significant impact on competition?			No		
Annual cost (£-£) per organisation (excluding one-off)		Micro N/A	Small N/A	Medium	Large
Are any of these organisations exempt?		No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices)

(Increase - Decrease)

Increase £ N/A

Decrease £ N/A

Net Impact £ N/A

Key:

Annual costs and benefits: Constant Prices

(Net) Present Value

Evidence Base (for summary sheets)

The background

The Products of Animal Origin (Disease Control) (England) Regulations 2008 ("the Regulations") is concerned with reducing the risk of spread of exotic diseases to animals via products of animal origin. In the early stage of the disease clinical signs may not be evident in live animals and, as a result, disease may not be spotted prior to slaughter. Whilst less likely than transmission between live animals, one route of disease transmission is via products produced from animals infected with exotic viral disease, including meat and milk. The most likely route of infection is through oral ingestion by susceptible animals of such products. The feeding of raw animal products to livestock is prohibited (legislation was updated subsequent to the outbreak of FMD in 2001) and this ban is an important measure in reducing the risk of disease spread.

Historically, numerous European Directives dealt with various control requirements. These were consolidated into a single Council Directive 2002/99/EC (referred to as "the Directive"). This lays down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption. Being a consolidation the relevant requirements of this Directive were already provided for in English law. However, as a consequence of domestic legislative changes in January 2006 a gap was created in the transposition of articles 3 and 4 of the Directive.

Article 3 of the Directive prohibits the sale and export of fresh meat, fresh meat products and meat preparations intended for human consumption produced from animals originating from areas subject to animal health restrictions. Article 4 provides for optional derogations subject to a number of conditions. Meat produced from animals originating from premises that are confirmed or suspected as being infected with disease cannot be sold for human consumption. The Directive similarly controls the production of milk and milk products.

Commission Decision 2007/118/EC amends the Directive in respect of an outbreak of Newcastle Disease. It provides for poultry meat produced from areas subject to animal health restrictions to be marked with an alternative mark and for such fresh poultry meat to be traded domestically without treatment (but not exported).

The animal diseases covered by the Directive are Classical Swine Fever (CSF), Swine Vesicular Disease (SVD), African Swine Fever, Rinderpest, Newcastle Disease, and Peste des Petits Ruminants (Sheep and Goat Plague). Separate legislation already transposes the requirements for Avian Influenza and Foot and Mouth Disease (FMD) as set-out in detail in subsequent Directives. To put these diseases in context:-

- The most recent outbreak of classical swine fever was in 2000 and involved 16 separate cases with almost 75,000 animals in total. CSF is widely distributed in the carcass 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 (SVD) in GB was in 1982, when 10,000 animals were affected in total. However, the illegal feeding of meat scraps and swill from infected pigs are still a significant risk 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.
- The last occurrence of Rinderpest (cattle plague) GB was in 1877.

- No UK outbreak of African Swine Fever has ever been recorded. However, the illegal feeding of meat scraps and swill from infected animals are a significant factor of transmission, as for SVD.
- No UK outbreak has ever been recorded of sheep and goat plague (Peste des Petits ruminants).
- It is likely that the feeding of livestock with untreated catering waste was a factor in the outbreaks of CSF in 2000 and FMD in 2001. Such feeding is currently prohibited under the Animal By-products Regulations 2005.

Consultation on options

A full written public consultation on the draft statutory instrument “The Meat (Disease Control) (England) Regulations” took place between January to April 2007, preceded by informal consultation with key stakeholders in December 2006. The formal consultation, which included a partial regulatory impact assessment, considered 3 options: option 1 to retain the status quo; option 2 to implement the prohibitions of article 3 and the derogations available in article 4; and option 3 to implement the prohibitions of article 3 only.

The first option, retaining the status quo, would under implement EU law and leave the UK at risk of infraction proceedings. This would also leave the UK exposed to the risk of spread of animal disease via animal products and it is likely the EU would impose draconian measures to reduce the risk UK meat and milk products would present to the rest of the EU during a disease outbreak.

The third option, to implement only article 3 of the Directive, would prevent the spread of disease through animal products but the effect would be to halt production of milk and meat from animals originating within protection and surveillance zones whilst the zones were in force. Farms within the zones would be unable to sell their animals for slaughter. This may give rise to animal welfare issues for which solutions would need to be found. This would also mean slaughterhouses and meat plants that handle meat from these farms would either be unable to operate or need to find alternative suppliers.

The second option, overcomes some of the difficulties of the third option by applying the derogations of article 4 which allow meat to be produced so long as it is treated prior to sale to end consumers. This would allow the slaughter of animals for human consumption, albeit the meat is likely to be of lower value reflecting the treatments applied.

Consultees agreed with the Government's preferred (second) option, and comments received led to areas of simplification to aid understanding and compliance, . The Government's response to the consultation has been published.

Preferred Option (Option 2)

Taking account of lessons from recent exotic disease outbreaks, further review of the legal obligations, and comments received during the consultation, the draft instrument has been revised and re-titled as "The Products of Animal Origin (Disease Control) (England) Regulations 2008" (referred to as “The Regulations”). This document assesses the impact of the Regulations.

The aim of the Regulations is to reduce the risk of spread of disease to animals from animal products intended for human consumption; any human health risks are addressed through separate food hygiene legislation.

The Regulations implement 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 Directive does not recognise any treatments for milk in an outbreak of Rinderpest or Sheep and Goat Plague. Thus milk from animals in the protection or surveillance zones could not be traded during an outbreak of such disease. The Regulations provide powers for the Secretary of State to implement such measures necessary to control milk during a relevant disease outbreak. The risk of an outbreak of these diseases is very low
- The Regulations provide 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.

Sectors and groups affected

In the event of an outbreak of the diseases covered by the Regulations, any or all of the livestock, meat production and export industry in the UK with susceptible animals (susceptible animals include cattle, sheep, pigs and goats) originating from the protection or surveillance zones or taking meat from such animals would be affected. This impact assessment considers the costs and benefits to industry and government in England only.

Statistical data shows relevant livestock numbers in England as⁴:

5.5 million cattle

15.9 million sheep

4.2 million pigs

83,000 goats

⁴ Statistical data from “Agricultural and Horticultural Census for England” June 2005

In our illustrative scenario we have used an estimate of 32,000 pigs in the surveillance and protection zones being affected.

This Regulations require any animals sent for slaughter from areas subject to health restrictions to be slaughtered at a designated slaughterhouse. This may mean farmers are unable to use their usual slaughterhouse or may not be able to negotiate usual contractual terms. However, they will benefit from a reduced risk of disease spread as the Designated slaughterhouse is less likely to transmit disease to transport (due to cleansing & disinfection requirements) and meat from animals is controlled. Thus there will be a reduction in the likely costs of controlling the disease on their farm. Reducing the risk of disease spread also reduces the likely size of any export ban. Any export ban is likely to influence the price paid for meat.

Under the proposed legislation a disease outbreak would also have an impact on the meat and haulage industries, including slaughterhouses, cutting plants, food processors and road haulers as a result of the control measures imposed.

Costs and benefits – England

General

To illustrate the potential costs and benefits of the preferred option, we have used an example involving an outbreak of classical swine fever (CSF). It is estimated that there is a 1/15 probability that CSF could occur in each year, which is higher than for all other diseases (apart from FMD, controls for which have been subject to a separate RIA and legislation). CSF also carries a high risk of disease spread through products of animal origin. Studies have shown that the risk of infection is by the oral route and it is capable of surviving for extended periods in some meat and meat products. In general, an outbreak of CSF is likely to be localised due to:

- The geographical distribution of the pig industry in UK
- The ban on swill-feeding
- CSF is not considered to be spread by the wind
- Movement controls: Identification, registration of premises and stringent movement controls for live pigs
- The centralised control of the industry and the general high standards of husbandry and management
- The vertical integration of the many pig producing companies (production pyramid).
- Pigs tend not to be sold in livestock markets nowadays
- The age batching of pigs in the production process
- The high-levels of bio-security present in the established industry
- The high levels of health and production monitoring, which are the norm in the industry
- Ante and post-mortem inspection at slaughter
- Wild boar which are the main wildlife host for CSF are currently present in very restricted areas, at relatively small population densities
- Backyard and though increasing pet pigs are still small in number and widely dispersed.

Whilst the swill feed ban mitigates the primary route of infection to animals (through oral consumption of meat) there remains a risk of non-compliance with swill feed regulations and

spread through contact. This risk is significantly lower than transmission from live animals but it is important to minimise this by preventing the meat from reaching end consumers, and epidemiologically being able to trace any infection from meat (via inspection of records). Thus the controls proposed in the Regulations minimise the additional burden on industry whilst achieving these control and traceability objectives.

According to expert opinion, in any year where a CSF outbreak did occur, there is thought to be approximately a two-in-three chance that it would be a moderate outbreak, affecting one IP in the UK and lasting 32 days. A larger outbreak scenario is thought to be likely to occur one-in-three times when an outbreak occurs. This scenario would be a large outbreak, estimated to cover 23 Infected Premises in the UK and lasting 47 days. The different probabilities are used to weight later cost and benefit calculations. If there were no controls, there would be a risk of disease spreading to the protection and surveillance zones and, from there, leading to more Infected Premises and increasing the duration of the outbreak.

Norfolk was used as our example county due to the regions sizeable pig industry and likelihood of being affected by any outbreak. By taking June Census data of the number of pigs in Norfolk and then calculating the average number of pigs per square kilometre we were able to calculate the average number of pigs that would be caught within a protection zone in the event of an outbreak. This is then used to find the number of pigs which would require heat treatment and hence the cost, and is also used in calculating the cost of the export ban.

Once disease had been confirmed and zones had been put in place, all fresh meat and meat products from animals in the protection and surveillance zones would be separated from products which were not subject to restrictions.

This legislation will require slaughterhouses to be designated before they can carry out the control measures and this will therefore incur an administrative cost. This is thought to be a small impact as, in the scenario considered, the protection and surveillance zones will not be large.

The conditions for designation of slaughterhouses should not be too onerous; primarily compliance with separation of animals and meat from those not controlled under the Regulations, marking of meat, the presence of MHS during slaughter (which is normal practice at many slaughterhouses). We assume that these costs will be passed back to the farmer in the form of a lower price paid for his pigs.

Hauliers would need to continue with normal cleansing and disinfection requirements, however they would not have derogation to cleanse and disinfect vehicles away from the slaughterhouse. Most slaughterhouses provide such facility as they are required to by food hygiene regulations. This may delay them in leaving the premises and they may incur charges by the slaughterhouse for use of cleansing and disinfection facilities. We assume that this cost to hauliers would also be passed back to farmers through a lower price being paid for the pigs.

Slaughterhouses that do not wish to meet the costs of compliance with the legislation or who feel that dealing with meat from protection and surveillance zones will have an adverse effect on their business will simply elect not to apply for designation, and hence will incur no designation costs. Depending on their and their clients physical location they may need to seek new suppliers of pigs to slaughter if their usual suppliers are from within the protection and surveillance zones, potentially affecting the price and margin, however this is uncertain and we have not attempted to cost this.

An outbreak of disease could also impact on those involved in the export business of fresh meat and meat products. If option 1 were taken it is almost inevitable that a disease outbreak would lead the Commission to implement a Decision prohibiting the export of all GB meat within the Community and to 3rd countries. Implementing the preferred option, controlling the meat from risk areas either by prohibiting its sale or by allowing its sale after heat treatment, should mitigate this risk, although the Commission may implement such a ban in the early stages whilst the extent of disease is confirmed

Costs of preferred option

The implementation and provisions of this Directive will cause additional burdens for the meat industry.

In the event of an outbreak, the Food Business Operator could choose not to designate their premises to handle restricted meat. 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. Therefore we assume that they would continue to market their pigs.

The cost to farmers would be in terms of a reduction in price per head, which we assume would decrease by between 30% and 50%. This is because most meat is sold fresh so cooked meat would have limited uses, and would therefore have a reduced price compared to fresh meat. 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.

This price reduction would also include the cost to slaughterhouses and processing plants in having to separate animals and products from restricted and non restricted areas, and having to stamp meat coming from a protection or surveillance zones with the unique mark. Processing plants would have to keep uncooked meat from Protection Zones and Surveillance Zones separate until such time as the raw meat had irreversibly entered the cooking process. Hauliers, slaughterhouses and food processors would also have to comply with cleaning and disinfecting requirements.

The cost of this price reduction has been estimated by looking at what the output the average number of pigs sent to slaughter per day would be within the area of the protection zone. The assumptions regarding the length and size of the outbreak is then used to estimate the amount of output farmers would have to sell at a reduced price. The value of the total price reduction is the cost to farmers. (See annex B for detailed calculation of the cost)

Average estimate cost to farmers of the reduced price in our scenario: £890,000.

There is a cost of applying to designate premises for producing and handling restricted meat and products. To be approved as designated premises, the food business operator must confirm their ability to meet the requirements of the legislation (such as marking and separation of meat) and additional conditions relevant to that type of operation, such as having adequate cleansing and disinfection facilities to cleanse livestock vehicles at slaughterhouses. We anticipate only those premises with adequate facilities will wish to apply for designation and therefore the cost to the meat industry would be the making the application, including paying official vets to inspect the premises for approval. However, costs are considered minimal.

The cost of applying for the designation includes MHS inspection costs (see annex B)

The estimated cost to meat processors of applying for designation in advance of any outbreak is: £3000.

Additional costs to government are in terms of checks and enforcement of control measures. The additional costs of inspection at abattoirs would be small because even when there is no outbreak, it is routine for MHS and Local Authorities to supervise at slaughterhouses, cutting plants, meat processing and cold storage – although some additional activity would be required. There would also be costs incurred by Government in designating slaughterhouses and any meat processing plant.

The cost is estimated by looking at the expected number of spot checks and the cost of performing them by MHS and LA under the different outbreak scenarios, weighting them to reflect the probability of the outbreak size. (see annex B)

In total costs incurred by inspection bodies are estimated to be £4,000.

The total economic cost to the State and industry in the event of an outbreak is estimated to be £894,000.

Benefits of preferred option

Under the status quo it is highly likely that the commission would, through a Commission Decision, prohibit the export of products from GB. This would result in a significant loss of export value.

Implementing the Directive and its controls reduces the risk of a GB export ban during a disease outbreak. The cost of an export ban would be the lost value of exports to the EU. This cost would be somewhat mitigated by sales on the domestic market instead, however increased supply on the domestic market would mean pig meat was sold at a lower price. Defra modelling estimates that 27% of the value of exports would be lost in the event of a GB export ban. Therefore, taking account of the likelihood of different outbreak durations and making the conservative estimate that the Commission would ban exports only during the period of the outbreak we can estimate the cost.

Average Cost of GB export ban under status quo £4,031,000.

When the Regulations are transposed the likelihood of the Commission imposing a broad ban on export of fresh meat products from outside the areas subject to animal health restrictions is significantly reduced. Whilst The Regulations prohibit the sale of fresh meat from these zones, it does allow the sale of meat once a specific treatment has been applied to the meat. Treated meat may also be exported. The Regulations do not imposed prohibitions on areas outside these zones. It is therefore likely that once the Regulations are implemented the impact of export trade will be much reduced compared to the status quo.

When the Regulations are implemented and the export ban on fresh meat is restricted to the surveillance and protection zones then we can calculate the cost of this much smaller export ban

by estimating the value of exports originating from these zones. Of course meat from these zones that has been treated may be exported.

The cost of the export ban from the protection and surveillance zones has been estimated by looking at the size of the market within our illustrative zone compared with nationally and limiting the size of the export market lost to the proportion of UK pigs with the zone. This takes into account our assumption of the likelihood of different outbreak sizes.

Average cost of Protection and Surveillance Zones export ban under the preferred option: £11,000.

Average net benefit of the preferred option: £4,020,000

A further benefit of this option is that the control measures reduce the risk of incurring the costs of the disease spreading. These costs would include: costs to animal health from infection and disease incidence; costs to government from taking action on infected premises beyond the original infected premises (including the costs of culling animals) and costs to industry in terms of lost production (including lost production due to both diseased animals being less productive and due to reduced numbers of animals for production due to culling controls). Of course it only reduces the costs of disease spread where meat is the mechanism of infection.

However, the likelihood of disease spread through meat productions is low partly due to the ban on the use of animal products in swill. As the risk is low and not properly understood we have not sought to quantify the expected benefit.

However, if disease were to spread, and there was a UK wide export ban the total cost in England in the illustrative scenario would be approximately £3.6 million.

Summary of Costs and Benefits

All costs presented here are for the illustrative example of a Classical Swine Fever (CSF) outbreak.

Costs in the example scenario under preferred option:

Cost of controls (using status quo as a baseline)	Preferred option
To farmer	£890,000
To government	£4000
To food processors	£3000
TOTAL COST	£897,000

Benefits in the example scenario under preferred option:

Benefits of controls (using status quo as a baseline)	Preferred option
To farmer	£4,020,000
TOTAL BENEFIT	£4,020,000

NET BENEFIT: £3,123,000

The preferred option also offers benefit in terms of the reduced likelihood of disease spread. If disease did spread because of a lack of those specific controls, in the illustrative scenario this is estimated to cost approximately £3.6m. This has not been included in the monetised benefits because the risks and probabilities are unknown

Specific Impact Tests

The outcome of specific impact tests is at annex A

Compensatory Simplification Measures

The following legislation provided various meat control provisions which are subsumed by the Regulations where necessary. These have already been repealed:-

Fresh meat (Hygiene and inspection) Regulations 1995

Poultry meat, farmed game bird meat (Hygiene inspection) Regulations 1995

Meat products (Hygiene) Regulations 1994

Minced Meat and Meat Preparations (Hygiene) Regulations 1995

Enforcement and Sanctions

In the event of an outbreak, enforcement of the control measures in England is mainly implemented by the Local Authorities.

At slaughterhouses, the Meat Hygiene Service (MHS) would be the enforcement body authorised to supervise the application of stamps to the fresh meat. When the meat leaves the slaughterhouse, the responsibility for enforcement is split between MHS for cutting plants and the Local Authorities (LA) to cover cold stores and meat processing plants.

Enforcement would include administrative costs for designation and certification of slaughterhouses; this could be estimated as £25- £50 per slaughterhouse. Slaughterhouses would also require stamps to be applied to fresh meat products.

Monitoring and Review

Monitoring of the effectiveness of the legislation will happen once it has been used in a disease outbreak situation.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	Results in Evidence Base?	Results annexed?
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	Yes
Sustainable Development	No	Yes
Carbon Assessment	No	Yes
Other Environment	No	Yes
Health Impact Assessment	No	Yes
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	Yes

Annexes

Annex A - Outcome of Impact Tests

Competition Assessment

In the event of an outbreak the Regulations would restrict the supply of animal products from a limited number of firms within the SZ. This would impact on the price that suppliers could charge by amongst other things limiting the sales channels that a supplier could use.

However, the extent of any restrictions means they would only affect a small proportion of producers nationally. In addition any restriction will be for a time limited period only. The Regulations may also help maintain competition on a national scale by reducing the likelihood of disease spread which could result in more stringent and wide ranging restrictions on suppliers at a later date. As discussed previously it also reduces the possibility of the EU imposing an export ban on our products which could have much wider ranging implications for competition.

In conclusion, we believe that the Regulations are not likely to have a significant impact on competition. This is due to the temporary nature of any restrictions which are not likely to have a long term impact on competition structures or performance.

Small firms impact test

In the event of a confirmed outbreak, this legislation would have an impact on small businesses, particularly the small number of farmers in the Protection Zone (PZ) and Surveillance Zone (SZ) (almost all farms are classified as small businesses). These costs 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 draft FMD Directive in 2003, small businesses were consulted on to determine the impact of the Directive (which also required heat treatments specified in the H4 Directive) on their business. We received no specific feedback from small businesses. After discussions with the Small Business Service, we carried out a further consultation exercise targeted specifically at those small business organisations recommended by the SBS but no feedback was received.

Legal Aid

As no new criminal sanctions or civil penalties are being introduced there are no implications for legal aid.

Sustainable development

I have considered the economic, environmental and social impact of the legislation. The conclusion is that it will have very little impact on sustainable developments as it is not expected to lead to any significant changes in the way the industry currently works.

Carbon assessment

The impact of the Regulations will vary depending on the type of disease and scale of outbreak. The Regulations will not directly lead to a change in carbon emissions. However, in the event of an outbreak the requirement for heat treatment may increase energy use and hence carbon emissions. However, the reduced cooking of meat at home may reduce carbon emissions. Any impact would be a very low level.

Given the uncertainty regarding the risk of an outbreak, its size and very low level of any potential change in carbon emissions the Regulations is unlikely to have any significant or measurable impact on carbon emissions.

Other environment

The impact on the volume of by-products being produced as a result of the Regulations would, be minimal since the additional amounts of meat that will need disposal will be negligible compared to normal volumes of by-product.

Health impact assessment

This legislation will not directly impact on health or well being and will not result in health inequalities.

Race equality

These proposals do not impose any restrictions or contain any requirements which a person or Community of a particular racial background would find difficult to meet. The conditions equally apply to all businesses involved in activities covered by this legislation.

Disability equality

The proposals are not expected to have any impact on disability equality.

Gender equality

There are no limitations on meeting the requirements of the Regulations on the grounds of race, disability or gender. The legislation does not impose any restriction or involve any requirement which a person of a particular racial background, disability or gender would find difficult to comply with. Conditions apply equally to all individuals and businesses involved in the activities covered by the Proposal.

Human rights

The legislation is consistent with the Human Rights Act 1998.

Rural proofing

This legislation will benefit the Rural Community because businesses within areas subject to animal health restrictions can continue to operate during a disease outbreak. This enables a revenue stream for farmers and the Rural Community that would otherwise be unavailable.

Annex B

Estimating the costs and benefits of the preferred option for controlling meat and meat products using an example scenario

Benefits

Calculating the Cost of Export Ban with the Adoption of the preferred option (option 2) and the status quo (option 1)

Porcine Exports

	Total Value of Exports Lost GB (millions)	% of which is lost value due to increase in domestic consumption	Cost of Export Ban (millions)
Sum of Jun 06	£11.37	0.27	£3.07
Sum of Jul 06	£11.41	0.27	£3.08
Sum of Aug 06	£10.86	0.27	£2.93
Sum of Sep 06	£11.33	0.27	£3.06
Sum of Oct 06	£12.67	0.27	£3.42
Sum of Nov 06	£11.05	0.27	£2.98
Sum of Dec 06	£11.78	0.27	£3.18
Sum of Jan 07	£11.50	0.27	£3.10
Sum of Feb 07	£11.44	0.27	£3.09
Sum of Mar 07	£11.36	0.27	£3.07
Sum of Apr 07	£10.13	0.27	£2.74
Sum of May 07	£22.58	0.27	£6.10
		Total/ year	£39.82

Average Cost Per Day (millions)

£0.11

Norfolk is the fifth largest ceremonial county in England, with an area of 5,371 sq km (2,074 sq mi).

June Agricultural Census 2004	No. Holdings	Number pigs
total pigs [see note *]	607	547852

Norfolk	
Number of pigs per sq km	102.00
Area of SZ	314.16
Number of pigs per SZ	32044.83

AUK 2005	2004
population total pigs	5161000

% of exports restricted per SZ	0.62%
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Cost per day of restriction per SZ	0.000677317
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Probability of 32 days and 1 IP	67%
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Probability of 47 days and 23 IP	33%
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SZ Export Ban only

Cost of 32 days and 1 IP (m)	0.021674145
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Cost of 47 days and 23 lps (m)	0.0318339
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Average cost of Export Ban under Option 2	£10,505.20
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GB Export Ban

Cost of 32 days and 1 IP (m)	3.490742865
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Cost of 47 days and 23 lps (m)	5.127028583
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Average cost of Export Ban under status quo (Option 1)	£4,030,717.15
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Net Benefit of Preferred Option (option 2)	£4,020,211.95
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Costs

Lost Value from Reduced Prices of Potentially Infected Meat

SZ duration

21 days

PZ duration

30 days

this method & data on deadweight prices & annual production consistent with Risk Solutions FMD

H4

AUK 2005

2004

Pigs -- Classical Swine Fever

population total pigs 5161000

homefed production (dressed carcass weight, tonnes) 677000

production -- tonnes per pig per year 0.13

production -- tonnes per pig per day 0.000

production -- kg per pig per day 0.359

2000 outbreak of Classical Swine Fever occurred in East Anglia

Wikipedia:

Norfolk is the fifth largest ceremonial county in England, with an area of 5,371 sq km (2,074 sq mi).

June Agricultural Census 2004

NORFOLK	total pigs [see note *]
No. Holdings	Number pigs
607	547,852

Norfolk

Number of pigs per sq km	102.0018619
Area of SZ	314
Number of pigs per SZ	32,045

Pig production losses -- 90% of value of pig & number of pigs for half duration of outbreak (industry estimate)

Kg production per day	11,516
half duration of 32 day outbreaks	16
half duration of 47 day outbreaks	24

KG production in 32 days 184,264

based on UK production figures

<http://defraweb/farm/pigs/ffig/pdf/uieursp.pdf>

average GB euro pig prices

£ per kg deadweight 1.025

Value of kg production in 32 days £188,870

KG production in 47 days 270,637

value of kg production in 47 days £277,403

Probability of 32 days and 1 IP 67%

Probability of 47 days and 23 IP 33%

heat treatment

price discount on heat treated meat (from FMD work)

min	30%
max	50%
Value of kg production in 32 days	£188,870
lost value (30% p reduction)	£56,661
lost value (50% p reduction)	£94,435
value of kg production in 47 days 23 IP	£6,380,276
lost value (30% p reduction)	£1,914,083
lost value (50% p reduction)	£3,190,138

Expected loss	
30% p reduction	£669,610
50% p reduction	£1,116,017

Average Total Expected Loss £892,814

Admin and Inspection Costs

Probability of 32 days and 1 IP	67%
Probability of 47 days and 23 IP	33%

Designation	Food processor cost
assume 20 abattoirs apply for designation pre-outbreak	20
MHS Employed OVS normal time charge per hour	£39.00
four hours of time (1/2)	£156.00
Cost of designation per abattoir	£150

Cost of abattoir designation pre-outbreak £3,120

Responsibility	
MHS	LA
abattoir	cold storage
cutting plants	processing plant

MHS spot checks -- during outbreak	Govt Cost
number of abattoirs	
1 IP and 32 days	3
23 IP and 47 days	6
cost MHS (£ per hour)	24.6
time per spot check (4 hours 1/2 day)	4
cost per spot check (£ per hour)	98.4
1 IP and 32 days	
assume 2 spot checks per abattoir & cutting plant during outbreak	£590
23 IP and 47 days	
assume 3 spot checks per abattoir during outbreak	£1,771

Expected cost MHS abattoirs	£980
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number of cutting plants	
1 IP and 32 days	3
23 IP and 47 days	6

Expected cost MHS cutting plants	£980
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Expected Total total MHS spot checks (abattoir and cutting plants)	£1,960
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LA spot checks -- during outbreak	Govt Cost
number of cold stores	
1 IP and 32 days	3
23 IP and 47 days	6
cost LA (£ per hour)	£26.30
time per spot check (4 hours 1/2 day)	4
cost per spot check (£ per hour)	£105.20
1 IP and 32 days	
assume 2 spot checks per cold store during outbreak	£631

23 IP and 47 days

assume 3 spot checks per cold store during outbreak

£1,894

Expected cost LA cold stores

£1,048

number of processing plants

1 IP and 32 days

3

23 IP and 47 days

6

Expected cost LA processing plants

£1,048

Expected total LA spot checks (cold store and processing plants)

£2,096

Govt Inspection Costs

£4,056

Food Processor Designation Costs

£3,120