

## Summary: Intervention & Options

**Department /Agency:**  
Department for Environment,  
Food and Rural Affairs

**Title:**  
Impact Assessment for the Eggs and Chicks  
Regulations 2009

**Stage: Implementation**

**Version: 1**

**Date: 29 July 2009**

**Related Publications:** Impact Assessment for *Salmonella* NCP

**Available to view or download at:**

<http://www.defra.gov.uk/corporate/consult/eggs-chicks2009/>

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

*Salmonella* poses a risk to human health. The Eggs and Chicks (England) Regulations 2009 update the provisions contained in the 2008 Regulations to include controls on eggs intended for human consumption. The amended Regulations provide fair and transparent enforcement powers for the obligations which the National Control Programme for laying flocks places on producers. This will enable government to enforce the controls of the *Salmonella* NCP for laying flocks through the egg marketing standards.

**What are the policy objectives and the intended effects?**

To protect human health by extending current legislation on marketing Class A eggs for human consumption. This will support the requirement of the layers NCP (which implements EU Regulations 2160/2003 and 1168/2006) that eggs from affected flocks are considered as Class B and cannot be sold for human consumption unless heat treated/pasteurised to guarantee elimination of all *Salmonella* serotypes of public health significance. The NCP prohibits eggs from holdings of unknown status, from flocks which are suspected or are infected with *Salmonella* Enteritidis/Typhimurium or eggs from flocks linked to a foodborne outbreak of *Salmonella* being marketed as Class A as required by EU legislation. This Impact Assessment recommends a system of enforcement powers which include monetary penalties for breach of the control provisions and criminal offences.

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

The options focus on enforcement powers and level of penalty and offences incurred by non-compliance. The specific options and their costs and benefits are described in detail in the Evidence Base. Our preference is for option 2.

Option 1 – do nothing (ie enforce under existing legislation and administrative means)

Option 2 – Introduce a system of variable monetary penalties with the possibility of a criminal offence penalty.

Option 3 – Criminal offence penalty but no monetary penalties.

**When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?** The IA for the laying flocks NCP estimated a net benefit of £61.4m. Government will monitor the effectiveness of enforcement when the layers NCP is due for review in late 2009.

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

***I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.***

Signed by the responsible Minister:

..... Date:

## Summary: Analysis & Evidence

<b>Policy Option: 1</b>	<b>Description: Reliance on current legislation (Zoonoses Order 1989)</b>
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<b>COSTS</b>	<b>ANNUAL COSTS</b>		Description and scale of <b>key monetised costs</b> by 'main affected groups' (A) <b>Industry:</b> (i) Admin burden (ongoing p.a. £4k) (ii) Egg marking cost (£15k - £31k p.a.). (B) <b>Government:</b> (i) Administrative cost of arranging official sampling at holdings of unknown health status (£21k p.a.) (ii) monitoring and enforcement costs (£118k p.a.) (iii) training (one off £6k)	
	<b>One-off</b>	<b>Yrs</b>		
	£ 6k	1		
	<b>Average Annual Cost (excluding one-off)</b>			
£ 148k – 164k		2	<b>Total Cost (PV)</b>	£ 324k – 357k
Other <b>key non-monetised costs</b> by 'main affected groups'				
Nil				

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>		Description and scale of <b>key monetised benefits</b> by 'main affected groups'	
	<b>One-off</b>	<b>Yrs</b>		
	£ 0			
	<b>Average Annual Benefit</b>			
£ 0		2	<b>Total Benefit (PV)</b>	£ 0
Other <b>key non-monetised benefits</b> by 'main affected groups'				
(i) Avoided loss of human health benefits due to proper enforcement of <i>Salmonella</i> controls (ii) Avoided loss of export value (iii) Avoided cost of infraction proceedings				

### Key Assumptions/Sensitivities/Risks

See evidence base for assumed levels of compliance. Costs to holdings of legal action for non-compliance not estimated. Time period of analysis 2 years, to reflect NCP programme timescale.

Price Base Year 2009	Time Period Years 2	<b>Net Benefit Range (NPV)</b> £ (-) 324k – (-) 357k	<b>NET BENEFIT (NPV Best estimate)</b>
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What is the geographic coverage of the policy/option?		England		
On what date will the policy be implemented?		2009		
Which organisation(s) will enforce the policy?		AH & EMI		
What is the total annual cost of enforcement for these organisations?		£ 118,000		
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?		£ N/A		
What is the value of changes in greenhouse gas emissions?		£ Negligible		
Will the proposal have a significant impact on competition?		No		
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	Yes/No	No	N/A	N/A

<b>Impact on Admin Burdens Baseline (2005 Prices)</b>		(Increase - Decrease)
Increase	£ 4,000 p.a.	Decrease
	£	<b>Net Impact</b> £ 4,000 p.a.

Key: Annual costs and benefits: Constant Prices (Net) Present Value

## Summary: Analysis & Evidence

**Policy Option: 2**

**Description: Introduce a system of variable monetary penalties with the possibility of a criminal offence penalty**

<b>COSTS</b>	<b>ANNUAL COSTS</b>		Description and scale of <b>key monetised costs</b> by 'main affected groups' (A) <b>Industry:</b> (i) Cost of operator sampling at holdings of unknown health status (£8.6k p.a.), (ii) Penalties for non-compliance (£6k p.a.) (iii) Admin burden (£6k p.a.), (iv) Egg marking costs (£15k – 31k p.a.); (B) <b>Government:</b> (i) Monitoring and enforcement (£38k p.a.); (ii) training (one-off £6k)
	<b>One-off</b>	<b>Yrs</b>	
	£ 6k	1	
	<b>Average Annual Cost (excluding one-off)</b>		
	£ 61k – 68k	2	<b>Total Cost (PV)</b> £ 157k – 189k
Other <b>key non-monetised costs</b> by 'main affected groups' Nil			

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>		Description and scale of <b>key monetised benefits</b> by 'main affected groups'
	<b>One-off</b>	<b>Yrs</b>	
	£ 0		
	<b>Average Annual Benefit (excluding one-off)</b>		
	£ 0	2	<b>Total Benefit (PV)</b> £ 0
Other <b>key non-monetised benefits</b> by 'main affected groups' (i) Avoided loss of human health benefits due to proper enforcement of <i>Salmonella</i> controls (ii) Avoided loss of export value (iii) Avoided cost of infraction proceedings			

### Key Assumptions/Sensitivities/Risks

See evidence base for assumed levels of compliance. Costs to holdings of legal action for non-compliance not estimated. Time period of analysis 2 years, to reflect NCP programme timescale.

Price Base Year 2009	Time Period Years 2	<b>Net Benefit Range (NPV)</b> £ (-) 157k – (-) 189k	<b>NET BENEFIT (NPV Best estimate)</b>
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What is the geographic coverage of the policy/option?		England		
On what date will the policy be implemented?		30 June 2010		
Which organisation(s) will enforce the policy?		AH & EMI		
What is the total annual cost of enforcement for these organisations?		£ 31,000		
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?		£ N/A		
What is the value of changes in greenhouse gas emissions?		£ Negligible		
Will the proposal have a significant impact on competition?		No		
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	Yes/No	No	N/A	N/A

<b>Impact on Admin Burdens Baseline</b> (2005 Prices)		(Increase - Decrease)
Increase	£ 5,000 p.a.	<b>Net Impact</b> £ 5,000 p.a.
Decrease	£	

Key: Annual costs and benefits: Constant Prices (Net) Present Value

## Summary: Analysis & Evidence

**Policy Option: 3**

**Description: Introduction of a criminal offence penalty only**

<b>COSTS</b>	<b>ANNUAL COSTS</b>		Description and scale of <b>key monetised costs</b> by 'main affected groups'(A) <b>Industry:</b> (i) Cost of operator sampling at holdings of unknown health status (ongoing p.a. £8.6k), (ii) Admin burden (ongoing £7k), (iv) Egg marking costs (ongoing £15 – 31) (B) <b>Government:</b> (i) Monitoring and enforcement (ongoing £92k). (ii) training (one-off £6k)
	<b>One-off</b>	<b>Yrs</b>	
	£ 6k	1	
	<b>Average Annual Cost (excluding one-off)</b>		
	£ 111k – 127k	2	<b>Total Cost (PV)</b> £ 254k – 286k
Other <b>key non-monetised costs</b> by 'main affected groups' Nil			

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>		Description and scale of <b>key monetised benefits</b> by 'main affected groups'
	<b>One-off</b>	<b>Yrs</b>	
	£ 0		
	<b>Average Annual Benefit (excluding one-off)</b>		
	£ 0	2	<b>Total Benefit (PV)</b> £ 0
Other <b>key non-monetised benefits</b> by 'main affected groups' (i) Avoided loss of human health benefits due to proper enforcement of <i>Salmonella</i> controls (ii) Avoided loss of export value (iii) Avoided cost of infraction proceedings			

### Key Assumptions/Sensitivities/Risks

See evidence base for assumed levels of compliance. Costs to holdings of legal action for non-compliance not estimated. Time period of analysis 2 years, to reflect NCP programme timescale.

Price Base Year 2009	Time Period Years 2	<b>Net Benefit Range (NPV)</b> £ (-) 254k – (-) 286k	<b>NET BENEFIT (NPV Best estimate)</b>
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What is the geographic coverage of the policy/option?		England		
On what date will the policy be implemented?		30 June 2010		
Which organisation(s) will enforce the policy?		AH & EMI		
What is the total annual cost of enforcement for these organisations?		£ 85,000		
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?		£ N/A		
What is the value of changes in greenhouse gas emissions?		£ Negligible		
Will the proposal have a significant impact on competition?		No		
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	Yes/No	No	N/A	N/A

<b>Impact on Admin Burdens Baseline</b> (2005 Prices)		(Increase - Decrease)
Increase	£ 7,000 p.a.	<b>Net Impact</b> £ 6,000 p.a.

Key: Annual costs and benefits: Constant Prices (Net) Present Value

### Impact Assessment on the Eggs and Chicks (England) Regulations 2009 ("The Eggs and Chicks Regulations 2009")

#### 1. Introduction

1.1 The Eggs and Chicks (England) Regulations 2009 will revoke and replace the Eggs and Chicks (England) Regulations 2008 (SI 2008/1718). They will come into force on 14 September 2009. The Regulations update the provisions contained in the 2008 Regulations to take account of certain marketing definitions and provide enforcement powers for marketing requirements contained in Commission Regulation 2160/2003 (as amended by Commission Regulation 1237/2007) on the control of *Salmonella* and other specified food-borne zoonotic agents. This will enable Animal Health officers to enforce the marketing controls required by the National Control Programme (NCP) for laying flocks as part of the Egg Marketing Regulations.

#### 2. Objective

##### ***Enforcement of the Salmonella National Control Programme***

2.1 The main objective is to expand the scope of the Eggs and Chicks Regulations 2008 to cover marketing controls on eggs intended for human consumption in accordance with the NCP for laying hens. The NCP for laying hens implements the monitoring and controls required by EU Regulations 1168/2006 and 2160/2003. The NCP requires that, from January 2009, eggs shall be considered and marked as Class B if they are:

- (i) from flocks of unknown health status (with regard to *Salmonella*),
- (ii) from flocks that are suspected of being infected or that are infected with *Salmonella* Enteritidis or *Salmonella* Typhimurium, or
- (iii) from flocks that are linked to a foodborne outbreak of *Salmonella* in humans.

2.2 If an egg is marked as Class B, in practice this means that it cannot be marketed for human consumption unless it is heat treated/pasteurised. The Eggs and Chicks Regulations 2008 require eggs which are damaged or unclean to be marked as Class B. The Eggs and Chicks Regulations 2009 will extend the definition of Class B eggs to cover those from laying flocks which are positive for *Salmonella* Enteritidis (SE) and Typhimurium (ST) and from suspected flocks and flocks of an unknown status. EU Regulation 2160/2003 (as amended by EU Regulation 1237/2007) also requires that eggs from affected flocks must undergo heat treatment before use. Affected eggs must be marked individually as class B eggs as described in Regulation 589/2008, in order to reduce the risk that these eggs are introduced into the food chain as class A eggs for direct human consumption.

2.3 The marking of eggs as Class B from holdings where *Salmonella* is suspected is a directly applicable EC requirement under Regulation 2160/2003. The only exception is where these eggs are not placed on the market. An example of this is where a producer sends the eggs to his own processing plant for processing. The producer and the processor must be one and the same person (or company) and there must be no sort of commercial arrangement involved. Since egg marking is an EU requirement all the implementation options below assume that eggs will be marked.

2.4 The costs and benefits of the NCP for *Salmonella* in laying hens were documented in a separate IA. This concluded that whilst the total cost of the layers NCP over its 3 year lifespan was £28.6 million the benefits over this period came to £61.4 million. This IA

deals solely with options for enforcing the required controls on eggs. Three options were considered which are described in this Impact Assessment. Their costs are assessed in terms of the saving to government and industry of an effective enforcement regime for the NCP controls on eggs (see Table 1). The benefits of the options are equivalent as it is Defra's policy to properly enforce the NCP whichever of the options is adopted. Our view is that the difference between the options is in terms of costs and efficiency.

2.5 Option 2 is our preferred option which will provide a system of variable monetary penalties to facilitate the enforcement of the NCP by Animal Health. We believe that monetary penalties could:

- Be applied rapidly and effectively
- Increase transparency
- Reduce the costs and uncertainty to government and industry
- Offer producers non-court disposal for minor offences

2.6 The average annual cost of option 2 to government and industry is £61- £68,000 against:

- £148-£164,000 if we continue with the current enforcement arrangements (option 1)
- £111- £127,000 if we introduce a criminal offence penalty without monetary penalties (option 3).

2.7 If option 2 is adopted the level of monetary penalties will range from £100 to £4,500. The range of factors involved in assessing the amount of the penalty mean it is difficult to produce an average estimate. The IA has assumed that non-compliant holdings will be subject to an average fine of £2,500. Clearly this is a cost which producers who comply with the NCP will never face.

### ***EC Eggs Marketing Regulations***

2.8 Although the Eggs and Chicks Regulations 2009 do not impose new additional costs on producers who comply with the NCP, the IA does seek to estimate more broadly the costs of the controls on egg production to give a realistic picture of the NCP's impact. This includes the NCP requirement that all eggs from holdings where SE or ST is detected will have to be marked as Class B on farm before being placed on the market. We estimate that the average cost to an affected producer will be £155.

2.9 The Eggs and Chicks Regulations 2009 make other changes regarding the marketing of eggs. They include definitions of the terms "local public market" and "region of production" for the purpose of the application of the derogations relating to eggs for consumption. They clarify which establishments benefit from the derogations relating to free-range eggs and barn eggs. The Regulations also refine the provisions relating to the use of alternative marking on eggs for hatching. The alternative mark for such eggs will be a black line or another black mark except for a spot. As before, the mark must be indelible, clearly visible and at least 10 mm<sup>2</sup> and must be carried out prior to inserting the eggs into the incubator. We do not expect these changes to have a direct impact on most producers. Instead they bring existing practice into law. Consequently they have not been considered as costs or implementation options in this Impact Assessment.

**Table 1:** *Summary of costs and benefits and their location throughout the evidence base*

		<b>Average Annual Costs</b>	<b>Location (para.)</b>
Option 1	<b>Costs to Government</b>	<b>£139,300</b>	
	<i>CA sampling of holdings of unknown status</i>	£21,300	13.7.3
	<i>Serving ZO2 notices on all infected holdings</i>	£28,500	13.7.4
	<i>Monitoring compliance with ZO2 notices</i>	£66,300	13.7.5
	<i>Prosecuting non-compliant holdings</i>	£23,200	13.7.6
	<b>Costs to Industry</b>	<b>£19,200 - £35,700</b>	
<i>Admin burden</i>	£4,500	13.7.3 - 13.7.6	
<i>Marking eggs</i>	£14,800 - £31,300	13.3.2 - 13.6	
	<b>Total costs</b>	<b>£147,900 - £164,300</b>	
Option 2	<b>Costs to Government</b>	<b>£38,000</b>	
	<i>EMI notification</i>	£29,800	13.8.2
	<i>Monitoring all non-compliant holdings</i>	£1,900	13.8.4
	<i>Prosecuting non-compliant holdings</i>	£6,300	13.8.6
	<b>Costs to Industry</b>	<b>£29,900 - £46,400</b>	
	<i>Operator sampling on holdings of unknown status</i>	£8,600	13.8.3
	<i>Admin burden</i>	£5,800	13.8.2, 13.8.4
	<i>Fines on non-compliant holdings</i>	£6,300	13.8.5
	<i>Marking eggs</i>	£14,800 - £31,300	13.3.2 - 13.6
	<b>Total costs</b>	<b>£61,300 - £77,800</b>	
Option 3	<b>Costs to Government</b>	<b>£92,000</b>	
	<i>EMI notification</i>	£29,800	13.9.2
	<i>Monitoring all non-compliant holdings</i>	£9,500	13.9.4
	<i>Prosecuting non-compliant holdings</i>	£52,700	13.9.5
	<b>Costs to Industry</b>	<b>£25,300 - £41,700</b>	
	<i>Operator sampling on holdings of unknown status</i>	£8,600	13.9.3
	<i>Admin burden</i>	£7,400	13.9.2, 13.9.4
	<i>Marking eggs</i>	£14,800 - £31,300	13.3.2 - 13.6
	<b>Total costs</b>	<b>£110,700 - £127,100</b>	

### 3. Definitions

- A **zoonosis** is any disease and/or infection which is naturally transmissible directly or indirectly between animals and humans.
- A **zoonotic agent** means any virus, bacterium, fungus, parasite or other biological entity which is likely to cause a zoonosis.
- A **National Control Programme (NCP)** is a framework of measures required by Regulation 2160/2003 for the control and monitoring of zoonoses and zoonotic agents which must be put in place by all EU Member States.
- A **flock** means poultry of the same health status kept on the same holding or in the same enclosure and constituting a single epidemiological unit which, in the case of housed poultry, includes all birds sharing the same airspace.
- A **laying flock** means a flock of poultry kept for the production of eggs intended for human consumption;
- A **rearing flock** means poultry which are reared for the production of eggs for human consumption.

- **Poultry** means birds of the species *Gallus gallus*, turkey, ducks and geese.
- **Laying hens** are *Gallus gallus* kept for the production of eggs for human consumption.
- **Competent Authority (CA)** means a government body, or agency of the government body with the overall responsibility for the implementation and enforcement of legislation.
- **Control Body (CB)** is an organisation responsible for management of the NCP which may undertake certain delegated duties on behalf of the CA.
- **Competent Authority Sampling** means sampling which takes place under the control of the Competent Authority (CA). Officials might be responsible for collecting these samples or supervising their collection by a third party or delegating the supervision of their collection to a third party. Such samples are sometimes also referred to as “official control samples”.

#### 4. Other legislation referred to in the Regulatory Impact Assessment

4.1 See Annex 5.

##### ***Detail on the Eggs and Chicks Regulations 2009***

4.2 The Eggs and Chicks Regulations implement directly applicable EC marketing standards relating to eggs for hatching and farmyard poultry chicks and directly applicable EC marketing standards relating to eggs in shell for human consumption. Animal Health is responsible for enforcing the majority of this legislation although some of the responsibilities for the registration of producers are with Local Authorities. They cover production, marking, transport, grading, packing and onward marketing of eggs, including eggs which are intended for human consumption as Class A eggs. The requirements of the Eggs and Chicks Regulations are well established and will be familiar to most commercial producers. They cover most aspects of egg production and have successfully ensured that eggs placed on the market comply with standards that are transparent and fair. They include:

- Registration of pedigree breeding establishments, breeding establishments and hatcheries.
- Authorisation of packing centres to grade eggs.
- Offences for failure to comply with directly applicable EC requirements relating to the quality and weight grading of eggs and the marking (stamping) of egg shells the labelling, packaging and marketing of eggs, and the use of marketing terms such as eggs from caged hens, barn, free range and organic eggs.

4.3 In addition to providing for the *Salmonella* control, the Eggs and Chicks Regulations 2009 will make some other less significant changes, including the incorporation of definitions previously contained in guidance and refining the wording of some of the derogations relating to barn and free-range eggs.

4.4 Most significantly they will include new controls relating to the marketing and use of eggs based on the status of the flock producing the eggs in terms of *Salmonella* serotypes of public health significance. This will provide a new standard for the marketing of eggs in shell intended for human consumption in relation to the *Salmonella* National Control Programme for laying flocks.

## 5. National Control Programmes

- 5.1 Defra is working in partnership with key industry representatives to implement NCPs in the pig and poultry sectors under EU Regulation 2160/2003. The overall objective of the NCPs is to improve public health through the detection and control of *Salmonellas* of human health significance in primary production. An NCP was introduced for breeding flocks in 2007 and for broiler flocks at the beginning of 2009. NCPs will also be introduced for turkeys (2010), fattening pigs and breeding pigs (2011) in all Member States.
- 5.2 The layer NCP came into force in February 2008 (as supported by the Control of *Salmonella* in Poultry Order 2008) and follows on from the NCP for breeding flocks. This was intended to ensure a consistent approach to the reduction of *Salmonellas* of public health significance and equivalent protection of human health from eggs traded between European Community Member States.
- 5.3 The NCP implements Commission Regulations 2160/2003 and 1168/2006 on the control of *Salmonella* and other specified food-borne agents. It sets out enhanced monitoring and controls for *Salmonella* in laying flocks to ensure that *Salmonella* serovars of human health significance are detected and controlled in laying hens and their environment in order to reduce any risk they may pose to human health further along the food chain.
- 5.4 Before the NCP reduction target was set surveys were carried out in all Member States between October 2004 and September 2005 in order to determine a baseline prevalence level for *Salmonella* Enteritidis and *Salmonella* Typhimurium on commercial layer flock holdings with at least 1,000 laying hens. The baseline figure for the UK was 8.0% for *Salmonellas* of public health significance. These are *Salmonella* Enteritidis and *Salmonella* Typhimurium. This put the UK in the group with the lowest prevalence levels (less than 10%) which was set a lower year-on-year improvement target. The prevalence in the UK must be reduced by 10% of the baseline figure each year from the start of 2008 for a period of 3 years.
- 5.5 Regulation 2160/2003 sets a general framework for control programmes which the NCP for layers integrates:
- Minimum sampling requirements detailing the phases of production which sampling must cover (Annex II, B). It requires that flocks are sampled twice during the rearing phase and then every 15 weeks during the laying phase. On holdings with more than 1,000 birds one of these samples must be collected under the control of the Competent Authority.
  - The relevant guides for good biosecurity and animal husbandry which cover issues such as rodent control to reduce the risk of maintaining *Salmonella* on the farm, the prevention of between-flock transmission (for instance through effective disinfection and pest control in poultry houses) and the monitoring of feed production.
  - The registration of poultry operators and record keeping at farms.
  - Controls on eggs intended for human consumption.

### **Controls on Eggs**

5.6 The Eggs and Chicks Regulations provide for specific measures on eggs laid down in Annex II of the Zoonoses Regulation 2160/2003 when a laying flock is, or is suspected of, being infected with *S. Enteritidis* or *S. Typhimurium* or is of an unknown health status. Since January 2009, if any of the operator or official samples are found to be positive for *Salmonella*, the eggs from the affected flocks cannot be sold as Class A. The same applies in relation to suspect flocks and flocks of an unknown health status. The new Regulations will put domestic provisions in place to comply with the provisions of points 1 and 2 of Annex II of Regulation 2160/2003 (as amended by Regulation 1237/2007). These require that eggs shall be considered and marked as Class B from January 2009 if they are:

1. From flocks of unknown health status.

These are flocks where the sampling requirements of the NCP are not being fulfilled. Producers must be able to produce evidence (such as laboratory receipts) that samples are being sent to an approved laboratory for *Salmonella* testing in accordance with the 2160/2003 requirements. This category also covers flocks when some sampling has been done but not to the proscribed schedule for all flocks on the site.

2. From flocks that are suspected of being infected or that are infected with *Salmonella* Enteritidis or *Salmonella* Typhimurium from 1<sup>st</sup> January 2009. These are flocks where one of the samples has not tested negative for SE or ST.
3. From a flock which is linked to a foodborne outbreak of *Salmonella* in humans. These are where a *Salmonella* of any serovar linked to a disease/salmonellosis outbreak is traced to a flock.

5.7 Preventing eggs from being marketed as Class A means that these eggs cannot be sold for human consumption unless heat treated/pasteurised to guarantee the elimination of all *Salmonella* serotypes with public health significance. These eggs will be:

- (a) considered as Class B eggs as defined in Article 2(4) of Commission Regulation (EC) No 589/2008.
- (b) marked with the indication referred to in Article 10 of Commission Regulation (EC) No 589/2008 ], which clearly distinguishes them from Class A eggs prior to being placed on the market.
- (c) prohibited access to packaging centres unless the Competent Authority is satisfied with the measures to prevent possible cross-contamination of eggs from other flocks.

5.8 Regulation 2160/2003 requires that eggs from affected holdings which will be diverted for heat treatment should be individually marked in accordance with article 10 of Regulation 589/2008 on marketing standards for eggs. This should be an easily visible colour spot of at least 5 mm diameter (in practice a paint or spray mark) or a circle at least 12 mm in diameter around the letter "B" at least 5 mm high on each individual egg. Defra's priority will be to ensure untreated eggs from an affected flock do not enter the food chain.

5.9 The only circumstance where eggs from a positive flock do not need to be marked would be when they are not placed on the market. "Placing on the market" is defined according to EU Regulation 178/2002 Article 3 (8) which states that "placing on the market" means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale,

distribution, and other forms of transfer themselves;”. This definition includes the transfer of eggs on the market to another operator for disposal (i.e. rendering). This may not apply where the eggs remain on the holding for the duration of optional testing under EU Regulation 1237/2007 or are sent to a processing or rendering plant which is operated by the producer, i.e. the producer and the operator of the processing or rendering plant are the same person (or company). In such a case the supply of the eggs to the processing or rendering plant must not be the subject of any sort of commercial transaction. There are no plans for government to provide compensation for operators who choose to depopulate or slaughter their infected flocks.

## **6. Egg Marketing amendments**

- 6.1 As noted above the Eggs and Chicks Regulations 2009 include a number of changes to the provisions contained in the 2008 Regulations. However, they should have little impact on producers.

### ***Definitions***

- 6.2 These changes relate to the inclusion of the definitions of “local public market” and “region of production” in the new Regulations. Currently the definitions are only provided in the Animal Health guidance and need to be incorporated in the Regulations.

- 6.3 These definitions are relevant to the derogation from all the requirements of the Egg Marketing Regulations relating to eggs sold directly by the producer without any quality or weight grading to the final consumer by door-to-door selling in the region of production or in a local public market in the region of production. As this derogation is existing practice we would not expect it to have any impact on producers.

### ***Alternative marking on eggs for hatching***

- 6.4 Regulation (EC) 617/2008 provides a derogation for the marking of eggs intended for hatching with the producer code. These eggs do not need to be individually marked with the producer code, provided that they are marked with any abstract black mark (apart from a spot) that is indelible, clearly visible, and at least 10 mm<sup>2</sup> in area. Such marking must be carried out prior to insertion into the incubator. This can be done either at a producer establishment or at the hatchery. This derogation is provided in regulation 7 of the draft Eggs and Chicks Regulations 2009. The marking of these eggs should not be confused with the marking of eggs from flocks which are *Salmonella* positive which would not be supplied to a hatchery.

### ***Derogation for barn and free range egg production***

- 6.5 Under Regulation 589/2008 there is a derogation which means that holdings with certain types and numbers of hens do not need to comply with the full requirements that apply when marketing eggs as “barn” and “free range”. This covers requirements for the internal design criteria of the units (litter, perching and floor space). The derogation applies to:

- (a) a holding with fewer than 350 laying hens.
- (b) a holding rearing any number of breeding laying hens.
- (c) a holding both rearing any number of breeding laying hens and that has fewer than 350 laying hens.

This derogation is contained in the draft Eggs and Chicks Regulations 2009.

## **7. Rationale for government intervention**

- 7.1 The purpose of the controls is to prevent eggs potentially infected with *Salmonella* from entering the human food chain. The public cannot readily identify which eggs are infected with *Salmonella* and there is a need to minimise the possibility of infected eggs entering the human food chain and putting human health at risk.
- 7.2 Under existing arrangements it would be possible to enforce the controls on eggs by serving a Restriction Notice under the Zoonoses Order 1989. The Order has been effective for enforcing the statutory controls on breeding flocks infected with *Salmonella*. However, it could prove to be unwieldy for the more extensive and varied laying flocks sector. There are 2,000 laying holdings against 564 breeding flock holdings affected by this legislation; there are also a greater variety of producers in a sector where commercial holdings can range from 500 birds to over 100,000. To attempt to enforce the controls through Restriction Notices would require an unnecessarily high degree of involvement from central government as these are usually requested and supervised centrally by Defra. Using the Zoonoses Order to enforce controls would also require the provision of movement licences for each premises receiving consignments of eggs from the infected flock.
- 7.3 As the eggs from SE/ST positive flocks can be marked as Class B for the whole productive life of a laying flock (possibly up to 72 weeks) this approach would also be more labour intensive than breeders, where the flocks are slaughtered immediately on receipt of a positive sample and therefore there is only a short term requirement for licensing paperwork. This would be likely to inflate costs and paper-work (the implementation options consider costs in more detail). An important objective of this project is to put in place an efficient monitoring system along the principles promoted by the Hampton review, in particular that enforcement is most effective if dealt with at local level by a body which has frequent contact with and a good understanding of a sector.
- 7.4 Incorporating the controls on eggs from infected/suspected holdings into the Eggs and Chicks Regulations 2009 means that they can be enforced by Animal Health. Animal Health officers are on-farm on a regular basis and are the most qualified and well placed officials to ensure that operators comply with the new controls. By incorporating the *Salmonella* controls into the more general requirements of the Egg Marketing Regulations, egg packers, distributors and retailers would be encouraged to ensure that their egg suppliers are in compliance with the NCP.
- 7.5 The Eggs and Chicks Regulations 2009 also incorporate the amendments on the marketing of eggs and eggs for hatching which will bring definitions which are relevant to certain derogations onto the face of the Regulations and will be more explicit about the alternative mark that may be used for eggs for hatching.

## **8. Consultation**

### **8.1 Outside government**

- 8.1.1 Regular meetings are held with major stakeholders in the UK egg production industry (including the British Egg Industry Council and the National Farmers Union) to discuss the controls on eggs and the amendment to the Eggs and Chicks Regulations 2009. It is clearly in the interests of the majority of compliant producers to ensure that effective action is taken against those who could undercut their costs by disregarding the NCP requirements. The consultation was concerned with the measures which will be taken by the Competent Authority if producers fail to comply with the NCP, not the costs and benefits of the NCP's monitoring and controls.

8.1.2 In 2007 a wide ranging consultation was carried out on the layers NCP. The responses revealed that industry was unhappy with the controls on eggs. It is likely that continuing production from a flock which was positive for *Salmonella* Enteritidis or Typhimurium would not be financially viable, which would have significant economic implications for individual producers. However industry recognises the need to comply with the legislation and a large proportion of the egg producing industry, as represented by the British Egg Industries Council (BEIC), could support Defra's preferred approach to implementation, following subsequent discussions.

## **8.2 Within government**

8.2.1 During the drafting of the Eggs and Chicks Regulations 2009 Defra officials have worked with colleagues in the Devolved Administrations, Animal Health, the Food Standards Agency, the Ministry of Justice and the Treasury.

## **9. Application and Scope**

9.1 The provisions of EC Regulation 2160/2003 apply to all of the UK and this IA considers UK-wide costs. It was agreed that the structured nature of the UK laying flock industry (the larger companies are UK wide) meant that separating the costs between England and the Devolved Assemblies would be an artificial exercise. Furthermore the assumptions behind the costs and benefits sections are not specific to England. Although the Eggs and Chicks Regulations 2009 apply to England only, parallel legislation will be introduced in Wales, Scotland and Northern Ireland.

9.2 Defra is the Competent Authority (CA) for implementation of the Eggs and Chicks Regulations 2009 in England. It will be supported by the Veterinary Laboratories Agency, Animal Health and Local Authorities. In Wales the Welsh Assembly Government will be putting legislation in place, in Scotland the Scottish Executive Environment and Rural Affairs Department (SEERAD) and in Northern Ireland the Department of Agriculture and Rural Development (DARDNI).

9.3 There are around 20,000 holdings which produce eggs for human consumption in the UK. The NCP applies to all those who produce eggs on a commercial basis. Enforcement will focus on producers which supply the highest proportion of eggs for human consumption. Census data indicates there are approximately 1,810 of these holdings. Around 85% of eggs produced in the UK are covered by the voluntary industry operated (British Egg Industry Council) 'Lion Quality Scheme', which has prepared its members for the imposition of the controls on eggs by a programme of intensive sampling. Some of the medium to small producers are covered by the United Kingdom Egg Producers Association (Laid in Britain Quality Assurance). There are also several significant producers not covered by assurance schemes.

## **10. Devolution**

10.1 This IA covers the costs and benefits to the UK. However the Eggs and Chicks Regulations 2009 will apply to England only. Parallel national legislation will be introduced by the Devolved Administrations.

## **11. Risk Assessment**

11.1 The immediate risk is that the failure to bring updated Eggs and Chicks Regulations into force could reduce the flexibility and cost effectiveness of the implementation and enforcement of the NCP. Without these powers government would face a greater challenge in achieving the overarching objective of the European legislation to reduce

or maintain the low prevalence of *Salmonella* serovars of major human health significance in laying flocks of domestic fowl in Member States and could face infraction proceedings. Non-compliance would also reduce government and industry ability to ensure that *Salmonella* does not spread to the wider food chain with subsequent adverse effects on human health. This would be a breach of community obligations and a failure to meet EU standards on health. Failure to have adequate enforcement tools and sanctions to deal with non-compliance would potentially disadvantage farmers who comply with the law and who could be under-cut by other less scrupulous producers.

## 12. Options

### 12.1 Option 1: Do nothing

12.1.1 The first option was to use existing legislative arrangements, namely the Zoonoses Order 1989. Defra would have the authority to serve a Restriction Notice on flocks where *Salmonella* is detected or suspected. Eggs from the flocks would then be licensed off the holding under a Movement Licence to be sent for rendering or a heat treatment plant on condition that each egg is marked as Class B. Section 29 of the Animal Health Act 1981 allows the Minister to designate any Zoonotic disease as being covered by any provisions of the 1981 Act. Article 4 of this Order designates *Salmonella* for the purposes of all the sections listed in Schedule 1 to the Order and Schedule 1 includes Section 64. This section, at (1), says “An inspector of the Ministry and, if so authorised by an order of the Minister, an inspector of a local authority, may at any time enter any pen, shed, land or other place in which he has reasonable grounds for supposing that poultry are or have been kept, for the purpose of ascertaining whether disease exists or has existed in or on them”.

12.1.2 The Zoonoses Order has been effective in enforcing the statutory controls on breeding flocks infected with *Salmonella*, but could prove to be unwieldy if it were the only enforcement instrument for the more extensive and varied laying flocks sector. It would require a higher degree of involvement from central government, in particular where the flock was not immediately depopulated and notices under the Zoonoses Order had to be monitored.

12.1.3 Another problem with this option is that it would not be possible under these arrangements to implement any direct sanctions on operators whose flocks are of unknown health status (i.e. holdings where there is no evidence that operator sampling is taking place). The only sanction available to the Competent Authority would be to send inspectors on to these holdings in order to actually perform the sampling or to place the flocks under restrictions under the Zoonoses Order. Although the cost of collecting and testing the sample could be recovered under The Zoonoses and Animal-By Products (Fees) (England) Regulations 2009 this would place a burden on Animal Health resources (i.e. providing and training additional staff) which would need to be taken away from other work and which would not be recoverable under the Fees Regulations.

In practice under this option the following steps would be taken to enforce the NCP (see Annex 3 for a comparison of the steps that would be taken under each option).

#### ***Holdings of unknown status***

As noted above these are holdings where the operator is not complying with the sampling requirements.

- 1) Inform producer of infringement (this would be most likely through a technical inspection report or warning letter). Warn that continued unknown health status will result in immediate restrictions on flocks and that AHO or EMI within specified period will require evidence of compliance.
- 2) Visit holding to check compliance if evidence of sampling is not forthcoming.
- 3) If an operator is non-compliant then conduct sampling under the Zoonoses Order and/or use Order to place flocks under restriction until a negative result has been confirmed (ZO5 notice). If positive then the restrictions on the eggs will remain in force on the flock).
- 4) Visit holding at a later date to check compliance.

### ***Holdings which are positive for Salmonella Enteritidis or Typhimurium***

- 1) Inform producer of positive status and issue of Restriction Notice requiring that eggs should be marked as Class B.
- 2) Serve Restriction Notice on premises requiring that eggs are moved off the premises only as Class B.
- 3) Visit holding to check compliance (on risk basis).
- 4) If non-compliant send notification letter.
- 5) If non-compliance continues begin prosecution proceedings.

## **12.2 Option 2: Introduce a system of variable monetary penalties with the possibility of a criminal offence penalty**

12.2.1 This option requires the amendment of the Eggs and Chicks Regulations so that controls on infected eggs can be enforced by Animal Health. Animal Health officers are on-farm on a regular basis and are the most qualified and well-placed officials to ensure that operators comply with the new controls and to decide which enforcement option would be most effective. This option puts in place a comprehensive system of financial administrative penalties (i.e. penalty notices) which should in many cases avoid the need for criminal sanctions, while having these available as a last resort.

12.2.2 The Eggs and Chicks Regulations give local enforcement authorities a flexible portfolio of sanctions which can be applied according to the circumstances of the contravention. This is in line with current regulatory thinking which aims to make a range of civil penalties available as an alternative to criminal sanctions. By keeping enforcement at local level it will mean that enforcement measures can be taken by Animal Health. This might for instance be a warning letter, a monetary penalty notice or prosecution. It would give the Competent Authority flexibility to deal proportionately with less serious offences where placing the holding under immediate restrictions might seem to be an overreaction: such as operators who fail to sample according to the proscribed schedule.

The penalty level ranges from £100 to £4,500 and will be determined by a number of factors, for example:

- (a) the history of non-compliance of the operator;
- (b) the financial gain made by the operator as a result of the non-compliance;

- (c) the seriousness of the non-compliance;
- (d) evidence of intention behind the non-compliance;
- (e) financial harm to competitors.

The enforcement authority will provide guidance to the industry about how, in an ordinary case, it intends to apply the penalties and which sets out the arrangements to operators.

The power to issue a penalty notice will not normally exist in relation to offences for obstruction, failure to comply with requirements made by authorized officers, or assaults and threats to them. These will be referred for prosecution. To reduce re-offending and encourage compliance, we are proposing that no more than two penalty notices will be issued for a similar category of offence within a 2-year period. A further offence within the same category would lead to automatic referral for prosecution, depending on the circumstances of the case.

In summary the availability of penalty notices has the following benefits:

- reduce uncertainties over action taken in response to infringements of the NCP by having a clear guidance to the range of penalties; and how they will be calculated;
- provide a consistent approach for dealing with infringements;
- a quicker and more responsive system to encourage compliance; and
- reduce the administrative burden on industry and government.

Annex 2 sets out the powers of the Eggs and Chicks Regulations 2009 in detail.

This is Defra's preferred option as monetary penalties are expected to be a quicker and more effective means of deterring non-compliance compared to one primarily based on criminal prosecutions. Although there could be circumstances where the Zoonoses Order was used (for instance when it was necessary to restrict the movement of eggs from a positive flock) these would be less frequent than under option 1. Instead the NCP will be enforced administratively which should largely avoid the need for inspectors to collect samples from non-compliant holdings and for the extensive use of Restriction Notices.

In practice under option 2 the following measures are likely to be taken when an operator fails to comply with the NCP. Under this option it is possible to continue to serve fines if an operator continues to infringe the NCP.

### ***Holdings of unknown status***

- 1) Inform producer of infringement (this would be most likely through a technical inspection report or warning letter). Warn that continued unknown health status will result in restrictions on eggs and that Animal Health will require evidence of compliance within a specified period.
- 2) Visit holding to check compliance if evidence not forthcoming.
  - 1) If non-compliant serve compliance notice under the Eggs and Chicks Regulations 2009 requiring eggs to be marked as Class B until sampling confirms negative result.

- 2) If non-compliance continues notify operator that sampling must commence or face possibility of financial penalties within specified period.
- 3) If operator still non-compliant issue penalty notice.

Under option 2 the Zoonoses Order will remain in force. There could still be circumstances where the Competent Authority would use the Order to collect samples on the operator's behalf – in particular if eggs were being sent from the holding for human consumption.

***Holdings which are positive for SE or ST***

- 1) Inform producer of positive status and issue notification requiring that eggs should be marked as Class B.
- 2) Serve Restriction Notice of infection on premises. Eggs to be moved off the holding only under a Movement Licence as Class B.
- 1) If non-compliant (i.e. operator continuing to send eggs for human consumption) issue penalty notice.
- 2) Further visit to holding to check compliance

**12.3 Option 3: Criminal offence penalty but no monetary penalties**

12.3.1 Under this option inspectors operating under the Eggs and Chicks Regulations 2009 would, as under option 2, have recourse to stop notices, seizure notices and compliance requirements. However they would not have the power to impose monetary penalties.

12.3.2 Option 3 would have many of the advantages of option 2 by giving local enforcement agencies discretion to deal with infringement according to the circumstances of the case whilst ensuring officers have sufficient guidance on the application of these sanctions to ensure consistency. However the absence of monetary penalties would mean that action taken against non-compliant operators would be intensive, involving entry and inspections of farm holdings and significant monitoring to gather evidence for prosecution.

***Holdings of unknown status***

- 1) Inform producer of infringement (this would be most likely through a technical inspection report or warning letter). Warn that continued unknown health status will result in restrictions on eggs and that Animal Health will require evidence of compliance within a specified period.
- 2) Visit holding to check compliance if evidence of sampling is not forthcoming.
- 3) Serve compliance notice under the Eggs and Chicks Regulations 2009 requiring eggs to be marked as Class B until sampling confirms negative result.
- 4) If non-compliance continues notify operator that sampling must commence or face possibility of prosecution under the Eggs and Chicks Regulations 2009 within specified period.
- 5) If operator still non-compliant begin prosecution proceedings.

As under option 2 the Zoonoses Order would remain in force and could be used to collect samples on the operator's behalf.

### ***Holdings which are positive for SE or ST***

- 1) Inform producer of positive status and issue of Restriction Notice requiring that eggs should be marked as Class B.
- 2) Serve Restriction Notice of infection on premises. Eggs to be moved off the holding only under a Movement Licence as Class B.
- 3) If non-compliance continues prosecute under the Eggs and Chicks Regulations 2009.

## **13. Benefits and Costs**

13.1 The costs of the sanctions to producers (whether action under the Zoonoses Order, penalty notices or criminal proceedings) will apply to producers who fail to meet the requirements of the NCP or refuse to comply with the controls on eggs. As previously stated enforcement officials would not seek to impose sanctions on producers without giving them notice of any action which could be taken if they fail to comply. Government will also incur costs. It is likely that these will vary according to how effectively the controls on eggs are enforced. Option 1 whereby the controls would be enforced through existing actions is likely to be the most expensive. Under options 2 and 3 enforcement would be more flexible and cost-effective.

13.2 The human health benefits of the layers NCP have been covered in the Impact Assessment for laying flocks. It follows that these benefits cannot be realised unless the NCP is properly enforced. However the majority of producers will stand to benefit by legislation which prevents a small number of producers undercutting their costs and potentially damaging the reputation of their industry by failing to comply with the legislation.

### **13.3 Shared Costs**

13.3.1 Although the costs applicable to each policy option differ, they share some of the same costs. These relate to Egg Marketing as well as training for government officials in the enforcement of the layers NCP. Training is a one-off cost which at this stage can only be an approximation. We are assuming it will be 6 hours for 20 individuals at about £50 per hour i.e. £6,000.

13.3.2 As mentioned above, all eggs from holdings where *Salmonella* is suspected will have to be marked before being placed on the market. The cost of marking infected eggs is therefore common to all three policy options. It was assumed that all infected holdings will eventually incur this cost (i.e. all cases of non-compliance would eventually be resolved).

13.3.3 The costs of using the following three alternative eggs marking techniques were considered:

- (i) Using an inkjet printer. These are generally suited to operating above a single line of eggs on in-feed to a grader. Producers will generally not have this kind of equipment available if they do not pack eggs as well. The approximate annual

cost for an 'average' inkjet printer is about £2,650 (including the printer, ink and servicing), i.e. about £50 per week. This represents the average rental charge.

- (ii) Using a hand-held professionally made 30-egg Class B (or spot) marking kit. These can stamp mechanically all 30 eggs on one tray at the same time. The rental charge is a maximum of £100 per week. Annual costs are therefore approximately £5,200 per annum per farm (max).
- (iii) Using a hand-held or semi-automatic 6-egg spot marking kit. These can be made by anyone using food-grade marker pens. It costs a maximum of £25 to make (fixed cost) and the ongoing cost is that of new pens as required (£7.50 for 6 pens)<sup>1</sup>. This kind of kit can either be used for automatic marking (by fitting above farm packer on production sites to automatically mark all eggs passing through on trays) or for hand-held marking (drawing by hand across trays of eggs at any point after farm-packing).

13.4 In order to estimate the labour cost, it was assumed that a farm worker would take 5 seconds to mark each tray of eggs (30 eggs in one tray). The cost of farm worker time (including 30% overheads) is about £9.1 per hour. The cost per tray is therefore 1.26p and the cost per egg 0.042p.

13.5 The number of eggs that would have to be marked was calculated by size of holding, as *Salmonella* prevalence rates vary widely by size of holding. Table 2 shows the total number of holdings, number of laying hens and baseline *Salmonella* prevalence rate in each size category. *Salmonella* prevalence in 2010/11 was assumed to reduce by 10% compared to 2009/10 levels.

13.6 The number of infected holdings in each year was calculated using the relevant prevalence rates. It was assumed that about 65% of laying hens on an infected holding would be infected (based on research conducted by the VLA in 2008) and that all the eggs produced by these hens would have to be marked. It was assumed that holdings with infected flocks would choose to cull them as soon as possible, but that it would take 10 days to obtain a spot in a slaughterhouse for this purpose. This assumption is based on the fact that that not economically viable to continue production as returns/profits from heat treated eggs are less than the cost of feeding and housing an affected flock. Therefore, egg production by infected layers to be marked was calculated for a period of 10 days only.

The cost of marking eggs is the same across all three policy options considered.

**Table 2. Production of *Salmonella* infected eggs**

Number of birds	500-999	1,000-2,999	3,000-4,999	5,000-9,999	10,000-29,999	>30,000
Total holdings	186	277	178	305	294	148
Total layers	134,627	540,177	734,557	2,205,877	4,934,931	20,611,146
Baseline <i>Salmonella</i> prevalence rate*	8.0%	3.2%	3.6%	3.0%	6.0%	28.2%
<b>Infected egg production in 2009/10</b>						
Infected holdings	15	9	6	9	18	42

<sup>1</sup> It was assumed that new pens would not be required as infected eggs would only be marked for 10 days before the infected flocks were culled.

Number of birds	500-999	1,000-2,999	3,000-4,999	5,000-9,999	10,000-29,999	>30,000
Infected layers	7,057	11,408	16,094	42,309	196,390	3,801,921
Infected eggs	53,556	86,889	122,581	322,247	1,495,793	28,957,096
<b>Infected egg production in 2010/11</b>						
Infected holdings	13	8	6	8	16	38
Infected layers	6,116	10,141	16,094	37,608	174,569	3,439,833
Infected eggs	46,415	77,235	122,581	286,442	1,329,594	26,199,277

\* As estimated in VLA report on 2004/5 survey of layer flocks

The costs of egg marketing are therefore shown below:

Egg marking costs	2009/10	2010/11	Additional Explanation
Number of infected holdings	99	89	10% reduction in infection in 2010/11
Average egg marking equipment cost - inkjet	£100	£100	2*1 week
Total egg marking equipment cost - inkjet	£9,900	£8,900	
Average egg marking equipment cost - inkjet	£200	£200	2*1 week
Total egg marking equipment cost - inkjet	£19,800	£17,800	
Average egg marking equipment cost - inkjet	£25	£25	No running cost: initial set of pens will last two weeks
Total egg marking equipment cost - inkjet	£2,475	£2,225	
Number of infected eggs	31,038,162	28,061,544	From table 2 above
Labour cost per egg (p)	0.042	0.042	
Total labour cost	£13,076	£11,822	
<b>Total cost max</b>	<b>£32,876</b>	<b>£29,622</b>	
<b>Total cost min</b>	<b>£15,551</b>	<b>£14,047</b>	

### 13.7 Option 1: Do nothing – reliance on current legislation (Zoonoses Order 1989)

13.7.1 It would be potentially difficult to catch holdings of “unknown health status”. It would mean that the NCP would be heavily centrally managed, in particular through serving Restriction Notices. The only sanction available to the Competent Authority to deal with holdings of unknown health status would be to send inspectors onto holdings to perform the sampling or placing the eggs under restrictions.

13.7.2 There would however be a greater cost of a system which would require a high degree of central management to serve notices under the Zoonoses Order; and a more frequent presence on farms from Animal Health to bring holdings of “unknown health status” into the scheme. Although official control samples would be collected at full cost recovery greater resources would need to be provided by Animal Health for the duration of the NCP. This approach would be feasible in the short term but would place a high burden on Defra as well as the enforcement authority. Furthermore this option would fail to link *Salmonella* controls to the marketing of eggs legislation. This would reduce the opportunity for the NCP to become self-enforcing through raising the awareness of the obligation on egg packing station operators only to accept eggs from holdings which are in compliance. It would also fail to share the responsibility for compliance between government and industry.

#### **CA sampling on holdings of unknown health status**

13.7.3 In the absence of an alternative sanction, holdings of unknown health status will have to be sampled by the CA under this policy option. We would expect powers under the

Zoonoses Order to be used. It was assumed that all flocks on the holding would be sampled on one occasion per year and that, on average, there are four flocks per holding.

It is difficult to predict exactly how many holdings will be found to be of unknown health status, but it was assumed here that there will be 100 such holdings in 2009/10 and 50 such holdings in 2010/11.

The costs of sampling were estimated to be £15 per sample for laboratory testing (one pooled sample required from each flock), 2 hours of operator time per holding (to organise and collate farm records - £21.1 per hour for owner/manager time including 30% overheads), £1.50 for equipment to collect samples (assume two sets required per flock), and a total of £170 for Animal Health time. This implies a sampling cost of about £284 per holding.

These costs will be recovered from operators under the Fees Regulations. As already stated, whilst this should cover the cost of sampling visits, it is a labour intensive approach which would have resource implications for AH that could not be covered by the Fees Regulations. The total costs from CA sampling are therefore estimated to be £28.4k (£284 \* 100) in 2009/10 and £14.2k (£284 \* 50) in 2010/11.

### ***Serving Restriction notices on premises***

13.7.4 Restriction notices will be served on all premises with infected flocks prohibiting the movement of eggs unless treated as Class B. Recent evidence suggests that there will be about 100 positive flocks in 2009/10 and about 90 such flocks in 2010/11.

It is assumed that Animal Health officers would take about 4 hours to prepare notices per flock and 2 hours to travel to/from the premises in order to notify the producer. The cost of Animal Health officer time is £50/hour. Hence costs to the CA from serving notices are estimated to be £30,000 in 2009/10 and £27,000 in 2010/11.

There is an administrative burden associated with notification as owners or managers of holdings will have to accompany officers when they visit the holding. It was assumed that officers will spend about 15 minutes on-site per holding. The cost of owner/manager time was estimated to be about £21.1/hour (including 30% overheads). The costs to industry from the CA serving notices are therefore estimated to be £528 in 2009/10 and £475 in 2010/11.

### ***Monitoring compliance with Restriction Notices***

13.7.5 All infected holdings will be inspected in order to ensure compliance with Restriction Notices. It was assumed that an average of 6 compliance inspections will be conducted on each holding during a 2-3 week period (say 3 inspections in the first week, 2 inspections in the second week, and one inspection in the third week). Inspectors will take 2 hours to travel to/from holdings for each inspection.

The time taken per inspection will depend on whether or not the holding is compliant. It was assumed that 75% of holdings (75 holdings in 2009/10 and 68 holdings in 2010/11) will be fully compliant with Restriction Notices. In such cases each inspection should take no more than 15 minutes. For holdings where non-compliance is suspected/detected, Animal Health officers may take about 30 minutes per inspection to check acceptable marking etc. It was assumed that 75% of the non-compliance cases (19 holdings in 2009/10 and 17 holdings in 2010/11) would be effectively dealt with in this way. The remaining 25% of non-compliant holdings (6 holdings in 2009/10

and 5 holdings in 2010/11) represent cases of serious non-compliance and it was assumed that 45 minutes would be required per inspection on these holdings.

Monitoring compliance is therefore estimated to cost £69.8k in 2009/2010 and £62.8k in 2010/11:

- Compliant holdings:
  - o 2009/10: 75 holdings \* 6 inspections \* [time taken to complete inspections (15 mins) + 2 hours travel time] \* CA cost per hour (£50) = £50.6k
  - o 2010/11: 68 \* 6 \* 2.25 \* £50 = £45.9k
- Non-compliant holdings – non-serious:
  - o 2009/10: 19 holdings \* 6 inspections \* [time taken to complete inspections (30 mins) + 2 hours travel time] \* CA cost per hour (£50) = £14.3k
  - o 2010/11: 17 \* 6 \* 2.5 \* £50 = £12.8k
- Non-compliant holdings – serious:
  - o 2009/2010: 6 holdings \* 6 inspections \* [time taken to complete inspections (45 mins) + 2 hours travel time] \* CA cost per hour (£50) = £5.0k
  - o 2010/11: 5 \* 6 \* 2.75 \* £50 = £4.1k

There is also an administrative burden relating to monitoring compliance. This is based on a farm manager / owner accompanying the CA authority during monitoring checks. The cost of owner/manager time was estimated to be about £21.1/hour (including 30% overheads). This cost is estimated to be £4.1k in 2009/10 and £3.7k in 2010/11:

- Compliant holdings:
  - o 2009/10: 75 holdings \* 6 inspections \* time taken to complete inspections (15 mins) \* Farm manager time cost (£21.1) = £2.4k
  - o 2010/11: 68 \* 6 \* 0.25 \* £21.1 = £2.2k
- Non-compliant holdings – non-serious:
  - o 2009/10: 19 holdings \* 6 inspections \* time taken to complete inspections (30 mins) \* Farm manager time cost (£21.1) = £1.2k
  - o 2010/11: 17 \* 6 \* 0.5 \* £21.1 = £1.1k
- Non-compliant holdings – serious:
  - o 2009/2010: 6 holdings \* 6 inspections \* time taken to complete inspections (45 mins) \* Farm manager time cost (£21.1) = £570
  - o 2010/11: 5 \* 6 \* 0.75 \* £21.1 = £475

### ***Prosecuting non-compliant holdings***

13.7.6 It was assumed that all the serious non-compliance cases would have to be prosecuted (6 holdings in 2009/10 and 5 holdings in 2010/11). It is expected that Animal Health officers would have to spend about 20 hours on each case at a cost of £50/hour, investigation officers would have to spend 14 days at a cost of about £167/day, and government lawyers would have to spend 4 days on each case at a cost of £220/day. It has not been possible to estimate the costs to holdings at this stage, e.g. legal fees, cost of time spent on dealing with the case etc.

The cost to the CA has therefore been estimated to cost £25k in 2009/10 and £21k in 2010/11:

- 2009/10:
  - o AH officer time cost = 20 \* £50 \* 6 = £6k
  - o Investigation officer time cost = 14 \* £167 \* 6 = £14k
  - o Government lawyer time cost = 4 \* £220 \* 6 = £5.3k

- 2010/11:
  - o AH officer time cost =  $20 * £50 * 5 = £5k$
  - o Investigation officer time cost =  $14 * £167 * 5 = £11.7k$
  - o Government lawyer time cost =  $4 * £220 * 5 = £4.4k$

**Table 3. Annual costs of option 1**

Category	2009/10 cost	2010/11 cost
CA sampling on holdings of unknown health status <sup>2</sup>	£28,420	£14,210
Serving Restriction Notices on all infected holdings		
<i>Annual cost to government</i>	£30,000	£27,000
<i>Annual admin burden to holdings</i>	£528	£475
Monitoring compliance with ZO2 notices		
<i>Annual cost to government</i>	£69,825	£62,775
<i>Annual admin burden to holdings</i>	£4,146	£3,703
Prosecuting non-compliant holdings	£25,308	£21,090
<i>Annual admin burden to holdings</i>	TBC	TBC
Cost of marking eggs	£15,551 to £32,876	£14,047 to £29,622
<b>Total annual cost</b>	<b>£173,778 to £191,103</b>	<b>£143,300 to £158,875</b>

### 13.8 Option 2: Introduce a system of variable monetary penalties with the possibility of a criminal offence penalty

13.8.1 As previously mentioned the benefit of this option is to introduce a flexible and cost effective enforcement system. By directly linking in the eyes of industry compliance with the *Salmonella* controls in the NCP to the marketing of eggs as Class A it will enable the NCP to become as far as possible self enforcing: packers and retailers will be more aware not to accept eggs from holdings which are not compliant. This approach also resonates with government policy on cost and responsibility sharing: the controls become part of the layer sectors operating procedures instead a requirement that requires frequent auditing and monitoring from government. By providing for financial penalties an alternative sanction is available to Animal Health apart from criminal prosecution.

#### ***Animal Health to notify all holdings of infected and unknown health status***

13.8.2 Animal Health officers will notify all infected holdings or holdings of unknown health status that they must mark their eggs as Class B. It is estimated that Animal Health officers would spend 1.5 hours on-site and 2 hours of travel time per holding in order to notify them.

Based on 200 holdings being notified in 2009/10 and 140 holdings being notified in 2010/11, the costs of EMI notification is estimated to be £17.5k and £15.8k respectively

- $£35k = 200 \text{ holdings} * 3.5 \text{ hours of EMI time} * £50 \text{ per hour}$
- $£24.5k = 140 * 3.5 * £50$

The admin burden, based on 1.5 hours of on-site visit, at £21.1 per hour at 200 holdings is estimated to be £6.3k in 2009/10. The commensurate cost in 2011/12 based on 140 holdings is estimated to be £4.4k.

<sup>2</sup> The cost of visiting and collecting samples from these holdings should be partially offset by the Fees Regulations.

### ***Operator sampling at holdings of unknown health status***

13.8.3 It assumed that, once notified, (most) most holdings of unknown health status would agree to begin sampling. The costs of operator sampling are similar to the costs of CA sampling described in option 1 above, with the exception of Animal Health costs as there is no Animal Health involvement in this case. The costs per visit are therefore estimated to be £114 [£284 - £170 (AH involvement cost)].

Based on there being 100 holdings of unknown status in 2009/10 and 50 holdings being of unknown status in 2010/11, the costs of EMI notification is estimated to be £11.4k and £5.7k respectively.

- £11.4k = £114 \* 100 holdings
- £5.7k = 50 \* £114

### ***Monitoring non-compliant holdings***

13.8.4 As for option 1, there were assumed to be about 100 infected flocks in 2009/10 and about 90 infected flocks in 2010/11. It was assumed that 90% of operators would comply after the initial notification visit and take their eggs off the market. The remaining 10% (representing 10 holdings in 2009/10 and 9 holdings in 2010/11) would require further monitoring or other activity to ensure compliance. It was assumed that these non-compliant holdings would be visited again and that Animal Health officers would be required to spend 2 hours on-site (plus 2 hours travel time as before).

Monitoring compliance is therefore estimated to cost £2k in 2009/2010 and £1.8k in 2010/11:

- Non-compliant holdings:
  - o 2009/10: 10 holdings \* [time taken to complete inspections (2 hours) + 2 hours travel time] \* CA cost per hour (£50) = £2k
  - o 2010/11: 9 \* 4 \* £50 = £1.8k

There is also an administrative burden relating to monitoring compliance. This is based on a farm manager / owner accompanying the CA authority during monitoring checks. The cost of owner/manager time was estimated to be about £21.1/hour (including 30% overheads). This cost is estimated to be £422 in 2009/10 and £380 in 2010/11:

- Non-compliant holdings:
  - o 2009/10: 10 holdings \* time taken to complete inspections (2 hours) \* Farm manager time cost (£21.1) = £422
  - o 2010/11: 9 \* 2 \* £21.1 = £380

### ***Penalties on non-compliant holdings***

13.8.5 It was assumed that 75% of the non-compliance cases would be resolved after the second visit. The remaining 25% (representing 3 holdings in 2009/10 and 2 holdings in 2010/11) will be subject to monetary penalties. The level of a fine can range from £100 to £4,500. The number of factors involved in assessing the amount of the penalty mean it is difficult to produce an average estimate. For the purposes of this Impact Assessment it is therefore assumed that non-compliant holdings will be subject to an average fine of £2,500.

The cost of penalties are therefore estimated to be £7.5k in 2009/10 (3 \* £2,500) and £5k in 2010/11 (2 \* £2,500).

## **Prosecuting non-compliant holdings**

13.8.6 It was assumed that 50% of the serious non-compliance cases would have to be prosecuted (2 holdings in 2009/10 and 1 holding in 2010/11). The lower rate of prosecution under this option reflects the belief that monetary penalties will encourage a higher rate of compliance than the threat of prosecution alone. Prosecution costs for this option were assumed to be similar to those for option 1<sup>3</sup>.

Therefore the costs of prosecution are estimated to be £8.4k in 2009/10 and £4.2k in 2010/11.

- 2009/10:
  - o AH officer time cost = 20 \* £50 \* 2 = £2k
  - o Investigation officer time cost = 14 \* £167 \* 2 = £4.7k
  - o Government lawyer time cost = 4 \* £220 \* 2 = £1.8k
- 2010/11:
  - o AH officer time cost = 20 \* £50 \* 1 = £1k
  - o Investigation officer time cost = 14 \* £167 \* 1 = £2.3k
  - o Government lawyer time cost = 4 \* £220 \* 1 = £880

**Table 4. Annual costs of option 2**

Category	2009/10 cost	2010/11 cost
Notifying all holdings of infected and unknown health status		
<i>Annual cost of EMI notification</i>	£35,000	£24,500
<i>Annual admin burden to holdings of notification</i>	£6,330	£4,431
Operator sampling on holdings of unknown health status	£11,420	£5,710
Monitoring non-compliant holdings		
<i>Annual cost of monitoring all non-compliant holdings</i>	£2,000	£1,800
<i>Annual admin burden to non-compliant holdings of monitoring</i>	£422	£380
Fines on non-compliant holdings	£7,500	£5,000
Prosecuting non-compliant holdings	£8,436	£4,218
Cost of marking eggs	£15,551 to £32,876	£14,047 to £29,622
<b>Total annual cost</b>	<b>£86,659 to £103,984</b>	<b>£60,086 to £75,661</b>

## **13.9 Option 3: Criminal offence penalty only**

13.9.1 By linking the NCP monitoring and controls to the marketing of eggs this will have the advantages of option 2. However the absence of financial penalties will mean that Animal Health will have a less flexible range of sanctions under the Eggs and Chicks Regulations 2009. Taking cases to a Magistrates court will only be a final sanction and costs will be recovered through a successful prosecution. However, the requirements of a criminal prosecution demand extensive staff time which cannot be recovered. Under this option criminal prosecution would only be the only available ultimate sanction available to Animal Health.

The costs of this option are explained in the following sections and listed in Table 4.

### ***Animal Health to notify all holdings of infected and unknown health status***

<sup>3</sup> This is likely to lead to over-estimation of the costs of option 2. In reality, prosecution costs are likely to be higher under option 1 whereby operators can only be prosecuted under the AH Act, requiring more evidence to be collected.

13.9.2 The cost of this is the same as in option 2.

### ***Operator sampling at holdings of unknown health status***

13.9.3 As in option 2, it was assumed here that, once notified, all holdings of unknown health status would agree to begin sampling.

### ***Monitoring non-compliant holdings***

13.9.4 This option is similar to option 2 in that non-compliant holdings will be visited and monitored by the Animal Health officer. However, without monetary penalties, there may be a higher rate of non-compliance than in option 2, as some producers might be more willing to risk criminal prosecution on the grounds that Animal Health would be reluctant to risk the expense and time of a prosecution. It was therefore assumed that only 50% (as opposed to 90% in option 2) of the notified holdings would comply after the initial visit. The remaining 50% (50 holdings in 2009/10 and 45 holdings in 2010/11) will require further monitoring or other activity to ensure compliance. It was assumed that these non-compliant holdings will be visited again and that Animal Health officers will be required to spend 2 hours on-site (plus 2 hours travel time as before).

Monitoring compliance is therefore estimated to cost £10k in 2009/2010 and £9k in 2010/11:

- Non-compliant holdings:
  - o 2009/10: 50 holdings \* [time taken to complete inspections (2 hours) + 2 hours travel time] \* CA cost per hour (£50) = £10k
  - o 2010/11: 45 \* 4 \* £50 = £9k

There is also an administrative burden relating to monitoring compliance. This is based on a farm manager / owner accompanying the CA authority during monitoring checks. The cost of owner/manager time was estimated to be about £21.1/hour (including 30% overheads). This cost is estimated to be £422 in 2009/10 and £380 in 2010/11:

- Non-compliant holdings:
  - o 2009/10: 50 holdings \* time taken to complete inspections (2 hours) \* Farm manager time cost (£21.1) = £2.1k
  - o 2010/11: 45 \* 2 \* £21.1 = £1.9k

### ***Prosecuting non-compliant holdings***

13.9.5 It was assumed that 50% of the non-compliance cases would be resolved after the second visit, but the remaining would still not comply. Under this option, the only way to resolve serious non-compliance is through the threat of prosecution, as there is no recourse to monetary penalties. It was assumed that 50% of the serious non-compliance cases would be prosecuted (13 holdings in 2009/10 and 12 holdings in 2010/11).

Therefore the costs of prosecution are estimated to be £54.8k in 2009/10 and £50.6k in 2010/11.

- 2009/10:
  - o AH officer time cost = 20 \* £50 \* 13 = £13k
  - o Investigation officer time cost = 14 \* £167 \* 13 = £30.4k
  - o Government lawyer time cost = 4 \* £220 \* 13 = £11.4k
- 2010/11:
  - o AH officer time cost = 20 \* £50 \* 12 = £12k

- Investigation officer time cost = 14 \* £167 \* 12 = £28.1k
- Government lawyer time cost = 4 \* £220 \* 12 = £10.6k

**Table 5. Annual costs of option 3**

Category	2009/10 cost	2010/11 cost
Notifying all holdings of infected and unknown health status		
Annual cost of EMI notification	£35,000	£24,500
Annual admin burden to holdings of notification	£6,330	£4,431
Operator sampling on holdings of unknown health status	£11,420	£5,710
Monitoring non-compliant holdings		
Annual cost of monitoring all non-compliant holdings	£10,000	£9,000
Annual admin burden to non-compliant holdings of monitoring	£2,110	£1,899
Prosecuting non-compliant holdings	£54,834	£50,616
Cost of marking eggs	£15,551 to £32,876	£14,047 to £29,622
<b>Total annual cost</b>	<b>£135,245 to £152,570</b>	<b>£110,203 to £125,778</b>

### 13.10 Benefits

13.10.1 The *Salmonella* NCP in laying flocks was established in order to reduce *Salmonella* prevalence in laying hens and the aim of the proposed legislation is the effective enforcement of *Salmonella* controls in laying flocks. *Salmonella* is an important zoonotic pathogen that can lead to disease in human beings. Human salmonellosis cases are usually characterised by fever, abdominal pain, nausea and sometimes vomiting. Symptoms are often mild and most infections only last a few days. However, sometimes the infection can be more serious and even fatal. The disease can also give rise to long-term or chronic conditions such as reactive arthritis. Salmonellosis can therefore impose a significant economic cost, including the cost of medical treatment, possible fatalities, lost work days, and the pain and suffering of affected persons.

13.10.2 The Impact Assessment of the *Salmonella* NCP in laying flocks estimated that the human health benefit of the *Salmonella* controls in laying flocks was about £15.4 m per annum, stemming from reductions in the number of infected eggs entering the food chain. These benefits will not be realised if the controls are not properly enforced through the proposed legislation.

13.10.3 The implementation and proper enforcement of the *Salmonella* controls in laying hens also helps protect the ability of UK egg producers to export their products to the EU. In 2006, UK egg producers exported eggs and egg products worth about £19m. If the controls are not properly enforced, there is a risk of restrictions on the EU trade in eggs which would result in a loss of value.

13.10.4 Effective enforcement would also reduce the possibility of some producers potentially damaging the reputation of the industry by failing to comply with the legislation. Failure to comply with the *Salmonella* controls would also put the UK at risk of infraction proceedings.

### 14. Issues of equity and fairness

14.1 The main issue of equity and fairness this amendment to the Eggs and Chicks Regulations 2009 introduces is to ensure that the majority of poultry farmers who comply with the NCP are not harmed by producers who deliberately flout the law.

## **15. Competition Assessment**

15.1 See Annex 1.

## **16. Enforcement and Sanctions**

16.1 See Annex 2.

## **17. Implementation and delivery plan**

The consultation period for the Eggs and Chicks Regulations 2009 began on 13 March and ended on 24 April 09. The target date for the SI to become law is 14 September 2009.

## **18. Post Implementation Review**

The Zoonoses Regulation 2160/2003 includes an amendment clause under which certain provisions could be changed to take account of technical and scientific progress. It also requires that the progress made under the NCPs is assessed at the end of their 3-year life span. The effectiveness of enforcement will be one of the issues Defra will wish to consider.

## Specific Impact Tests: Checklist

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	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
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



## **Annex 1 - Outcome of Impact Tests not referred to in the Evidence Base**

### **Competition assessment**

The Eggs and Chicks Regulations 2009 implement EU requirements on the marketing of eggs which it is the duty of all Member States to enforce. This should ensure a level playing field for competition between EU producers.

It is not felt that these requirements will reduce the number or range of suppliers of layer flocks nor limit the ability of suppliers to compete with each other. Compliance with the Statutory Instrument's requirements will not limit firms' ability to choose the price, range, quality and location of their products. The measures will not impose additional costs on new entrants compared to incumbent firms. The UK industry is modern and efficient but is not characterised by rapid technological change.

The layer sector is dominated by a small number of large suppliers. However, it is not thought that the NCP would affect the ability of other firms to compete with them – all farms would have to comply with the legislation.

### **Small Firms Impact Test**

Almost all layer producers would be classified as a small business, as they employ fewer than 250 full time equivalent employees.

A key consideration in analysing the options has been to ensure that the enforcement of the controls on the marketing of eggs is fair and equitable to producers regardless of the size and profitability of their companies. In particular it has been our concern to ensure that producers who comply with the egg marketing requirements are not undercut by those in the industry who are less scrupulous.

### **Legal Aid**

The draft Regulations create new civil penalties for producers who fail to comply with the monitoring and controls required by the National Control Programme for laying flocks. The penalties are monetary. A producer who refused to pay a penalty would risk prosecution. A producer who faced prosecution in this circumstance would not usually be eligible for legal aid.

### **Sustainable Development**

The Regulations are in accordance with the shared UK principles of sustainable development.

### **Carbon Impact Assessment**

The NCP will have no significant effect on carbon emissions, as in the main the nature and scale of conventional layer production and marketing is likely to remain the same.

### **Other Environmental Issues**

As the nature of conventional layer production and marketing is likely to remain the same, the NCP has no implications in relation to climate change, waste management, landscapes, water and floods, habitat and wildlife or noise pollution.

## **Health Impact Assessment**

As explained earlier in the Impact Assessment one of the key objectives of this amendment of the Eggs and Chicks Regulations is to incorporate the controls on eggs from flocks which are positive for *Salmonella* Typhimurium or Enteritidis required by the National Control Programme for laying flocks. *Salmonella* is an important zoonotic pathogen that can lead to disease in human beings. Data from the European Food Safety Authority indicates that eggs are one of the potential primary sources of *Salmonella* infection. Benefits to human health should occur as a result of the efficient enforcement of the National Control Programme which is intended to reduce the level of *Salmonella* prevalence in layer flocks in the UK to a target set by EU Regulation 1168/2006.

## **Race /Disability/Gender**

The NCP does not introduce any questions of equity or fairness.

## **Human Rights**

The NCP is consistent with the Human Rights Act 1998.

## **Rural Proofing**

Although the majority of producers and many suppliers are based in rural areas the NCP will not have a negative effect on the rural community.

## Annex 2 - Scope and enforcement of the National Control Programme

1. The NCP states that any producers who are not exempted in Regulation 2160/2003 under Article 1.3 will be included in its requirements. This Article states that the legislation does not apply to producers who supply:
  - ...small quantities of primary products to the final consumer or to local retail establishments directly supplying the primary products to the final consumer.
2. When considering the threshold of the NCP we also took into account the 6th recital to Council Regulation 1907/90 on egg marketing standards. This paves the way for 'small quantities' of direct to consumer sales to be excluded from the scope of the standards:
  - Whereas the standards must be applicable to all hen eggs marketed on the territory of the Community; whereas it nonetheless seems advisable to exclude from the scope of their application certain forms of sale from producer to consumer where small quantities are involved;

Furthermore Article 3 of the Regulation states:

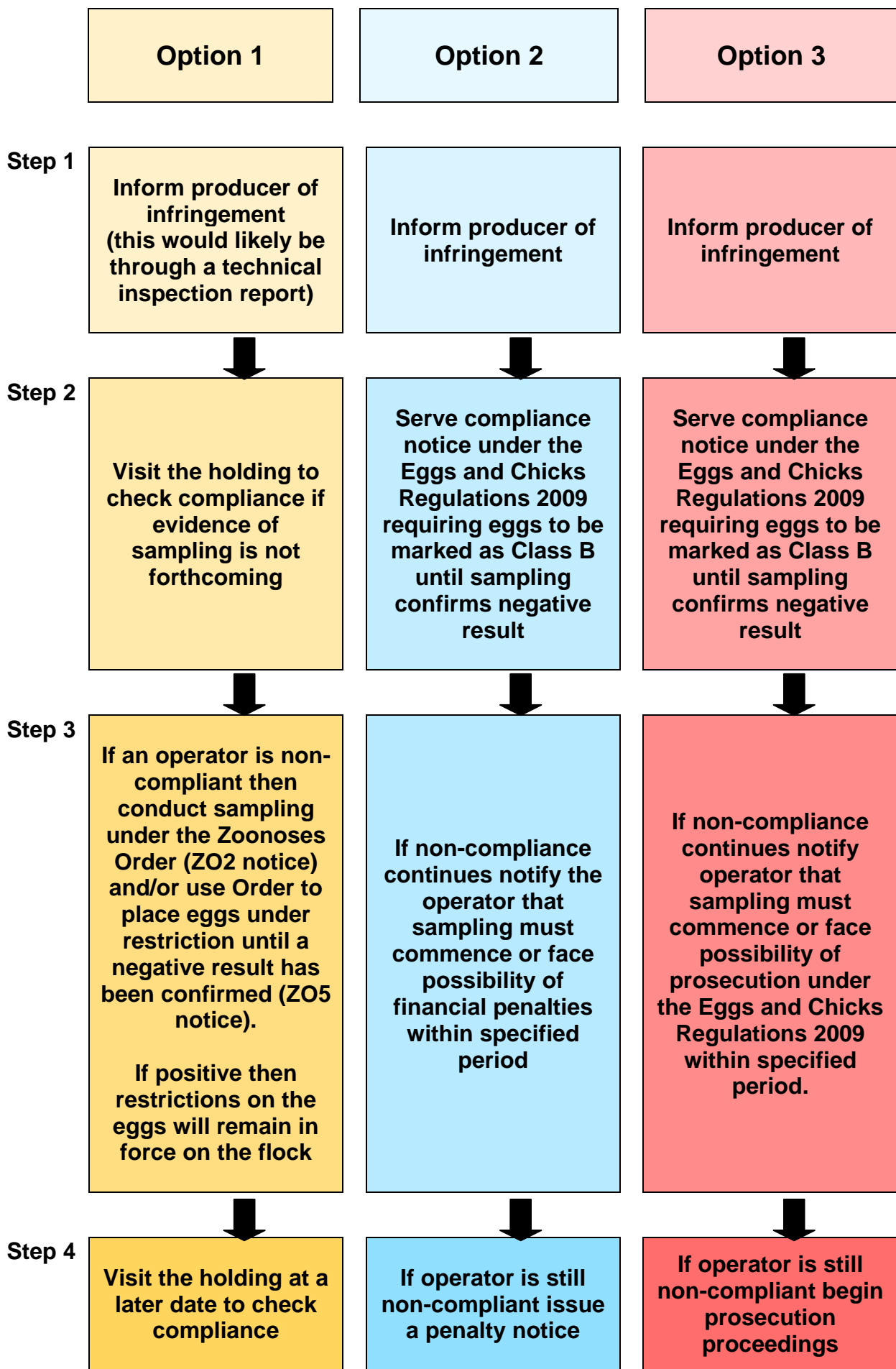
- 3. This Regulation shall not apply to:

eggs sold directly to the consumer for his own use, by the producer on his own farm, in a local public market with the exception of auction markets, or by door-to-door selling,
3. The farm census indicates that there are around 20,000 holdings which produce eggs for human consumption. Of these up to 3,000 holdings are known to regularly sell eggs either on farm, door to door, at markets or retail. Those that sell eggs at markets or retail are likely to fall within the scope of the NCP. This would include registered producers (possibly in the region of 350) which sell small quantities of graded eggs to local retail outlets.
  4. For government to attempt to audit the sampling and testing conducted by these producers annually would conflict with government policy on proportionality, be of limited public health benefit and result in a considerable burden on resources. Nor would it be necessary to meet the requirements of Regulation 2160/2003 or 1168/2006. Other considerations which have lead us to this decision are that:
    - Producers who sell eggs, door to door, on farm or limited quantities at farmers markets are unlikely to produce them in sufficient quantities to make a significant contribution to human levels of *Salmonella* (although depending on farm and egg handling hygiene and storage – may be a significant local problem).
    - The direct relationship between producers and the customer ensures traceability.
    - Such holdings were not included in the survey which set the reduction target and there would not be a baseline against which to monitor their progress.

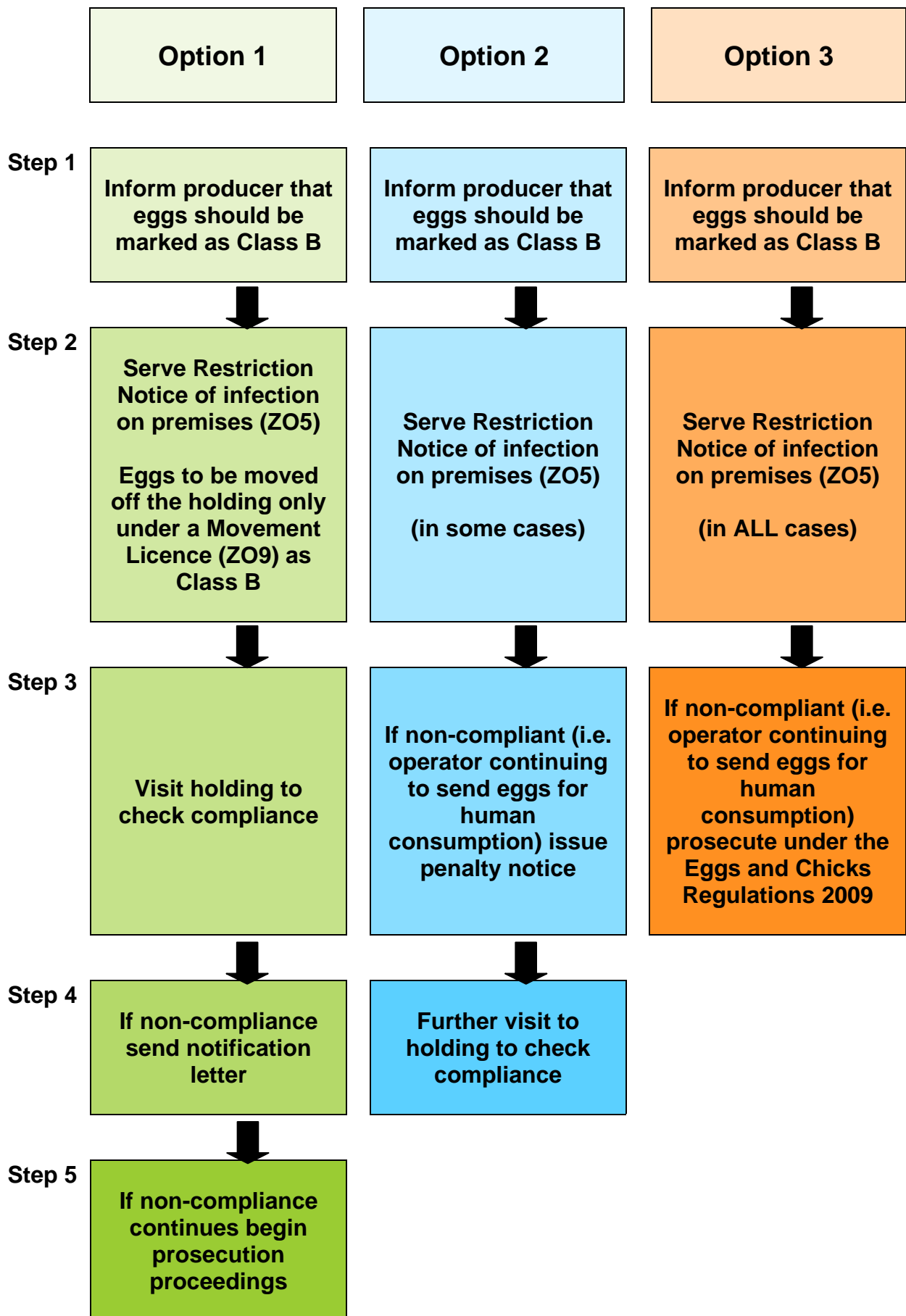
## Enforcement through Animal Health Agency

5. Under the Egg Marketing Regulations all eggs sold at retail must be graded. Egg Marketing Inspectors (EMI) visit all producers of eggs intended for sale as Class A on a regular basis (Quality Assurance Inspectors carry out this task in Northern Ireland) to check their procedures and grading machines. Consequently all flocks which have over 1,000 hens and which therefore meet the criteria for Competent Authority sampling will be eligible for annual visits under the Egg Marketing Regulations.
  
6. Defra officials have taken the view that concentrating resources on producers with 350 hens or more will enable us to cover the most significant companies. Over 90% of eggs sold for human consumption are produced in the UK by companies over this threshold. Government will have powers to audit holdings below this threshold, although it will be on a risk basis (i.e. whether the holding is supplying a group that would be especially vulnerable to *Salmonella* or if the holding has been linked to a previous outbreak). The measures which must be taken by government when *Salmonella* is detected in hens or eggs will apply to all commercial holdings regardless of whether they are regularly audited.

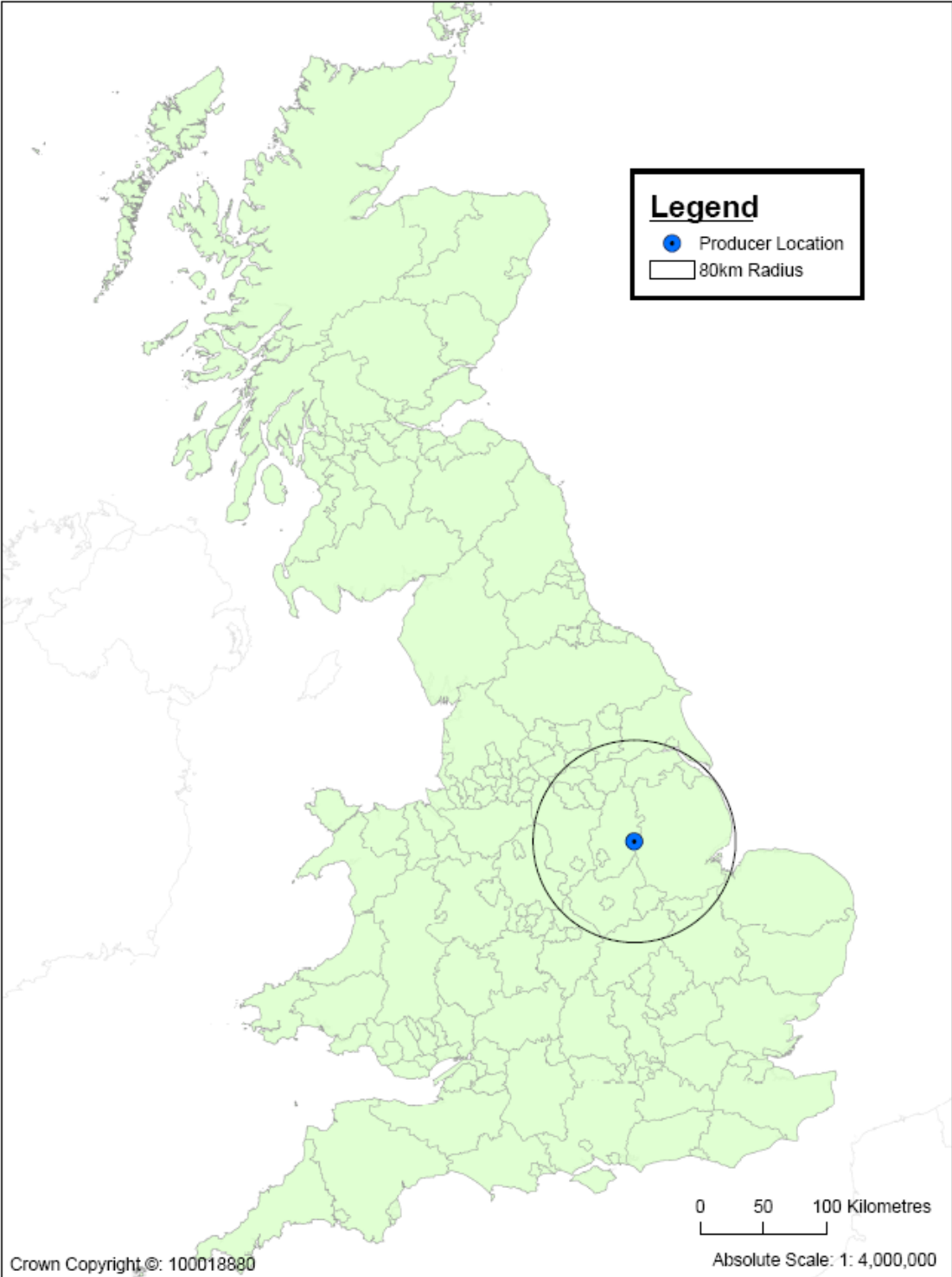
**Annex 3 - Holdings of an unknown status**



**Holdings which are positive for *Salmonella* Enteritidis or *Salmonella* Typhimurium**



**Annex 4 – Map indicating the 80km radius**



## Annex 5

### Legislation Referred to in the Impact Assessment

The Zoonoses Regulation 2160/2003 the “The Zoonoses Regulation”

[http://eur-lex.europa.eu/LexUriServ/site/en/oj/2003/l\\_325/l\\_32520031212en00010015.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2003/l_325/l_32520031212en00010015.pdf)

Commission Regulation (EC) No 1168/2006 on Community target for the reduction of *Salmonella*:

[http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l\\_211/l\\_21120060801en00040008.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_211/l_21120060801en00040008.pdf)

Commission Regulation (EC) No 1237/2007 on the placing on the market of eggs from *Salmonella* infected flocks of laying hens:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:280:0005:0009:EN:PDF>

Commission Regulation (EC) No 589/2008 laying down detailed rules for implementing Council Regulation (EC) No 1234/2007 on marketing standards for eggs:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:163:0006:0023:EN:PDF>

Commission Regulation (EC) No 598/2008 of 24 June 2008 amending Regulation (EC) No 589/2008 laying down detailed rules for implementing Council Regulation (EC) No 1234/2007 as regards the marketing standards of eggs:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:164:0014:0015:EN:PDF>

Commission Regulation (EC) No 617/2008 on laying down detailed rules for implementing Regulation (EC) No 1234/2007 as regards marketing standards for eggs for hatching and farmyard poultry chicks:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:168:0005:0016:EN:PDF>

Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 on laying down health rules concerning animal by-products not intended for human consumption:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:273:0001:0095:EN:PDF>

The Animal Health Act 1981

Food Safety Act 1990

European Communities Act 1972

The Zoonoses Order 1989

The Animal by Products Regulations 2005 (implementing EU Regulation (EC) No 1774/2002)

All EU legislation can be viewed at:

[http://eurlex.europa.eu/RECH\\_legislation.do?ihmlang=en](http://eurlex.europa.eu/RECH_legislation.do?ihmlang=en)

UK legislation can be viewed at:

[www.defra.gov.uk](http://www.defra.gov.uk)

Or printed copies of both EU and UK legislation can be obtained from (or emailed by):

[zdri@DEFRA.GSI.GOV.UK](mailto:zdri@DEFRA.GSI.GOV.UK)

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