EXECUTIVE NOTE

THE CONTROL OF SALMONELLA IN POULTRY (SCOTLAND) ORDER 2008 (SSI 2008/266)

The above instrument was made under sections 1 and 8(1) of the Animal Health Act 1981 and section 2(2) of and paragraph 1A of Schedule 2 to the European Communities Act 1972. It is subject to negative Parliamentary procedure.

Policy Objective

The Control of Salmonella in Poultry (Scotland) Order 2008 ('The Poultry Order') sets out specific sampling requirements for breeding and laying flocks of domestic fowl (*Gallus gallus)* required by the National Control Programmes (NCPs) for Salmonella.

The EU Zoonoses Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents and Regulation (EC) 2160/2003 on the control of salmonella and other food-borne zoonotic agents, provide for the protection of human health against zoonoses and zoonotic agents in animals and products of animal origin.

Commission Regulation EC 1168/2006 which implements Regulation 2160/2003 sets a Community target for the reduction of salmonella in laying flocks. The aim is to reduce the prevalence of the two most important types of salmonella affecting humans, which are *Salmonella* Enteritidis and *Salmonella* Typhimurium. An EU wide survey established that current levels of these two particular serotypes in the UK are amongst the lowest in Europe at 8%. As a result, the UK has been set a target to reduce the prevalence of these salmonellas by 10% annually for the next 3 years, from February 2008.

The NCP for layers will apply to holdings with more than 350 birds, and will require operators to take samples from both birds and their environment during the rearing and production phase. Further sampling will be required on holdings with more than 1,000 birds, at which point the use of antimicrobials will be checked for in accordance with Regulation EC1177/2006. Powers to conduct this official sampling are already provided for by virtue of The Zoonoses (Monitoring) (Scotland) Regulations 2007.

In addition, from the start of 2009, eggs originating from flocks which are confirmed to be infected with *Salmonella* Enteritidis or *Salmonella* Typhimurium must be heat treated before going for human consumption to ensure the elimination of *Salmonella*. From November 2007, these requirements have applied to flocks producing eggs which are linked to a foodborne outbreak of *Salmonella* in humans.

A NCP covering breeding flocks of domestic fowl was introduced in January 2007 by virtue of The Poultry Breeding Flocks and Hatcheries (Scotland) Order 2007. This Order will be revoked however by the introduction of The Poultry Order which will implement the EU requirements for the layer NCP and incorporate the NCP requirements for breeder flocks as required by Regulation EC 1003/2005.

Regulation EC 1003/2005 implements Regulation EC 2160/2003 and sets an annual target to reduce the prevalence of *Salmonella* Enteritidis, *Salmonella* Hadar, *Salmonella* Infantis, *Salmonella* Typhimurium and *Salmonella* Virchow in commercial adult breeding flocks

(comprising at least 250 birds) of domestic fowl in the UK. The 3 year UK target was to maintain the prevalence of these serotypes to a level of 1% or less in breeding flocks by the end of 2009.

Consultation

A UK-wide consultation exercise ran from July 2007 to October 2007. In addition, the Scottish Government ran an informal consultation on the Regulatory Impact Assessment with Stakeholders in Scotland from September 2007 to November 2007. Regular working group meetings have taken place with major stakeholders across the UK poultry industry. Stakeholders and Government officials from all UK administrations continue to meet regularly to discuss the implementation of the National Control Programmes. Technical experts at the Veterinary Laboratories Agency, the Food Standards Agency and the Health Protection Agency have also contributed to the programme.

Financial Effects

The implementation of the National Control Programme will have financial implications for organisations, groups and individuals responsible for the health and welfare of poultry. Costs will be borne by the operators and not Scottish Government. Powers to recover costs associated with official sampling will, in respect of the layers NCP, be provided for by way of an amendment to The Zoonoses and Animal By-Products (Fees) (Scotland) Regulations 2007. Presently the Fees Order only allows for recovery of costs for services required under Commission Regulation (EC) 1003/2005 and the Animal By-Products (Scotland) Regulations 2003.

Implications for producers will depend on the *Salmonella* status of their flocks. All producers will face some increased costs in relation to sampling of their flocks and submitting samples to approved laboratories for testing. From 1 January 2009, eggs originating from infected flocks cannot be sent for human consumption unless they are heat treated. It is likely that continuing production from such a flock would not be financially viable.

Operator Sampling
Operator samples are those collected by the operator (or their staff) without direct supervision from the Competent Authority. The cost estimates include baseline costs which will cover the operator sampling, these include the cost of collecting and testing the samples. The estimates also include charging by Government for services in relation to official control sampling.

<u>Rearing flocks</u>
Samples should be collected on two occasions from the rearing flock. Assuming that there will be one flock per holding the cost will be:

£32.00 x 2 for collecting the samples (assuming 2 hours per flock of operator time)
£18.50 x 2 for testing the sample (1 pooled sample per flock)
£1.50 x 4 for sampling equipment (2 samples per flock)

Total: £107.00 for two sampling occasions for one rearing flock

It is assumed that it will be possible to check that sampling and testing is taking place at rearing flocks when auditing the laying flock holding. Producers currently operating under the Lion Code are expected to only accept rearing flocks accompanied with a "passport" that confirms that the rearing farm belongs to the Lion Code and complies with its testing requirements.

Laying flocks
Samples should be collected from each flock on a holding every 15 weeks during the production phase. It is assumed that there will be three annual operator sampling occasions. On each sampling occasion for a holding with 5 flocks the cost is estimated at:

£1.50 x 10 for equipment to collect the ten samples
£18.50 x 5 for testing the five pooled samples
£16 x 2 for operator time
Assuming the holding has 5 flocks all the above estimates are multiplied by 2.8 (one flock tested twice, four tested three times)

Total: £139.50 per sampling occasion. £390.60 per annum.

Sampling under the control of the Competent Authority
Official control samples are those which are collected under the control of an authorised Government official. Under the NCP these samples will be collected from one laying flock per year on holdings with more than 1,000 birds.

The costs of sampling are estimated to be £18.50 per sample for laboratory testing (one pooled sample required from each flock), £16 per hour for operator time (assume two hours is required per holding on each sampling occasion), £1.50 for equipment to collect samples (assume two sets per flock) and a total of £124 for Animal Health staff time (a base fee, plus a charge per half hour for two hours) when Competent Authority sampling is required. For those keepers who are already sampling to the requirements it is assumed that only the additional costs of the legislation are incurred (any extra testing occasions, the costs of AHA time etc). For example, members of the Lion Code already sample flocks just before depopulation.

The administration costs for operators include the cost of familiarisation with legislation (two hours per annum at £16 per hour), the costs of keeping records of test results (six hours per annum), the costs of accompanying inspectors around the unit (two hours per annum) and the cost of producing records for inspection (half an hour per annum).

Estimates of the costs for official control sampling for layers are based on charges which have been applied to breeding flock holdings from August 2007. The table below sets out the basis of the proposed charges.

Service provided	**Service provider**	**Unit costs**
Taking or supervising the taking of official control samples	Animal Health where not carried out by the Independent Control Body	Base fee £32 plus investigation fee of £23 per ½ hour (or part thereof)

Examination of Official Control Samples	Veterinary Laboratories Agency	£18.50 per sample

On the basis of the above assumptions the estimated annual cost to a keeper with 5 flocks and more than 1,000 birds is estimated to be £736.

Operator testing:
£1.50 x 10 for equipment to collect the ten samples
£18.50 x 5 for testing the five pooled samples
£16 x 2 for operator time

All above multiplied by 2.8 (one flock tested twice, four tested three times)

CA testing:
£46 x 2 + £32 for two hours of Control Body time (plus base fee) to take samples and audit
£1.50 x 2 for equipment to collect two samples
£18.50 to test the pooled sample

Admin burden:
£200 (familiarisation with requirements, keeping records etc)

Total: £736

The estimated annual cost to a keeper with 2 flocks and a total of more than 1,000 birds is estimated to be £485 per annum.

Operator testing:
£1.50 x 4 for equipment to collect the four samples
£18.50 x 2 to test the two pooled samples
£16 x (2/5) x2 for operator time (since it is assumed it takes two hours for a 5 flock holding it is assumed it will take two fifths of this time for a 2 flock holding)

All above multiplied by 2.5 (one flock tested three times, one two)

CA testing:
£46 x 2 + £32 for two hours of Control Body time (plus base fee) to take samples and audit
£1.50 x 2 for equipment to collect two samples
£18.50 to test the pooled sample

Admin burden:
£200 (familiarisation with requirements, keeping records etc)

Total: £485

The estimated annual cost to a keeper with 1 flock of 500 birds is estimated to be £274.

Operator testing:
£1.50 x 2 for equipment to collect the two samples
£18.50 x 1 for testing the pooled sample
£16 x (1/5) for operator time (since it is assumed it takes two hours for a 5 flock holding it is assumed it will take a fifth of this time for a 1 flock holding)

All above multiplied by three (three test occasions per year)

Admin burden:
£200 (familiarisation with requirements, keeping records etc)

Total: £274

The increase in costs to keepers who are, for example, members of an assurance scheme and are already sampling to the required specifications will be less.

It is assumed that, for Competent Authority sampling, those producers that would be allowed to take samples themselves would not incur costs associated with Animal Health time, nor the time accompanying Animal Health staff. For the purposes of roughly estimating the costs it is assumed that 50% of producers would be allowed to do this – although the actual number will depend on the criteria used to select them and compliance rates which are currently unknown.

SCOTTISH GOVERNMENT RURAL DIRECTORATE

THE CONTROL OF SALMONELLA IN POULTRY (SCOTLAND) ORDER 2008

IMPLEMENTATION OF THE REQUIREMENTS UNDER EC REGULATIONS 2160/2003 AND 1168/2006

REGULATORY IMPACT ASSESSMENT

SCOTTISH GOVERNMENT
SEPTEMBER 2007

1. Title of the legislation

The Control of *Salmonella* in Poultry (Scotland) Order 2008 ("The Poultry Order").

The Poultry Order implements the UK National Control Programme for layers *(Gallus gallus).*

This National Control Programme (NCP) will come into effect by February 2008 as required by the Zoonoses Regulation 2160/2003.

Legislation implemented by The Poultry Order

- Commission Regulation (EC) No 1168/2006 implementing Regulation (EC) No 2160/2003 as regards a Community target for the reduction of the prevalence of certain *Salmonella* serotypes in laying hens of *Gallus gallus* and amending Regulation (EC) No 1003/2005.

- Commission Regulation 2160/2003 on the control of *Salmonella* and other specified food-borne zoonotic agents. This provides for a Community target for the reduction of the prevalence of certain *Salmonella* serotypes in laying hens of *Gallus gallus* at the level of primary production. The Poultry Order provides for the establishment of NCPs in the breeding sector and layer sector of the poultry industry. The Poultry Order replaces and revokes The Poultry Breeding Flocks and Hatcheries (Scotland) Order 2007 (see background).

- Commission Regulation (EC) 1003/2005 implementing Regulation 2160/2003 on a Community target for the reduction of the prevalence of certain *Salmonella* serotypes in breeding flocks of *Gallus gallus* and amending the Zoonoses Regulation 2160/2003.

2. Purpose and intended effect

The Objective

The Scottish Government is working in partnership with key industry representatives to implement National Control Programmes in the pig and poultry sectors under EU Regulation 2160/2003. The overall objective of the NCPs are to improve public health through the detection and control of *Salmonellas* of human health significance in primary production. The enhanced monitoring requirements should ensure that information on *Salmonella* status can be more easily compared across the EU and the aim for a more unified approach to the control of *Salmonella* can be achieved. A NCP has been introduced for breeding flocks and over the next three years NCPs will be introduced for broilers (2009), turkeys and fattening pigs (2010) and then breeding pigs in all Member States.

The layer NCP as enforced by The Poultry Order meets the requirements of EU legislation to reduce the level of *Salmonella* infection of public health significance on layer holdings in the EU, and in turn aims to help reduce the level of human infection caused by *Salmonella* across the UK. The NCP seeks to accomplish this by ensuring 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. It is likely to apply to all holdings with more than 350 hens, and to some holdings with less than 350 hens.

Background – prevalence

A survey of flocks of laying hens for *Salmonella* was carried out in each Member State from 2004-2005. In the UK samples of faeces, litter and dust material were collected from 454 farms. The results of this survey were used to establish a baseline prevalence of *Salmonella* in laying flocks on holdings in individual Member States and for the EU Community as a whole. Member States with the highest prevalence figures are required to reduce their levels by the greatest proportion each year. 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 will need to be reduced by 10% of the baseline figure each year from the start of 2008 for a period of 3 years. Member States were set a year-on-year reduction target according to the prevalence found in the survey: 20% reduction if the prevalence was in the region of 10% - 19%, 30% reduction if between 20% - 39%, and 40% reduction if 40% or above.

Background – legislation

The establishment of a baseline prevalence of *Salmonella*

EU Zoonoses Regulation 2160/2003 on the control of *Salmonella* and other specified zoonotic agents was agreed by the Secretary of State in 2003. This was in response to the opinion on zoonoses adopted on 12 April 2000 by the Scientific Committee on Veterinary Measures relating to public health. That opinion found that the measures in place in some Member States at the time to control food-borne zoonotic infections were insufficient and that the epidemiological data that Member States were collecting was incomplete and not fully comparable. It was agreed that the reduction of prevalence levels of *Salmonellas* of public health significance were of particular importance and as a result the EU agreed in 2003 to set targets for reducing prevalence at the farm level. The breeding flock sector had met this target when the legislation was implemented.

This Regulation provides for the setting of Community targets for reducing the prevalence of *Salmonella* serovars (infections) of public health significance in pigs (fattening and breeding) and poultry (layers, breeders, broilers and turkeys). 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. A total of 5,310 holdings with validated results were included in the study analyses. In the specific Member States, the observed holding prevalence of *Salmonella* ranged from 0% to 79.5%. The European Food Safety Authority (EFSA) published the final report of this study in February 2007 following their preliminary report published in June 2006. The results of this survey work were used to set the reduction targets for EU Member States. In the UK 454 holdings were sampled over a 12 month period. After the results were examined the baseline figure for UK was 8% for *Salmonella* Enteritidis and *Salmonella* Typhimurium (combined).

The Establishment of National Control Programmes

The first NCP covered breeding flocks of domestic fowl and came into operation in March 2007 under The Poultry Breeding Flocks and Hatcheries (Scotland) Order 2007 (which as already stated will be revoked and replaced with The Poultry Order). This set out the official controls necessary to verify the target level set out in EU Regulation 1003/2005 which was made under Regulation 2160/2003. This was for a maximum percentage of adult breeding flocks (comprising at least 250 birds) remaining positive for the five serovars (*Salmonella* Enteriditis, *Salmonella* Typhimurium, *Salmonella* Hadar, *Salmonella* Infantis and *Salmonella* Virchow) to be 1% or less by

31 December 2009. The breeding flock sector had met this target when the legislation was implemented.

The NCP for layer flocks follows on from the breeders NCP and will need to be in place for February 2008. By February 2008 all Member States are required to have a NCP for *Salmonella* for laying flocks in place which matches the standards of Regulation 2160/2003 and 1168/2006. As stated earlier over the next three years NCPs will also be implemented for broiler flocks and turkeys.

The NCP for laying flocks was submitted for approval by the Commission in February 2007 after the setting of the reduction target by Regulation 1168/2006. Over the next 2 years, separate NCPs will be drawn up for broiler flocks of domestic fowl, for turkeys and then for fattening and breeding pigs. The broiler and turkey NCPs will be implemented through separate schedules annexed to The Poultry Order and will be subject to separate RIAs.

Rationale for government intervention

The UK is committed to reducing *Salmonella* serotypes of public health significance at national and European Community level. There is currently no statutory monitoring programme for *Salmonella* in laying hens in the UK producing eggs for human consumption. The current system involves voluntary monitoring with the requirement for all laboratories which isolate *Salmonella* from a laying flock or its environment to report the finding, and supply the isolate to the National Reference Laboratory to be recorded and analysed.

These reports provide useful information on the serovars which are most common in the birds, and indicate trends. However they do not give information on the number of holdings or flocks sampled and so it is not possible to establish the prevalence of *Salmonella* in layer flocks from these figures. The number of reports which have been made depend on the level and sensitivity of monitoring undertaken by the producers. Therefore, in order to establish whether or not the target of a 10% reduction in prevalence for three years is being met, government must ensure that all flocks are monitored for *Salmonella* in a regular and consistent manner.

The 2004/5 layer survey demonstrated that industry has been successful in controlling the prevalence of *Salmonella*. This is supported by other research which is available to government. A survey of retail eggs by the Food Standards Agency in 2003 tested 28,518 eggs and found that one in every 290 boxes of six eggs on sale had *Salmonella* contamination (on shells only), compared with 1 in 100 in a 1995/6 survey. The 2004 survey also found that *Salmonella* was not present in the contents of any of the eggs. Data from the Health Protection Agency on *Salmonella* levels in humans indicates cases of Salmonellosis linked by serotyping to UK produced eggs are reducing. Nonetheless, the layer survey revealed that *S*. Enteritidis and *S*. Typhimurium was present on 8% of UK holdings. Since the public cannot readily identify which eggs are infected with *Salmonella*, there is a need to minimise the possibility of infected eggs entering the human food chain and putting human health at risk.

It is recognised that some Farm Assurance Schemes in the poultry sector set out monitoring and testing requirements beyond those currently recommended as good practice and those which will be required in government legislation. The Farm Assurance Schemes are expected to incorporate the sampling programme in their codes of practice.

3. Consultation

Outside Government

Regular meetings have been held with major stakeholders in the UK poultry industry to discuss the requirements and implications of Regulation 2160/2003 and 1168/2006 for the layer flock sector and the draft NCP. These meetings continue to date. A formal written consultation has not taken place as the requirements of the EC Regulation are directly applicable to and legally binding on all Member States. The Scottish Industry were however consulted on the options and costs set out in this Regulatory Impact Assessment.

Within government

During the drafting of the NCP Scottish Government officials have also worked with colleagues in the other Government Administrations, technical experts at the Veterinary Laboratories Agency and the Food Standards Agency. Colleagues from the Health Protection Agency have also contributed to this document.

4. Application and Scope

The NCP applies to all of the UK and therefore this RIA 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 Scotland and the rest of the UK would be an artificial exercise. Furthermore the assumptions behind the costs and benefits sections are not specific to Scotland. Although The Poultry Order applies to Scotland only, parallel legislation will be introduced in England, Wales and Northern Ireland. This SSI will be made under the powers of the Animal Health Act 1981.

The Scottish Government is the Competent Authority (CA) for implementation of this NCP in Scotland. It will be supported by the Veterinary Laboratories Agency, Animal Health Agency and Food Standards Agency. In England the Department of Environment, Food and Rural Affairs (Defra) is the CA for implementation of this NCP, in Wales it is the Welsh Assembly Government.

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. Implementation 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 requires its members to vaccinate their layer flocks and to operate to specified hygiene standards. Some of the medium to small producers are covered by the United Kingdom Egg Producers Association (Laid in Britain Quality Assurance).

Organic producers are inspected and certified by approved organic inspection bodies. These are currently: Bio-Dynamic Agricultural Association, Irish Organic Farmers and Growers Association, Organic Farmers and Growers Ltd, Organic Food Federation, Organic Trust Ltd., Quality Welsh Food Certification Ltd., Scottish Organic Producers Association and Soil Association Certification Ltd. These bodies inspect for organic integrity rather than food safety issues so would not necessarily test for *Salmonella* on a routine basis.

5. Risk Assessment

The immediate risk is that the failure to bring The Poultry Order into force could result in the absence of powers to enforce the monitoring and controls required to implement the NCP. Without these powers government could fail to support the overarching objective of the European Commission 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. There could also be a trade restriction on UK egg movements within the EU, which would have a significant financial impact on some egg producers.

6. Sampling and testing requirements of the National Control Programme

The NCP requires that samples are collected from birds and their environment for the detection of *Salmonella*. These are set out in Table 1.

Table 1

Production Stage	Current sampling required by Lion Code and other Farm Assurance Schemes	NCP requirements from 2008 per flock
Chicks	1. Chick box liners 2. Dead on arrival chicks	1. One chick box liner for every 500 chicks delivered. Up to maximum 10 for every batch of chicks delivered. 2. Carcasses of all dead-on arrival chicks (maximum 60) from each hatchery delivery
Pullet rearing	• 60 cloacal swabs per house • 5 dust samples • 30 swabs from house before next flock	2 pairs of boot swabs or large composite faeces sample: • 2 weeks before point of lay/move to layer unit
During lay	• 60 cloacal swabs per house • 5 dust samples • 5 swabs from each house • 35 swabs from each house before next flock	2 pairs boot swabs or 2 x 150g composite faeces sample taken at: • 22-26 weeks of age • Every 15 weeks during production In holdings comprising 1,000 birds a sample should be collected under the control of the Competent Authority. **Such a sample will replace one by the operator**.

Cloacal swabs have been widely used by industry. Boot swabs are required by the NCP for sampling in non-caged units as this method was required by the protocol for the layer survey which sets the baseline that was used to set the target for reduction. It is considered to be most effective for *Salmonella* monitoring by the EU Commission and was also required for the breeding flocks NCP.

The detection of *Salmonella* has been shown to be dependent on the number of faecal samples taken and the volume of material (faecal or dust) which is mixed and sub-sampled for testing. The EU baseline survey was designed to detect a prevalence of 1% *Salmonella* positive birds within the flock by collecting large naturally pooled composite faecal samples, in the case of caged flocks, or boot swabs in the case of non-caged flocks. To further increase sensitivity dust was added. These samples include a much larger volume of material from a larger number of birds than can be gathered on 60 cloacal swabs or stick swabs taken from dust or house surfaces so the detection level is improved. In the survey of 2004-5 the protocol required that 5 composite faeces samples or 5 pairs of boot swabs and 2 large dust samples were taken in each house. This would be prohibitively cumbersome and expensive for normal use, hence a programme of repeated sampling using 2 faecal or 2 pairs of boot swabs samples every 15 weeks was agreed.

Operator Sampling

Rearing flocks

- Day old chicks, and two weeks before moving to laying phase (all flocks on holding).

Laying flocks

- Every 15 weeks during laying phase, starting when the birds are 22-26 weeks of age (all flocks on holding).

Regulations 1168/2006 and 2160/2003 set out specific minimum sampling requirements for sampling at the initiative of the operator to ensure that the monitoring and control of *Salmonella* is comparable across all Member States. Operator samples are defined as samples which are collected by the operator (or their staff) without direct supervision from the CA.

The operator of the flock is required to submit these samples to a laboratory authorised by the Competent Authority which applies quality assurance systems that conform to the requirements of the current EN/ISO standard. A record should be kept of the date when each flock is sampled for *Salmonella*, the identity of the flock sampled, the age of the flock sampled and the laboratory which undertook the analysis. The results of the tests should be made available to the Competent Authority or its agent.

Sampling under the control of the Competent Authority

Laying flocks

- In one flock per year on holdings which have at least 1,000 birds.

Competent Authority (or 'official control') samples are defined as samples which are collected under the control of the Competent Authority (i.e. the CA officer could collect the sample or supervise the collection of the sample by a third party – for instance a farm operator). Under the NCP these will be collected from one layer flock on each holding with more than 1,000 birds during the period of production of eggs for human consumption as specified in 2.1 of Annex to Commission Regulation (EC) No 1168/2006. Sampling carried out under the control of the CA may replace one sampling at the initiative of the operator.

The use of antimicrobials (as defined in Regulation (EC) No 1177/2006) will be checked when the official sample is taken. If the flock is under antimicrobial medication for animal health or animal

welfare reasons the flock will be sampled again after the period of withdrawal for the product given in its Marketing Authorisation.

The records of samples taken by the operator will be made available for inspection to the Competent Authority or its agent and provide details of date of sample, type of sample, laboratory carrying out the examination, and the result.

Application of the requirements of the National Control Programme

Article 1 of Regulation (EC) 2160/2003 specifies which holdings can be excluded from the official controls.[1] The NCP covers almost all operators producing eggs direct for human consumption on a commercial basis. Exceptions include where production is for private domestic use or where eggs are supplied in small quantities directly to the consumer such as farm gate sales.

There are around 20,000 holdings which produce eggs direct for human consumption. It is important that all operators consider what they need to do to meet the requirements of the NCP and, in particular, whether the sampling and testing requirements apply to them. In enforcing these requirements government needs to focus its resources on industry sectors in which the majority of production takes place or on the operations that present the greatest risk of passing on *Salmonella* infection to the consumer. Around 90% of all the eggs produced in the UK direct for human consumption come from 3,000 laying flock holdings and most of those come from a much smaller number of very large holdings. These 3,000 holdings are required to be registered under The Registration of Establishments (Laying Hens) (Scotland) Regulations, which cover all holdings with more than 350 hens.

It is proposed that, in terms of auditing performance against the requirements of the NCP, government focuses efforts on the 3,000 holdings which are required to register under The Registration Regulations, while retaining the powers to investigate any holding, irrespective of size, on which it is considered that there may be increased risk of eggs for direct human consumption being produced from infected flocks.

7. Options for management of the National Control Programme

The implementation options below focus on the collection, testing and auditing of operator and Competent Authority (CA) samples required by Regulations 1168/2006 and 2160/2003. The Annex to Regulation 1168/2006 requires that sampling by the Competent Authority should take place annually. This implies that government or a Control Body acting on the government's behalf should play a substantial role in the collection of these samples.

If Options 2 and 3 are adopted the agent of the CA with overall responsibility for monitoring the implementation of the NCP will be staff from the Animal Health Agency. If Option 4 is adopted these responsibilities will come under the remit of an Independent Control Body (IBC). Over the next three years Animal Health Agency officials will manage the monitoring and controls of the NCP by:

- undertaking and/or supervising the collection of CA samples
- monitoring and auditing the operator sampling

[1] Regulation (EC) 2160/2003 applies to all primary production except where it is a) for private domestic use, or b) leading to the direct supply, by the producer of small quantities of primary products to the final consumer or to local retail establishments directly supplying the primary products to the final consumer.

- providing support to an Independent Control Body (if such a body is established).

The Poultry Order will enforce the minimum sampling and record keeping requirements of the EU legislation. Whichever option is implemented government would retain full powers to collect samples and check records if required to implement the NCP. Under existing arrangements all samples under the control of the Competent Authority are tested at an approved laboratory. It should also be noted that all the implementation options have been developed and costs have been estimated on the assumption of full cost recovery.

Option 1 – do nothing (continue with sampling and testing under current voluntary arrangements)

Option 2 – for auditing and CA sampling to be under the direct control of government

Option 3 – for responsibilities for the management and auditing of the NCP to be shared by government and industry

Option 4 – for an Independent Control Body to conduct auditing and CA sampling.

Option 1 – do nothing (continue with existing controls and support for voluntary industry schemes).

The measures required by Regulations 2160/2003 and 1168/2006 cannot be implemented through current legislation and administration. It is possible that a number of the larger producers, in particular those which export eggs, might be willing to adopt the controls on a voluntary basis. However, unless government can ensure that the controls and testing by all eligible producers meets the new requirements on a voluntary basis, the UK will fail to have the same public health measures in place as those that will be implemented in other Member States.

Secondly, failure to implement the NCP – or partial implementation – would be a breach of Community obligations as well as a potential threat to public health. The NCP for breeding flocks establishes comprehensive monitoring and controls which should minimise the risk of *Salmonella* being brought onto holdings from breeding farms. Non-compliance would prevent the laying flock sector from reinforcing and benefiting from the NCPs which have been established for breeding flocks and which will be put in place for broilers and turkeys.

The results of the EU wide survey of laying flocks indicate that industry and government actions to control *Salmonella* over recent years have contributed to a relatively low baseline level for the UK. Non-compliance with the monitoring and controls which other Member States should have in place would undermine future attempts to promote the reputation of the poultry sector. It would also have an impact on producers wishing to trade within the EU, who could be prevented from trading their eggs to EU Member States. In 2006 the UK traded approximately £19 million worth of eggs for human consumption and egg products to the EU (of which approximately £15 million worth were eggs in shell for human consumption).

Finally although the current prevalence of *Salmonella* on layer holdings is relatively low, it could still represent a reservoir for potential dissemination and amplification of existing and "new" *Salmonellas,* which could be a future public health concern. It should also be noted that improved hygiene and biosecurity to reduce *Salmonella* can be beneficial for wider disease control purposes.

Option 2 – for auditing and sampling by the CA to be under the control of government.

This option would ensure a comprehensive system which could be managed directly by government and minimise possibilities for non-compliance. It is also the one which is likely to make the highest demands on government resources. In the UK there are 1,561 holdings with over 1,000 hens which are eligible for the collection of CA samples. Additionally, all holdings with more than 350 birds (but less than 1000) will need to be regularly audited for the collection of operator samples.

Option 3 – for responsibilities for the management and auditing of the NCP to be shared by government and industry.

Under this option government would retain full responsibility for the monitoring and controls required by The Poultry Order. However management of the auditing and collection of CA and operator samples would be shared jointly by government and industry. In practice companies with a consistently good history of biosecurity might be authorised to collect CA samples in accordance with Regulation 1168/2006, despatch them to an approved laboratory for testing; and use their existing auditors to confirm compliance with the operator sampling.

This option would involve government working with individual farms, whereas Option 4 would require government to work with a Control Body. If properly implemented it could combine the rigour of Option 2 with the flexibility of Option 4. It would take a light touch approach to the implementation of legislation to a sector where *Salmonella* monitoring and controls have been on a voluntary basis, and demonstrate trust in those producers which consistently work to high standards. It could also ensure that compliance with the NCP was driven by commercial incentives: verifiable adoption of the NCPs requirements would mean a greater chance of avoidance of the costs associated with a farm visit for government. For government it would have the advantage of allowing the Animal Health Agency to manage their resources more flexibly and to concentrate them on those areas where there was greatest need. Such an approach would be consistent with the principle that food business operators should take responsibility for the safety of their products, which underlies much of the legislation.

To verify that the sampling was taking place as set out in the NCP, auditing "spot checks" could be initiated by government. Furthermore the samples will be sent to an approved laboratory which would enable checks on the quality of samples. Under the Zoonoses Order 1989 laboratories are compelled to report positive samples to the CA. Controls on *Salmonella* positive farms would then be put in place. Sampling and testing work conducted to investigate a holding where the presence of *Salmonella* is suspected (as per the Annex to Regulation 1168/2006) would be overseen by the CA as a standard procedure.

It should also be noted that the validity and impartiality of official controls outside of direct CA control can be open to challenge by a Food Veterinary Office visit and competitors. Such an approach could not be implemented until producers have been given time to accustom themselves to the new testing requirements. After this stage it would only be possible to authorise specific companies to manage the NCP with more independence from the CA. This is

not an option that government would wish to require of industry. Instead the onus would be on laying flock companies to produce their own case for greater independence. This would be contingent on an adequate information flow on sampling and transparent processes.

Option 4 – for an Independent Control Body to conduct auditing and CA sampling.

There is scope under the Official Feed and Food Controls Regulation (Regulation (EC) No. 882/2004) for the delegation of specific tasks related to official controls to Independent Control Bodies, if it can be demonstrated that such a body has, amongst other things, sufficient expertise and independence to carry out the tasks. This option requires any prospective organisation to demonstrate that it can:

- Meet the criteria in Regulation 882/2004 for the delegation of specific tasks relating to official controls – including accreditation to EN 45004 or a more relevant standard.

- Take responsibility for the supervision of the collection of official samples and the auditing of operator samples.

- Ensure an exchange of information with the CA which includes reliable data on the audits of operator samples, the collection of CA samples and regularly updated lists of holdings covered.

- Take part in audits by the CA and the Food Veterinary Office.

- Remain free from any conflict of interest with the companies it covered.

If this option was implemented it would mean that although The Scottish Government/Animal Health Agency would be the CA for the NCP, a non-government organisation would be accredited to act as the Control Body for the day to day management of the sampling programme. This would most likely be proposed or established by industry under a Farm Assurance Scheme, possibly after an interim period for the new sampling requirements to become established. There could be a number of control bodies specific to each of the sectors of industry. These might be:

- Farmers covered by the Lion Code (British Egg Industry Council).

- Organic farmers certified by appropriately accredited organic inspection bodies.

- Non-affiliated farmers who do not belong to accreditation schemes.

These bodies would be covered by protocols with the CA to enable proper monitoring and auditing. Their respective roles could be expanded as the National Control Programmes for the different sectors came into force. For instance the organisation contracted to BEIC might cover, breeding flocks and layers.

The role of the CA would be to ensure that the Independent Control Body was managing the monitoring and controls to an acceptable standard. This would be contingent on regular external appraisal by The Scottish Government (or Animal Health Agency), possibly through a programme of on the spot auditing at layer farms and other relevant stages of production.

If properly managed by industry this option could offer the rigour of Option 2 with the flexibility of Option 3. Since an Independent Control Body would be likely to operate through one of the Farm Assurance Schemes it might encourage industry acceptance of the case for regulation and give a sense of ownership of the NCP. However it must be accepted that not all producers will see an advantage in joining an Independent Control Body which was supported by a Farm Assurance Scheme. Although government could oblige producers to use such a service, it is unlikely that the industry organisation would agree to such an obligation, which would take away any element of competition. Therefore the potential saving to government resources might be limited by the need to set up a parallel control and auditing system for these producers.

8. Benefits and Costs

There would be human health benefits to society as a whole of effective sampling practice and action as detailed in the legislation to reduce further the risk of *Salmonellas* of public health significance entering the food chain. It should also be noted that improved farm hygiene and biosecurity to reduce *Salmonella* can be beneficial for other disease control purposes and demonstrably consistent with EU standards.

The success of the control programme in breeding flocks means that the day old layer chicks placed on farms should be free of *S.* Enteritidis and *S.* Typhimurium. Whichever of the options from 2 to 4 that can be successfully implemented they should enable the layer flock sector to be part of an integrated approach to food safety through adequate and harmonised monitoring and controls across the EU. In this way our industry and consumers should be able to benefit from other Member States implementing this legislation and reaching their targets.

Costs (Estimated)

Options 2 – 4 implement the minimum sampling and testing requirements of the NCP. The Scottish Government do not intend to go beyond these requirements. The cost estimates of these options include baseline costs which will cover the operator sampling. These include the cost of familiarising staff with the new sampling requirements and the cost of collecting and testing the samples. The estimates also include charging by government for services in relation to official control sampling where provided by the Animal Health Agency and the VLA. More details are provided in the section on cost recovery.

<u>Rearing flocks</u>

Samples should be collected on two occasions from the rearing flock. Assuming that there will be one flock per holding the cost will be:

£32.00 x 2 for collecting the samples (assuming 2 hours per flock of operator time)
£18.50 x 2 for testing the sample (1 pooled sample per flock)
£1.50 x 4 for sampling equipment (2 samples per flock)

Total: £107.00 for two sampling occasions for one rearing flock

For the purposes of this RIA it is assumed that it will be possible to check that sampling and testing is taking place at rearing flocks when auditing the laying flock holding. Producers currently operating under the Lion Code are expected to only accept rearing flocks accompanied with a “passport” that confirms that the rearing farm belongs to the Lion Code and complies with its

testing requirements. A similar auditing system could be adapted for the requirements of the NCP.

Laying flocks

Samples should be collected from each flock on a holding every 15 weeks during the production phase. It is assumed that there will be three annual operator sampling occasions. On each sampling occasion for a holding with 5 flocks the cost is estimated at:

£1.50 x 10 for equipment to collect the ten samples
£18.50 x 5 for testing the five pooled samples
£16 x 2 for operator time
Assuming the holding has 5 flocks all the above estimates are multiplied by 2.8 (one flock tested twice, four tested three times)

Total: £139.50 per sampling occasion. £390.60 per annum.

Costs of Option 1

There would be no additional costs to industry or government from sampling, auditing or controlling eggs from infected flocks under Option 1 (apart from farmers who adopted the NCP on a voluntary basis). However, there is a risk that the UK egg industry could incur costs if UK egg exporters could not trade with EU Member States, and it would not fulfil government's obligations to EU legislation.

Costs of Option 2

It is estimated that in the UK approximately 249 holdings (24 in Scotland) with *fewer* than 1,000 birds (but >350) and 1,561 holdings (101 in Scotland) with *more* than 1,000 birds will be required to conduct operator sampling. All premises will need to be audited. It is assumed that a further 480 operators of rearing holdings will be required to sample their birds at day old, and just before moving to laying accommodation.

The costs of sampling are estimated to be £18.50 per sample for laboratory testing (one pooled sample required from each flock), £16 per hour for operator time (assume two hours is required per holding on each sampling occasion), £1.50 for equipment to collect samples (assume two sets per flock) and a total of £124 for Animal Health Agency staff time (a base fee, plus a charge per half hour for two hours) when Competent Authority sampling is required. For those keepers who are already sampling to the requirements it is assumed that only the additional costs of the legislation are incurred (any extra testing occasions, the costs of AHA time etc). For example, members of the Lion Code already sample flocks just before depopulation.

The administration costs for operators include the cost of familiarisation with legislation (two hours per annum at £16 per hour), the costs of keeping records of test results (six hours per annum), the costs of accompanying inspectors around the unit (two hours per annum) and the cost of producing records for inspection (half an hour per annum).

Estimates of the costs for official control sampling for layers are based on charges due to be applied to breeding flock holdings from August 2007. Table 2 below sets out the basis of the proposed charges.

Table 2

Service provided	Service provider	Unit costs
Taking or supervising the taking of official control samples	Animal Health where not carried out by the Independent Control Body	Base fee £32 plus investigation fee of £23 per ½ hour (or part thereof)
Examination of Official Control Samples	Veterinary Laboratories Agency	£18.50 per sample

On the basis of the above assumptions the estimated annual cost to a keeper with 5 flocks and more than 1,000 birds is estimated to be £736.

Operator testing:
£1.50 x 10 for equipment to collect the ten samples
£18.50 x 5 for testing the five pooled samples
£16 x 2 for operator time

All above multiplied by 2.8 (one flock tested twice, four tested three times)

CA testing:
£46 x2 + £32 for two hours of Control Body time (plus base fee) to take samples and audit
£1.50 x2 for equipment to collect two samples
£18.50 to test the pooled sample

Admin burden:
£200 (familiarisation with requirements, keeping records etc)

Total: £736

The estimated annual cost to a keeper with 2 flocks and a total of more than 1,000 birds is estimated to be £485 per annum.

Operator testing:
£1.50 x 4 for equipment to collect the four samples
£18.50 x 2 to test the two pooled samples
£16 x (2/5) x2 for operator time (since it is assumed it takes two hours for a 5 flock holding it is assumed it will take two fifths of this time for a 2 flock holding)

All above multiplied by 2.5 (one flock tested three times, one two)

CA testing:
£46 x2 + £32 for two hours of Control Body time (plus base fee) to take samples and audit
£1.50 x2 for equipment to collect two samples
£18.50 to test the pooled sample

Admin burden:
£200 (familiarisation with requirements, keeping records etc)

Total: £485

The estimated annual cost to a keeper with 1 flock of 500 birds is estimated to be £274.

Operator testing:
£1.50 x 2 for equipment to collect the two samples
£18.50 x 1 for testing the pooled sample
£16 x (1/5) for operator time (since it is assumed it takes two hours for a 5 flock holding it is assumed it will take a fifth of this time for a 1 flock holding)

All above multiplied by three (three test occasions per year)

Admin burden:
£200 (familiarisation with requirements, keeping records etc)

Total: £274

The increase in costs to keepers who are, for example, members of an assurance scheme and are already sampling to the required specifications will be less.

Costs of Option 3

The costs of operator sampling will be the same as under Option 2. However, it is assumed that, for Competent Authority sampling, those producers that would be allowed to take samples themselves would not incur costs associated with Animal Health Agency time, nor the time accompanying Animal Health Agency inspectors. For the purposes of roughly estimating the costs of Option 3, it is assumed that 50% of producers would be allowed to do this – although the actual number will depend on the criteria used to select them and compliance rates which are currently unknown.

Costs of Option 4

If CA sampling and auditing of operator samples are handled by an Independent Control Body charges will be between the organisation and its members. The Control Body may aim to undercut the charges set by government and be able to achieve efficiencies that would allow lower charges to be levied than those set by government. The costs of operator sampling will be the same as under Option 2. However, it is assumed that, for Competent Authority sampling by an industry Control Body, the costs of Control Body time would be half those of Animal Health time. For the purposes of roughly estimating the costs of Option 4, it is also assumed that all producers would choose this cheaper option, and use the Independent Control Body for their Competent Authority testing.

It may however not be appropriate to assume that an Independent Control Body would be able to offer a cheaper service to farmers than the Competent Authority in all cases. If, as seems likely, the organisation was established by a Farm Assurance Scheme it might charge for special journeys to those producers which were not members of the scheme and to whom it would not normally make auditing visits. Indeed the main advantage of the Independent Control Body for operators could be convenience rather than price. For instance membership of a Farm Assurance Scheme which was allied to an Independent Control Body would ensure full compliance with the NCP without the possibility of more frequent inspections and auditing requests from government.

Cost Recovery

Breeding flock operators have been charged for the collection and testing of official control samples by government inspectors since the introduction of The Poultry Breeding Flocks and Hatcheries Order 1993. The introduction of new legislation to enforce the NCP for breeding flocks, The Poultry Breeding Flocks and Hatcheries (Scotland) Order 2007, has meant that powers that would enable government to recover its costs for services provided under this Order have lapsed. A new charging scheme, enabling government to recover costs in full for the collection and testing of official control samples, is due to be introduced in Autumn 2007. This charging scheme will be enforced and enabled by The Zoonoses and The Animal By-Products (Fees) (Scotland) Regulations 2007 ("The Fees Regulations"). The charging scheme also includes charges in relation to laboratories operating under The Poultry Breeding Flocks and Hatcheries (Scotland) Order 2007 and The Animal By-Products (Scotland) Regulations 2003.

It is our intention to amend The Fees Regulations to coincide with the introduction of the NCP for laying flocks. This amendment would enable the recovery of the costs to government resulting from any testing and collection of official control samples from laying flock operators carried out by government inspectors. Further amendments to The Fees Regulations are planned to coincide with the introduction of NCPs for broilers, turkeys and pigs over the next few years for cost recovery for government services.

It is The Scottish Government's policy to ensure that any charges placed on food producers avoid providing either a subsidy to producers or a source of taxation to government. The fees placed on laying flock operators will seek to recover costs incurred by government for services provided. It is our intention that all charges will be reviewed annually to reflect changes in the costs borne by government. The reviewed charging levels will be developed in consultation with key industry representatives through an agreed procedure and will then be published on the Scottish Government's website and distributed through appropriate communication channels.

There are many similarities in the services provided in relation to the NCPs for breeding flocks and laying flocks. The proposed charges for breeding flocks have been used as a basis for estimating charges in relation to laying flocks.

Options for cost recovery

Government costs for disease control services are usually recovered by directly invoicing the holding where the inspection took place. The charges placed on hatcheries for the collection of monthly samples by Animal Health under The Poultry Breeding and Hatcheries Order 1993 is an example with which many stakeholders in the poultry industry will be familiar. This is likely to be our initial arrangement for the recovery of costs for the collection of CA samples. However the cost of the collection of relatively small sums of money from individual holdings can lead to administrative costs outweighing the amount collected. Neither industry nor government will benefit from such a situation. ***We are looking for the most efficient system and would welcome the views of stakeholders on whether the collection of fees from other points might be more effective.***

Measures to be taken by the Competent Authority if *Salmonella* is detected on a holding

Regulation 2160/2003 prohibits the sale of eggs from flocks infected with *S*. Typhimurium or *S*. Enteritidis to consumers unless "treated in a manner that guarantees the elimination of all

Salmonella serotypes with public health significance" (i.e. heat treated). From 1 January 2009 those holdings which are found to be positive for *Salmonella* Enteritidis or Typhimurium will not be able to sell eggs for human consumption unless they have been marked as Class B and the sale of fresh eggs from these flocks is restricted accordingly. The marking of these eggs can be done on farm. There are no plans for government to provide compensation for operators who choose to depopulate or slaughter their infected flocks. Eggs from infected flocks can be disposed of via food processors in line with the requirements described in SANCO/1188/2006r11 which requires that the eggs are:

(a) considered as Class B eggs as defined in Article 2(4) of Commission Regulation (EC) No [AGRI/2007/60969];

(b) marked with the indication referred to in Article 10 of Commission Regulation (EC) No [AGRI/2007/60969], 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.

The reduction of *Salmonella* at farm level is the most effective way of controlling the potential costs to industry. During the survey of laying flocks the VLA analysed data collected by the Animal Health Agency to identify risk factors which made holdings vulnerable to infection. This involved the recruitment of holdings which were found to be positive for *Salmonella* Enteritidis and Typhimurium to look into the variables associated with on-farm *Salmonella*. The VLA also assessed the data from voluntary questionnaires which provided information on 204 visits by the SVS to collect samples. Other information which was available to The Scottish Government from existing research and surveillance in the layer flock sector and from cases of *Salmonella* Enteritidis in humans was used to put the layer survey data in context.

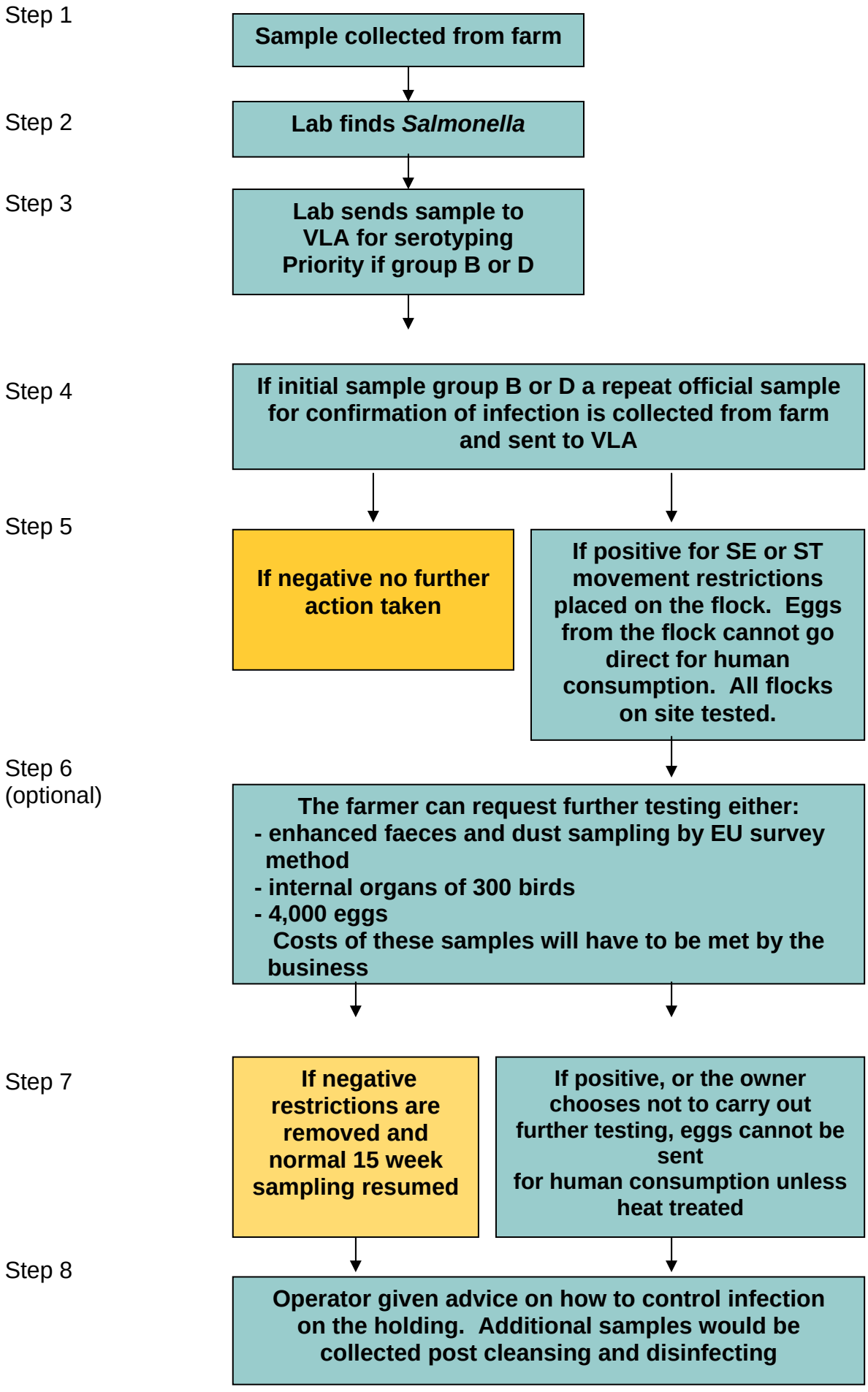
This research has highlighted steps which can be taken for reductions in *Salmonella* prevalence in the national flock to be delivered to the NCPs timescale. These include effective vaccination practices, cleansing and disinfection between flocks, rodent and other pest control and increased biosecurity for feed and water. These measures will take time and money to put into effect. The length of time a flock is in production limits the opportunity to take action to eliminate contamination in houses, which is only possible when a flock has been depopulated. Consequently the reduction of *Salmonella* in layers at the farm level is likely to be a gradual process.

The Scottish Government intends to continue to work in partnership with industry to help reduce the level of *Salmonella* on infected flocks before heat treatment is required in 2009. Work has begun on the production of new and revised versions of existing codes of practice which will take account of the most recent research. These cover risk management measures such as the vaccination of flocks, controls on cleaning and disinfection, and pest control.

The British Egg Industry Council intends to update the Lion Code to include the requirements of the NCP. Around 85% of UK egg production is covered by the Lion Code.

Procedures to be followed when *Salmonella* is suspected on a holding

The following procedures will be followed if *Salmonella* Enteritidis or *Salmonella* Typhimurium is suspected on a holding from 2009:


Step 1
Sample collected from farm
Step 2
Lab finds *Salmonella*
Step 3
Lab sends sample to VLA for serotyping Priority if group B or D
Step 4
If initial sample group B or D a repeat official sample for confirmation of infection is collected from farm and sent to VLA
Step 5
If negative no further action taken
If positive for SE or ST movement restrictions placed on the flock. Eggs from the flock cannot go direct for human consumption. All flocks on site tested.
Step 6 (optional)
The farmer can request further testing either:
- enhanced faeces and dust sampling by EU survey method
- internal organs of 300 birds
- 4,000 eggs
Costs of these samples will have to be met by the business
Step 7
If negative restrictions are removed and normal 15 week sampling resumed
If positive, or the owner chooses not to carry out further testing, eggs cannot be sent for human consumption unless heat treated
Step 8
Operator given advice on how to control infection on the holding. Additional samples would be collected post cleansing and disinfecting

Holdings linked to specific *Salmonella* food-poisoning outbreaks

Eggs will require heat treatment from November 2007 if an epidemiological link was conclusively established between a foodborne outbreak and eggs from a flock infected with any strain of *Salmonella* (not just *S*. Enteritidis or *S*. Typhimurium). Demonstrating a definite link between an outbreak of *Salmonella* in humans with eggs from a specific holding requires detailed investigation. For the RIA we will assume that one holding per annum will be linked to a specific outbreak. The estimated costs for an affected holding are the same as those set out below for measures taken if *Salmonella* Enteritidis or Typhimurium is suspected on a holding.

Costs of measures taken if *Salmonella* Enteritidis or Typhimurium is suspected on a holding

Given the current prevalence rate of 8% indicated in the *Salmonella* baseline survey, it is anticipated for the purposes of this RIA that there may be around 200 infected holdings identified in the first year. In following years, this figure will fall, assuming the target of a 10% reduction each year is met, to 7.2%, then 6.5% and finally 5.8% (approximately 145 holdings). There is no firm information on the number of infected flocks on an infected holding, so we have used a VLA estimate, based on limited studies, that 65% of flocks on a positive holding would be infected. It should also be noted that because of the lesser sensitivity of private sampling against the methods used for the *Salmonella* survey it is likely that the actual figures will be lower.

Affected holdings will have to repeat an official sample from all flocks on the holding, which is estimated to cost £380 per suspected holding (including Control Body time, operator time, laboratory costs and equipment). This will be paid for by government. Assuming this is found to be positive as well, then the supply of untreated eggs into the human food chain will be prevented from the infected flocks. However farmers will be offered the option of requesting the collecting of additional samples to demonstrate that the infection is not present. The owners will be expected to meet the cost of these samples.

If infection is confirmed the keeper of the flock then has to decide whether the eggs can be disposed of and destroyed, or sent for heat treatment and whether the flock should be culled and replaced. If the eggs were disposed of, the farmer would incur the costs of disposal (£0.07 per dozen), and the loss of the value of the eggs (currently £0.55 per dozen). For a farm with 30,000 birds and five flocks, of which three were infected during a year, the cost of disposal is estimated to be £130,000 per year. This will depend on the stage during production that the infection is found: this estimate assumes that each infected flock has a remaining laying period of six months. Experience indicates that the period when infection in flocks is most likely to be identified is at the beginning and the end of lay.

If the eggs went for treatment, the loss to farmers would be approximately £0.21 per dozen eggs (as against a loss of £0.55 plus £0.07 per dozen eggs for disposal). For the same farm with 30,000 birds and the same assumptions as above, the cost of treating the eggs is estimated to be £45,000 per year.

If the flock was culled, the farmer would lose the remaining value from the culled birds (the birds are assumed to be an average age of 46 weeks, with a value of £2). The birds would also need to be culled and incinerated at an assumed cost of £0.20 each. For the same illustrative farm as above, with the same assumptions about flock size and number of birds infected, costs are estimated to be approximately £40,000. The birds do not have to be culled: they could be kept for the production of eggs intended for heat treatment. However this would not be a profitable option

for many farmers and it is expected that most would choose to cut their losses and have the birds culled.

Whichever option farmers chose, before a new flock could be placed in the house, the house would need to be cleaned and disinfected (in most cases enhanced cleansing and disinfection would be required which would lead to increased cost) and samples taken and tested to ensure no remaining infection. This testing is estimated to cost approximately £230 per holding.

The total costs of the control measures on eggs from infected flocks required by the NCP are below. These estimates assume a starting prevalence of 8% as indicated by the layer survey.

Year	0	1	2	3 onwards
Prevalence	8%	7.2%	6.48%	5.83%
Number hens infected (million)	2.46	2.21	1.99	1.79
Total eggs infected (million)	340	308	277	249
*Heat treatment (million) of eggs or	£6.0	£5.4	£4.8	£4.4
Disposal (million) of eggs or	£17.7	£15.9	£14.4	£12.9
Cull (million)	**£5.6**	**£5.0**	**£4.5**	**£4.1**

*assumes the bird continues production until it would be culled out at the end of the production cycle of approx 12 months and that the eggs it produces in this period would go for treatment.

Of these costs, all but approximately £45,000 (for confirmatory official control sampling) are expected to be borne by industry. It is anticipated that industry will choose the cheapest option for them (culling the flock) and therefore the shaded figures should be seen as the likely total costs of the control measures.

Total costs and benefits the National Control Programme

The total costs of the sampling and the controls on eggs from infected holdings, are estimated in the table below according to the different implementation options for the Competent Authority sampling:

Year	0	1	2	3 onwards
TOTAL (Option 2 plus control measures) (million)	£7.2	£6.7	£6.2	£5.7
TOTAL (Option 3 plus control measures) (million)	£7.0	£6.4	£5.9	£5.5
TOTAL (Option 4 plus control measures) (million)	£7.0	£6.4	£5.9	£5.4

The benefit of the measures proposed above is that they reduce the risk to human health from the dissemination of *Salmonella* Enteritidis and Typhimurium into the environment from infected laying flocks and humans. Through time this should ensure that the number of cases of salmonella

related illness reduces. Economically there will also be benefits as the number of sick days lost annually will also come down.

Implementation also helps to protect the ability of egg producers to export their products to the EU. In 2006 UK egg producers exported eggs and egg products worth approximately £19 million. Without implementation, there is a risk that these exports would be banned.

9. Small Firms Impact Test

Almost all egg producers would be classified as a small business, as they employ fewer than 250 full time equivalent employees. The proposed NCP applies equally to all eligible sectors of the industry and is not therefore considered to be discriminatory.

10. Issues of equity and fairness

The NCP does not introduce any issues around equity or fairness as it applies to all eligible producers in all EU Member States

11. Competition Assessment

All eligible farms in the UK will be subject to the requirements of the National Control Programme. It is not felt that these requirements will reduce the number or range of suppliers of fresh, graded shell eggs nor limit the ability of or incentives for suppliers to compete with each other. Compliance 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.

All EU Member States will need to implement the legislation and so there will be a more level playing field for EU competition. Few untreated shell eggs are imported into the UK from outside the EU.

12. Enforcement, Sanctions and Monitoring

The proposed Order primarily makes provision for the administration and enforcement of Commission Regulation (EC) 1003/2005, Commission Regulation (EC) 1168/2006 and Commission Regulation (EC) 1177/2006. It makes provision for the registration of hatcheries, breeding flocks and laying flocks, imposes record keeping requirements and makes provision for a salmonella sampling programme for breeding and laying flocks of the species Gallus gallus. The proposed Order will be enforced by local authorities.

In order to monitor the progress of the National Control Programme official samples will be taken from one flock per laying cycle (effectively once a year) on holdings that have 1000 birds or more. The powers to allow for this official sampling derive from The Zoonoses (Monitoring) (Scotland) Regulations 2007 which in turn implement the requirements of the Zoonoses Directive (2003/99/EC).

13. Implementation and delivery plan

To meet the requirements of The Zoonoses Regulation 2160/2003 it is proposed that the Order will come into force on 1 February 2008. NCPs are also to be introduced over the next few years for broilers, turkeys and pigs. Animal Health will be responsible for the collection of official

samples and for monitoring implementation and progress on achieving the annual reduction targets for salmonella prevalence.

14. 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 National Control Programmes are assessed at the end of their three year life span.

15. Summary & Recommendation

The EU Regulations are prescriptive in their requirements and so there has been limited scope to minimise the impact on industry. Efforts have therefore focused on controlling the implementation costs to producers. On this basis Option 3 is the recommended option. This option is recommended as it will allow for industry and Government to share responsibility for delivery of the NCP. This approach is consistent with that being adopted in England and Wales.

Regulation 2160/2003 allows for producers and their representative bodies to put forward their own control programmes to run alongside the NCP. The British Egg Industry Council (BEIC), which represents major UK producers and covers some 85% of egg production, intends to submit their Lion Code scheme for approval as an industry control plan. When this option is implemented Lion Code members will be sampled and audited by an independent auditor which would work closely with Animal Health to ensure that all the requirements of the Regulation are being met and delivered. Under this option, producers subject to official sampling requirements (those with 1000 birds or more), but have such samples taken by BEIC auditors (instead of Animal Health) will not be liable for any costs associated with Animal Health staff.

16. Declaration

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

Signed: _____

Date: _____

Richard Lochhead
Cabinet Secretary for Rural Affairs and the Environment
Scottish Government