

## **EXECUTIVE NOTE**

### **The Zoonoses and Animal By-Products (Fees) (Scotland) Regulations 2007 SSI 2007/577**

The above instrument was made under sections 56(1) and (2) of the Finance Act 1973 and section 2(2) of the European Communities Act 1972. It is subject to negative Parliamentary procedure.

#### **Policy Objective**

The main objective of The Zoonoses and Animal By-Products (Fees) (Scotland) Regulations 2007 is to allow the Scottish Ministers to recover costs for services provided in relation to the implementation of the National Control Programme (NCP) for Salmonella in poultry breeding flocks and for a scheme under which private laboratories are authorised to test samples for particular zoonotic organisms or diseases.

Breeding flock owners and private laboratories are accustomed to charges being raised for these services as legislation to recover such costs has been in place since 1993. The power to recover these costs is provided by The Poultry Breeding Flocks, Hatcheries and Animal By-Products (Fees) (Scotland) Order 2002. Prior to the introduction of the 2002 Fees Order it was The Poultry Breeding Flocks, Hatcheries and Processed Animal Protein (Fees) Order 1993 that provided the necessary cost recovery powers. The 2002 Fees Order enabled the recovery of costs for services provided under The Poultry Breeding Flocks and Hatcheries Order 1993 and The Animal By-Products Order 1999. A new Poultry Breeding Flocks and Hatcheries (Scotland) Order 2007 came into force on 21 March 2007 however. This new Order revoked the powers of the 1993 Order. In addition the Animal By-Products (Scotland) Regulations 2003 have replaced the Animal By-products (Scotland) Order 1999.

The 2002 Fees Order makes particular reference to The Poultry Breeding Flocks and Hatcheries Order 1993 and The Animal By-Products Order 1999. As explained above both of these Orders have since been revoked and replaced. By applying the terms of the Interpretation Act however it is still lawful to use the 2002 Fees Order to recover costs for services provided under the Poultry Breeding Flocks and Hatcheries (Scotland) Order 2007 and The Animal By-Products (Scotland) Regulations 2003. Notwithstanding this however, it has been agreed that for the sake of clarity and to ensure best practice a new updated Fees Order should be introduced.

The fees to be charged for specific services will not appear on the face of the legislation, but will instead be published on the Scottish Government web site. This approach removes the need to amend legislation each time the fees are reviewed. England and Wales are also adopting this approach. Government will of course discuss with industry any future increase in the charges to be levied to ensure that those affected have the opportunity to scrutinise and comment on any proposed changes to the fee structure.

#### **Consultation**

There has been no formal consultation carried out as our policy is to set fees at such a level as to achieve full recovery of costs. Accordingly, decisions on the fees to be charged would not alter as a result of consultation. Key industry representatives have, however, been involved in the development of this policy through regular NCP stakeholder meetings.

## Financial Effects

The businesses affected would be those to whom the fees set out in the Fees Regulations are directly applicable. These include registered owners of breeding flocks of domestic fowls and laboratories approved by the Scottish Government to test for salmonella under the Poultry Breeding Flocks and Hatcheries (Scotland) Order 2007 and for salmonella, enterobacteriaceae and clostridium perfringens under Animal By-Products (Scotland) Regulations 2003.

### Compliance costs

The existing and proposed fees are set out in the following table. The activities in column one are listed as they appear in Regulation 3(2) in the new Fees Regulations. In this table, as in the proposed Fees Regulations, “the European Regulation” means Regulation (EC) No 2160/2003 and “the Regulations” means the Animal By-Products (Scotland) Regulations 2003.

| Activities  | 2002 charge (£)  | Proposed 2007 charge (£)   |
|---|--|--|
| (a) taking or supervising the taking of official control samples  | 28.20 per ½ hour   | Base fee £32 plus investigation fee of £23 per ½ hour (or part thereof). |
| (b) examining official control samples  | N/A <sup>*(1)</sup>  | 18.50  |
| (c) processing of an application for approval of a laboratory under Regulation 21 of the Regulations or Article 12 of the European Regulation | 10.60  | 12.50  |
| (d) Processing of the approval documentation further to an application referred to in (c).  | 24.60  | 29.50  |
| (e) processing of an annual renewal application from an approved laboratory   | 24.60  | 29.50  |
| (f) inspecting a laboratory, for the purpose of Regulation 21 of the Regulations or Article 12 of the European Regulation, for                |  |  |
| i) 1 test e.g. Salmonella PBFH(S)O or Salmonella ABP(S)R  | 348.40   | 613.50   |
| ii) 2 tests e.g. Salmonella PBFH(S)O and Salmonella ABP(S)R   | 359.70   | 632.50   |
| iii) 3 tests e.g. all ABP(S)R, or 2 of ABP(S)R with Salmonella PBFH(S)O   | 370.90   | 651.50   |
| iv) 4 tests e.g. all ABP(S)R and Salmonella PBFH(S)O  |  | 670.50   |
| (g) administering a quality control test, under Regulation 21 of the Regulations or Article 12 of the European Regulation, for                |  |  |
| i) Salmonella (PBFH(S)O, poultry)   | 25.10/26.73 <sup>*(2)</sup>                                | 32.00  |
| ii) Salmonella (ABP(S)R, isolation and culture)   | 25.10/26.73 <sup>*(2)</sup><br>48.90/50.55 <sup>*(2)</sup> | 32.00<br>57.00   |

|   |                             |       |
|---|-----------------------------|-------|
| iii) Enterobacteriaceae (ABPR, isolation and culture)     | 48.90/50.55 <sup>*(2)</sup> | 57.00 |
| iv) Clostridium Perfringens (ABPR, isolation and culture) |                             |       |

<sup>\*(1)</sup> - Charges for testing official samples have been simplified since 2002 and so it is difficult to make a direct comparison. Several possible tests were applicable to samples taken under the previous sampling protocol and each was charged separately. Further details below

<sup>\*(2)</sup> - these charges were split in the 2002 Order such that fees were published separately for costs of sending one set of QA samples at first application, the first charge, and 4 sets of QA samples per year for an approved lab, the second figure, which includes a Government administration charge.

### Breeding flock Holdings

Official control samples are those which are collected and tested under the control of an authorised Government official. These are collected to provide official verification that the target for the control of Salmonella in breeding flocks is being met. Official sampling is required at three intervals during the production cycle of a breeding flock: near the beginning of lay (within 4 weeks of moving to the laying accommodation); the middle of lay; and near the end of lay (within the last 8 weeks of production).

The Animal Health Agency will arrange for official samples to be collected from each adult breeding flock annually. There are three options for collecting the official samples:

- a) Animal Health visit and collect the samples;
- b) Animal Health visit and supervise the sampling;
- c) Animal Health authorises another competent person to take the official samples under instruction.

As a minimum each holding of a breeding flock operator should receive at least one visit from Animal Health staff each year for sampling and auditing purposes. Given the structure of the industry, on a risk based approach it is anticipated that two of these samples could be taken under option (c) in most cases.

So, while all official samples will be under control of the competent authority, it is anticipated that under normal circumstances Animal Health will be actively involved in the collection of only one of these three samples. Charges will be applied only where Animal Health staff visit the holding for sampling and auditing purposes. All official samples collected will be examined at the VLA.

Under the PBFHO 1993 official samples were taken from hatcheries and tested by “an officer of the Minister” every 28 days in the case of grandparent flocks and every 56 days in the case of parent flocks. In practice a hatchery supplied with eggs from grandparent flocks could expect 12 visits per annum. A hatchery supplied by eggs from parent flocks could expect 6 visits per annum. In practice more visits had to be carried out at some hatcheries in order to sample all the flocks supplying eggs to the hatcheries. Official sampling under the PBFH(S)O 2007 will now move from the hatchery to the breeding flock holding.

## *Cost comparison*

As the methods for collection of official samples has changed it is difficult to present a direct comparison of the total cost to industry between the old fees order and the proposed fees regulation. The following figures are an approximation based on best available information.

According to figures from the GB Poultry Register there are 620 breeding flock holdings in GB of which 68 are in Scotland. Assuming that on average each holding keeps 4 flocks then around 272 flocks in Scotland would be subject to the new sampling and testing regime.

In order to estimate costs under the proposed fees regulation it is assumed that each breeding flock would require a visit by Animal Health once in each production cycle for the purpose of collecting or supervising the collection of the official samples and that one production cycle last roughly one year. However as Animal Health charges are based on the costs of visits rather than then total number of samples taken and it is expected that Animal Health would be able to collect or supervise the collection of official samples from all the flocks on a holding at a single visit then costs for sampling should be minimised. Therefore a range of costs for Animal Health component of the charge for official testing has been produced below. The higher cost assumes that Animal Health makes a separate visit to sample each flock (272 flocks) and that the visit would last for a half hour (meaning a charge per visit of £55) (*£55 comprises of the basic fee of £32 + the ½hourly rate of £23*). The lower cost assumes that all flocks on a holding (68 holdings) are sampled in a single visit but that the visit takes one hour (visit charge of £78). All official samples would be examined by the VLA at a cost of £18.50 per sample tested (*£78 comprises of the basic fee of £32 + 2 X the ½ hourly rate of £23*).

Accordingly the projected cost for official control sampling in Scotland would range from **£5304** per annum to **£14690** per annum for sampling. The cost for examination of all official samples collected is estimated at **£15096** per annum (*272 flocks x 3 x £18.50*). Therefore the estimated total combined cost to business in Scotland for official sampling and testing of breeding flocks under the proposed fees regulations ranges from **£20400 per annum** to **£29786 per annum**. The average cost for each holding would range from **£300** to **£438 per annum**.

## Approved Laboratories

9 Laboratories in Scotland are approved currently under the approved laboratory scheme.

The fees applicable to laboratories under the approval scheme are not straightforward as they depend on the status of approval (i.e. first application, renewal etc.) and the organisms for which approval to test is sought. The various charges applicable to laboratories are however set out in the table above.

When a laboratory wishes to become an approved laboratory, under Regulation 21 of the Animal By-products (Scotland) Regulations 2003 or Article 12 of the Regulation (EC) No 2160/2003, an application must be sent to The Scottish Government along with **fee (c)** to cover the administration of this initial application. Once the application has been processed the VLA will issue a quality assurance sample for which **fee (g)** is applicable. A laboratory that successfully identifies the quality assurance sample and completes the relevant paperwork will be added to the list of approved laboratories once **fee (d)** has been received and processed.

From that point the VLA will issue four quality assurance samples each year. **Fee (g)** is applicable to each sample issued. Laboratories in the scheme need to apply annually to retain their approved

status under the approval scheme and **fee (e)** must be included with this annual registration to cover the Government's administration costs.

The VLA arrange for inspections of the approved laboratories to be scheduled on a regular basis (every two to three years) or in response to a laboratory's failure to correctly identify a succession of quality assurance samples. **Fee (f)** is applicable for this service.

**Note**

Regulation (EC) No 2160/2003 requires that all laboratories authorised to carry out tests for zoonoses and zoonotic agents conform to EN ISO 17025 standards. From 31 December 2009 the Official Feed and Food Controls (Regulation (EC) No 882/2004) will require that all laboratories wishing to meet this ISO standard will need to be accredited by UKAS (as this is the only body in the UK currently able to accredit to this standard). As a result laboratories under the approved scheme will no longer be inspected by VLA from that date, as UKAS carry out their own inspections as part of the accreditation, and so will not need to pay the accompanying charge. This change will come into effect immediately for laboratories with existing UKAS accreditation.

The VLA quality assurance scheme will continue during and after this transition period and will run alongside UKAS accreditation.

**SCOTTISH GOVERNMENT RURAL DIRECTORATE**

**THE ZOOONOSES AND ANIMAL BY-PRODUCTS (FEES) (SCOTLAND)  
REGULATIONS 2007  
SSI 2007/577**

**REGULATORY IMPACT ASSESSMENT**

**THE SCOTTISH GOVERNMENT  
December 2007**

# REGULATORY IMPACT ASSESSMENT

## 1. Title of the regulatory proposal

The Zoonoses and Animal By-Products (Fees) (Scotland) Regulations 2007.

## 2. Purpose and intended effect

### Issue

A new fees regulation is being introduced to replace the Poultry Breeding Flocks, Hatcheries and Animal By-Products (Fees) (Scotland) Order 2002 so that Government is able to recover costs associated with the new Poultry Breeding Flocks and Hatcheries (Scotland) Order (2007) and the Animal By-products (Scotland) Regulations (2003).

The fees set out in the 2002 Fees Order have not been reviewed since it came into force. As such it has been some time since the fees charged allowed full cost recovery for the services provided on behalf of the Scottish Ministers. The proposed new Regulations therefore allow for increased fee levels compared to the previous order.

The format of the proposed regulations is also slightly changed compared to the previous order. The regulations give the Scottish Ministers the powers to charge fees at an appropriate level on the basis of certain criteria. The fees will be published on the Scottish Government website and will not appear on the face of the regulation itself. This will allow the fees to be revised without the need for a new statutory instrument and so it will be easier to update the fees in line with inflation and other increases in costs.

### Objective

To provide the Scottish Ministers with powers to set fees at a level to achieve full cost recovery, to avoid providing either a subsidy, or a source of taxation, through the administration of this scheme. The fees will therefore be amended to reflect more clearly the charges that are applicable under the current legislation and to take account of administrative costs.

### Background

The powers to charge under the Poultry Breeding Flocks, Hatcheries and Animal By-Products (Fees) (Scotland) Order 2002 relate to fees levied to enable the Government to recover costs for services provided under the Poultry Breeding Flocks, Hatcheries Order 1993 and Animal By-Products (Scotland) Order 1999. A new Poultry Breeding Flocks and Hatcheries (Scotland) Order (2007) came into force on 21 March 2007. The new order revoked the powers of the 1993 Order. In addition the Animal By-products (Scotland) Regulations 2003 have replaced the Animal By-Products (Scotland) Order 1999.

The 2002 Fees Order makes particular reference to The Poultry Breeding Flocks and Hatcheries Order 1993 and The Animal By-Products Order 1999. As explained above both of these Orders have since been revoked and replaced. By applying the terms of the Interpretation Act however it is still lawful to use the 2002 Fees Order to recover costs for services provided under The Poultry Breeding Flocks and Hatcheries (Scotland) Order 2007 and The Animal By-Products (Scotland) Regulations 2003. Notwithstanding this however, it has been agreed that for the sake of clarity and to ensure best practice a new updated Fees Order should be introduced.

The Poultry Breeding Flocks and Hatcheries (Scotland) Order 2007 (PBFH(S)O 2007) sets out, among other things, the requirements for registration and sampling in the National Control Programme (NCP) for breeding flocks. The NCP for Salmonella in breeding flocks of domestic fowl was written in partnership with representatives from the poultry industry. It sets out the new requirements for the monitoring and control of Salmonella in breeding flocks contained in EU Regulations (EC) No 2160/2003 and (EC) No 1003/2005. These Regulations set a target of not more than 1% of adult breeding flocks being infected with Salmonella of public health significance by the end of 2009. The National Control Programme for Salmonella applied to breeding flocks of domestic fowl (*Gallus gallus*) in the UK from 1 January 2007.

In order to chart progress towards meeting the reduction target specified in the EC legislation operators of breeding flocks will be required to provide official control samples on three occasions during the production cycle. These samples are in addition to samples taken at the operator's initiative. Official control samples will then be tested at the National Reference Laboratory. We are considering if official control samples could be tested by an authorised laboratory. The collection and testing of these official control samples will be under the control of competent authority. Samples to confirm the salmonella status of breeding flocks have previously been taken from hatcheries but with the introduction of the new PBFH(S)O 2007 these samples will be taken from the breeding flock holdings themselves.

Charges are proposed to cover costs incurred by Animal Health (formerly the State Veterinary Service (SVS)) in their role in managing the collection of official samples on behalf of the Scottish Ministers and by the Veterinary Laboratories Agency (VLA) in examining any samples received.

The Official Feed and Food Controls (Regulation (EC) No 882/2004) provides, in Articles 26 and 27, for recovery of costs by the competent authority for official controls although this requirement is not mandatory. Annex VI to the Official Feed and Food Controls sets out criteria to be taken into account for the calculation of fees. The items listed under Regulation 3(3) of the proposed fees regulation have been used as the basis for determining the appropriate charges for Scotland. The items are:

- (a) travel costs in relation to sampling, supervision, inspection and testing.
- (b) personnel costs in relation to sampling, supervision, inspection, testing and any application.
- (c) accommodation costs in relation to sampling, supervision, inspection, testing and any application.
- (d) equipment costs in relation to sampling, supervision, inspection, testing and any application.

The proposed fees regulation will also allow for VLA and the Scottish Government to recover costs for services in respect to the approved laboratory scheme. Under this scheme private laboratories are authorised by the competent authority to test operator samples for Salmonella under the National Control Plan and Salmonella, Enterobacteriaceae and Clostridium Perfringens under the Animal By-products (Scotland) Regulations 2005.

### **3. Risks**

In the context of the Fees Regulation, there is no perceived hazard, or situation, which would lead to any harm or detriment to any individual or organisation.



## 4. Options

Four main options have been identified.

**Option 1** – Produce a new fees regulation but continue to charge fees outlined in the previous Fees Order.

**Option 2** – Produce a new fees regulation with revised fees set out in a schedule

**Option 3** - Produce new regulations providing the Scottish Ministers with powers to publish fees, determined for each of the activities in the order on the basis of the cost to Government, on the Government's website

**Option 4** – Do nothing

### Option 1

The fees charged would fall further behind input costs. Government is required to collect an official sample three times during the production cycle of each breeding flock and test those samples in an approved lab. These costs are presently borne by The Scottish Government, Animal Health and the VLA. However it has been agreed, by all Government administrations, that these costs should be recovered fully. Similarly it has been agreed that services provided in relation to the authorised laboratory scheme should be recovered fully from the laboratories in the scheme.

If the fees were not updated then full cost recovery would not be achieved.

### Option 2

This would not introduce any new procedures or regulatory requirements with which the relevant businesses are not already complying. However, the increase in fees would allow The Scottish Government to achieve full cost recovery for 2007.

While the fees in the schedule would represent full cost recovery for 2007, this would not be achieved in subsequent years, as has been the case with previous orders, until another new order is produced.

### Option 3

As with option 2 above, this option would allow The Scottish Government to achieve full cost recovery for 2007. However this option provides increased flexibility and longevity to the proposed fees regulation. By using the regulations simply to give Government powers to determine fees on the basis of the costs attributed to the services provided it will be possible to update the level of fees annually by amending the fees published on the Scottish Government website without the need to produce new legislation. Details of the charges will be made available in other formats for operators without easy internet access.

This simplified process removes significant Government costs and administrative effort associated with the development of new legislation and ensures that Government can ensure that fees track more effectively other prices in the economy. At present fees are amended on an ad-hoc basis. This

means that Government is able to achieve full cost recovery only in the first year that the order is in place and that when revised fees are published they represent a significant increase in a single year.

Option 3 would allow a mechanism to be established that would see the published fees revised on a regular and agreed timescale which would provide increased certainty for businesses and Government with regard to the level of fees levied and collected. **The level of fees proposed at each revision (likely to be annually) would be discussed fully with affected parties.**

**This is Government's proposed option and is reflected in the draft statutory instrument.**

#### Option 4

This option would mean that no new fees order would be introduced. Consequently, Government would not be in a position to fully recover its costs for services provided. Furthermore the lab authorisation scheme would have to be amended as a lab can only be considered for authorisation if appropriate payment of fees accompanies its application.

As all Government administrations have agreed to recover fees for these services, this option is not considered to be feasible.

### **5. Issues of equity or fairness**

The revised fees will be set at levels to achieve full cost recovery and are therefore considered to be no more onerous than when originally introduced in 1993 and revised in 2002. Fees for official sampling and testing apply to all breeding flock operators who fall within the scope of the breeders NCP and to all approved laboratories.

### **6. Benefits**

Option 1 – No perceived benefits in terms of cost recovery.

Option 2 – Will ensure cost recovery to The Scottish Government for 2007 by revising the present fees in line with current input costs and allow for the recouping of the department's administrative costs.

Option 3 - as option 2, but with the benefit that fees could be updated regularly in line with increases in input costs without significant administrative costs.

Option 4 – No perceived benefits in terms of cost recovery.

### **7. Costs to business**

#### Businesses affected

The businesses affected would be those to whom the fees set out in the Fees Regulations are directly applicable. These include registered owners of breeding flocks of domestic fowls and laboratories approved by The Scottish Government to test for salmonella under the Poultry Breeding Flocks and Hatcheries (Scotland) Order 2007 and for salmonella, enterobacteriaceae and clostridium perfringens under Animal By-Products (Scotland) Regulations 2003.

In UK there are around 620 breeding flock holdings with an estimated 2000 flocks which would be subject to the new sampling and testing regime. 68 of these holdings are located in Scotland.

9 laboratories in Scotland are approved currently under the approved laboratory scheme. Laboratories may decide to pass the costs solely on to their customers who submit samples to them for testing under these Orders (breeding flock owners and renderers) or to spread the costs over all customers using their services. This would include, for example, those submitting samples under the various Government and industry codes of practice for the control of salmonella.

### Compliance costs

The existing and proposed fees are set out in the following table. The activities in column one are listed as they appear in Regulation 3(2) in the proposed fees regulation. In this table, as in the proposed fees regulation, “the European Regulation” means Regulation (EC) No 2160/2003 and “the Regulations” means the Animal By-Products (Scotland) Regulations 2003.

| <b>Activities</b>   | <b>2002 charge (£)</b>      | <b>Proposed 2007 charge (£)</b>  |
|---|-----------------------------|--|
| (h) taking or supervising the taking of official control samples  | 28.20 per ½ hour            | Base fee £32 plus investigation fee of £23 per ½ hour (or part thereof). |
| (i) examining official control samples  | N/A <sup>*(1)</sup>         | 18.50  |
| (j) processing of an application for approval of a laboratory under Regulation 21 of the Regulations or Article 12 of the European Regulation | 10.60                       | 12.50  |
| (k) Processing of the approval documentation further to an application referred to in (c).  | 24.60                       | 29.50  |
| (l) processing of an annual renewal application from an approved laboratory   | 24.60                       | 29.50  |
| (m) inspecting a laboratory, for the purpose of Regulation 21 of the Regulations or Article 12 of the European Regulation, for                |                             |  |
| i) 1 test e.g. Salmonella PBFH(S)O or Salmonella ABP(S)R  | 348.40                      | 613.50   |
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\*<sup>(1)</sup> - Charges for testing official samples have been simplified since 2002 and so it is difficult to make a direct comparison. Several possible tests were applicable to samples taken under the previous sampling protocol and each was charged separately. Further details below

\*<sup>(2)</sup> - these charges were split in the 2002 Order such that fees were published separately for costs of sending one set of QA samples at first application, the first charge, and 4 sets of QA samples per year for an approved lab, the second figure, which includes a Government administration charge.

### Breeding flock Holdings

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The Animal Health will arrange for official samples to be collected from each adult breeding flock annually. There are three options for collecting the official samples.

- a) Animal Health visit and collect the samples
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- c) Animal Health authorises another competent person to take the official samples under instruction.

As a minimum each holding of a breeding flock operator should receive at least one visit from a member of Animal Health staff each year for sampling and auditing purposes. Given the structure of the industry, on a risk based approach it is anticipated that two of these samples could be taken under option (c) in most cases.

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Accordingly the projected cost for official control sampling in Scotland would range from **£5304** per annum to **£14690** per annum for sampling. The cost for examination of all official samples collected is estimated at **£15096** per annum (*272 flocks x 3 x £18.50*). Therefore the estimated total combined cost to business in Scotland for official sampling and testing of breeding flocks under the proposed fees regulations ranges from **£20400 per annum** to **£29786 per annum**. The average cost for each holding would range from **£300** to **£438 per annum**.

#### Approved Laboratories

The fees applicable to laboratories under the approval scheme are not straightforward as they depend on the status of approval (i.e. first application, renewal etc.) and the organisms for which approval to test is sought. The various charges applicable to laboratories are however set out in the table above.

When a laboratory wishes to become an approved laboratory, under Regulation 21 of the Animal By-products (Scotland) Regulations 2003 or Article 12 of the Regulation (EC) No 2160/2003, an application must be sent to The Scottish Government along with **fee (c)** to cover the administration of this initial application. Once the application has been processed the VLA will issue a quality assurance sample for which **fee (g)** is applicable. A laboratory that successfully identifies the quality assurance sample and completes the relevant paperwork will be added to the list of approved laboratories once **fee (d)** has been received and processed.

From that point the VLA will issue four quality assurance samples each year. **Fee (g)** is applicable to each sample issued. Laboratories in the scheme need to apply annually to retain their membership of the approval scheme and **fee (e)** must be included with this annual registration to cover the Government's administration costs.

The VLA arrange for inspections of the approved laboratories to be scheduled on a regular basis (every two to three years) or in response to a laboratory's failure to correctly identify a succession of quality assurance samples. **Fee (f)** is applicable for this service.

9 laboratories in Scotland are approved currently under the approved laboratory scheme.

#### **Note**

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December 2009 the Official Feed and Food Controls (Regulation (EC) No 882/2004) will require that all laboratories wishing to meet this ISO standard will need to be accredited by UKAS (as this is the only body in the UK currently able to accredit to this standard). As a result laboratories under the approved scheme will no longer be inspected by VLA from that date, as UKAS carry out their own inspections as part of the accreditation, and so will not need to pay the accompanying charge. This change will come into effect immediately for laboratories with existing UKAS accreditation.

The VLA quality assurance scheme will continue during and after this transition period and will run alongside UKAS accreditation.

## **8. Impact on Small Businesses**

The proposed fees will apply equally across the industry, which includes small businesses, and are not considered to be discriminatory.

## **9. Securing Compliance**

The regulations will not introduce any new procedures or regulatory requirements with which the relevant businesses are not already complying. Fees will be levied through the existing mechanisms.

## **10. Consultation**

A formal consultation was not carried out in advance of the laying of the Fees regulations. Through the relevant legislation and the guidance for the laboratory approval scheme, which was consulted upon at the time of introduction, the services for which fees must be set are clear. Samples to confirm the salmonella status of breeding flocks have previously been taken from hatcheries but with the introduction of the new PBFH(S)O 2007 these samples will be taken from the breeding flock holdings themselves. Accordingly it is proposed that fees are collected from the breeding flock holding operator instead of from the hatchery owner. The move from hatcheries to flock holdings has been considered in a consultation on the implementation of the PBFH(S)O 2007 and the application of fees to follow where the sampling takes place is not considered to be a new issue. As fees must be set at the level indicated to achieve full cost recovery it was not considered that consultation on the proposed new fees regulation was appropriate as Cabinet Office guidance states that consultation is not necessary where decisions to be taken would not be changed as a result of the comments received. Businesses directly affected, and relevant industry organisations, will be notified suitably in advance of the regulations coming into force. These groups will have the opportunity to comment on the levels of charges proposed each time they are due to be updated.

## **11. Competition Assessment**

The Competition Filter has been applied to the proposals. As a result we do not believe that there will be a competitive impact as a result of these proposals. The revised fees will be set at levels to achieve full cost recovery and are therefore considered to be no more onerous than when originally introduced in 1993 or revised in 2002. Although there may be minor differences in the costs on some businesses due to the date that the order will come into force, over the long-term costs will fall equally on all firms directly affected. It is not considered that the proposed regulations will affect the market structure or erect barriers to entry for new firms. A detailed assessment is not considered necessary.

## **12. Post-implementation Review**

Annual accounts will be produced to assess progress against the target of full cost recovery for the provision of the relevant services. It is intended that the level of fees will be reviewed annually

### **13. Recommendation**

Of the three options identified the third, to introduce new fees regulations with fees set at a level for full cost recovery and published on The Scottish Government's website, is the recommended choice. Full cost recovery would follow immediately from the introduction of the new regulations.

### **14. Declaration**

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

Signed: RICHARD LOCHHEAD

Date: 21st DECEMBER 2007

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