

**EXPLANATORY MEMORANDUM TO  
THE ZONOSSES AND ANIMAL BY-PRODUCTS (FEES) (ENGLAND)  
REGULATIONS 2007**

**2007 No. 2074**

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

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

2. **Description**

2.1 This instrument provides the Secretary of State with powers to charge farmers and operators of private laboratories in order to recover costs incurred by the government in providing the following services:

- official sampling and testing of Salmonella in Breeding flocks of domestic fowl
- approval of private laboratories to carry out testing under the Poultry breeding flocks and Hatcheries Order 2007 and the Animal By-products regulations 2005

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

*For official sampling and testing under the breeding flocks NCP*

- The estimate of total costs to business in England for official sampling and testing of breeding flocks ranges per annum ranges from **£266,232 to £451,000 per annum**. This compares to **£76,584 per annum** collected under the previous fees legislation.
- The average cost per annum for each holding would range from **£528.24 to £894.84**.

*For the laboratory approval scheme*

- the total combined cost to laboratories in England was estimated to be **£15,576 per annum** (average **£354 per annum** per lab). This compares with **£10,692 per annum** under the previous charging arrangements (**£243 per annum** per lab).

4. **Legislative Background**

4.1 The Poultry Breeding Flocks and Hatcheries Order 2007 (PBFHO 2007) sets out, among other things, the requirements for registration and sampling in the National Control Programme (NCP) for breeding flocks. 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 applies to breeding flocks of domestic fowl (*Gallus gallus*) in the UK from 1 January 2007.

- 4.2 In order to chart progress towards meeting the reduction target specified in the EC legislation each breeding flocks will be required to provide official control samples on three occasions during the production cycle. Official control samples will then be tested at the National Reference Laboratory. Charges are made to recover costs incurred by the State Veterinary Service (SVS) in their role in managing the collection of official samples on behalf of the Secretary of State and by the Veterinary Laboratories Agency (VLA) in examining any samples received.
- 4.3 The proposed fees regulation will also allow for VLA and Defra 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 (as required under EU Regulations (EC) No 2160/2003 and (EC) No 1003/2005) and Salmonella, Enterobacteriaceae, Clostridium Perfringens and other organisms as required under the Animal By-products Regulations 2005.
- 4.4 This instrument is made under section 56(1) and (2) of the Finance Act 1973 which permits a Government department to require the payment of fees or other charges for the provision of any services or facilities or the issue of any authorisation, certificate or other document, in pursuance of any Community obligation. As an instrument made under the Finance Act 1973, the Regulations are subject to Treasury consent.

## **5. Extent**

- 5.1 This instrument applies to England.

## **6 European Convention on Human Rights**

- 6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

## **7 Policy background**

- 7.1 This regulation will be introduced to ensure that the Secretary of State is able to recover costs for services provided by Government in relation the implementation of European Legislation on the control of Salmonella and other zoonotic diseases in primary production. The regulation is necessary as the powers to charge for these services had lapsed with the introduction of the new Poultry Breeding Flocks and Hatcheries Order 2007.

## **8 Impact**

- 8.1 A Regulatory Impact Assessment is attached to this memorandum which describes in detail the impact and associated costs related to the proposed legislation

## **9 Contact**

David Collins at the Department of Environment, Food and Rural Affairs.  
Tel 020 7904 6465 or e-mail: david.p.collins@defra.gsi.gov.uk can answer any queries regarding the instrument.

## **Annex to the Explanatory Memorandum**

### **REGULATORY IMPACT ASSESSMENT**

#### **1. Title of the regulatory proposal;**

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

#### **2. Purpose and intended effect;**

##### Issue

1) A new fees regulation is needed to replace the Poultry Breeding Flocks, Hatcheries and Animal By-Products (Fees) (England) Order 2002 so that Government is able to recover costs associated with the new Poultry Breeding Flocks and Hatcheries Order (2007) and the Animal By-products Regulations (2005).

2) 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 Secretary of State. The proposed new Regulations therefore allow for increased fee levels compared to the previous order.

3) The format of the proposed regulations is also slightly changed compared to the previous order. The regulations give the Secretary of State the powers to charge fees at an appropriate level on the basis of certain criteria. The fees will be published on the Defra website and will not appear on the face of the regulations 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 Secretary of State 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) (England) 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 Order 1999. A new Poultry Breeding Flocks and Hatcheries Order (2007) came into force on 7 March 2007. The new order revoked the powers of the 1993 Order. In addition the Animal By-products Regulations 2005 have replaced the Animal By products Order 1999.

As a result the fees charged under the Poultry Breeding Flocks, Hatcheries and Animal By-Products (Fees) (England) Order 2002 are no longer applicable. Therefore a new fees regulation is needed to ensure that Government is able to recover the

costs for certain services provided to food business operators relating to control measures for reducing the prevalence of Salmonella in breeding flocks of *Gallus gallus*.

The Poultry Breeding Flocks and Hatcheries Order 2007 (PBFHO 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 applies 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 each 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 PBFHO 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 Secretary of State 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 in to 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 determine the appropriate charges for England. 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 Defra 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 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. At present, however, Defra, Animal Health and the VLA are in a position where costs cannot be recovered.

### 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 Secretary of State with powers to publish fees, determined for each of the activities in the order on the basis of the cost to Government, on the Defra 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 borne by Defra, Animal Health and VLA and it has been agreed, by Defra and the devolved 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 Defra 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 Defra 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 Defra 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 the 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. As a result Government would not be able to recover any costs with regard to official control sampling for Salmonella in breeding flocks and the Laboratory Authorisation scheme. 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.

Defra and the devolved administrations have agreed to recover fees for these services and so 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.

From the date that the PBFHO 2007 came into force and the date on which the proposed revised fees order comes into force Government will not be able to recover costs for official control sampling for Salmonella in breeding flocks and the Laboratory Authorisation scheme. During this time some operators will have been sampled more than others and so will have benefited from not paying the fees due compared to operators who will be sampled once the fees order is in force. However each breeding flock will be sampled at least once during the production cycle and most operators will have more than one flock so the effect of the change in fee collection is not considered to have a significant impacts between operators.

## 6. Benefits;

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

Option 2 – Will ensure cost recovery to Defra 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 Defra to test for salmonella under Poultry Breeding Flocks and Hatcheries Order 2007 and for salmonella, enterobacteriaceae and clostridium perfringens under Animal By-Products Regulations 2005.

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. 90% of these flocks are located in England.

44 laboratories in England 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 Regulations 2005.

Full details of how the proposed charges are derived can be found in **the Appendix to this RIA**

Activities	2002 charge (£)	Proposed 2007 charge (£)
(a) taking or supervising the taking of official control samples	28.20 per ½ hour	Base fee £37 plus investigation fee of £28 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 PBFHO or Salmonella ABPR	348.40	613.50
ii) 2 tests e.g. Salmonella PBFHO and Salmonella ABPR	359.70	632.50
iii) 3 tests e.g. all ABPR, or 2 of ABPR with Salmonella PBFHO	370.90	651.50
iv) 4 tests e.g. all ABPR and Salmonella PBFHO		670.50
(g) administering a quality control test, under Regulation 21 of the Regulations or Article 12 of the European Regulation, for		
i) Salmonella (PBFHO, poultry)	25.10/26.73 <sup>*(2)</sup>	32.00
ii) Salmonella (ABPR, isolation and culture)	25.10/26.73 <sup>*(2)</sup>	32.00
iii) Enterobacteriaceae (ABPR, isolation and culture)	48.90/50.55 <sup>*(2)</sup>	57.00
iv) Clostridium Perfringens (ABPR, isolation and culture)	48.90/50.55 <sup>*(2)</sup>	57.00

\*<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 Defra 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 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 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.

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 by 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 PBFHO 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 in December 2006 there were 620 breeding flocks holdings in GB of which 503 were in England. Assuming that on average each holding keeps 4 flocks then around 2000 flocks would be subject to the new sampling and testing regime.

At the time of the introduction of the previous fees order a Regulatory Impact Assessment was produced in which estimates for the total costs to industry for official sampling were produced. The estimated total combined cost to business in England for official sampling and testing under the previous fees order was **£76,584 per annum**.

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 (2000

flocks) and that the visit would last for a half hour (meaning a charge per visit of £65). The lower cost assumes that all flocks on a holding (504 holdings) are sampled in a single visit but that the visit takes one hour (visit charge of £93). All official samples would be examined by the VLA at a cost of £18.50 per sample tested.

Accordingly the projected cost for official control sampling in England would range from **£46,872** per annum to **£130,000** per annum for sampling. The cost for examination of all official samples collected is estimated at **£111,000** per annum. Therefore the estimated total combined cost to business in England for official sampling and testing of breeding flock under the proposed fees regulations ranges from **£157,872 per annum** to **£241,000 per annum**. The average cost for each holding would range from **£313** to **£478 per annum**.

### Approved Laboratories

The fees applicable to laboratories under the approval scheme are complicated as they depend on the status of approval (i.e. first application, renewal etc.) and the organisms for which approval to test is sought.

When a laboratory wishes to become an approved laboratory, under Regulation 21 of the Animal By-products Regulations 2005 or Article 12 of the Regulation (EC) No 2160/2003, an application must be sent to Defra 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 Defra 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.

44 laboratories in England are approved currently under the approved laboratory scheme.

#### **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.

### *Cost comparison*

It is difficult to compare total costs between the previous Fees order and the proposed Fees Regulations as the charges are broken down into many constituent parts. However to make a useful comparison it is assumed that

- the number of laboratories covered by the approved laboratory scheme have remained constant with 2 new laboratories applying to join the scheme each year and 2 leaving the scheme.
- laboratories are subject to inspections every 3 years so in any given year one in three laboratories would be inspected.
- the tests carried out by the labs are the same under the fees order and the fees regulation, with each laboratory testing for Salmonella under PBFHO and Enterobacteriaceae under ABPR

This allows for the calculation of an average cost per laboratory under the previous fees order, **£243 per annum**, and an average cost per laboratory of **£354 per annum** under the new fees regulation.

As a result it is calculated that under the previous Fees Order the total combined cost to laboratories in England would have been **£10,692 per annum**. With the revised fees this figure would be expected to rise to **£15,576 per annum**

## **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 PBFHO 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 PBFHO 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. Monitoring and 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 Defra 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.

BEN BRADSHAW

27 June 2007

MINISTER OF STATE (COMMONS)

DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

Contact Point: David Collins, Surveillance, Zoonoses and Emerging Issues Division  
Rm 601, 1A Page St, London, SW1P 4PQ Tel: 020 7904 6465  
Email: david.p.collins@defra.gsi.gov.uk

## Appendix - Detailed breakdown of how proposed charges are derived

### Summary of charges

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 Regulations 2005.

Activity	2002 charge (£)	Proposed 2007 charge (£)
(a) taking or supervising the taking of official control samples	28.20 per ½ hour	Base fee £37 plus investigation fee of £28 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 PBFHO or Salmonella ABPR	348.40	613.50
ii) 2 tests e.g. Salmonella PBFHO and Salmonella ABPR	359.70	632.50
iii) 3 tests e.g. all ABPR, or 2 of ABPR with Salmonella PBFHO	370.90	651.50
iv) 4 tests e.g. all ABPR and Salmonella PBFHO		670.50
(g) administering a quality control test, under Regulation 21 of the Regulations or Article 12 of the European Regulation, for		
i) Salmonella (PBFHO, poultry)	25.10/26.73 <sup>*(2)</sup>	32.00
ii) Salmonella (ABPR, isolation and culture)	25.10/26.73 <sup>*(2)</sup>	32.00
iii) Enterobacteriaceae (ABPR, isolation and culture)	48.90/50.55 <sup>*(2)</sup>	57.00
iv) Clostridium Perfringens (ABPR, isolation and culture)	48.90/50.55 <sup>*(2)</sup>	57.00

<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 Defra administration charge.

Note - this fees Regulation covers activities required under the Poultry breeding Flocks and Hatcheries Order (England) 2007 (PBFHO) (which implements Commission Regulation (EC) No 2160/2003) and the Animal By-products Regulations 2005 (ABPR). The PBFHO and ABPR annotations are used in this section of the RIA to identify whether the charges proposed relate to either PBFHO or ABPR requirements.

### **Basis for published charges**

The proposed fees regulations will give powers to the Secretary of State to determine fees for the activities undertaken on his behalf with regard to sampling and testing official control samples required under Regulation (EC) 2160/2003 and the authorisation of approved laboratories under the Animal By-Products Regulations 2005 [or/and] Regulation (EC) No 2160/2003.

The applicable fees will be published on the Defra website. The charges are derived on the basis of the following principles of the HM Treasury Fees and Charges Guide (2004)

- The financial objective should be full cost recovery for the services provided. In principle the full cost should be recovered each year.
- The full cost should be calculated on an accruals basis. It is the total cost of all the resources used in providing the service (direct and indirect costs, including a full proportional share of overhead costs and any selling and distribution expenses, insurance, depreciation and cost of capital, etc, both cash and “non-cash” costs).
- The costs should be actual whenever possible, with estimates (e.g. based on periodic surveys) used only when the actual information is not available (or only available at disproportionate cost). Whenever possible, the method of assessing costs should be that used for the operating cost statement of departments’ resource accounts (or other public bodies’ annual accounts). Where necessary, a method of apportioning overhead costs should be determined and applied consistently

The items which make up the costs of the services which are intended to be recovered by the charges specified in the proposed fees legislation cover:

- (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 details of the proposed charges are set out in the following pages including information about the purpose of each charge and how each charge is derived. Some rounding (to the nearest 50 pence) has been applied to the proposed charges to simplify invoicing and collection.



## Details of each charge proposed

### (a) taking or supervising the taking of official control samples

#### *Purpose of charge*

This charge covers duties carried out by Animal Health (formerly the State Veterinary Service (SVS)), on behalf of the Secretary of State, in visiting and collecting or supervising the collection of official control samples from breeding flock holdings for the purpose of verifying progress towards Salmonella reduction targets specified in Regulation (EC) 2160/2003 and Regulation (EC) 1003/2005.

<i>2002 Charge:</i>	<i>Proposed 2007 Charge:</i>
£28.20 per ½ hour (or part thereof)	Base fee £37 plus investigation fee of £28 per ½ hour (or part thereof).

#### *How the charge is derived:*

The charge is based on two components

a) the base charge is a fixed fee that covers costs that are associated with the supervision of or the taking of official control samples on all holdings. -Costs are derived on estimates of the time taken to process an application (e.g. organising visits, systems inputs, checking test results etc.) by the various grades of staff involved. These estimates of time have been multiplied by the Animal Health charge out rate. The Animal Health charge out rates are based upon the average employment costs for each grade of Animal Health staff (includes salary, employer's NIC and employer's pension contributions) plus overheads and notional costs (taken from the Animal Health budgets for 2006/07). These rates are then adjusted for productivity. An hourly rate is then calculated by dividing the annual rate by 215 working days and 7.4 hours per day. The 215 working days are arrived at by taking 260 weekdays and adjusting for holiday and estimated other non delivery time (e.g. training and sick).

The other costs relating to the 'Basic Application Fee' are based upon estimates of DFSSD invoice processing costs, management time, development and maintenance time and VLA charges (for animal testing only - VLA to charge separately in this case). An estimate of the total annual cost has been calculated and spread over the estimated number of tests required per annum to produce a fixed charge. This current fixed cost has been calculated on an estimate of 500 breeding flocks being tested. The fixed charge is sensitive to any fluctuation in volume.

b) The additional investigation fee is a time based charge calculated on a per test basis, and include all relevant travel time as well as onsite sampling time. This charge will vary from breeding flock to breeding flock. The rate for this part of the charge is based on the hourly rate of an Animal Health Officer (AHO) who would be conducting the official visit for the purpose of supervising the collection of official samples.

(b) examining official control samples

*Purpose of charge*

This charge covers duties performed by the VLA, on behalf of the Secretary of State, in examining the official control samples collected by Animal Health under (a). This examination will determine the presence or absence of Salmonella in the sample.

*2002 Charge:*

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 as follows

a) Examination of composite faecal samples	17.70
b) Examination of	
i) composite meconium	17.70
ii) chicks dead in shell and	37.10
iii) culled chicks at hatchery	37.10

*Proposed 2007 Charge:*

A single charge is applicable for the examination by the VLA of all official samples supplied to them. **The charge is proposed to be £18.50**

*How the charge is derived:*

This is a new test. The cost derives from an average time to perform the test plus necessary test consumables and reagents. The cost of staff time is based mainly on the approved rate for a VLA grade F in the Laboratory Testing Department (£45.87 per hour).

(c) processing of an application for approval of a laboratory under Regulation 21 of the Regulations or Article 12 of the European Regulation

*Purpose of charge*

This charge covers duties performed by Defra in administering an application for a private laboratory to be authorised under the approved laboratory scheme. This charge only applies where the laboratory is not included in the scheme at the time of the application (i.e. this charge is additional to the annual charge for renewing membership of the scheme)

<i>2002 Charge</i>	<i>Proposed 2007 Charge</i>
£10.60	£12.50

*How the charge is derived:*

This charge is based on a Defra official at the AO grade spending 0.5 hours to complete this initial administration of an application. The AO hourly rate is £25.21 which includes salary costs (pay, pension and national insurance contribution), accommodation and general overheads. This rate has increased at just over 3.5% per annum since 2002.

The charge has been rounded down to the nearest 50 pence

(d) Processing of the approval documentation further to an application referred to in (c).

*Purpose of charge*

This charge covers duties performed by Defra in processing a successful application from a private laboratory under the approved laboratory scheme. This charge would be levied only in the first year of the approval. the annual renewal charge (e) is not applicable where the fee for processing of the approval documentation further to an application referred to in (c) is levied. This charge covers administrative costs to Defra for the first year in which the laboratory is part of the approved laboratory scheme.

<i>2002 Charge</i>	<i>Proposed 2007 Charge</i>
£24.60	£29.50

*How the charge is derived:*

This charge is based on a Defra official at the AO grade spending 1 hour 10 minutes to complete the administration of a successful application. The AO hourly rate is £25.21 which includes salary costs (pay, pension and national insurance contribution), accommodation and general overheads. This rate has increased at just over 3.5% per annum since 2002.

The charge has been rounded up to the nearest 50 pence.

(e) processing of an annual renewal application from an approved laboratory

*Purpose of charge*

This charge covers duties performed by Defra in processing an application from a private laboratory to renew membership of the approved laboratory scheme. This charge would be levied for each year that the laboratory would wish to remain part of the approved laboratory scheme.

<i>2002 Charge</i>	<i>Proposed 2007 Charge</i>
£24.60	£29.50

*How the charge is derived:*

This charge is based on a Defra official at the AO grade spending 1 hour 10 minutes to complete the administration of an annual renewal. The AO hourly rate is £25.21 which includes salary costs (pay, pension and national insurance contribution), accommodation and general overheads. This rate has increased at just over 3.5% per annum since 2002.

The charge is levied at the same rate as for charge (d) as many of the functions of this service are the same.

The charge has been rounded up to the nearest 50 pence

(f) inspecting a laboratory for the purpose of Regulation 21 of the Regulations or Article 12 of the European Regulation

*Purpose of charges*

This charge covers duties performed by the VLA, on behalf of the Secretary of State, and Defra in arranging and carrying out inspections of approved laboratories. Inspections will 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. The VLA carry out the inspection and Defra provides administrative support to this function.

	2002 Charge:	Proposed 2007 Charge		
		VLA cost	Defra cost	<b>Final charge</b>
inspection of a laboratory for				
i) 1 test e.g. Salmonella PBFHO or Salmonella ABPR	348.40	588.50	25.00	<b>613.50</b>
ii) 2 tests e.g. Salmonella PBFHO and Salmonella ABPR	359.70	607.50	25.00	<b>632.50</b>
iii) 3 tests e.g. all ABPR, or 2 of ABPR with Salmonella PBFHO	370.90	626.50	25.00	<b>651.50</b>
iv) 4 tests e.g. all ABPR and Salmonella PBFHO		645.50	25.00	<b>670.50</b>

*How the charge is derived*

The charge is made up of two parts. Most of the cost covers VLA activities but a smaller amount covers Defra administrative costs. Costs have been rounded to the nearest 50 pence.

a) The VLA part of the charge is derived to take account of the time taken by VLA Band C staff to prepare for, attend and carry out the inspection and produce a report following the inspection. The charge includes travelling time to the customer and return, inspection time, consideration time, writing the report and answering customer queries.

The proposed 2007 charging level sees a significant increase from previous levels. The increase reflects higher personnel costs, up by 69% to £75.93/hr for April 2007, and a recognition that the 'average' inspection process, which could only be estimated for the previous Fees Order, is more time consuming than had previously been accounted for - an extra half hour has been allocated on the basis of VLA experience. The time allocated for a laboratory inspection is up to 8.5 hours.

b) The Defra part of the charge is based on a Defra official at the AO grade spending one hour to liaise with VLA inspectors to arrange the laboratory visit, issue paperwork regarding the visit and keep a record of the outcome of the visit. This results in a Defra administration charge of £25.21 per visit, which is rounded down to £25.00. The AO hourly rate is £25.21 which includes salary costs (pay, pension and national insurance contribution), accommodation and general overheads. This rate has increased at just over 3.5% per annum since 2002.

(g) administering a quality control test under Regulation 21 of the Regulations or Article 12 of the European Regulation

*Purpose of charges*

This charge covers duties performed by the VLA, on behalf of the Secretary of State, and Defra in managing a quality assurance scheme for approved laboratories. VLA issue samples to laboratories who are required to examine the sample to determine the presence or absence of specific organisms and then return results to VLA. Defra provides administrative support to this function.

The charges below relate to a single distribution of a QA sample for each organism listed. As noted in the main section of the RIA one QA sample per organism will be distributed when a laboratory first applies to join the scheme. Thereafter 4 QA samples will be distributed to approved laboratories each year for each organism for which they are approved.

	2002 Charge:	Proposed 2007 Charge		
		VLA cost	Defra cost	Final charge
i) Salmonella (PBFHO)	25.10/26.73*	30.00	2.00	<b>32.00</b>
ii) Salmonella (ABPR)	25.10/26.73*	30.00	2.00	<b>32.00</b>
iii) Enterobacteriaceae (ABPR)	48.90/50.55*	55.00	2.00	<b>57.00</b>
iv) Clostridium Perfringens (ABPR)	48.90/50.55*	55.00	2.00	<b>57.00</b>

\* - 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 Defra administration charge.

*How the charge is derived:*

The charge is made up of two parts. Most of the cost covers VLA activities but a small amount covers Defra administrative costs.

a) The VLA cost derives from staff time at the approved rate/hour for the appropriate grade (which includes all salary costs and overheads), and test consumables and reagents. The cost of staff time is based on the approved rate for a VLA grade E in the Quality Assurance Unit (£47.76 per hour).

Under the previous fees order a charge was applied for when samples for iii) and iv) were sent together. This charge represented a small saving compared to issuing the 2 samples separately. However on reflection no saving was achievable by the issuing body (VLA). Although there was a small saving in postage, the additional time taken

for manual intervention in automated systems to achieve it was of greater cost so it is proposed to revert to simple unit costs for each applicable QA sample issued. Furthermore the previous Order had a single charge for Salmonella whether this was for the purposes of the Poultry Breeding Flocks and Hatcheries Order or for the Animal By-Products Regulations. In fact these are two different QA schemes under the two sets of legislation. This is now reflected in the charging scheme.

b) The Defra part of the charge is based on a Defra official at the AO grade spending five minutes per sample issued to check that each sample has been issued and to note the results of each sample completed. This results in a Defra administration charge of £2.10 per QA sample – which is rounded down to £2.00. The AO hourly rate is £25.21 which includes salary costs (pay, pension and national insurance contribution), accommodation and general overheads. This rate has increased at just over 3.5% per annum since 2002.

27 June 2007



## ADDENDUM TO REGULATORY IMPACT ASSESSMENT FOR THE ZOOSES AND ANIMAL BY-PRODUCTS (FEES) (ENGLAND) REGULATIONS 2007

1. Following informal consultation on the RIA with key representatives of the industry affected by the legislation a number of changes were necessary to update the RIA. These changes are set out in this document.
2. The main changes concern the charges to be applied services carried out by Animal Health with regard to official control sampling under the National Control Programme for breeding flocks.
  - a. Amendments to unit charges for Animal Health services

The unit charges for services provided by Animal Health in taking or supervising the taking of official control samples for Salmonella in breeding flocks have been reduced since the RIA was issued. These reductions have been achieved through administrative savings within Animal Health and, in particular, savings in IT provision. Therefore the base fee is reduced from **£37 to £32**. The investigation fee is reduced from **£28 to £23**. The following table should replace the table on page 5 in the RIA and page 1 of the Appendix to the RIA.

Activities	2002 charge (£)	Proposed 2007/8 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 PBFHO or Salmonella ABPR	348.40	613.50
ii) 2 tests e.g. Salmonella PBFHO and Salmonella ABPR	359.70	632.50
iii) 3 tests e.g. all ABPR, or 2 of ABPR with Salmonella PBFHO	370.90	651.50
iv) 4 tests e.g. all ABPR and Salmonella PBFHO		670.50
(g) administering a quality control test, under Regulation 21 of the Regulations or Article 12 of the European Regulation, for		
i) Salmonella (PBFHO, poultry)	25.10/26.73 <sup>*(2)</sup>	32.00

ii) Salmonella (ABPR, isolation and culture)	25.10/26.73 <sup>*(2)</sup> 48.90/50.55 <sup>*(2)</sup>	32.00 57.00
iii) Enterobacteriaceae (ABPR, isolation and culture)	48.90/50.55 <sup>*(2)</sup>	57.00
iv) Clostridium Perfringens (ABPR, isolation and culture)		

Consequential amendments are also required the section of Appendix to the RIA providing details of how the charge for services provided by Animal Health in relation to official control sampling is derived. The following table should replace the table on page 4 of the Appendix to the RIA

<i>2002 Charge:</i>	<i>Proposed 2007 Charge:</i>
£28.20 per ½ hour (or part thereof)	Base fee £32 plus investigation fee of £23 per ½ hour (or part thereof).

b. Amendments to cost estimates for official control sampling by Animal Health

An analysis of the estimated costs to industry resulting from proposals to charge for official control sampling under the Breeding flock National Control Programme are provided on page 7 under the section headed “Cost comparison”. The costs under the proposed fees regulation are based on the proposed unit costs for the provision of the services and an estimate of the time that would be taken by Animal Health in providing these services. Charges relating to the examination of official control samples by the VLA are also included.

Estimates of the time required by Animal Health to collect or supervise the collection of all official control samples on a holding were based on based on experiences of VLA experts in carrying out similar surveillance work in breeding flocks. The Breeding flock National Control Programme has now been in operation for several months. Accordingly Animal Health have been able to provide more accurate information on how long official sampling is taking. In fact sampling is taking between three and six hours rather than the half hour to one hour that was estimated in the RIA. As a result the estimated costs for sampling in the RIA significantly underestimated the likely actual costs to industry. The estimated average cost per holding per annum in the original RIA was £313 to £478 per holding. Revised costings suggest a range that the average cost per holding would be between £528 (based on 3 hours sampling) and £894 (based on 6 hours).

The following paragraphs should be replaced on page 7 of the RIA:

*“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 in December 2006 there were 620 breeding flocks holdings in GB of which 503 were in England. Assuming that on average each holding keeps 4 flocks then around 2000 flocks would be subject to the new sampling and testing regime.

At the time of the introduction of the previous fees order a Regulatory Impact Assessment was produced in which estimates for the total costs to industry for official sampling were produced. The estimated total combined cost to business in England for official sampling and testing under the previous fees order was **£76,584 per annum**.

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. Animal Health charges are based on the cost of visits rather than the total number of samples taken and it is anticipated that Animal Health would collect or supervise the collection of official samples from all the flocks on a holding at a single visit. Since the start of the NCP for breeding flocks in January 2007 Animal Health staff have gained valuable experience in carrying out visits to breeding flock holdings to collect or supervise the collection of official control samples. It is now estimated that visits to holdings by Animal Health staff will take between three and six hours. Therefore a range of costs for Animal Health component of the charge for official testing has been produced below. The higher cost assumes that a visit lasts six hours (meaning a charge per visit of £308). The lower cost assumes that a visit takes three hours (visit charge of £170). All official samples would be examined by the VLA at a cost of £18.50 per sample tested.

Accordingly the projected cost for official control sampling in England would range from **£155,232 per annum** to **£340,000 per annum** for sampling. The cost for examination of all official samples collected is estimated at **£111,000 per annum**. Therefore the estimated total combined cost to business in England for official sampling and testing of breeding flock under the proposed fees regulations ranges from **£266,232 per annum** to **£451,000 per annum**. The average cost for each holding would range from **£528** to **£894 per annum**.”

3. The following minor amendments are also made

- In the Background section - Paragraph 1 notes that “the Animal By-products Regulations 2005 have replaced the Animal By products Order 1999.” This should read “the Animal By-products Regulations 2005 have replaced the Animal By products Order 2003”
- Throughout the RIA references to the State Veterinary Service (SVS) should be changed to Animal Health.

27 June 2007