

EXPLANATORY MEMORANDUM TO THE ZONOSSES AND ANIMAL BY-PRODUCTS (FEES) (WALES) REGULATIONS 2008

This Explanatory Memorandum (EM) has been prepared by the Office of the Chief Veterinary Officer and is laid before the National Assembly for Wales in accordance with Standing Order 24.1.

Description

1. This instrument provides the Welsh Ministers with powers to charge farmers and operators of private laboratories in order to recover costs incurred by government in providing the following services.
 - Official sampling and testing of Salmonella in laying flocks of domestic fowl.
 - 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.

Matters of Special Interest to the Subordinate Legislation Committee

2. There are no matters of special interest to the Committee. The opportunity has been taken to make corrections pursuant to report of Subordinate Legislation Committee meeting of 25 September 2007.
3. Treasury consent to these regulations has been obtained.

Legislative Background

4. The Control of Salmonella in Poultry Order 2008 enforces National Control Programmes (NCP) for breeding and laying flocks of domestic fowl. The NCPs set out the new requirements for the monitoring and control of Salmonella in breeding flocks and laying of Regulation (EC) No 2160/2003, Regulation (EC) No 1003/2005 and Regulation (EC) No 1168/2006.

5. In order to chart progress towards meeting the reduction target specified in the EC legislation, each breeding flock will be required to provide official control samples on three occasions during the production cycle. Each laying holding must provide at least one official control sample from one flock each year. Official control samples will then be tested at the National Reference Laboratory. Charges are made to recover costs incurred by Animal Health in its

role in managing the collection of official samples and by the Veterinary Laboratory Agency (VLA) in examining any samples received.

6. Welsh Ministers make this instrument under section 56 (1) and (2) of the Finance Act 1973. This 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. The powers are vested in Welsh Ministers by section 59(5) of the Government of Wales Act 2006. As an instrument made under the Finance Act 1973, the Regulations are subject to Treasury consent, which was received on 22nd September 2008.

7. These Regulations follow the negative resolution procedure

8. Failure to bring the Zoonoses and Animal By-Products (Fees) (Wales) Regulations 2008 into force would mean that Welsh Ministers could not recover the costs incurred for the services provided as described in paragraph 3.

Purpose and Intended Effect of the Legislation

9. The Zoonoses and Animal By-Products (Fees) (Wales) Regulations 2008 replace legislation introduced in August 2007. The Regulations impose new costs on operators of laying flocks for the collection and examination of official controls under the national control programme (NCP) for Salmonella in laying flocks which started on 1 February 2008.

10. In order to reflect changes in the costs faced by delivery agents, Animal Health and VLA, in providing services, the Regulations also give Welsh Ministers the powers to charge fees at an appropriate level on the basis of certain criteria. The fees will be published on the Welsh Assembly Government website and will not appear on the face of the Regulations themselves.

11. The proposed fees regulation will also allow for VLA and the Minister for Rural Affairs to recover costs for services in respect of the approved laboratory scheme. Under this scheme private laboratories are authorised by the competent authority to test operator samples for Salmonella under National Control Programmes and Salmonella, Enterobacteriaceae, Clostridium Perfringens and other organisms as required under the Animal By-products Regulations 2005.

12. The objective is to provide the Welsh Ministers with powers to set fees at a level to achieve full cost recovery through the administration of this scheme. The fees will therefore be amended to reflect more clearly the charges that are applicable under current legislation and to take account of administrative costs.

Implementation

13. The instrument was laid on 17 October 2008 and is intended to come into force on 7 November 2008. The equivalent Regulations in England came into force on 3rd October.

REGULATORY IMPACT ASSESSMENT

Consultation

1. No formal consultation was conducted, as the issue is very specialised with a limited range of stakeholders. There was a full consultation on the introduction of the National Control Plans (NCP) for laying flocks in summer 2007. Full details regarding plans to revise the charging legislation were included in that consultation. Although the levels of charges have changed this year, to reflect the costs faced by Animal Health, VLA and Defra in providing services, the principles on which charges are calculated have remained the same. The proposed charges have been considered by industry representatives through the GB wide regular stakeholder forum.

Options

2. Three main options have been identified which are set out below.

Option 1 – Produce a new fees regulation with revised fees set out in a schedule for official control sampling for Salmonella in breeding flocks and laying flocks

Option 2 – Produce new regulations for official control sampling for Salmonella in breeding flocks and laying flocks which continue to provide the Minister for Rural Affairs with powers to publish fees, determined for each of the activities in the order on the basis of the cost to Government, on an appropriate website.

Option 3 – Do nothing

Option 1 - Produce a new fees regulation with revised fees set out in a schedule for official control sampling for Salmonella in breeding flocks and laying flocks

3. This would not introduce any new procedures or regulatory requirement with which the relevant businesses are not already complying. However, the increase in fees would allow the Welsh Assembly Government to achieve full cost recovery for 2008 (taking into account the proposal to phase in some of the increased costs. The detail of this is set out in paragraphs 13 - 39). While the fees in the schedule would represent full cost recovery for 2008, this would not be achieved in subsequent years, as has been the case with previous orders until another new order is produced.

Option 2 - Produce new regulations for official control sampling for Salmonella in breeding flocks and laying flocks which continue to provide the Welsh Ministers with powers to publish fees, determined for each of the activities in the order on the basis of the cost to Government, on an appropriate website.

4. As with option 1 above, this option would allow the Welsh Assembly Government to achieve full cost recovery for 2008 (taking into account the proposal to phase in some of the increased costs. The detail of this is set out in paragraphs 13 - 39). 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 appropriate 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.
5. Option 2 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.

Option 3 – Do Nothing

6. This option would mean that no new fees order would be introduced. As a result the Welsh Assembly Government would not be able to recover any costs with regard to official control sampling for Salmonella in laying flocks and the Laboratory Authorisation scheme. Furthermore, the laboratory authorisation scheme would have to be amended as a laboratory can only be considered for authorisation if appropriate payment of fees accompanies its application.
7. The Welsh Assembly Government, Defra and the other devolved administrations have agreed to recover fees for these services and so this option is not considered to be feasible.

Benefits

Option 1

8. Option 1 will ensure cost recovery for 2008 by revising the present fees in line with current input costs and allow for the recouping of administrative costs.

Option 2

9. As option 1, but with the benefit that fees could be updated regularly in line with increases in input costs without significant administrative costs.

Option 3

10. No perceived benefit in terms of cost recovery.

Costs to business

11. Two options have been identified with regards to the fee applicable for Animal Health officers taking or supervising the taking of official control samples under the national control programmes (NCP) for Salmonella.

Option 1

12. The first option would be to set charging at full cost recovery such that charges would reflect the full cost to Animal Health in providing the service to the operator. For each visit arranged to collect a sample, full cost recovery would result in a base fee of £56 plus investigation fee of £25 per ½ hour (or part thereof)

Option 2

13. The second option recognises that the full costs to Animal Health in providing this service have risen sharply in the last year and were not anticipated by industry when the implementation of the NCP for laying flocks was consulted on in 2007. In the most part these increases have been due to changes in the mechanism for government accounting between Defra and Animal Health. The new accounting procedures provide a more accurate reflection of the costs to Animal Health in providing these services as costs are no longer subsumed/subsidised by core Defra.
14. The overall Defra charge to Animal Health for Shared Services has increased to £2.9m this year from £900k in 2007 (322% increase). These shared services provide many of Animal Health's back office finance functions. The increases of costs also affect the charges for the collection of samples from breeding flocks.
15. Defra and the Welsh Assembly Government recognise the pressures facing the poultry industry including rising fuel and feed costs, increases in investment needed to ensure regulatory compliance and increased competition from imports. Option 2 proposes phasing in the increased cost of the shared service component of this administration charge over the next 2 years: 50% of the increase in this component this year; 75% next year; and 100% in year three. For each visit arranged to collect a sample in the first year of the proposed Fees Regulations this would result in a Base fee of £45 plus investigation fee of £25 per ½ hour (or part thereof). In the second year the base fee would be £50 and in the third year it would be £56 (as in option 1) reflecting the full economic cost of the testing activity.

Option 1 – Full cost recovery

Costs to operators of laying flocks

16. As noted above the full cost to Animal Health of visiting a holding to collect/supervise the collection of an official control sample has risen and charges at Full economic cost (FEC) would result in a Base fee of £56 plus investigation fee of £25 per ½ hour (or part thereof)
17. The charge for VLA to examine each official control sample is set at £15. All official samples to be examined by VLA.
18. In order to estimate costs it is assumed that each eligible laying holding would require a visit by Animal Health once in each production cycle for the purpose of collecting or supervising the collection of one official sample from one flock on that holding and that one production cycle lasts 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 one flock on a holding at a

single visit, which would last between 1 and 2 hours. It is estimated that 1500 holdings in UK are eligible for official control sampling under the Salmonella National Control Programme in Laying holdings.

19. Defra are considering proposals to approve industry control programmes within the scope of the National Control Programme. If approved an independent body would be authorised to act on behalf of the competent authority to collect official samples and submit them to VLA for examination. For these holdings the only fee payable to Government will be for the examination of samples (£15).

20. The table below shows average costs of charging for each holding which receives a visit from Animal Health. It also shows total costs to industry assuming all eligible holdings are sampled by Animal Health **(A)** (1500 holdings) and if half of all holdings are sampled under approved industry control programmes **(B)**.

	High estimate (£)	Low estimate (£)
Average cost of AH visit	156	106
Examination of sample (by VLA)	15	15
Average cost per holding	171	121
total sampling revenue (A)	234,000	159,000
total testing revenue (A)	22,500	22,500
Total costs to industry (A)	256,500	181,500
NPV over 3 years	743,772	526,295
total sampling revenue (B)	117,000	79,500
total testing revenue (B)	22,500	22,500
total costs to industry (B)	139,500	102,000
NPV over 3 years	404,507	295,769

Note

**For high estimates sampling time is 2 hours
For low estimates sampling time is 1 hour**

Examples:

21. Costs for small and large producers are unlikely to be significantly different. For holdings with more than 1000 birds an official control sample will be taken from one flock once a year. It may take slightly longer to collect the sample on a large holding (100,000+ birds) than a small holding (e.g. 5000 birds) but as noted above the difference in costs may not be large.
22. Many egg producers would be classified as a small business as they employ fewer than 250 full time equivalent employees.

Costs to operators of breeding flocks

23. As noted above the full cost to Animal Health of visiting a holding to collect/supervise the collection of an official control sample has risen and charges at Full economic cost (FEC) would result in a base fee of £56 plus investigation fee of £25 per ½ hour (or part thereof). Breeding flocks were subject to official control sampling in 2007/8. At FEC the charges for 2008/9 would result in a £22 increase in the base fee for each visit and £2 increase per ½ hour (or part thereof).
24. The charge for VLA to examine each official control sample is set at £15. This represents a £3.50 decrease for each sample compared to 2007/8 prices.
25. In order to estimate costs 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. 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.
26. It is estimated that visits to breeder holdings by Animal Health staff would take between three and six hours. The time taken depends on the size and complexity of each holding. 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. The lower cost assumes that a visit takes three hours. It is estimated that 500 holdings in UK are eligible for official control sampling under the Salmonella National Control Programme in breeding flocks.
27. The table below includes costs of examining the official samples at the Veterinary Laboratories Agency. The estimates also include the costs of examining at the VLA the two other official samples which are taken by the

operator under direction of Animal Health. It is assumed that an average holding contains 4 flocks, on which basis each holding will supply 4 official samples on three occasions (total 12) each year for examination by VLA.

	High estimate (£)	Low estimate (£)
Average cost of AH visit	356	206
Examination of samples (by VLA)	180	180
Average cost per holding (change since 07/08)	536 (+6)	386 (-6)
total sampling revenue	178,000	103,000
total testing revenue	90,000	90,000
total costs to industry 08/09	268,000	193,000
total estimated costs to industry 07/08	265,000	196,000
Change in total costs (%)	3,000 (1.1%)	- 3,000 (-1.5%)
NPV Over 3 Years	8,669	-8,669

Note

For high estimates sampling time is 6 hours
For low estimates sampling time is 3 hour

Examples:

Small breeding flock holding with 2 flocks of 400 birds

Collection of samples (1 per year per flock): £206 (£36 increase)

Examination of samples (all samples from all flocks 3 times per year): £90 (£21 reduction)

Total: £296 (£15 increase)

Large breeding holding with 6 flocks of 1000 birds

Collection of samples (1 per year per flock): £356 (£48 increase)

Examination of samples (all samples from all flocks 3 times per year): £270 (£63 decrease)

Total: £626 (£15 decrease)

Costs to laboratories

The two options present the same costs to laboratories

30. Individual charges applicable to laboratories under the scheme have risen in 2008/9 compared with charges for 2007/8. Key changes include;

- A charge for postage and packaging of samples has been incorporated into the unit cost for each quality control test this year and this charge accounts for most of the increases compared with 2007/8 costs. In previous years an annual charge for postage and packaging was charged by VLA to Defra separately for each organism tested but was not included in the Fees Regulations. This charge was estimated in 2002 at £17 per organism. This charge has been recalculated on the basis of current costs. As a result unit costs of quality control tests have risen by £5 for Salmonella and by £10 for Enterobacteriaceae and Clostridium Perfringens.
- Costs of laboratory inspections have risen by an average of around 2.8%

31. It should be noted that from the start of 2010 any laboratory wishing to remain approved for testing samples as required under the Animal By-Products Regulations 2005 or/and Regulation (EC) No 2160/2003 will need to be accredited to the ISO 17025 standard. As a result of this change VLA will be carrying out progressively fewer inspections in 2008/9 and 2009/10.

Service	2007/8	2008/9	Change
Number of annual registrations (cost to industry)	46 (£1357)	46 (£1426)	£69 (5%)
Number of new applications (cost to industry)	1 (£12.5)	1 (£13)	£0.5 (4%)
number of Quality control samples (cost to industry)			
- Salmonella	184 (£5888)	184 (£6808)	£920 (15.6%)
- Clostridium Perfringens	60 (£3420)	60 (£4020)	£600 (17.5%)
- Enterobacteriaceae	44 (£2508)	44 (£2948)	£440 (17.5%)
number of inspections (cost to industry)	6 (£3909)	6 (£4020)	£111 (2.8%)
Totals	£17094.5	£19235	£2140.5 (12.5%)
Average cost per laboratory	£372	£418	£46 (12.4%)
NPV Cost Over 3 Years			£6207

Assumptions

- Each inspection was for 2 tests
- Number of lab inspections for 2008/9 same as for 2007/8

Examples:

Laboratory with existing approval to test Salmonella and existing ISO17025 accreditation

Annual registration:	£31 (£1.50 increase)
Quality control samples:	£148 (£20 increase)
Total:	£179 (£21.50 increase)

Laboratory with existing approval to test Salmonella, Clostridium Perfringens and Enterobacteriaceae. No ISO17025 accreditation and due an inspection.

Annual registration:	£31 (£1.50 increase)
Quality control samples:	£684 (£100 increase)
Inspection	£670 (£18.50 increase)
Total:	£1385 (£120.0 increase)

Benefits of option 1

32. Under this option Government, including VLA and Animal Health, would recover all costs in relation to the collection and testing of official control samples under the National Control Programmes for breeding and laying flocks. Costs in relation to the Defra Approved laboratory scheme would also be recovered in full.

Option 2- Phase-in of increased collection costs

Costs to operators of laying flocks

33. As noted above the cost to Animal Health of visiting a holding to collect/supervise the collection of an official control sample has risen. Under Option 2 the charge would be derived from a base fee of £45 plus investigation fee of £25 per ½ hour (or part thereof).

34. The charge for VLA to examine each official control sample is set at £15. All official samples to be examined by VLA.

35. In order to estimate costs it is assumed that each eligible laying holding would require a visit by Animal Health once in each production cycle for the purpose of collecting or supervising the collection of one official sample from one flock

on that holding and that one production cycle lasts 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 one flock on a holding at a single visit, which would last between 1 and 2 hours. It is estimated that 1500 holdings in UK are eligible for official control sampling under the Salmonella National Control Programme in Laying holdings.

36. Defra are considering proposals to approve industry control programmes within the scope of the National Control Programme. If approved an independent body would be authorised to act on behalf of the competent authority to collect official samples and submit them to VLA for examination. For these holdings the only fee payable to Government will be for the examination of samples (£15).

37. The table below shows average costs of charging for each holding which receives a visit from animal health. It also shows total costs to industry assuming all eligible holdings are sampled by Animal Health (A) (1500 holdings) and if half of all holdings are sampled under approved industry control programmes (B).

	1st Year		2 nd Year		3 rd Year	
	High estimate (£)	Low estimate (£)	High estimate (£)	Low estimate (£)	High estimate (£)	Low estimate (£)
Average cost of AH visit	145	95	150	100	156	106
Examination of sample (by VLA)	15	15	15	15	15	15
Average cost per holding	160	110	165	115	171	121
total sampling revenue (A)	217,500	142,500	225,000	150,000	234,000	159,000
total testing revenue (A)	22,500	22,500	22,500	22,500	22,500	22,500
total costs to industry (A)	240,000	165,000	247,500	172,500	256,500	181,500
NPV over 3 years	High Estimate			Low Estimate		
	718,576			501,099		
total sampling revenue (B)	108,750	71,250	112,500	75,000	117,000	79,500
total testing revenue (B)	22,500	22,500	22,500	22,500	22,500	22,500

total costs to industry (B)	131,250	93,750	135,000	97,500	139,500	102,000
NPV Over 3 Years	High Estimate			Low Estimate		
	391,910			283,171		

Note

**For high estimates sampling time is 2 hours
For low estimates sampling time is 1 hour**

Examples:

38. As with option 1 costs for small and large producers are unlikely to be significantly different. For holdings with more than 1000 birds an official control sample will be taken from one flock once a year. It may take slightly longer to collect the sample on a large holding (100,000+ birds) than a small holding (e.g. 5000 birds) but as noted above the difference in costs are may not be large.

39. Many egg producers would be classified as a small business as they employ fewer than 250 full time equivalent employees.

Costs to operators of breeding flocks

40. Under Option 2 the charge would be derived from a base fee of £45 plus investigation fee of £25 per ½ hour (or part thereof). Breeding flocks were subject to official control sampling in 2007/8. Under option 2 the charges for 2008/9 would result in a £11 increase in the base fee for each visit and £2 increase per ½ hour (or part thereof).

41. The charge for VLA to examine each official control sample is set at £15. This represents a £3.50 decrease for each sample compared to 2007/8 prices.

42. In order to estimate costs 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. 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.

43. It is estimated that visits to breeder holdings by Animal Health staff would take between three and six hours. The time taken depends on the size and complexity of each holding 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. The lower cost assumes that

a visit takes three hours. It is estimated that 500 holdings in UK are eligible for official control sampling under the Salmonella National Control Programme in breeding flocks.

44. The table below includes costs of examining the official samples at the Veterinary Laboratories Agency. The estimates also include the costs of examining at the VLA the two other official samples which are taken by the operator under direction of Animal Health. It is assumed that an average holding contains 4 flocks, on which basis each holding will supply 4 official samples on three occasions (total 12) each year for examination by VLA.

	Year 1		Year 2		Year 3	
	High estimate (£)	Low estimate (£)	High estimate (£)	Low estimate (£)	High estimate (£)	Low estimate (£)
Average cost of AH visit	345	195	350	200	356	206
Examination of samples (by VLA)	180	180	180	180	180	180
Average cost per holding (change since 07/08)	525 (- 5)	375 (- 17)	530 (0)	380 (-12)	536 (+6)	386 (-6)
total sampling revenue	172,500	97,500	175,000	100,000	178,000	103,000
total testing revenue	90,000	90,000	90,000	90,000	90,000	90,000
total costs to industry 08/09	262,500	187,500	265,000	190,000	268,000	193,000
total estimated costs to industry 07/08	265,000	196,000	265,000	196,000	265,000	196,000
Change in total costs (%)	-2,500 (- 0.9%)	- 8,500 (- 4.3%)	0 (0%)	-6,000 (-3.15%)	3,000 (1.1%)	- 3,000 (-1.5%)
NPV Over 3 Years	High Estimate			Low Estimate		
	300			- 17,098		

Note

For high estimates sampling time is 6 hours
For low estimates sampling time is 3 hour

Examples

Small breeding flock holding with 2 flocks of 400 birds

Collection of samples (1 per year per flock): £195 (£25 increase)

Examination of samples (all samples from all flocks 3 times per year: £90 (£21 decrease))

Total: £285 (£4 increase)

Large breeding holding with 6 flocks of 1000 birds

Collection of samples (1 per year per flock): £345 (£37 increase)

Examination of samples (all samples from all flocks 3 times per year): £270 (£63 decrease)

Total: £615 (£26 decrease)

Costs to laboratories

45. The two options present the same costs to laboratories

Benefits of option 2

46. Under this option Government, including VLA and Animal Health, would recover the majority of costs in relation to the collection and testing of official control samples under the National Control Programmes for breeding and laying flocks. Costs in relation to the Defra Approved laboratory scheme would also be recovered in full.

47. Operators of laying and breeding holdings would be given additional time to prepare for increases in costs of collecting official control samples.

Financial implications to Defra of phased approach to increased Animal Health Administration costs

48. By passing on 50% of the full increase in the shared service component of the AH administration cost industry will be charged £11 less than full economic cost for each visit to a holding by Animal Health officers.

49. It is estimated that Animal Health will visit 750 layer holdings each year and 500 breeding holdings. The number of layer holdings visited by Animal Health is reduced from the total number of 1500 layer holdings subject to official controls as around 50% of these holdings will be independently audited as part of an approved industry control programme. Accordingly the cost to government of not passing on the full increase in the administration costs in the first year is estimated to be about £13,750.

Summary of proposed charges

50. Proposed charges are set out below. Activities are set out as they appear in the schedule to the Zoonoses and Animal By-products (Fees) (England) Regulations 2008

51. 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.

Activities	2007/8 charge (£)	2008/9 charge (£)
Taking or supervising the taking of official control samples	Base fee £32 plus investigation fee of £23 per ½ hour (or part thereof).	Base fee £45 plus investigation fee of £25 per ½ hour (or part thereof).
Examining official control samples	18.50	15.00
Processing of an application for approval of a laboratory under Regulation 21 of the Regulations or Article 12 of the European Regulation	12.50	13.00
Processing of annual registration documentation in respect of a laboratory approved under Regulation 21 of the 2005 Regulations or Article 12 of the European Regulation	29.50	31.00
Inspecting a laboratory, for the purpose of Regulation 21 of the Regulations or Article 12 of the European Regulation, for		
a) one test	613.50	631.00
b) two tests	632.50	650.50
c) three tests	651.50	670.00
d) four tests	670.50	689.50
Administering a quality control test, under Regulation 21 of the Regulations or Article 12 of the European Regulation, for		
a) Salmonella	32.00	37.00
b) Enterobacteriaceae	57.00	67.00
c) Clostridium Perfringens	57.00	67.00

Note - this fees Regulation covers activities required under the Control of Salmonella in Poultry Order 2007 (CSPO) and the Animal By-products Regulations 2005 (ABPR).

Full details of individual charges are set out in the annex to this IA.

Small Firms Impact Test

52. The proposed fees will apply equally across the industry, which includes small businesses, and are not considered to be discriminatory.
53. Almost all egg producers (laying flock holdings) would be classified as small businesses, as they employ fewer than 250 full time equivalent employees at the site level. For both options considered in the Impact Assessment, costs for small and large producers are unlikely to be significantly different. It may take slightly longer to collect the sample on a large holding (100,000+ birds) than a small holding (e.g. 5000 birds). However, using figures from option 2 (preferred) the upper range of costs per year are estimated to be around £160 and lower range of costs estimated at £110.
54. Using the criteria for small businesses employing fewer than 250 full time equivalent employees it is assumed that all operators of breeding flocks would be classed as small businesses. Accordingly it should be noted that the examples given in sections 3.1.2 and 3.2.2 are likely to apply small business such that the very smallest businesses may see a small increase in costs - £4 increase in the example given for option 2- and slightly larger businesses may see a small decrease in costs - £26 in the example.
55. Again approved laboratories under the scheme are likely to fall under the small business category. Depending on the services provided costs for these business may have risen around £20 to £120.
56. In summary the majority of the operators affected by the proposed Fees Regulations would be classified as small businesses. It is not considered that these businesses would be disproportionately affected by the proposed charges as the charges themselves are relatively small and fall equally across all parts of the industry.

Issues of equity and fairness

57. There is no unequal impact by gender, age, or by race. It is not expected that any impact on particular income groups will be significant. 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.

Competition Assessment

58. We do not believe there will be a competitive impact as a result of these proposals. 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.

Post Implementation Review

59. Annual accounts will be produced (by Defra) 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.

Annex - Summary of charges (for 2008/9) relating to official control samples under the Salmonella National Control Programmes for breeding flocks and laying flocks

Charges are set out as they appear in the schedule to the Zoonoses and Animal By-products (Fees) (England) Regulations 2008

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.

Activities	2007/8 charge (£)	2008/9 charge (£)
Taking or supervising the taking of official control samples	Base fee £32 plus investigation fee of £23 per ½ hour (or part thereof).	Base fee £45 plus investigation fee of £25 per ½ hour (or part thereof).
Examining official control samples	18.50	15.00
Processing of an application for approval of a laboratory under Regulation 21 of the Regulations or Article 12 of the European Regulation	12.50	13.00
Processing of annual registration documentation in respect of a laboratory approved under Regulation 21 of the 2005 Regulations or Article 12 of the European Regulation	29.50	31.00
Inspecting a laboratory, for the purpose of Regulation 21 of the Regulations or Article 12 of the European Regulation, for		
a) one test	613.50	631.00
b) two tests	632.50	650.50
c) three tests	651.50	670.00
d) four tests	670.50	689.50
Administering a quality control test, under Regulation 21 of the Regulations or Article 12 of the European Regulation, for		
a) Salmonella	32.00	37.00
b) Enterobacteriaceae	57.00	67.00
c) Clostridium Perfringens	57.00	67.00

Note - this fees Regulation covers activities required under the Control of Salmonella in Poultry Order 2007 (CSPO) and the Animal By-products Regulations 2005 (ABPR). The CSPO and ABPR annotations are used in this section of the RIA to identify whether the charges proposed relate to either CSPO or ABPR requirements.

Basis for published charges

The proposed fees regulations provide Welsh Ministers with powers to recover costs for the activities undertaken on his behalf with regard to:

- sampling and testing official control samples required under point 2.1.2.2 of the Annex to Commission Regulation (EC) No 1003/2005 implementing Regulation (EC) No 2160/2003 as regards a Community target for the reduction of the prevalence of certain salmonella serotypes in breeding flocks of Gallus gallus and amending Regulation (EC) No 2160/2003
- sampling and testing official control samples required under point 2.1 of the Annex to Commission Regulation (EC) No 1168/2006 implementing Regulation (EC) No 2160/2003 as regards a Community target for the reduction of the prevalence of certain salmonella serotypes in laying flocks of Gallus gallus and amending Regulation (EC) No 1003/2005.
- the authorisation of approved laboratories under the Animal By-Products Regulations 2005 [or/and] Regulation (EC) No 2160/2003.

The applicable fees for each service are published in the schedule to these fees regulations. 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, on behalf of the Welsh Ministers, in visiting and collecting or supervising the collection of official control samples from breeding flock holdings or laying flock holdings for the purpose of verifying progress towards Salmonella reduction targets specified in Regulation (EC) 2160/2003, Regulation (EC) 1003/2005 (breeding flocks) and Commission Regulation (EC) No 1168/2006 (laying flocks).

Option 1

2007/8 Charge:	Proposed 2008/9 Charge:
Base fee £32 plus investigation fee of £23 per ½ hour (or part thereof).	Base fee £56 plus investigation fee of £25 per ½ hour (or part thereof).

Or

Option 2

2007/8 Charge:	Proposed 2008/9 Charge:
Base fee £32 plus investigation fee of £23 per ½ hour (or part thereof).	Base fee £45 plus investigation fee of £25 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 2007/08). 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 from Defra Shared Service Division (SSD) which provides most of Animal Health's back office functions including: accounts receivable, accounts payable, human resources costs, etc. Due to changes in the mechanism for government accounting between Defra and Animal Health, the overall SSD charge to Animal Health has increased to £2.9m from £900k in 2007 (322% increase). This change provides a more accurate reflection of the costs to Animal Health in providing these services as costs are no longer subsumed/subsidised by core Defra.

An estimate of the total annual cost of these services in relation to official control sampling has been calculated and spread over the estimated number of tests required per annum to produce a fixed charge. In the previous fees regulations the costs of these services was only partially reflected in the charge to operators. We have recognised that passing on this increased charge to operators in full in a single year would represent a significant and unexpected increase and so we would consider whether it was possible to phase these increases.

The full cost for shared services for 2008/09 has been calculated at £35. Including this cost in full would have led to a base fee of £56 for 2008/09.

As noted in the table below, the component of the charge for Shared service costs for 2007/8 (item 8) was £13. The full cost for shared services for 2008/09 has been calculated at £35. Including this cost in full would have led to a base fee of £56 for 2008/09. This would have represented a 75% increase on the £32 charge for 2007/8. By passing on 50% of the estimated shared service costs this year the 2008/9 base fee would be £45 compared to £32 for 2007/8. This represents option 2 in the Impact Assessment.

Analysis of basic application fee by cost factors -	2007/8 £	2008/9 £
1. Salaries, overtime, national insurance and superannuation costs	15	16
2. Recruitment and training costs	1	1
3. Travel and incidental expenses	1	1
4. Office accommodation, equipment and services	2	3
5 & 6. Protective clothing and equipment	-	-
7. Sampling and analysis costs	-	-
8. Shared service costs	13	35
Total	32	56

b) The additional investigation fee is a time based charge calculated on a per test basis. 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. This charge has risen to £25 per half hour from £23 per half hour in 2007/8.

This is based on the different elements of salary, overhead and other charges as follows:

Component	2007/8	2008/9
Salary (£)	15	15
Overheads (£)	4	4.50
Other charges including accommodation and shared services (£)	4	5.50
Total	23	25

Note that costs are rounded to nearest 50p

(b) Examining official control samples

Purpose of charge

This charge covers duties performed by the VLA, on behalf of Welsh Ministers, 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.

2007/8 Charge (£)	Proposed 2008/9 Charge (£)
18.50	15.00

How the charge is derived:

A single charge is applicable for the examination by the VLA of all official samples supplied to them. 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.

Pay costs per chargeable hour	£24.70
Non pay	£6.92
Overhead	£13.18
Total cost per chargeable hour	£44.80

A small proportion of the £15 charge takes account of weekend work that may be needed to process a proportion of all samples received. Weekend work is charged at an increased rate. This increase will be spread across all samples and so samples received at VLA over a weekend will not be subject to a surcharge.

(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 registration charge under the scheme)

2007/8 Charge (£)	Proposed 2008/9 Charge (£)
12.50	13.00

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 £26.40 which includes salary costs (pay, pension and national insurance contribution), accommodation and general overheads.

The charge has been rounded down to the nearest 50 pence

(d) Processing of annual registration documentation for laboratory approval

Purpose of charge

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

2007/8 Charge (£)	Proposed 2008/9 Charge (£)
29.50	31.00

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 £26.40 which includes salary costs (pay, pension and national insurance contribution), accommodation and general overheads.

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

(e) 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 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 carries out the inspection and Defra provides administrative support to this function.

2007/8 Charge (£)

Number approved tests carried out by lab inspected	VLA component	Defra administration charge	Total
1 test	588.50	25.00	613.50
2 tests	607.5	25.00	632.50
3 tests	626.50	25.00	651.50
4 tests	645.50	25.00	670.50

Proposed 2008/9 Charge (£)

Number approved tests carried out by lab inspected	VLA component	Defra administration charge	Total
1 test	604.50	26.50	631.00
2 tests	624.00	26.50	650.50
3 tests	643.50	26.50	670.00
4 tests	663.00	26.50	689.50

1 test e.g. Salmonella testing for CSPO or Salmonella testing for ABPR

3 tests e.g. 2 of ABPR tests with Salmonella test for CSPO

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 2008/9 prices have increased by around 2.8% compared with 2007/8 costs (with 50p rounding as usual). This is an estimated figure based on expected VLA staff rates for 2008/09. The time allocated for a laboratory inspection is 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 result in a Defra administration charge of £26.40 per visit, which is rounded up to £26.50. The AO hourly rate is £26.40 which includes salary costs (pay, pension and national insurance contribution), accommodation and general overheads.

(f) 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, in managing a quality assurance scheme for approved laboratories. VLA issue samples to laboratories that 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.

2007/8 Charge (£)

Organism tested	VLA component	Defra administration charge	Total
Salmonella (CSPO)	30.00	2.00	32.00
Salmonella (ABPR)	30.00	2.00	32.00
Enterobacteriaceae (ABPR)	55.00	2.00	57.00
Clostridium Perfringens (ABPR)	55.00	2.00	57.00

Proposed 2008/9 Charge (£)

Organism tested	VLA component	Defra administration charge	Total
Salmonella (CSPO)	35.00	2.00	37.00
Salmonella (ABPR)	35.00	2.00	37.00
Enterobacteriaceae (ABPR)	65.00	2.00	67.00
Clostridium Perfringens (ABPR)	65.00	2.00	67.00

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), test consumables and reagents, and postage and packaging.

A charge for postage and packaging of samples has been incorporated into the unit cost for each quality control test this year and this charge accounts for most of the increases compared with 2007/8 costs. In previous years an annual charge for postage and packaging was charged by VLA to Defra separately for each organism tested but was not included in the Fees Regulations. This charge was estimated in 2002 at £17 per organism. This charge has been recalculated on the basis of current costs.

The cost of staff time is based on the approved rate for a VLA grade F in the Quality Assurance Unit:

Pay costs per chargeable hour £	£24.70
Non pay	£6.92
Overhead	£13.18
Total cost per chargeable hour	£44.80

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 £2.11 per QA sample – which is rounded down to £2.00. The AO hourly rate is £26.40 which includes salary costs (pay, pension and national insurance contribution), accommodation and general overheads.