EXPLANATORY MEMORANDUM TO

THE ANIMALS AND ANIMAL PRODUCTS (IMPORT AND EXPORT) (ENGLAND) (LABORATORIES, CIRCUSES AND AVIAN QUARANTINE) REGULATIONS 2007

2007 No. 1621

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

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

2. Description

2.1 The Animals and Animal Products (Import and Export) (England) Regulations 2006 ("the principal Regulations") (SI 2006 No. 1471) regulate intra-Community trade in live animals and products (namely, semen, ova and embryos) and imports from third countries of live animals. The Animals and Animal Products (Import and Export) (England) (Laboratories, Circuses and Avian Quarantine) Regulations 2007 amend the principal Regulations.

2.2 These Regulations extend existing powers for the approval of laboratories to those carrying out official testing for salmonella in poultry for export to other Member States. This change is being made as a consequence of a new EC Regulation on zoonoses (animal diseases with public health risks). In addition, these Regulations make provision for charging for activities relating to the approval of laboratories.

2.3 These Regulations revoke SI 2007/1044 which extended a ban on imports of captive birds from third countries. They also give effect to Commission Regulation 318/2007, laying down animal health conditions for imports of certain birds into the Community and the quarantine conditions thereof[1], which replaced Commission Decision 2000/666/EC. These Regulations introduce the revised import conditions and quarantine requirements in the Commission Regulation.

2.4 These Regulations also apply and enforce Commission Regulation 1739/2005 laying down animal health rules for the movement of circus animals and animal acts between Member States[2]. They provide for registration of circuses and animal acts and for charging by the Secretary of State for administrative costs of registration.

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

3.1 The Committee's attention is drawn to new charges introduced in these Regulations:

- in Schedule 5 of the principal Regulations, inspection and administration fees in relation to laboratories approved under the Poultry Health Scheme (in so far as not covered under the annual fee);

[1] OJ No. L84, 24.3.2007, p. 7.
[2] OJ No. L279, 22.10.2005, 47.

- in regulation 5 of the principal Regulations, administration fees in relation to registration of circuses and animal acts;
- in Schedule 8 of the principal Regulations, inspection and administration fees in relation to the approval of avian quarantine centres and facilities.

3.2 In particular, regulation 10 of these Regulations extends regulation 31 of the principal Regulations to provide for the determination and publication by the Secretary of State of a rate known as the inspector's rate. This may be charged for an inspector's time spent on official veterinary supervision of captive birds during quarantine[3], inspections of avian quarantine centres and facilities[4], and additional inspections of laboratories under the Poultry Health Scheme[5].

3.3 The changes are introduced to the principal Regulations by way of an amending Statutory Instrument, rather than the Department's more usual practice with these Regulations which is to consolidate new provisions in re-made Regulations. This is because a more substantial review and overhaul of the principal Regulations is to be undertaken later in the year which will consolidate these and other amendments, with the goal of simplifying and improving the structure of the principal Regulations. This revision will take advantage of recent amendments to the Interpretation Act 1978 and the European Communities Act 1972 introduced by the Legislative and Regulatory Reform Act. To assist those who refer to the principal Regulations, an unofficial consolidation of the principal Regulations, including the amendments to be made by these Regulations, is to be posted on the Defra website (www.defra.gov.uk), accessed through the pages covering international animal health.

3.4 The Committee may also wish to note that the review of the principal Regulations planned for later this year is expected to take a new approach to an aspect of the specification of offences which the Department understands may have been considered by the Committee previously. This concerns the need, or otherwise, expressly to exempt the Secretary of State and other officials from offence provisions. In the principal Regulations, regulation 34 provides that contravention of the Regulations or any notice served under them is an offence. There is no express exemption for the Secretary of State and officials, and indeed this reflects previous criticisms by the Committee of an exempting provision of this sort as otiose. It is expected that future Regulations will specify which contraventions constitute an offence, so that it is clear without making any express provision regards the functions of the Secretary of State and officials. The Department mentions this point in relation to the present amendment, however, because the same approach is taken in these Regulations as has been adopted in the principal Regulations (see the new text for paragraph (3) of regulation 21 – substituted by regulation 9 of these Regulations), which was not subject of criticism when the principal Regulations were made last June.

[3] In regulation 19(2) of, and paragraph 8(1) and (2) of Part II, Schedule 8 to, the principal Regulations as they will be amended by these Regulations.
[4] regulation 19(2) and paragraph 7(5) and (6) of Part II of Schedule 8, to the principal Regulations, as they will be amended by these Regulations.
[5] regulation 9 of, and paragraph 5 of Part I, Schedule 5 to, the principal Regulations as they will be amended by these Regulations.

4. Legislative Background

4.1 The principal Regulations were made under section 2(2) of the European Communities Act 1972, and in respect of charges made by the Secretary of State, under section 56(1) and (2) of the Finance Act 1973. In outline, they implement Directive 90/425/EEC relating to intra-Community trade in live animals and animal products (semen, ova and embryos) and Directive 91/496/EEC relating to imports of live animals from non-EU countries.

4.2 Regulation 5 of the principal Regulations prohibits exports to other Member States of live animals (including poultry and circus animals) unless they meet the provisions of the EU legislation listed in Part I of Schedule 3 and any additional requirements specified in that list. Consignments must also be accompanied to their destination by a valid health certificate, signed by a government-approved veterinarian.

Laboratories

4.3 The approval of laboratories to carry out testing under the Poultry Health Scheme (a monitoring scheme operated by the Secretary of State in accordance with regulation 9 of and Schedule 4 to the principal Regulations) is undertaken in pursuance of the obligation in Annex II, Chapters I and III of Directive 90/539/EEC, which requires poultry exporters trading in the Community to participate in a disease surveillance programme approved by the competent authority. Hatching eggs, day old-chicks and live poultry must originate from an establishment that is a member of the Scheme. Regulation 4 of these Regulations amends regulation 9 of the principal Regulations, and regulation 12 amends Schedule 5 to cover approvals for laboratories undertaking salmonella testing and charging in relation to those and approvals for other testing under the Scheme.

Circuses

4.4 Regulation 3 of these Regulations amends regulation 5 of the principal Regulations to provide for the Secretary of State's designation as competent authority for the purpose of registering circus or animals acts and ensuring compliance with the other requirements of Commission Regulation 1739/2005/EC. This regulation also provides for charges to be made for expenses incurred in registering circuses and animal. Regulation 12 adds Commission Regulation 1739/2005 to the list of instruments imposing conditions on the movement of animals within the Community in Part I of Schedule 3 to the principal Regulations. Registration of the circus or animal act, holding of a venue register, passporting of the animals travelling as part of the circus or act, and other animal health requirements are the chief conditions of movement.

Avian Quarantine

4.5 Regulation 16 of the principal Regulations prohibits imports from third countries of live animals (including captive birds) unless they comply with Council Directive 91/496/EC and the EU legislation set out in Schedule 7. Regulation 16(4) of the principal Regulations, as most recently amended by SI 2007/1044, postponed these provisions in the case of captive birds (other than pets, which are not generally covered by the principal Regulations), so

that their import into England was not permitted until 1 July 2007. When these Regulations come into force on 1st July captive bird imports will be permitted subject to meeting the new import and quarantine conditions in these Regulations (described in detail in paragraph 7.3 below). These Regulations give effect to Regulation 318/2007 through amendments to regulations 16, 18, 19, 21, 31, 34, Schedules 7, 8 and 9.

5. Territorial Extent and Application

5.1 The SI applies in England. Similar Regulations are being introduced in Scotland, Wales and Northern Ireland. However, Northern Ireland does not intend to legislate for the avian quarantine measures as birds are quarantined in other parts of the British Isles and transported there.

6. European Convention on Human Rights

6.1 The Secretary of State, David Miliband, makes these Regulations in exercise of the powers conferred on him. As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The objective of Directives 90/425/EEC and 91/496/EEC and the related legislation implemented through the Regulations is to protect the health of animals within the European Community.

Laboratories

7.1.1 Under the poultry trade Directive 90/539/EEC, live poultry may be traded between Member States only if they come from farms or hatcheries which comply with the biosecurity measures and perform the prescribed routine testing for Salmonella of certain genotypes and Mycoplasma that are laid down in the Directive. In Great Britain, the Poultry Health Scheme is the means by which the Directive conditions are implemented.

7.1.2 Up to 1 January 2007, members of the Poultry Health Scheme were able to benefit from the Salmonella testing regime which existed for the Poultry Breeding Flocks and Hatcheries Order 1993 (PBFHO). The PBFHO sampling and testing regime identified the Salmonellas of public (ie, human) health interest (zoonotic Salmonella types). However, it was also suitable for identifying Salmonella types relevant for the animal health requirements of the Poultry Health Scheme. Since the same test served both statutory testing purposes, Scheme members requiring Salmonella testing were able to rely on zoonoses testing carried out by PBFHO approved laboratories.

7.1.3 From 1 January, a new EC Regulation on zoonoses came into force which set out new public health Salmonella testing arrangements. Consequently the sampling and testing methodologies for PBFHO have had to change and the new methodologies are not suitable for identifying the Salmonellas of interest under the Poultry Health Scheme.

7.1.4 The Salmonella testing for animal health types which is required for Scheme producers is continuing but can no longer ‘piggy back’ on the testing regime for PFBHO. Laboratories for Poultry Health Scheme Salmonella testing now

need to be approved separately, by reference to different testing criteria, under the principal Regulations. The approvals will be conducted by Defra and the Veterinary Laboratories Agency, and charged for, on the same basis as the existing approvals for Mycoplasma testing. The Department is ensuring co-ordination between policymakers concerned with the Poultry Health Scheme, and those responsible for approval of laboratories for the Poultry Breeding Flocks and Hatcheries Order, to combine approval processes where possible and keep the burden on industry to a minimum. Further provision has been made for charges to be made for the costs of inspections which are not taken into account in the annual approval fee, reflecting government policy that *costs ought to be borne by the party causing them to be incurred*.

7.1.5 In the future, as a result of the changes in EC requirements for testing methodologies for zoonotic Salmonella types, producers will have to pay for separate tests to meet animal health and public health requirements for salmonella testing, whereas previously tests for one served for both, thus making a saving for producers. Regards the laboratories themselves, charging the costs of the approval process to the operators of laboratories is in line with the Government's policy of recovering actual costs for the services it provides.

7.1.6 The Poultry Health Scheme Handbook for Members and Traders and operating instructions for veterinary inspectors (known as VIPER) are being reviewed and updated as necessary to reflect these new Salmonella testing arrangements. This will provide key parties with the guidance so that exports of poultry to other member States can continue in compliance with EU rules.

Circuses

7.2 The purpose of Commission Regulation 1739/2005 is to provide a uniform set of animal health rules to facilitate movements of animals between Member States whilst maintaining a level of protection against spread of animal disease within the European Community. This sector has not previously been covered by harmonised animal health rules. Prior to this Regulation coming into force, movements of these animals between Member States were agreed on a case by case basis.

7.2.1 The Commission Regulation covers circus animals or animal acts which are kept for the (primary) purpose of public exhibition or entertainment and which are to be moved to other Member States. It does not cover pets or farm animals or animals kept in a zoo, or animals not travelling to other Member States. (There are other regimes which cover movements between Member States of certain pet animals (cats, dogs and ferrets), farm animals and animals that are kept in zoos or bodies approved under EU Directive 92/65/EEC.)

7.2.2 The circus operator or animal act owner must apply to Animal Health (an executive agency of Defra, previously the State Veterinary Service) for registration at least 40 days prior to the intended date of movement. On processing the application, Animal Health will forward to the applicant's nominated Official Veterinarian the register of animals and a venue register required under Commission Regulation 1739/2005, and passports for issue in respect of the animals in the circus/animal act. Official Veterinarians nominated by operators must be on the panel of private vets approved to

carry out limited official functions on behalf of the Secretary of State, known as Local Veterinary Inspectors (LVIs). The Official Veterinarian will visit the circus/animal act to determine whether the requirements for registration have been met and issue passports for the animals as necessary. These Regulations give the statutory basis for fees to be charged by Animal Health to meet the expenses of registering a circus or animal act.

7.2.3 Animals to be moved with the circus/animal act must meet the specific animal health requirements, including for testing and vaccination, set out in Commission Regulation 1739/2005. All animals to be moved with the circus must have passports. Horses and cats, dogs and ferrets are "passported" and meet the animal health conditions under existing requirements in Decision 93/623/EC (horses) and EC Regulation 998/2003 (which ordinarily applies to pet cats, dogs and ferrets). Passports for other animals are prescribed in the Commission Regulation. Once satisfied that the animal health requirements have been met, the Official Veterinarian will issue the applicant with a unique registration number and the documentation referred to in paragraph 7.2.2 above.

7.2.4 At least 10 working days prior to movement to another Member State, the circus operator/animal act operator must give notice to the local Animal Health Divisional Office and apply for an export health certificate. The Official Veterinarian will visit to check that the register of animals is up to date and that all animals to be moved have passports. If these and other animal health requirements of Commission Regulation 1739/2005 are complied with, the Official Veterinarian may sign the venue register and the export health certificate to authorise movement to take place. The circus operator/animal act owner is required to notify the local Animal Health Divisional Office within 48 hours of the move so that notice may be given to transit and destination Member States. The circus operator or animal act owner is required to retain the information in the Register for five years.

Avian Quarantine

7.3 Commission Regulation 318/2007 lays down the animal health import conditions, including quarantine requirements, for the import of captive birds - a class which excludes pet birds, racing pigeons and poultry and birds destined for certain approved institutes and zoos. Laboratory testing of quarantined animals is provided for, together with measures to be taken during quarantine in the event of avian influenza, Newcastle Disease or *Chlamydopyla psittaci* being found.

7.3.1 The Commission Regulation requires all costs of quarantine of captive birds to be met by the importer. These Regulations continue to provide for charges for official veterinary supervision and laboratory testing of birds. They introduce new charges to be paid by quarantine managers in respect of approvals of quarantine centres and facilities. The Regulations also continue to provide powers for veterinary inspectors in relation to quarantine premises and consignments. Laboratory testing is carried out and charged for by the Veterinary Laboratories Agency, also an executive agency of Defra.

Import ban

7.3.2 The temporary EU import ban introduced on 28 October 2005 in response to avian influenza risks posed by third countries imports (Commission Decision 2005/760/EC (OJ No. L285, 28.10.2005, p. 60 which has been amended[6]) expires on 1 July 2007, when Commission Regulation 318/2007 comes into force.

Consultation

7.4 A consultation on and regulatory impact assessment on the veterinary regulation of quarantine of captive birds from outside the EU, and full cost recovery took place between 6 July and 28 September 2006. The consultation was conducted despite the ongoing ban, to ensure that when there is a relaxation of the ban on 1 July 2007, stakeholders will have been consulted on quarantine supervision and charging and have a full picture about the future of the trade.

7.4.1 A separate consultation on a regulatory impact assessment regarding veterinary controls for the movement of circus animals and animal acts between EC Member States and full cost recovery took place between 14 July and 6 October 2006. Departmental Directorates, Government Departments, Devolved Administrations, the Channel Islands and key industry bodies were consulted in respect of minimising the administration burdens under the EU Regulations. Interested parties were also consulted on applications for registration and charges for veterinary services to be provided under the regulations.

8. Impact

8.1 A Regulatory Impact Assessment (RIA) was prepared for the Animals and Animal Products (Import and Export) Regulations 2000. Separate Regulatory Impact Assessments have been prepared for Laboratories (Annex 1), Circuses (Annex 2) and Avian Quarantine (Annex 3).

8.2 In relation to the public sector, these changes will impact on Defra, Animal Health, the Veterinary Laboratories Agency. It will also impact on Local Authorities who have been consulted. The impact on these Departments/Agencies has been considered and where the changes will generate future administrative or physical work, a legal basis for the full economic recovery of costs has been included in these Regulations.

9. Contact

Amanda Furlonger, International Animal Health, Food and Farming Group, Telephone: 020 7904 6358 e-mail: amanda.j.furlonger@defra.gsi.gov.uk can answer queries regarding the instrument.

[6] By Commission Decisions 2005/862/EC (OJ No. L317, 3.12.2005, p. 19) and 2006/79/EC (OJ No. L36, 8.2.2006, p. 48).

ANNEX 1

REGULATORY IMPACT ASSESSMENT

1. TITLE OF PROPOSAL

1.1 The Animals and Animal Products (Import and Export) (England) (Approval of Laboratories and Circuses and Avian Quarantine) Regulations 2007 (hereinafter referred to as the "2007 Regulations".

2. PURPOSE AND INTENDED EFFECT

(i) Objective

2.1. To introduce the Animals and Animal Products (Import and Export) (England) (Approval of Laboratories and Circuses and Avian Quarantine) Regulations 2007 which will amend the Animals and Animals Products (Import and Export) (England) Regulations 2006 hereinafter referred to as the "principal Regulations". The purpose of these amendments is to:

- **Approve Laboratories**: Provide the statutory basis for Defra or the Veterinary Laboratories Agency (VLA) to approve laboratories so that they can test poultry flocks for salmonella to confirm compliance with EU requirements of Directive 90/539/EEC. The laboratories will provide this testing service to poultry flocks and hatcheries which are part of Defra's Poultry Health Scheme who wish to engage in intra Community trade. The changes will also provide a mechanism for Defra/VLA to charge Laboratories for carrying out the approval process;

- **Introduce charges for additional inspecting and sampling**: Provide a statutory basis for Defra or the VLA to charge Laboratories for inspections and sampling kits that are for purposes other than those that are conducted for routine approval.

(ii) Background

Approve Laboratories

2.2 Under the poultry trade Directive 90/539/EEC, live poultry may be traded between Member States only if they come from flocks or hatcheries which comply with the biosecurity measures that are laid down in the Directive and, if the prescribed, routine testing for Salmonella and mycoplasma is carried out. In Great Britain, the PHS is the means by which the Directive conditions are implemented.

2.3 In relation to certain birds (fowl, turkeys, guinea fowl, ducks, geese, quail, pigeons, pheasants, partridges and ratites) if you wish to either:

- export more than 20 birds or their eggs to another Member State
- sell birds or their eggs to other PHS Members
- export to certain third countries

then you need to be a member of the PHS. Before PHS Membership can be granted, flock and hatchery owners must submit an application, satisfy the requirements of a premises inspection and in some cases have their flock or hatchery satisfactorily tested.

2.4 Up to 1 January 2007, PHS members were able to benefit from the salmonella testing regime which existed for the Poultry Breeding Flocks and Hatcheries Order (PBFHO). The PBFHO testing regime identified the Salmonellas of both public health interest (for PBFHO) and those of poultry/animal health interest (for PHS). Since the same test served both statutory testing purposes, PHS members Salmonella testing was able to 'piggy back' onto the PBFHO testing regime.

2.5 From 1 January, a new EU Zoonoses Regulation came into force which set out new public health Salmonella testing arrangements. Consequently the testing arrangements for PBFHO have had to change and the new testing arrangements are not suitable for identifying the Salmonellas of PHS interest.

2.6. The Salmonella testing for PHS members is continuing but since 1 January it has no longer been able to 'piggy back' on the testing regime for PBFHO. To allow PHS Salmonella testing to continue interim Laboratory approvals have been granted based on existing approvals and a sample quality assurance exercise. These interim approvals will be superseded shortly when approvals are granted under the principal Regulations. The approvals will be conducted by Defra or the Veterinary Laboratories Agency (VLA) who will charge for providing that service. In future, the PHS members will also have to pay a separate charge to the Laboratories for carrying out their Salmonella testing under the PHS regime.

2.7 The legal mechanisms to enable Defra or the VLA to approve laboratories and to charge for that service are being made via 2007 Regulations which revise the principal Regulations. Laboratories may charge the PHS member for the testing they carry out however since this is a commercial matter between those parties; no mention in the legislation is required.

2.8 In addition to these issues there is considerable activity in various Defra Departments, with responsibility for Laboratories tasked with official duties, to help Laboratories meet the requirements of the Official Feed and Food Controls (EU Regulation 882/2004 – which requires all such Laboratories to conform to international Laboratory standards). The opportunity is being taken to, where possible, rationalise the inspections and sample quality assurance testing because many Laboratories are approved for more than one type of test/disease or scheme.

Introduce charges for additional inspecting and sampling

2.9 In addition to routine inspection and sampling it is sometimes necessary (for example when a Laboratory is not performing satisfactorily) for a Laboratory to receive additional inspections or sample quality assurance exercises. To date the costs for these additional inspections and quality assurance exercises has not been charged directly to the responsible Laboratory because there has not been a legal basis to do so.

2.10 It is appropriate and reasonable for the responsible Laboratory to absorb such costs. Laboratories can of course avoid such additional costs by, for example, working within standard operating procedures, routinely maintaining their facility and training their staff appropriately.

3. CONSULTATION

3.1 Approve Laboratories

(i) Within Government

3.1.1 The Veterinary Laboratory Agency (VLA), the National Assembly for Wales, Scottish Executive Environment and Rural Affairs Department and Department of Agriculture and Rural Development Northern Ireland were made aware of these developments in September 2006 and we have not received any significant comments or concerns from any of these parties.

(ii) Public consultation

3.1.2 On 27 June 2006, Defra wrote to approved Laboratories explaining the changes. The letter outlined the new testing options and advised laboratories that they would have the opportunity to be approved to conduct these tests and then offer their testing services to over 500 PHS members. No significant comments were received.

3.1.3 On 20 September 2006, a letter was sent to PHS members advising of the new arrangements and inviting their comments. No comments were received. The change in the EU Regulation will mean that PHS members will now have to (independently of any Salmonella testing under PBFHO) arrange for their flocks and hatcheries to be tested for Salmonella annually and pay for this testing service.

3.2. Introduce charges for additional inspecting and sampling

3.2.1 A consultation exercise has not been performed because these requirements have only come to light in the course of implementing arrangements to approve Laboratories. We have decided to proceed with implementing these charges without consultation because, in the light of experience, we know that they will rarely be used as Laboratories generally perform satisfactorily and it is reasonable that Laboratories should meet such costs.

4. Options

4.1 Approve Laboratories

Option 1 – Discounted option. To do nothing.

4.1.1 To do nothing would mean we would not put in place revised arrangements for traders to have their flocks tested for salmonella of types which need to be tested under the poultry trade Directive.

4.1.2 This option was discounted as poultry must test negative for salmonella (in accordance with Directive 90/539/EEC) in order to be sent for intra Community trade. Therefore it would result in the poultry being unsuitable for intra Community trade, denying traders a legitimate market opportunity.

Option 2 - Recommended option.

4.2 Set up a system to approve Laboratories to offer a Salmonella testing service to PHS members.

4.2.1 Currently, the existing powers to determine charges in the principal Regulations apply to charges for annual approvals for Laboratories which test for Mycoplasma. The VLA carry out the approvals work (inspection and quality assurance testing) and report results to

Defra. Based on these results Defra then confirm directly to the Laboratory whether or not they have achieved approval status.

4.2.2 Mycoplasma is one of two types of disease which poultry producers trading within the EU must test for if they are to export live poultry (Salmonella being the other). Previously, there was no need to approve Laboratories for testing for PHS Salmonellas because of the arrangements to piggy back onto the PBFHO Salmonella testing arrangements. For the reasons described in the Background Section this can no longer continue. Therefore a similar arrangement of Laboratory approval and Laboratory testing service used for mycoplasma will be introduced for Salmonella.

4.2.3 The arrangements under the principal Regulations for determining annual fees for approvals about Mycoplasma testing Laboratories have been in place for about three years.

4.3 Introduce charges for additional inspecting and sampling

Option 1. Discounted Option. Do nothing.

4.3.1 To do nothing would mean that the charges for these services would not be borne by the Laboratories responsible for them.

Option 2. Recommended option. Introduce a legal basis to directly charge Laboratories for these services.

Inspections

4.3.2 The 2007 Regulations introduce further provisions for calculating fees for additional inspections intended to help monitor Laboratories approvals (whether they test for Salmonella or mycoplasma). This is a charge for inspector's time, referred to in the 2007 Regulations as the "inspector's rate". This rate is a formula the Secretary of State will use to determine the rate for a given chargeable activity. The charge is intended to represent "the reasonable costs and expenses incurred in employing an inspector to undertake that activity during any given unit of time". Time may be charged at units of up to and including half an hour.

4.3.3 The inspector's rate will be charged for additional inspections which are more frequent than routine (to date and under the PHS mycoplasma regime routine has been 1 inspection every 3 years). This is to reflect Defra's policy that those attracting the most regulatory attention in terms of checking compliance should bear the cost themselves and not be subsidised which may occur where the extra costs of checking specific cases are lumped into the annual fee that every approval holder pays.

Sampling

4.3.4 There is a new charge for the provision of additional sampling kits used to assess whether a Laboratory has the competence to analyse samples. The charge is for samples provided more frequently than routine (to date and under the PHS mycoplasma regime routine has been 1 sample kit per year).

5. Costs and benefits

5.1. Approval of Laboratories

Option 1: Discounted option. Do nothing (i.e. make no amendment to the principal Regulations.)

5.1.1 This option would mean that we have no statutory base for approving or charging for the approval of Laboratories to offer a PHS Salmonella testing service. Under the Directive 90/539/EEC PHS Members must use approved Laboratories to perform their testing requirements. Without convenient access to such Laboratories the UK poultry export trade may be seriously jeopardised. The value of poultry exports from the UK in 2006 was approx £45 million.

Option 2: Recommended option. To introduce amendments into the principal Regulations via the 2007 Regulations.

5.1.2 Those affected by these amendments are approx 18 Laboratories and 500 PHS Members. The Defra financial objective is full cost recovery.

Laboratory Charges

5.2. The charge to approve a Laboratory to offer the PHS Salmonella testing service is made up of inspection costs (table 1), administering a quality control exercise (table 2) and some administrative charges (table 3). An illustration of what two Laboratories might expect to be charged is provided (table 4).

5.2.1. INSPECTION COSTS: Charged once in every three year period. VLA (approx every 3 years) visit and inspect Laboratories. Such inspections are performed for a variety of Schemes/diseases/test types. The costings below allow visits to be (where possible) rationalised and the charge reduced. Each subsequent inspection for additional tests during the same visit increases the initial £613.50 by £20. For example 1 inspection visit for 1 test is £613.50. During the same inspection visit a Laboratory can be inspected for a 2nd test for £632.50 (an additional £20). This is not an annual charge and is only charged as and when a Laboratory is inspected.

Table 1

i) Inspection for 1 test e.g. PHS Salmonella bacteriology	613.50
ii) Inspection for 2 tests e.g. PHS Salmonella bacteriology and Salmonella serology	632.50
iii) Inspection for 3 tests e.g. all above PHS Salmonella tests and PHS mycoplasma	651.50
iv) Inspection 4 tests e.g. all PHS Salmonella, PHS mycoplasma and PBFHO Salmonella	670.50

5.2.2 ADMINISTERING A QUALITY CONTROL EXERCISE: ANNUAL CHARGE: Charged annually. VLA annually administer a quality control exercise issuing samples for Laboratories to test for PHS Salmonellas.

Table 2

Salmonella culture (pullorum, gallinarum, arizonae)	107.00
Salmonella serology (pullorum, gallinarum)	342.00

5.2.3 ADMINISTRATIVE CHARGES. These charges will be made as and when appropriate for certain clerical activities.

Table 3

Stage 1 processing an application for Laboratory approval	12.50
Stage 2 further processing of the approval documentation	29.50
Processing an annual renewal application from an existing approved Laboratory	29.50

5.2.4 Illustration of charges to Laboratories.

Table 4

	New Laboratory seeking approval to offer Salmonella culture tests	Existing approved Laboratory seeking renewal of approval to offer Salmonella culture and Salmonella serology tests
2008	Charges from Table 1: £613.50 Charges from Table 2: £107.00 Charges from Table 3: £12.50 £29.50 £29.50 Total £792.00	Charges from Table 1: £632.50 Charges from Table 2: £107.00 £342.00 Charges from Table 3: £29.50 Total £1,111.00
2009	Charges from Table 1: £0 Charges from Table 2: £107.00 Charges from Table 3: £29.50 Total £166.00	Charges from Table 1: £0 Charges from Table 2: £107.00 £342.00 Charges from Table 3: £29.50 Total £478.50
2010	Charges from Table 1: £0 Charges from Table 2: £107.00 Charges from Table 3: £29.50 Total £166.00	Charges from Table 1: £0 Charges from Table 2: £107.00 £342.00 Charges from Table 3: £29.50 Total £478.50
2011	Charges from Table 1: £613.50 Charges from Table 2: £107.00 Charges from Table 3: £29.50 Total £750.00	Charges from Table 1: £632.50 Charges from Table 2: £107.00 £342.00 Charges from Table 3: £29.50 Total £1,111.00

5.2.5 Laboratories will often offer testing for a variety of Schemes, diseases and test types, although occasionally they may only test for one Scheme/disease/test type. There is provision for different fees to be charged for the various combinations of Schemes, diseases and testing types. The inspections (see Table 1 above) and sample quality assurance exercises are where possible being combined to help reduce the burden on Laboratories.

5.2.6 The charge for approving a Laboratory for mycoplasma testing under the PHS is shortly to be reviewed and updated in line with the principles above.

5.2.7 The table below summarises the costs and benefits of the 2 options upon the parties affected by these arrangements.

	Option 1 (Do nothing)		**Option 2** (Approve Labs to offer testing service to PHS members)	
	Costs	Benefits	Costs	Benefits
PHS Laboratories (approx 18)	No cost.	No benefit.	Will receive an additional charge to be approved (approval subject to an inspection and quality assurance exercise) to offer a Salmonella testing service. See costing illustration at No. 5, Table 4. (In practice this is likely to be passed on to PHS members).	Able to generate new income for themselves by charging PHS Members directly for the Salmonella testing they require to comply with PHS/EU requirements for export of poultry and hatching eggs.
PHS Members (approx 500)	No cost.	No benefit.		Able to continue generating income for themselves by continuing exports of poultry and hatching eggs in full compliance with PHS/EU requirements. The value of poultry exports from the UK in 2006 was approx £45 million.

5.2.8 There will be an economic impact due to these changes. However, the majority of the Laboratories applying for approvals belong to large companies, including two VLA Laboratories. About 20% of those who applied for approvals are small independent Laboratories. If these small Laboratories have their own veterinary staff to collect QA samples, the cost is considerably less than if they employ an outside veterinarian to supervise the sample collection.

PHS Members Charges

5.2.9 The costs to a Laboratory for obtaining approval may be passed on to PHS Members in charges to carry out Salmonella testing. As these charges are of a commercial nature (directly between the Laboratory and the PHS Member) there is no need for them to be mentioned in the 2007 Regulations.

5.2.10 PHS members were invited to comment (and Laboratories have had the opportunity to comment) on these new arrangements and no substantial comments were received from either parties. From evidence available we believe that those affected by these new arrangements expect to be able to absorb them with only a minimal impact upon them.

5.3 Introduce charges for additional inspecting and sampling

Option 1: Discounted option. To do nothing would mean that we would not have a legal basis to charge the responsible Laboratories for these services.

Option 2: Recommended option. To introduce a legal basis via the 2007 Regulations to enable the Laboratories receiving these services to be directly charged for them.

5.3.1 The parties requiring these services and so incurring the charges are the Laboratories. They will have to absorb the costs for these additional activities but if they meet the required approval standards they will not incur them.

5.3.2 In the year 06/07 it was necessary to arrange 3 additional inspections and 4 additional quality assurance sampling exercises. Using 06/07 numbers, and the costings at No. 5 above, the likely charges for these activities are £2,913.50. A breakdown of this charge is shown below (more detail is available in the spreadsheet, sheet 3 attached):

3 x £613.50 (for inspections) = £1,840.50

1 x £107 (Salmonella QA exercise) = £107.00
1 x £342 (Salmonella QA exercise) = £342.00
1 x £342 (Salmonella QA exercise) = £342.00
1 x £282 (Salmonella QA exercise) = £282.00

6. CONSULTATION WITH SMALL BUSINESSES: THE SMALL FIRMS IMPACT TEST

6.1 Results of consultations with small businesses: Defra has written to communicate these arrangements to all the interested businesses several times. The earliest letter sent to the Laboratories was in June 2006 and the earliest letter sent to PHS Members was in September 2006. No significant feedback has been received from any of these communications.

6.2 Number of businesses consulted: Defra has communicated with all the businesses with an interest in these arrangements (all the Laboratories that perform official animal health testing (approx 50 but only 18 of these perform PHS testing) and all PHS Members (approx 500)).

6.3 Reason for concluding no significant or disproportionate impact: We conclude there is minimal impact because of the small response we have had to communications that report these arrangements; the arrangements that rationalise some costs mean little increase in costs to some businesses and the costs under PHS have not been reviewed for many years and therefore businesses are not surprised that new arrangements and costs are being introduced.

7. COMPETITION ASSESSMENT

7.1 The Market Sectors affected are the PHS Laboratories, and indirectly, the PHS Members. As there is no significant risk of impact on competition a detailed assessment has not been prepared.

7.2 The affected markets are the approx 18 PHS Laboratories (and indirectly approx 500 PHS Members – although the costs on PHS Members are likely the costs placed on Laboratories being recovered).

7.3 These arrangements are unlikely to affect the structure or distribution of the market services. There are some smaller firms but there is no single large dominating firm.

7.4 The fees being introduced appear to be accepted by all firms. We have not received any complaint or concerns about the fees from either the larger or the smaller firms. That said it can be expected that the fees will affect the smaller firms greater than they will affect the larger firms.

7.5 As the fees being introduced are reasonable (only achieving the recovery of costs) and also do in fact offer opportunities for combining and rationalising costs we do not expect them to alter the number or size of firms significantly.

7.6 A new firm choosing to be approved to offer this service will incur some extra costs to those existing firms that re-new their approval to continue offering the service. The costs are for administrative functions, are less than £50 and are borne by the new firm for the first year only. This fee is not viewed as an obstacle for a new firm to compete with existing firms.

7.7 This market is not subject in any way to rapid technological change.

7.8 These arrangements do not obstruct Laboratories from being approved to offer additional official services or indeed offering their services privately. For these specific arrangements they do not set the prices that the Laboratories should charge for the service.

8. ENFORCEMENT, SANCTIONS AND MONITORING

8.1. Enforcement, sanctions and monitoring arrangements are already in place for Laboratories approved to perform PHS mycoplasma testing via the principal Regulations. These same arrangements (summarised below) are applied to Laboratories approved to perform PHS Salmonella testing.

8.2 Enforcement powers are set out in the principal Regulations. These powers are enforced by Defra through the VLA. The VLA inspect Laboratories and administer a sampling quality assurance exercise upon them. The VLA reports the results of these activities to Defra. Based on these reports Defra confirms directly to the Laboratories their approval status.

8.3 Sanctions: Along with an annual process to approve Laboratories as suitable for offering a Salmonella testing service to PHS members there is also a process to suspend, revoke and reinstate approvals under specific circumstances. Decisions surrounding sanctions may be based (in part at least) upon the additional inspections and sampling quality assurance exercises.

8.4 Monitoring: Each laboratory's performance is monitored by Defra. Approvals are applied for and granted on an annual basis. An annual approval is subject to the successful completion of an annual sampling quality assurance exercise and an inspection visit by VLA officials at least once every three years. Their approval status would be affected by either a routine/non routine unsatisfactory sampling exercise or inspection report.

9. IMPLEMENTATION AND DELIVERY PLAN

9.1. The recommended options of the 'Laboratory approval' and 'additional inspections and sampling' arrangements are to be implemented through the new Animals and Animal Products (Import and Export) (England) (Approval of Laboratories and Circuses and Avian Quarantine) Regulations 2007. These amend the Animals and Animals Products (Import and Export) (England) Regulations 2006.

Approve Laboratories

9.2. Because the Regulations were not updated in time to deliver the arrangements from 1 January 2007 an interim procedure has been put in place and has successfully enabled the temporary approval of Laboratories. This temporary approval was granted based upon existing similar approvals and completion of a successful sample quality assurance exercise. This has allowed exports to other Member States to continue uninterrupted. Once the Regulations are in place official approvals will supersede the temporary ones and an annual approval cycle will be implemented.

Introduce charges for additional inspecting and sampling

9.3. Charges for these activities will be activated immediately upon them being introduced into the 2007 Regulations.

10. POST IMPLEMENTATION REVIEW

10.1. In June 2010, a review of the 2007 Regulations will be performed to establish whether they are having the intended effect and whether they are implementing policy objectives effectively. The review will consider:

- Whether the 2007 Regulations enabled the approval of Laboratories to perform Salmonella testing which in turn allowed continuation of intra-Community trade exports in poultry

- Whether Laboratories are reasonably meeting the costs of any inspections or sampling exercises that are performed more frequently than routine

- Whether there are any ways to reduce the resulting burdens on Laboratories or PHS members

- Whether anything further could be done to facilitate trade more effectively

11. SUMMARY AND RECOMMENDATION

11.1 **Summary**: The 2007 Regulations enable Laboratories to be approved and charged to offer a PHS Salmonella testing service to PHS members; and they enable Laboratories to be charged for inspections and sampling exercises that may be performed in addition to those that may form part of their routine approval. The charges aim to recover full costs.

11.2 **Approve Laboratories:** PHS Members must use approved Laboratories to perform their Salmonella testing (as required by PHS/Directive 90/539/EEC rules) for their flocks and hatcheries to be eligible for trade. Up to 1 January 2007 the PBFHO regime identified the Salmonellas of PHS interest and so it allowed PHS Salmonella testing to 'piggy back' onto its testing regime. From 1 January 2007 a new EU Zoonoses Regulation came into force which changed the PBFHO testing regime in a way so that PHS Salmonella testing could no longer piggy back onto it. PHS Salmonella testing needs to continue and so Laboratories are having to be specifically approved and charged to perform PHS Salmonella testing under the Animals and Animal Products (Import and Export)(England) Regulations 2006 (in a similar way that Laboratories are approved and charged to perform PHS mycoplasma testing). PHS Members will be subjected to a separate charge directly from the approved Laboratory for their PHS/ Directive 90/539/EEC Salmonella testing requirements.

11.3 **Introduce charges for additional inspecting and sampling :** Occasionally PHS Laboratories require additional (i.e. additional to the routine requirements) inspections and sampling quality assurance exercises to establish their competence. It's reasonable and appropriate that the costs for these additional activities are borne by the Laboratory and these Regulations enable these costs to be charged to the responsible Laboratory.

11.4 **Recommendation**: It is recommended that these Regulations be accepted and implemented with immediate effect.

12. DECLARATION AND PUBLICATION

Ministerial Declaration

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

SIGNED: Ian Pearson

Minister of State (Climate Change and the Environment)

DATE: 27th May 2007

Department for Environment, Food and Rural Affairs
Month/Year

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ANNEX 2

REGULATORY IMPACT ASSESSMENT

1. TITLE OF PROPOSAL

1.1 The Animals and Animal Products (Import and Export) (England) (Laboratories, Circuses and Avian Quarantine) Regulations 2007.

2. Purpose and Intended effect

(i) The Objective

2.1 The Animals and Animal Products (Import and Export) (England) (Laboratories, Circuses and Avian Quarantine) Regulations 2007 (hereinafter known as the "control regulations") provide for enforcement of EU Commission Regulation 1739/2005, which establishes harmonised animal health controls for the movement of circus animals and animal acts between Member States.

2.2 The 2007 regulations amend the Animals and Animal Products (Import and Export) (England) Regulations 2007 (SI 2006/1471) ("the principal Regulations"), which regulate intra Community trade in live animals. They introduce to the principal Regulations the new requirements in EC law for the movement of animals in circuses and animal acts within the Community, and provide for registration of circuses and animal acts which move to another Member State. They also establish a statutory basis for Animal Health to charge for expenses incurred in registering circuses and animal acts.

2.3 This RIA applies to England only. Separate RIAs are being prepared by Scotland, Wales and Northern Ireland. The competent authority in England is Defra and the agency, Animal Health.

(ii) Background

2.4 EC Commission Regulation 1739/2005 is a derogation from Council Directive 92/65/EC (also known as the 'Balai Directive') which sets out animal health rules for the movement between Member States of species of animals not subject to other animal health rules in legislation referred to in Annex A to EU Directive 90/425/EEC. Regulation 1739/2005 covers mammals (including bats), birds, bees, salmon and trout kept primarily for the purpose of public exhibition or entertainment and that are to be moved between Member States. It imposes a number of responsibilities on circus operators and owners of animal acts and the competent authority of each Member State. The Regulation does not apply to movements within the UK of circus animals or animal acts or to animals which are used primarily for another purpose such as a pet, farm animal or animals in zoos.

2.5 Until this EC Regulation came into force, circuses were not subject to specific EC animal health rules, which rely on animals having some form of permanent residence. In England, we understand that there are 9 circuses containing animals, two of which move between Member States. According to information obtained during the consultation period, we understand that those circuses tend to move around within a specific county or area, but do not have a permanent residence in the same way as domestic species of animals. Movements between EU countries have been dealt with on an individual basis in accordance with national rules agreed between the competent authorities of the Member States of origin and

destination. The proposal to change to a harmonised approach at EU level recognised that animal health rules could be put in place to facilitate movements and provide an improved means of monitoring and reacting to the risk of diseases that could be associated with these movements.

2.6 EU Regulation 1739/2005 does not weaken England's rabies controls in any way. Neither does it affect the requirements for animals travelling under EU Regulation 998/2003 for the non-commercial movement of pet animals and the Non-Commercial Movement of Pet Animals (England) Regulations 2004 which enforces the EU Regulation. Free movement of such animals directly between the UK and the Republic of Ireland is not affected by Regulation 1739/2005. It also does not remove the need for animal owners to meet any CITES licensing requirements or animal welfare rules.

Rationale for government intervention

2.7 As this EC Regulation deals with animal health which is within Community competence, the UK (Defra and the agriculture departments in Wales, Scotland and Northern Ireland) are under an obligation to the EU to ensure that appropriate measures are in place to enforce it. Although the EC Regulation is directly applicable in law, domestic legislation is required to provide the necessary enforcement provisions to ensure that movements of animals covered by the Regulation comply with EU requirements. In addition, administrative measures need to be in place to enable circus operators and animal act owners to obtain registration for their circus/animal act and to comply with the other requirements of the Regulation. These measures need to be enforceable by the UK authorities. Not having the measures in place to allow compliance with the EU Regulation may lead to a legal challenge from the industry. In addition, if the Food and Veterinary Office of the European Commission visited the UK and considered UK implementation measures not sufficient, a range of actions could follow, including the potential for infraction proceedings by the European Commission.

3. CONSULTATION

(i) Within Government

3.1 Defra consulted internally, with its delivery agencies, such as Animal Health (an executive agency of Defra) and consulted with other Government Departments including the Department for Culture, Media and Sport, the Devolved Administrations of Scotland, Wales and Northern Ireland and the Isle of Man and Channel Islands via the Department for Constitutional Affairs.

(ii) Public consultation

3.2 Key industry bodies were consulted in Spring 2005 during the negotiation of this Regulation and a 12 week public consultation was held from 14 July to 6 October 2006. The consultation focussed on explaining the requirements of the Regulation to interested groups. It also asked for comments, in particular on how to minimise the administrative burden of the EU Regulation but at the same time retain the necessary measures for enforcement. Two written responses were received from the consultation exercise. The consultation documents (including the responses) and Customer Information Note AI/06/294 are available from the Information Resource Centre, Lower Ground Floor, Ergon House, 17 Smith Square, London, SW1P 3JR, tel: 020 7238 6575.

3.3 Consultees asked for any guidance to make clear who the competent authority would be for the purposes of the EC Regulation. They also asked for clear details of the information required by that Department/Agency to carry out specific functions, such as dispatching a notification of movement to another Member State. The guidance documents provide this

information. Consultees requested consideration be given to a single registration system for applications for both Travelling Exhibition certificates (for animals qualified under Commission Regulation 865/2006) and for registration under EC Regulation 1739/2005. This option was considered but rejected due to the significant differences between the two schemes established to enforce these Regulations.

3.4 A meeting was held with interested parties on 25 May 2006. Following the meeting letters were received seeking clarification on the scope of the EC Regulation. In particular, whether it applied to animals which appeared on television or in films.

3.4a The Customer Information Note AI/2006/294 dated 17 November 2006 clarified that the EC Regulation applied to "circus animal acts" and to other "animal acts" kept for the **primary** purpose of public exhibition or entertainment. Animals kept **primarily** for another purpose, such as a pet or a farm animal would be excluded because they would fall within other regimes that regulate movements within the EU. Those regimes would impose controls appropriate to the species of animal and the disease risk. It should therefore not be necessary for **any** animal to be required to have more than one passport or health certificate.

3.4b Some circuses were also visited where the cost of registration was raised as an issue. Animal Health have set the charges to operators/owners at a level to recover costs. Comments were also made that it was necessary for the policy to be implemented in the same way throughout Member States. Defra has provided information to the French Embassy, in particular, to facilitate consistent application with that Member State.

3.5 Other comments were received relating to access to information for enforcement purposes. The application form for registration will contain a consent section permitting Animal Health to release information for such purposes.

4. OPTIONS

Option 1 – Do Nothing, i.e. not implement the EC Regulation.

4.1 Regulation 1739/2005 applied directly to circuses and animal acts in England from 1 January 2007. As this Regulation is being introduced throughout the EU, non-implementation would mean that any circuses (which have animals) and animal acts that are covered by the Regulation would be moving animals illegally if they moved to another EU country. It would also mean that Defra and Animal Health would have no effective enforcement powers to deal with circuses (containing animals) or animal acts which came to England not in compliance with the EU Regulation.

Option 2 – Full Implementation of the EC Regulation

4.2 Full and proportionate implementation will allow circuses and animal acts to move to other EU Member States in accordance with the law and provide Defra, Animal Health and the Local Authority Trading Standards Offices with enforcement powers to deal with non-compliances.

4.3 Implementation would mean that circus operators and animal act owners moving animals between EU Member States would have to comply with all the requirements set out in the Regulation. They would have to:

(i) Apply in writing for registration of their circus or animal act, at least 40 working days before the first planned movement to another Member State. The application should be made from the place where the circus has its legal residence or in the Member State where it is situated and be submitted to the central competent

authority for that Member State. In the case of a circus or animal act residing in England, applications will be made to Animal Health, Lincoln (as the competent authority for Defra);

(ii) Be registered with the competent authority (ie. Animal Health, Lincoln) and be inspected by an Official Veterinarian (nominated by the applicant) before registration is granted;

(iii) Maintain a register of animals within the circus/act*;

(iv) Maintain a venue register*, signed and stamped by a nominated Official Veterinarian prior to each movement to a different Member State;

(v) Maintain passports** for the animals within the circus/animal act;

(vi) Apply for an Intra Trade Animal Health Certificate. Applications can be made through completion of the form available at http://defraweb/animalh/int-trde/traces/pdf/traces_exa.pdf. Alternatively, applicants may wish to apply to use TRACES, a web-based service for the application for, and issuing of, Intra Trade Animal Health Certificates (ITAHCs) for intra-Community trade in live animals. Guidance on registering to use this system is available http://defraweb/animalh/int-trde/traces/guide.htm

(vii) Inform the competent authority for the Member State of departure at least 10 working days before the intention to move to another Member State. (In the case of movements out of England to other Member States, the competent authority will be the local Animal Health Divisional Office of the place where the animals are resident). An Official Veterinarian will need to visit the premises to check on compliance and sign the export health certificate.

(viii) Keep animals covered by the registration away from animals not registered under the principal Regulation;

(ix) Keep all information contained in the register of animals and the venue register for at least 5 years;

(x) Confirm departure date and other required information to the competent authority in the Member State of departure at least 48 hours prior to any intended movement to another Member State. (In the case, of movements out of England, the competent authority will be the local Animal Health Divisional Office);

(xi) Comply with the testing and vaccination requirements*** as set out in the animal passports.

*Register of animals and Venue Register

Animal Health have prepared a booklet which combines Annexes I and II of the EU Regulation (the register of animals and the venue register respectively) into a single document. During the registration visit, the Official Veterinarian will complete a number of checks to ensure that the requirements of the EC Regulation have been met. Once satisfied, this document will be presented to the circus operator/animal act owner.

**Passports

Animal Health have produced passports for animals covered by the EC Regulation. Separate passports have been prepared for 'individual animals' and 'groups' of animals, such as rodents or birds. Cats, dogs and ferrets will be required to have passports in accordance with EC Regulation 998/2003. Horses will be required to have passports in accordance with Commission Decision 93/623/EEC. No animal will be expected to have more than one passport.

***Testing and vaccination requirements

Ovine and caprine animals require annual testing for brucellosis in accordance with EU Directive 91/68/EEC and bovine animals require testing for brucellosis and tuberculosis testing in accordance with Directive 64/432/EEC. Camelids require annual testing for brucellosis and tuberculosis in accordance with Decision 79/542/EEC. Pigeons are required to have an annual vaccination for Newcastle Disease.

4.4 Full and proportionate implementation of the Regulation also requires the competent authority to:

(i) Check and register circuses/acts which wish to move to other Member States;
(ii) Issue registered circuses with a unique registration number, register of animals, venue register and animal passports;
(iii) Keep a record of all documents issued;
(iv) Issue documents in conformity with the models set out in the EU Regulation;
(v) Ensure that the place of departure is not subject to any restrictions for diseases to which the animal species are susceptible before planned movements take place;
(vi) Inspect all animals to be moved within 10 days of the intended movement to ensure that are clinically healthy;
(vii) Verify that all registers and passports are up to date;
(viii) If movement conditions are met, sign and stamp the venue register;
(ix) Inform the Member States of transit and destination of movement via TRACES.

Risks

4.5 Not implementing the Regulation in England would leave Defra open to legal challenge from the industry which would not be able to move their animals to other EU Countries in compliance with EU law. If non-compliant animals were moved to another Member State, the circus operator/animal act owner would risk enforcement action by the competent authority in the receiving Member State. Non-implementation would also leave the UK at risk of infraction proceedings from the European Commission. In addition, it would mean that there would be a small risk of possible disease spread if animals were moved without the required testing, vaccination or inspections required under the Regulation.

4.6 Implementing the EU Regulation in full may pose a small risk of putting additional burdens on the circus industry in England at a time when they are facing other legislative changes such as requirements relating to the Animal Welfare Act and licensing of public events. However we believe that this risk is low as evidence during the consultation indicated that the number of circuses that move to other EU countries is very small.

4.7 The number of animal acts that may fall under this EU Regulation is unclear. It is unknown how many animal acts moving to another Member State from England would fall under the description of ‘primarily used for the purpose of public exhibition or entertainment’. Whilst it is expected to be small, there is a risk that a significant number of animal acts may be affected and therefore the costs of compliance with the Regulation may be higher than estimated.

Compliance and enforcement

4.8 Not implementing the Regulation 1739/2005 would mean insufficient legislative powers in place to deal with non-compliances and potential for legal challenges.

4.9 Implementing the EU Regulation in full will require measures to be put in place to ensure that checks on compliance are carried out. These measures include:

a. Pre-movement inspections on circuses and animal acts which wish to move to another EU Member State which will be carried out by the applicant's nominated Official Veterinarian (on behalf of Animal Health). An initial inspection is required prior to registration to confirm compliance with the requirements of the EU Regulation. A further inspection is required to certify the animals for movement to another Member State.
b. Notification by the competent authority (the local Animal Health Divisional Office) of where the consignment is leaving. This notification is carried out via the EU's electronic animal movement monitoring system known as TRACES and is submitted to the competent authorities of the Member States of transit and destination.
c. Animal Health staff to carry out random and non-discriminatory checks on circuses and animals acts which have arrived in England. (These checks are prompted via the electronic notifications (via TRACES) received from the competent authorities of other Member States.)
d. The Secretary of State and Local Authority Trading Standards Offices will have the statutory basis under regulation 5 of the principal Regulations as amended by the 2007 Regulations to take legal action against circus operators and animal act owners who have not complied with the relevant Articles of Regulation 1739/2005. Breach of conditions for movement, the registration requirements or the obligation to keep information contained in the registers for a period of at least 5 years will be an offence under the principal Regulations.

Unintended consequences

4.10 Implementing the Regulation in full is likely to have few unintended consequences given the size of the circus industry in England. It is possible however, that the Regulation may impose unintended costs on animal acts. The number of animal acts that may fall under this legislation is unknown, but it is expected to be small. Also, due to our rabies import requirements, it is unlikely that other European circuses (or animal act owners) would want to undergo the additional expense of quarantining animals after they entered England. The rules on the quarantine of rabies susceptible species when they enter England remain unchanged by this Regulation 1739/2005.

4.11 Implementing the EC Regulation in full may give the circus industry an opportunity to bring in animal acts from other EU countries, as the harmonised controls are intended to make movements easier. Providing that the movements are carried out in accordance with the Regulation, there is little additional animal health risk from these potential movements.

Implementation and delivery plans for options 1 and 2

4.12 Not implementing the EC Regulation (as in option 1) would have meant that there would be nothing to implement or deliver. However additional work would have arisen to deal with the consequences of the decision not to implement.

4.13 Defra, Animal Health and the Devolved Administrations have worked together to produce a workable and proportionate policy which provides adequate enforcement for the EC Regulation (as in Option 2). Animal Health have set up an administrative system to manage the registration of circuses and animal acts and ensure full cost recovery. General information in the form of a Customer Information Note (CIN) is to be issued to all interested parties weeks before the domestic Regulations come into force. The CIN and a Question and Answer document and an application for registration will be placed on the Defra website. In addition, Guidance for Official Veterinarians and Exporters will be made available to interested parties.

5. COSTS AND BENEFITS

Sectors and groups affected

5.1 The key groups affected are circuses operators and animal act owners.

5.2 Other groups which will be affected by the EC Regulation are –

- Animal Health
- Local Authority Trading Standards Offices
- The Devolved Administrations (for Wales, Scotland and Northern Ireland).
- Groups representing circuses and animal acts
- Other groups which may be interested in the Regulation including:
  Animal welfare groups
  The Arts Council
  Other Government Departments with a interest in circuses

Costs

Option 1- Do nothing, i.e. not implement the EC Regulation

5.3 Costs could arise through non-implementation if Defra was subject to legal challenge from the industry or other action via the European Commission. Non-implementation could also result in lost profits for circuses and animal acts unable to move to other Member States.

Option 2- Implementing the EC Regulation in full

5.4 Providing full enforcement for the Regulation 1739/2005 will have costs to Defra, Animal Health, Local Authority Trading Standards offices and to the industry. The costs to Defra include the development of a workable policy. Animal Health costs are in the form of setting up the administrative system for registration and providing the mechanism to charge circus operators and animal act owners for that service. These costs and any charges by the Official Veterinarian for inspections and testing/vaccinations associated with the EU Regulation will need to be met by the circus operator/animal act owner. Any costs to the Local Authority Trading Standards Offices will be in the form of charges associated with enforcement.

5.5 As the EC Regulation affects small numbers of businesses it has been difficult to obtain information to quantify the costs that this Regulation may impose on circuses and animal acts. Three circuses were visited to obtain more information about how the Regulation will affect them.

Government Costs

5.6 The 2007 Regulations provide a statutory basis for Animal Health to charge circus operators and animal act owners for registration. The actual charges will be published on the Defra website.

a). Administration cost for approval, including the production of a register of animals and venue register (which has been published in the form of a combined book) in accordance with Annexes I and II of the EC Regulation and preparation of the animal passport (in accordance with Annex III or IV of the EC Regulation), equals 1 hour of administrative time per circus charged at full absorption rates at AO grade = £37.

b). Production of combined venue and animal register: each document is estimated to cost £5.

c). Production of passports – this is a separate charge to that of registration . It is estimated that the passports will cost £200 per 100 or £2 each.

d) cost of management of administrative system is £86 per year. Cost of processing an invoice is £8 per invoice.

5.7 These costs result in an estimated charge of £133 per circus registration. The exact charges depend on the number of passports required. If all 9 circuses with animal acts wanted to move to other Member States, each circus would require 1 register and assuming that they required 20 passports, the costs incurred will be approximately £941.

5.8 It is unknown how many animal acts would fall under this Regulation. However, the estimated cost of registration for one animal act will be £95.

Private Industry costs (ie. costs for circus operator or animal act owner)

5.9 Private industry will bear the costs in the following areas:-

a) Registration and issue of documents by Animal Health to the Official Veterinarian
b) Registration – time to apply and undergo the initial visit by the Official Veterinarian
c) Movements – time to apply and undergo visit by the Official Veterinarian
d) Operating costs

5.10 The costs have to be estimated as Official Veterinarians are private veterinarians authorised by Defra to perform certain official functions on behalf of the Secretary of State. They may charge for their time at their own rates for work they carry out as a nominated Official Veterinarian. The time of a circus operator cannot be accurately costed due to lack of information available. It has also been estimated.

A. Registration and issue of documents by Animal Health

(i) It is estimated that applying for registration could take 4 hours of a circus manager's time. This time would be used to read through the relevant documentation and complete the forms. In the absence of other information on circus profitability, we can estimate working time costs using the average suggested by the Department of Transport of £27 per hour in 2002 prices. 4 hours will therefore cost approximately £120 adjusting for inflation. If all 9 circuses register, this would be a total cost of slightly over £1,000.

B. Registration- time to apply and undergo initial visit by the Official Veterinarian

(i) The circus operator or animal act owner would pay for his nominated Official Veterinarian's fees for visiting premises (including his travel or other expenses) checking documentation and issuing passports. If the Official Veterinarian charged for two hours visiting this would be approximately £100 per registration – assuming a cost of £50 per hour.

C. Movements – time to apply and undergo visit by the Official Veterinarian

(i) The circus will have to inform Animal Health of their planned move at least 10 days before. They will have to arrange for a visit by an Official Veterinarian and subsequently confirm their departure date at least 48 hours prior to departure. If it is assumed that 2 hours of circus staff time is taken on these tasks then this time is valued at approximately £60 per move.

(ii) Official Veterinarian time and expenses for carrying out pre-movement visits, checking the register of animals (Annex I) and issuing further passports; assuming this could require a one hour visit, the approximate cost would be £50 per move.

(d) Operating costs

(i) Routine testing – Tuberculosis (TB) and Brucellosis tests: The Official Veterinarian must order the tuberculin from the local Animal Health Office in order to carry out the TB test. The Official Veterinarian will make charges to the circus owner for his time to carry out the test. If each animal required on average 1 extra hour of veterinary care per year due to the Regulation then the cost would be approximately £500 per circus. However, some of these tests may be done in absence of Regulation so the costs could be lower.

(ii) Other specific requirements – This relates to any other vaccine requirements specific to particular species which will be detailed on passports. Time and expenses of the Official Veterinarian will be chargeable.

(iii) Separation of animals- The EC Regulation requires that animals not covered by the circus or animal act registration be kept separate from animals that are registered. The circus operator or animal act owner will be responsible for keeping animals separated and for any costs associated with separation.

(iv) Issue of passports: The circus operator or animal act owner will need to meet any costs associated with the issue of new passports, including those which are mislaid or need to be replaced.

Summary

5.11 Table 1 presents a summary of the cost estimates.

Table 1 - Cost estimates

Private Industry costs – per circus or animal act		
Cost per registration	Animal Health services	£88 + £5 for each combined venue and animal register £2 per passport
	Administrative time	£120
	Official Veterinarian time and expenses	£100
	Total	Around £300
Cost per move	Administrative time	£60
	Official Veterinarian time and expenses	£50
	Total	£110+
Operating costs per year	Routine testing	£500
	Other specific requirements	Unknown
	Separating animals	Unknown
	Replacement passports	Around £50 per passport
	Total	£500+
Circuses in the UK with animal acts	9 known	
Other animal acts that will come under the legislation	Unknown, expected to be small numbers	
Costs borne by Government		
Setting up of administrative system	Small	
Inspection and enforcement	Unknown	
Welfare issues	Unknown	

Benefits

5.12 Not implementing the EU Regulation in full will have no benefits to Defra. It would also provide no benefit to the industry as although the rules for moving animals would not change, circuses and animal acts leaving England to go to another EU country would not comply with the Regulation and may be subject to enforcement action in the country of destination.

5.13 Full implementation of the Regulation will allow English circuses and animal acts to move legally to other EU Member States. It will also reduce the burden on English circuses seeking to employ animal acts from other European countries as the animal health rules for the movement of the animal act to England will be the same for all EU countries.

6. CONSULTATION WITH SMALL BUSINESSES: THE SMALL FIRM'S IMPACT TEST

6.1 The Small Business Service were contacted but due to the nature of the industry insufficient information was available to provide meaningful assessment of the impact on small firms.

7. COMPETITION ASSESSMENT

7.1 Insufficient information was available to apply the competition assessment filter test. According to information received during the consultation period there are 9 circuses in England, two of which may move animals to other Member States. We understand that the circuses tend to focus on a particular area of the country. Despite research, the number and nature of animal acts that may be affected by this EC Regulation is unclear. The charge for registration will be fixed per act or circus but costs of passports and testing will vary depending on numbers required. Cost of Official Veterinarian's time may vary depending on time and tasks that are carried out and the particular commercial arrangements reached between circus operator and Official Veterinarian. Cost for setting up and maintaining a circus or animal act are unknown as are projected income which will all depend on the size and nature of the business. As so little information is available about the industry it is very difficult to assess the true impact on the market structure.

8. ENFORCEMENT, SANCTIONS AND MONITORING

Enforcement

Option 1

8.1 There would be no changes to the current enforcement system.

Option 2

8.2 Implementing the Regulation in full will not lead to any significant changes to the enforcement of existing animal health legislation. Local Authorities will carry out enforcement for this Regulation in line with current practice for other live animal movements. Local Authorities will not carry out any routine inspections under the control regulations, however they have authority to take legal action to deal with non-compliances.

Sanctions

8.3 The penalties set out in the principal Regulations (SI 2006/1471) will apply. On summary conviction, a fine not exceeding level 5 on the standard scale, currently £5,000 may be imposed, or imprisonment for up to 3 months, or both. On conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or both may apply.

Monitoring

8.4 The principal Regulations implement Council Directive 90/425/EEC which lays down the veterinary and zootechnical checks required on movements into and out of England of live animals. The checks set out in the Directive are carried out by inspectors empowered under these Regulations and can be in the form of random and non-discriminatory checks at the place of destination for the consignment. Circuses and animal acts will be subject to these types of checks which are in addition to the visits by the Official Veterinarian to consider applications for registration and certify consignments for movement to other Member States.

8.5 Veterinary inspectors are also authorised under the above Regulations to inspect animals imported from other Member States, if they have information to suspect an infringement of the above Regulations. Animal Health will report serious non-compliances of the EC Regulation to the relevant Local Authority Trading Standards Office to consider further action, which may ultimately result in prosecution.

8.6 In addition to being an web-based application system for Intra Trade Animal Health Certificates, TRACES notifies competent authorities in Member States of movements of live animals into or through their territories to allow checks and monitoring to be carried out.

9. IMPLEMENTATION AND DELIVERY PLAN

9.1 Implementation of the Regulation in full in England will be carried out by Defra and Animal Health, the delivery agent for this work.

9.2.The timetable for completion of the work is as follows:

- Public consultation from 14 July until 6 October 2006;
- Response to consultation in November 2006;
- Legal and administrative measures to enforce the provisions of EU Regulation 1739/2005 in July 2007.

10. POST-IMPLEMENTATION REVIEW

10.1 The arrangement for monitoring and evaluating the effectiveness of the proposal's enforcement regime is to be agreed by senior officers. There is also the need to set a time limit and a mechanism for recording any complaints received from those affected by the proposals.

10.2 The cost of providing these services will be reviewed periodically and appropriate fees/rates applied. Increases in rates will not exceed the level needed to recover the costs of the services concerned and industry will be given reasonable notice of any change.

11. SUMMARY AND RECOMMENDATION

Summary

11.1 This RIA has sought to address the practical and financial impact of this Regulation on those affected by it. The main industry representatives affected by this Regulation are the circus operators and animal act owners who have animals primarily used for the purpose of public exhibition or entertainment, that are intended for movement between Member States. The two options considered were 1. to implement and 2. not to implement. As the EU Regulation deals with animal health which is within Community competence, there is an obligation on the UK to provide the necessary enforcement for this Regulation and to establish the mechanisms to enable the industry to comply with its requirements.

Option	Total cost per year	Benefit
1. Do nothing	Defra could face legal challenges from the industry for not having the necessary administrative or legal measures in place to enable circus operators or animal act owners to comply with the	None.

	requirements of the EU Regulation. Defra could also face costs associated with potential infraction proceedings by the European Commission for not putting in place measures to enforce the EU Regulation.	
2. Implement the EU Regulation in full.	Costs to Defra and Animal Health for setting up mechanisms for enforcement of the EU Regulation. Costs to Local Authorities for providing enforcement.	Administrative and legal measures which enable effective and proportionate implementation of the EU Regulation.

Recommendation.

11.2 It is recommended that EU Regulation 1739/2005 is implemented in full.

12. DECLARATION AND PUBLICATION

Ministerial Declaration

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

SIGNED: Ian Pearson

Minister of State (Climate Change and the Environment)

DATE: 27th May 2007

Department for Environment, Food and Rural Affairs
Month/Year

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ANNEX 3

REGULATORY IMPACT ASSESSMENT

1. TITLE OF PROPOSAL

1.1 The Animals and Animal Products (Import and Export) (England) (Laboratories, Circuses and Avian Quarantine) Regulations 2007, hereinafter referred to as the 2007 Regulations.

1.2 This Final Regulatory Impact Assessment (RIA) considers options available for the veterinary regulation of quarantine of captive (non-poultry) birds. The RIA examines options for charging for services linked to importation and quarantine.

1.3 A consultation on options outlined in a partial RIA version of this final RIA was conducted in England between 5 July to 28 September 2006. This final RIA takes into account responses from that consultation and updates cost figures. The consultation was carried-out with reference to the previous EU legislation on bird imports: European Commission Decision 2000/666/EC. This was replaced by EC Regulation, 318/2007, both sets of EU legislation require full cost recovery.

2. PURPOSE AND INTENDED EFFECT

(i) The Objective

2.1 The objective of this RIA is to examine options for cost recovery for services linked to avian quarantine.

2.1.2 This RIA has been prepared on an England-only basis as implementation is being considered separately in the Devolved Administrations. The Devolved Administrations have consulted on their approach as well.

2.1.3 It does not take into account any services or charges that are outside the control of the UK Government i.e. wholesale costs of purchasing birds for import, international transport, transport from the aeroplane to the Border Inspection Post (BIP). These are commercial costs which are not affected by the proposals examined below.

(ii) Background

2.2 Newcastle Disease and Avian Influenza (bird flu), both diseases of birds, pose serious risks to animal health and, if they were to be introduced into the UK, could cause serious economic damage to the poultry, and other bird, industry. In addition, avian influenza carries a potential public health risk. To guard against the risk of these diseases, animal health requirements, veterinary certification, and conditions for quarantine of captive birds apply to the importation of captive birds from outside the EU. These controls are based on EU and UK legal provisions.

2.2.1 Commission Regulation 318/2007 (http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_084/l_08420070324en00070029.pdf) lays down the animal health requirements and veterinary certification for the importation of birds other than poultry and the conditions for quarantine. Article 18 of this Regulation, requires that all quarantine costs incurred by the application of the Regulation shall be borne by the importer. In England, the Regulation is being implemented under the 2007 Regulations, an amendment to the Animal and Animal Products (Import and Export) (England) Regulations 2006 (SI 2006/1471). This provides the legal base for charging in England.

Captive bird trade

2.3 As a result of the Avian Influenza disease situation, an EU import ban on captive birds from outside the EU has been in place since October 2005. The European Commission asked the European Food Safety Authority (EFSA) to carry out a report into the animal health and welfare risks of the importation of captive birds, this was published in November 2006. As a result of this report the EU published Regulation 318/2007 on 23 March 2007. The import ban has been extended several times to enable implementation of the new regulation and ends on 30 June 2007, the day before the new regulation comes into effect.

2.3.1 The importation of captive birds into the UK from countries outside the EU was a relatively small trade before the ban. Around 70,000 birds were imported per year, in around 100 separate consignments - of these 15-20,000 birds were from the parrot family. The retail value of the birds ranged from a few pounds for a finch, to tens of thousands of pounds for a rare macaw. The turnover and profit margins for individual businesses varied widely according to the species and numbers of birds imported.

2.3.2 In addition, the trade underpinned a wider industry of pet bird peripherals such as cages and food, which is estimated to be worth around £200m per year[7]. However, this peripheral industry is also supported by an active internal EU trade and is not wholly reliant on third country imports. In 2006 around 150 000 were imported into the UK from other Member States.

2.3.3 As of May 2007, there were no approved avian quarantine premises in the UK approved for commercial import. This is a result of the import ban and consequently quarantine owners letting their approvals lapse. Previous to the import ban 8 large commercial importers accounted for over 95% of imports in the 12 months of records prior to the ban. Most of these were quarantine centres with more than one quarantine unit on the same site. There were also several quarantine facilities, not owned by an importer, which were used intermittently by a number of smaller importers. A significant number of approved quarantines belonged to individual bird keepers or breeders who imported on an infrequent basis - most did not import in the year to 31 October 05 - but maintained their approval on a 'just in case basis' as, previously, there was no charge for this.

2.3.4 There are a small number of importers dealing specifically with birds of prey that have their own quarantine units and import small numbers of high value birds for breeding purposes, although the progeny may be sold as part of a commercial enterprise. An importer such as this would typically bring in one to four birds, once or twice a year. There have been a small number of these imports under conservation rules during the commercial import ban, subject to the granting of a specific licence and close veterinary supervision.

2.3.5 Regulation 318/2007 does not apply to birds imported for conservation programmes although in the UK the same standards have previously applied under national rules. Zoo birds from outside the EU are imported infrequently, again subject to the granting of a specific licence and close veterinary supervision.

2.3.6 The captive bird trade in the UK faced a great deal of uncertainty before the publication of the EC Regulation. As a result of the EU import ban commercial importers have suffered serious economic losses to their businesses.

[7] Annex 2, Dimmock report, www.
http://www.defra.gov.uk/animalh/diseases/control/avianquarantine/independentreview/index.htm

2.3.7 There is some evidence that bird retail prices have increased as a result of the ban and other anecdotal evidence suggests surplus birds were being destroyed due to lack of demand.

Rationale for Government intervention

2.4 The highly pathogenic Avian Influenza virus, along with Newcastle Disease and Psittacosis, pose serious threats to animal health, and, potentially in the case of avian influenza to human health. This is coupled with the serious potential impact of disease entering the UK, justifying the need to ensure high compliance with strict legislation. The independent review of avian quarantine (see paragraph 20) invoked the need for tighter regulation and audit of avian quarantine, and the Government accepted this in its response to the report.

2.4.1 Commission Regulation 318/2007 lays down harmonised rules for the import of captive birds into the EU. Article 18 of this Regulation states that "All quarantine costs incurred by the application of the present Regulation shall be borne by the importer". The Government has a legal obligation to ensure the requirements of this Regulation are met.

2.4.2 In addition, the Government undertook to review the whole subject of cost sharing and associated issues in its response to the Dimmock review of avian quarantine (paragraph 20).

Regulation and supervision of quarantine

2.5 Commission Regulation 318/2007 lays down the requirements for avian quarantine. This covers veterinary supervision of quarantine consignments, and the *minimum* conditions for the approval of quarantine premises, including construction, equipment and management provisions, and requirements for the examination, sampling and testing procedures for Newcastle Disease and Avian Influenza.

2.5.1 From when the previous EU legislation - Decision 2000/666 - came into force in 2002 until the import ban in October 2005, each quarantine operator had a private contractual arrangement with a Local Veterinary Inspector (LVI) to carry out the statutory veterinary supervision and sampling of birds in quarantine. The State Veterinary Service (SVS) (now called Animal Health) was responsible for quarantine approvals and training of LVIs, and in some cases carried out additional, unannounced, visits to check compliance.

2.5.2 Following the case of Avian Influenza in a quarantine premises in Essex, the Defra Secretary of State, Margaret Beckett, announced an independent Review (the "Dimmock review") of Avian Quarantine procedures for captive birds on 26 October 2005. This review was set up to examine quarantine arrangements and procedures and to make recommendations on any changes needed in order to ensure that the quarantine regime is as secure as possible in light of the evolving disease situation. The report was published on 15 December 2005 and made 32 recommendations for changes to the quarantine regime. It can be found at:
www.defra.gov.uk/animalh/diseases/control/avianquarantine/independentreview/index.htm

2.5.3 As a key element of its response to this review - published on 19 April and available at: www.defra.gov.uk/animalh/diseases/control/avianquarantine/gov-strategy/index.htm - the Government and the Devolved Administrations decided the SVS should resume responsibility for all aspects of veterinary supervision and regulation of quarantine, at least until the long term future of the trade and regulation of quarantine was settled. The Dimmock review also recommended certain additional measures which were accepted in the Government response.

2.5.4 For example, Dimmock recommended at least one unannounced visit per quarantine period, in order to determine whether or not all requirements are being observed at all times and, in particular, if there are undisclosed illnesses or deaths, or unexplained reductions in numbers of birds. If non-compliance was found, additional visits would also be required to establish that quarantine was carried out satisfactorily.

Charging

2.6 Defra's overall rationale for charging is that if an industry or group, or individual undertakes an activity that causes an adverse effect on others, such as pollution or risk of disease, and which requires regulation, or which receives benefits from the regulation or service, then it should face the cost of enforcing and implementing the regulation.[8]

2.6.1 Since the 1980's, however, costs for avian quarantine have been shared between Government, importers and quarantine operators which is inconsistent with the principle that risk owners pay for risk mitigation.

2.6.2 For the purposes of this impact assessment, cost recovery falls into two categories:

a) Cost recovery for Animal Health services which have previously been free of charge – i.e. administration of quarantine approvals, administration and release of consignments.

b) Cost recovery for Animal Health services which have previously been carried out and paid direct to Local Veterinary Inspectors – supervisory visits and sampling.

2.6.3 These are examined in more detail in Annex 1. In addition, charges for tests by the Veterinary Laboratories agency are outlined in the Annex and are subject to an annual revision. These were already charged to the importer but could rise with requirements for additional testing.

3. CONSULTATION

(i) Within government

3.1 Other government agencies and departments that have been consulted on this proposal include:

- Animal Health (AH – previously called Stave Veterinary Service (SVS))
- Veterinary Laboratories Agency (VLA)
- Treasury
- Cabinet Office
- Department for Trade and Industry - including the Small Business Service
- the Devolved Administrations in Wales, Scotland and Northern Ireland
- Office of Fair Trading in relation to competition/consumer issues

(ii) Public consultation

Stakeholders with an interest in avian importation and quarantine for captive birds have been consulted. A list of consultees is available.

[8] Defra Charging Handbook 2005
http://www.defra.gov.uk/farm/policy/regulation/pdfs/charging-handbook.pdf

4. Options for cost-sharing for supervision and regulation of quarantine

4.1 This section identifies the main options after the consultation, and the potential of each to achieve the objectives. The costs are outlined in Annex 1. Overall costs for Animal Health supervision of quarantine, will in most cases be higher than previously charged by LVIs before the independent review of avian quarantine because:

- Animal Health previously carried out some tasks such as LVI training and supervision and release of consignments free of charge;
- Post-Dimmock supervision will be intensified
- Higher travel costs may be incurred.

4.1.1 Illustrative fees for Animal Health services are provided at Annex 1 and take into account ways of reducing overall costs i.e. by using Animal Health Officers rather than Veterinary Officers where appropriate to carry out non-veterinary work; and by combining visits to reduce travel time where appropriate.

Summary of charges based on the costs in Appendix 1:

Approval of quarantine facility: £377
Animal Health routine visits and sampling: Ranging from £600-£3000 - depending on the size of the consignment, mortality and compliance
VLA testing fees: Ranging from £64 (for up to 5 birds) to £761 (for 60 birds)

4.1.2 Non-compliance, high mortality or increased sampling and testing requirements, among other factors outlined in the Appendix, increase costs significantly and would put them at the high end of estimates.

4.2 Option A: Full cost to be borne by industry - Full cost recovery

Pros

- Full compliance with Article 18 of Commission Decision 318/2007, thereby reducing risk of legal challenge, and minimising action under EU law on State Aids
- Consistent with Government objective of cost recovery, and with the principle that risk owners pay for risk mitigation
- Taxpayer would not pay for any of the services linked to avian quarantine and all costs paid by those using services
- Quarantine operators who maintain their approvals on a "just-in-case" basis with no plans to import, are likely to withdraw, thus reducing burden on Animal Health to carry out approval visits and supervision

Cons

- In the short-term, any existing, uneconomic quarantines could be driven-out of business
- Illegal trade may result by those wanting to avoid costs

4.3 Option B: Cost-sharing

4.3.1 There is a range of possibilities within this option for apportioning costs between industry and taxpayer. In due course, the Government could reconsider resuming the use of LVIs to carry out some quarantine-related tasks where this is more efficient although this would be done under a high level of Animal Health supervision.

4.3.2 Measures for the veterinary regulation of quarantine of captive birds are specified in Commission Regulation 318/2007 which lays down the *minimum* conditions. Others were recommended in the Dimmock review as additional measures to ensure the effectiveness of avian quarantine and accepted by the Government. Taking this into account, those measures which could be covered by the taxpayer are - in approximate order of priority:

- Visits - including unannounced visits - solely for the purpose of checking compliance with legislation
- Costs of reverting to the use of LVIs at any stage in the future for inspection and sampling of each consignment including training, assessment and monitoring of their performance.
- Administration related to individual consignments including assessment of veterinary reports and laboratory results, reconciliation of bird numbers, updating records and releasing the birds.
- Administration of the approval process including time spent evaluating compliance specifically with a view to granting/renewing approval

Pros

- Costs could be reduced to the point where it is very attractive to import birds through into the EU through the UK and with captive bred birds, thus protecting the UK industry
- Quarantine managers could be given the option of veterinary supervision by privately contracted LVIs which could be engaged at a competitive rate and who might be able to provide a cheaper service than Animal Health because of reduced travel time.
- Animal Health could be relieved of the need to recover small amounts of money at disproportionate cost.

Cons

- Much higher risk of legal challenge in regard of compliance with Article 18 of Commission Decision 318/2007/EC, and increased likelihood of action under EU law on State Aids
- The taxpayer would be subsidising a commercial enterprise.
- This would be against Defra policy of full cost recovery
- A state subsidy would be available to sustain importation of low value birds prone to high mortality.

Risks

4.4 It is possible a higher regulatory burden and cost could result in an increase in smuggling. This risk was identified in the Dimmock independent review of avian quarantine. This could increase the disease risk and result in CITES listed birds and others being imported and traded without proper checks. However, the evidence in terms of seizures since the import ban has been in place is that smuggling has decreased, perhaps because the total ban is simpler to enforce. The new regulation only allows birds to be imported from a short list of countries so will also be easy to enforce.

4.4.1 A high regulatory burden and cost could have the effect of driving any remaining English importers and operators out of business, or encourage them to divert trade through other Member States. This would increase the burden on quarantine regimes in other Member States.

5. COSTS AND BENEFITS

Sectors and groups affected

5.1 The main sector that will be affected are importers of captive birds from outside the EU and quarantine operators. In many cases these were one and the same. 8 business accounted for 95% of these kind of importer. However, many of these businesses have already left the trade due to the ban. All of those affected are micro-businesses with 1-9 employees.

6. CONSULTATION WITH SMALL BUSINESSES: SMALL FIRM'S IMPACT TEST

6.1 The small businesses who responded to the consultation would prefer to see charges set which do not place them at a competitive disadvantage with their competitors in other Member States. During the consultation a small firms impact test was not organised concurrently as interest was extremely low due to the import ban in place. Many of these businesses have already left the trade due to the ban and the strict new import rules that will be introduced. The Small Business Service has been consulted as part of this assessment.

7. COMPETITION ASSESSMENT

7.1 None of the options would have an unfair impact on any particular sector of the industry, as all are required to meet the same regulatory standards while taking account of their various circumstances, and charges will apply across the board. However, the costs associated with the quarantine regime will apply whether it is a large consignment or a small consignment of birds, and likewise if it is a consignment of high value birds or low value birds and thus may have a disproportionate impact on smaller consignments or lower value birds. The differential impact on different businesses depends on the cost structure.

8. ENFORCEMENT, SANCTIONS AND MONITORING

8.1 Animal Health as the delivery body will be responsible for implementation of the EC Regulation. If non-compliance is found Local Authorities are the enforcement body for the Animal and Animal Product (Import and Export)(England) Regulations 2006 under which this legislation falls. We expect extremely low numbers, if any, of birds to be imported but will re-examine the impact if higher levels are experienced.

Compensatory simplification

8.2 Quarantines will not have to be re-approved each year as they were under previous Animal and Animal Products Regulations. Once gained, approval status will continue until the operator decides to leave the trade or if, during regular inspections, Animal Health find significant breaches of the minimum conditions stipulated in the EU regulation.

9. SUMMARY AND RECOMMENDATION

9.1 All of the consultees who responded on costs accepted or supported that at least some of the costs of quarantine should be borne by the importer. There was a range of views on the extent to which government should pay: a commercial bird importer and pet industry organisation proposed a low level of Animal Health charges and a significant government subsidy; British and Irish Association of Zoos and Aquariums and the RSPCA suggested

Animal Health administrative costs should be borne by the taxpayer and the rest paid by the importer and a former importer said the cost of quarantine should be borne by importers.

Option A - full cost recovery - is strongly recommended given the requirement on all EU Member States that all costs be borne by the importer. This is consistent with the Government's commitment to full cost recovery and EU rules on state aids. Since the consultation was conducted, the new EU regulation 318/2007 will introduce very strict rules that ban wild-caught birds being imported and only allow birds to be imported from approved breeding establishments in a short list of countries. As a result we expect very low numbers of bird imports and consequently very little impact of full cost recovery.

10. DECLARATION AND PUBLICATION

I have read the Regulatory Impact Assessment and I am satisfied that full cost recovery in quarantine approvals and supervision is justified.

Signed by the responsible Minister

SIGNED: Ian Pearson DATE: 27th May 2007

Minister of State (Climate Change and the Environment)

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Appendix 1

SECTION A

Estimated costs of veterinary supervision and regulation of quarantine

Costs are based on updated information provided by Animal Health. Rates will be reviewed on an annual basis to reflect salary, rent and rate increases.

Assumptions

Cost of staff time:
£73 per hour for veterinary officers (VO)
£45 per hour for animal health officers (AHO)
£37 per hour for administrative support staff (AO)

Travel costs:

Animal Health is based at Animal Health Divisional Offices (AHDO) spread around Great Britain. In addition, some veterinary and technical staff are based at outstations in order to better serve areas distant from the AHDO.

Travel costs consist of:

a) a mileage allowance paid to travelling officers set at 40p per mile, regardless of car size. This is reduced to 25p when an officer's mileage exceeds 10 000 miles in a year.
b) time spent travelling. For the purposes of this consultation this has been valued at the full cost of staff time as outlined above. However, travel costs will form part of the overall review of Animal Health charges and may eventually differ from the full hourly rate.

It is likely travel costs for LVIs would be lower because they tend to be based closer to their clients and would have competed for the work partly on the basis of cost. It is also possible their regulatory visits could be combined with attendance at the quarantine to deal with non-notifiable disease.

A study was carried out of 87 consignments which were quarantined in the UK over 13 months in 2004 and 2005 in authorised quarantine units.

The times, distances and Animal Health travel costs (based on £73 per hour for a VO, £38 per hour for an AHO and 40p per mile from the nearest AHDO or outstation, doubled to make the round trip) were as follows:

	Time	Distance	AHO Cost	VO Cost
Minimum	0.3h	4m	£31	£47
Maximum	1.7h	61m	£211	£297
Mean*			£69	£102

*The mean values were calculated by weighting the cost for each quarantine in proportion to the number of consignments taken by each quarantine so there is no contribution from quarantines which took no consignments.

Time taken for quarantine tasks

Quarantine is currently suspended because of the import ban. The time taken to undertake each of the tasks detailed has not previously been recorded and in any event would be different in future because of changes introduced in response to the Dimmock report. The times have therefore been estimated by Animal Health staff using their judgement of how long they would expect the job to take and may vary in practice. This could be influenced by a range of factors including:

- The size of the facility or consignment
- The degree of compliance found and the time required to resolve any problems
- How well organised the manager is and how much assistance they provide
- The extent to which work can be scheduled to fit in with other tasks at the same centre or facility or at other premises in the area.

In the event of major non-compliance requiring the quarantine to be re-approved or the episode re-started under close Animal Health supervision then costs will be much higher.

Billing

The cost to Animal Health of processing an invoice is estimated to be around £68.

Approvals

Quarantines are currently subject to approval with a specific VO visit. Approval is required by EU law, although the frequency is not specified. The Dimmock review of avian quarantine recommended recovery of the cost of approving a quarantine premises, which until now has been a service provided free of charge by Animal Health.

The process to administer this takes approximately 1 hour of AO time in total including receiving the application, issuing the approval letter, raising an invoice and updating central records. In future an 'applicant history check' will be required. It will also take on average, 0.17 hours VO time and 0.17 hours of DVM time.

Processing licence application cost = 1h x £37 + 0.17h x £73 + 0.17h x £89 + other Animal Health costs = £121

There is also the additional cost of travelling and inspection time of a VO conducting the approval.

Total cost of approval = processing cost + 3.5h x £73 = £377

In future it may be possible to combine the VO approval visit with an inspection of a consignment if the quarantine has a regular throughput.

Check birds on arrival

EU law requires a veterinary inspection of all birds on arrival to check their health and identities. It is not unusual for birds to arrive late at night, in which case Animal Health staff are likely to incur additional travel costs and overtime. Some checking of compliance with requirements for structure and management should also be carried out.

Higher cost, not including any additional out-of-hours costs, for detailed inspection of a large consignment with some waiting time = 2h x £73 + travel £102 = £248

Lower cost for a small, well-organised consignment = 0.5h x £73 + travel £102 = £139
An LVI would have previously carried this out at the operator's expense.

Visit to collect samples

EU law requires a visit to collect samples either from sentinels or from the quarantined birds themselves. This should also include a veterinary clinical inspection and some checking of compliance with requirements for structure and management, again with a mechanism in place if necessary to apportion costs. Packing and despatch of samples would take an AHO approximately 0.5 hours. We assume this could be carried out by a VO assisted by quarantine staff. If an AHO is also required this would result in additional cost.

Higher cost for cloacal swabbing of multiple groups of birds in a large consignment = 5h x £73 + travel £102 + sample despatch £19 = £486

Lower cost for a small consignment = 0.5h x £73 + travel £102 + sample despatch £19 = £158

An LVI would have previously carried this out at the operator's expense, but in large consignments it is likely that 4 sentinel birds would have been used.

Laboratory fees must be added to the above costs as outlined in Section B below.

Additional visit to investigate mortality

When there is ongoing disease or mortality in a consignment then the supervising VO should be aware of it and carry out an investigation which must include submission of carcases for laboratory examination. This will require a visit.

Typical cost only if required = 0.5h x £73 + travel £102 = £139

An LVI would have previously carried this out at the operator's expense.

Laboratory fees must be added to the above costs and are outlined in section B below.

Veterinary visit at the end of quarantine

This is required by EU law to clinically examine the birds. Some checking of compliance with requirements for structure and management should also be carried out. Live birds, dead birds and laboratory results must be reconciled. The amount of time taken will depend on the size of the consignment, the efficiency of the operator and whether any problems are found.

Higher cost for a large consignment = 1h x £73 + travel £102 = £175

Lower cost for a small consignment = 0.3h x £73 + travel £102 = £124

An LVI would have previously carried this out at the operator's expense.

Releasing the consignment

A VO, on behalf of the DVM, must assess each consignment including a reconciliation of laboratory results and make a decision on whether or not to release the consignment. This will be reduced if the VO is already familiar with the consignment through clinical inspections – approximately half an hour. Administrative staff must then issue a release letter, update central records and invoice the operator – another half an hour.

Typical cost 0.5h x £73+ 0.5h x £31 = £52

This would previously have been done by Animal Health at no cost to the operator, therefore this is a new cost.

Summary

EC Regulation 318/2007 requires the cost of quarantine approval to be recovered from the importer. The full economic cost of this is estimated at around £121 per approval.

Animal Health previously carried out occasional checks of birds in quarantine and administered their release. Dimmock recommended at least one unannounced visit per quarantine episode, and the Government accepted this as part of its response to the Dimmock report. The cost of this and administration of the release of birds from quarantine would amount to approximately £100-£150 per quarantine episode.

LVIs previously carried out pre-arrival, arrival, sampling, disease investigation and pre-release visits to each episode. These will in future be carried out by Animal Health. Taking into account the supervision to be put in place under 318/2007, total Animal Health costs are likely to be in the region of:

For a small, trouble-free consignment in a well-organised, highly compliant quarantine - £600-£800
For a large consignment with high mortality and reasonable compliance but with no additional out-of-hours costs - £1200-£1700
For a large consignment with serious non-compliance requiring additional visits and re-start of quarantine - £2200-£3000

Animal Health costs will also depend on the actual time and distance travelled on each occasion. In order to simplify this analysis, mean figures have been used as discussed above.

VLA laboratory fees will also vary with consignment size and mortality rate are additional to those estimated above and are detailed in the next section.

SECTION B

Laboratory Costs: Charges for testing of samples taken from captive birds in quarantine – Veterinary Laboratories Agency (VLA)

Annex VI of Commission Regulation 318/2007 lays down the testing requirements for captive birds in quarantine. This requires testing of up to 60 birds in a consignment, as well as testing dead birds as outlined in the Regulation.

2007/08 charges

- Charges for post mortem tissue removal and testing:
  per batch of up to five birds: £53.85
  per batch consisting of three birds: £45.70
  per batch consisting of two birds: £35.55
  per batch consisting of a single bird: £20.40

- Charges for a single virus culture (that is, avian virus isolation in SPF eggs via allantoic cavity for avian influenza virus, Newcastle Disease virus, and avian paramyxovirus) in one pool of up to five birds:

  a) of cloacal swab or faeces sample: £63.45

  b) of tissue samples from post mortem examination: £190.35

- Charges for serology of sentinel birds (Newcastle Disease, Influenza (H5) and Influenza (H7)):

  Per set of 3 tests for each sentinel bird: £15.00

  Charges for testing for Chlamydophila Polymerase Chain Reaction:
  Per sample tested: £30.00

Typical Scenarios: Laboratory costs at 2007/08 rates for -

Serological testing of 10 sentinel birds twice. Total cost = £300

Laboratory testing for one bird = £63.45
Testing 60 individual birds - cloacal swabs/faecal samples in 12 pools of 5. Total cost = £761

Depending on mortality, there are also costs of testing dead birds. EU rules require testing of all dead birds or, in the case of high mortality in small birds of large consignments, from at least 10% of the dead birds.