

Proposed Human Tissue Authority fee structure for 2011/12

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1.1 INTRODUCTION

This paper sets out the background for the licence fee revision, provides information on how the proposals for the new fee structure were developed, and sets out indicative fee levels.

1.1.1 Background

The last fees consultation was launched in December 2008. Following the setting of the licence fee structure for 2009/10, the Human Tissue Authority (HTA) held three development workshops in June 2009 to share views and ideas about alternative fee structure options and to provide mechanisms for licence fee payers to contribute to proposals for change.

Key messages that came through in these workshops were that:

- licence fees should reflect the differing sizes of establishments and reflect the differing volume and nature of regulatory activity
- fees should bear some relationship to the regulatory risk attributed to an establishment
- the level and complexity of site visit inspections required/undergone should influence the licence fee
- there should be some scope for staggering payment through the financial year
- the timing of invoices could be better aligned with establishments' financial processes to allow them to forecast expenditure
- information provided on licence fee invoices should be improved for better clarity and transparency

The HTA decided to hold the 2010/11 fees at the same level as for 2009/10 and investigate how we might develop a fee structure for 2011/12 and beyond based, in part at least, on the activities and services provided, and to consult on the proposals.

This paper presents the HTA's proposals for the fee structure for 2011/12 and beyond. It describes:

- the overarching rationale for change
- the process followed so far to reach a proposed fee structure
- the proposed fee structure – in general terms and for each type of establishment in each sector
- the questions on which the HTA would like to consult

1.1.2 The rationale for change now

Through the development workshops and the public consultation on the 2009/10 fee structure, the HTA received suggestions from fee payers and other stakeholders. This has now been taken into account in exploring options for the development of a fee structure that better matches, where possible, our stakeholders' views.

The main principle behind setting fees in Government organisations relates to cost recovery. Fees should be set at a level that will recover costs, and cross-subsidisation between services needs to be avoided. When fees were originally set, the HTA had little information on which to base its fees. Now the HTA has three years experience to draw on in costing activities and setting fee structures and levels. The organisation has established most of the approaches and processes needed to be an effective regulator in line with the Better Regulation principles. We are therefore now in a position to set in place a more robust fee structure starting from 2011/12. Specific fee levels will be reviewed annually to take account of efficiencies and other factors such as changes in the number of establishments.

1.1.3 The remainder of this paper

The remainder of this paper explains:

- how activities were costed to enable a fair and transparent set of fees to be developed
- the fee structure options that were considered and how the proposed fee structure was developed
- finally, we set out the indicative fees proposed

1.2 APPROACH TO DEVELOPING A COST MODEL

The main principle that government organisations have to adhere to when setting fees is that the fee levels should be set to recover full costs (including overheads) and that cross-subsidisation between sectors should be avoided. In the HTA's case, this means that the costs of all activities associated with licensing should be recovered, and that there should not be cross-subsidisation between the sectors being licensed by the HTA.

To adhere to these principles, the first stage in the costing methodology was to separate out activities relating to licensing from those that relate to Government business (covered by Government Grant-in-Aid). We did this by undertaking a series of structured interviews.

The second stage of the costing methodology was to agree how different costs would be allocated to each of the sectors, to avoid cross-subsidisation between sectors. This was done by applying a set of "allocation keys" to the cost lines in the financial ledger. Allocation keys were developed using existing data where possible. Where there were no data available, suitable proxies were established or structured interviews were held with staff to elicit estimates of how time was spent across sectors. Where possible, allocation keys were based on verifiable data (e.g. the number of licences).

We then identified the costs relating to each activity. This included activity recording by all of the Regulation Directorate, interviews with managers from across the organisation, and the development of a "bottom-up" costing model.

The results of these approaches were triangulated, and a workshop was held with Regulation Managers at which the split between regulation activities was agreed. This information was then used to determine how much of the overall HTA cost should be recovered when charging separately for activities such as site visits.

Finally, overheads were apportioned and allocated across the organisation using accepted accounting principles.

The approach resulted in an agreed cost base for each sector, based on activity, which was then used as a basis for recovering fees from that sector.

1.3 APPROACH TO DEVELOPING A FEE STRUCTURE

In exploring possible fee structure options, the HTA has considered:

- input from stakeholders and from HTA Directorates
- Better Regulation principles
- HM Treasury guidance
- selection criteria based on fairness, transparency, ease of understanding and implementation, and the scale of change for establishments
- fee models in use by other regulatory bodies

A “long list” of 31 fee model options was drawn up – setting out the full range of fee structures that could, in principle, be used. Through two stages, these have been tested against the defined selection criteria in order to reach the proposed model. This process has also highlighted the areas in which the HTA would like to seek stakeholders’ input to the final fee structure.

1.3.1 Selection criteria

Seven criteria have been used in order to assess each possible option. These are:

- **Cultural fit** with the HTA and with licence holders. This includes whether the option supports the objectives of Better Regulation and the intent of the Human Tissue Act
- **Fairness and transparency.** This includes whether the option is equitable in the fees set between and within sectors. It also considers whether the option is clear in the way that it relates the fee structure and levels to regulatory risk and to the regulatory activity needed
- **Ease of understanding.** Testing how clear and straightforward the option is
- **HTA implementation.** This considers how manageable the option is for implementation with the HTA, and how costly its operation would be
- **Licensee implementation.** This criterion considers how manageable the option is for implementation for licence holders
- **Change.** This includes considering the likely scale of change in fees and in the structure for different licence holders
- **Financial Risk.** This covers the risk to the HTA that our costs may not be fully recovered (not the regulatory risk attributed to establishments)

In applying these criteria we have drawn on the expertise and experience of the HTA’s Regulation Managers and those in other Directorates who are involved in licensing activity.

1.3.2 Options rejected

During this evaluation process, a number of options have been rejected. In order to inform and guide the consultation, we have summarised here the main types of options that have not been taken forward, and provide summary reasons to explain their rejection:

- Additional fee costs will not be charged for licence variations or for the provision of advice and guidance. This is because the HTA does not want to set up any perverse incentives that might lead to establishments not seeking advice or avoiding mentioning changes in their licensable activities.
- A risk-based approach to charging fees has been considered but not taken forward. This is because risk is reflected in the level of activity relating to each sector, so risk will have been taken into account when establishing the allocation keys to apportion costs across sectors (for example using previous enforcement activity to predict future levels moving forward). Within a sector it was considered inappropriate to use a risk-based model to determine fee charges, since this may incentivise unwanted behaviour from establishments trying to manipulate a risk score and would introduce complex timing issues as to when risk scores were established and fees set. In addition an organisations risk rating could change at any time and potentially many times throughout the year.
- For the human application sector, there are currently pilots running to investigate the amount of work involved in regulating Third Party Arrangements (TPAs). The results of these are not yet available so explicit charging for TPA activity has been considered out of scope for this current exercise.

1.4 SUMMARY OF THE PROPOSED FEE STRUCTURE

The proposed fee structure for 2011/12 and beyond is as follows:

- In all sectors there would be an initial application fee and then an annual renewal fee, which would apply for both main and satellite applications
- Fees for annual fees for satellite sites would be banded, reflecting the fact that additional sites become less onerous in regulatory terms the more there are of them
- A separate tariff would be retained for smaller public display establishments (for displays with less than 20 items), and a new separate fee would be introduced for temporary public display licenses
- Costs of site inspection visits would be banded by the complexity of the site visit. We wish to consult on whether site visit costs should be charged only to those establishments visited or spread across all establishments in a sector. If establishments visited are charged, we recognise the need to notify establishments in good time of scheduled visits so they can set funds aside to pay the fee.
- Annual fees in the human application sector would be determined with reference to the number of licensable activities carried out and the number of tissue types handled

It may be possible to vary the fee structure for different sectors. For example, it may be preferred that site visits should be charged separately in the human application sector, but spread across all establishments in sectors where only a small proportion of establishments are visited each year.

Specific fee levels will be reviewed and advised annually. Fee levels will be set using the structure described and reasonable estimates of activity and of new applications. The costs of delivering licence activities will be determined annually, taking account of efficiencies. Fees will be set to recover the HTA costs associated with licence activity only. The HTA will take on a reasonable level of financial risk arising from uncertainties in future estimates, and will meet any shortfall in fee income from reserves.

In addition:

- annual fees could be paid in two instalments
- the first annual fee for new licence holders would be charged on a pro-rata basis for the number of months remaining in the year before the next fee is due
- fees would be invoiced when an application was received and when a site visit took place, with annual fees being invoiced at the same time of year as at present

In summary, the HTA's proposals for the 2011/12 fee structure:

- more fairly reflect the regulatory work involved in each sector
- better align the actual cost of relevant sector activity and the size of licensed establishments
- improve transparency by making clear the cost basis of the fees charged

1.5 ILLUSTRATIVE FEES BY SECTOR

The fees in the following section are illustrative only at this stage, to inform the consultation on the fees structure proposals. Fees will be finalised following the Authority's agreement of the 2011/12 budget and published on the HTA website in September 2010.

1.5.1 Human application sector

THESE FIGURES ARE ILLUSTRATIVE ONLY

Current fees

Main fee:	£11,000
Satellite fee:	£3,800
Procurement organisation:	£6,000
Simple skin and bone establishment:	£5,500

Proposed fees (without breakdown of licensed activity and tissue type)**

	Site visit included*	Site visit separate*
Application fee: (main licence)	£1,750	£1,750
Application fee: (satellite licence)	£350	£350
Annual fee: (main licence)	£11,000	£8,500
Annual fee: (procurement only licence)	£6,000	£4,600
Annual fee: (per satellite for first 3 satellites)	£3,800	£2,980
Annual fee: (per satellite for 4-10 satellites)	£1,900	£1,490
Annual fee: (per satellite for over 10 satellites)	£950	£745
Site visit fee: (very simple - 1 day, 1 person)	-	£2,800
Site visit fee: (simple - 1 day, 2 people)	-	£5,100
Site visit fee: (complex - 2 days, 2 people)	-	£7,500
Site visit fee: (very complex - 3+ days, 2 people)	-	£9,900

Proposed fees (with breakdown of licensed activity and tissue type)**

Site visit included:*

Licensed Activities	Tissue types		
	1	2,3	4-7
1,2	£6,000	£7,000	£8,000
3,4	£8,500	£10,000	£11,500
5-8*	£11,000	£13,000	£15,000

- First 3 satellites 35% per satellite
- 4-10 satellites 17.5% per satellite
- 10+ satellites 8.75% per satellite

Site visit separate:*

Licensed Activities	Tissue types		
	1	2,3	4-7
1,2	£4,600	£5,400	£6,200
3,4	£6,500	£7,700	£8,900
5-8*	£8,500	£10,000	£11,500

Human application sector continued

Licensed Activities	Tissue Type groupings
Storage (Human Tissue Act)	Skeletal tissue
Procurement	Haematopoietic stem cells
Testing	Ocular tissue
Processing	Cardiovascular tissue
Storage	Skin
Distribution	Tissues or cells procured for ATMPs or IMPs
Import	Other tissues or cells
Export	

* We wish to consult on whether or not stakeholders would like to see the cost of site visits included in their annual fee or charged for separately.

** We wish to consult on whether stakeholders would like to see the human application sector annual fee stratified by tissue types and licensed activities.

Further Comments

- The overall amount of money to be recovered from licensing in the human application sector has increased. This is due to a high proportion of regulation activity taking place for this sector including the following activities:
 - enforcement activity
 - advice and guidance
 - site visits being required every two years
 - activity data and SAERS reporting
- The separate charge for simple skin and bone establishments would be removed as there have been no establishments which meet the criteria for these licenses
- The adjustment of satellite bandings has the greatest impact in the human application sector. The fee increase which would have been seen in the sector due to the introduction of satellite banding is offset by the increase in the number of licenses held in the human application sector.

1.5.2 Post mortem sector

THESE FIGURES ARE ILLUSTRATIVE ONLY

Current fees

Main fee:	£8,000
Satellite fee:	£2,000

Proposed fees

	Site visit included*	Site visit separate*
Application fee: (main licence)	£1,750	£1,750
Application fee: (satellite licence)	£350	£350
Annual fee: (main licence)	£8,000	£6,250
Annual fee: (per satellite for first 3 satellites)	£2,000	£1,560
Annual fee: (per satellite for 4-10 satellites)	£1,000	£780
Annual fee: (per satellite for over 10 satellites)	£500	£390
Site visit fee: (very simple - 1 day, 1 person)	-	£2,800
Site visit fee: (simple - 1 day, 2 people)	-	£5,100
Site visit fee: (complex - 2 days, 2 people)	-	£7,500
Site visit fee: (very complex - 3+ days, 2 people)	-	£9,900

* We wish to consult on whether or not stakeholders would like to see the cost of site visits included in their annual fee or charged for separately.

Further Comments

- Licence fees in the post mortem sector would remain at previous levels, on these assumptions
- The overall amount of money to be recovered from licensing in the post mortem Sector has remained constant. This is due to licence numbers remaining fairly steady and the sector continuing to require a relatively large amount of regulatory effort.
- Regulatory activity taking place for this sector includes the following activities:
 - enforcement activity
 - advice and guidance due to non compliance
 - visits to all post mortem establishments over 3 years
 - media enquires

1.5.3 Research sector

THESE FIGURES ARE ILLUSTRATIVE ONLY

Current fees

Main fee:	£6,000
Satellite fee:	£900

Proposed fees

	Site visit Included*	Site visit separate*
Application fee: (main licence)	£1,750	£1,750
Application fee: (satellite licence)	£350	£350
Annual fee: (main licence)	£4,900	£3,850
Annual fee: (per satellite for first 3 satellites)	£1,200	£940
Annual fee: (per satellite for 4-10 satellites)	£600	£470
Annual fee: (per satellite for over 10 satellites)	£300	£235
Site visit fee: (very simple - 1 day, 1 person)	-	£2,800
Site visit fee: (simple - 1 day, 2 people)	-	£5,100
Site visit fee: (complex - 2 days, 2 people)	-	£7,500
Site visit fee: (very complex - 3+ days, 2 people)	-	£9,900

* We wish to consult on whether or not stakeholders would like to see the cost of site visits included in their annual fee or charged for separately.

Further Comments

- Licence fees in the research sector would decrease for main licences. This is due to a decrease in the total amount of money to be recovered for the sector
- Licence fees in the research sector would increase for satellite licences. This is following a review of the effort required in dealing with satellite licenses in this sector
- All establishments would pay less than under the previous fee structure
- The overall amount of money to be recovered from licensing the research sector has decreased slightly. This is due to a lower number of site visits in this sector than previously estimated, and a relatively lower amount of enforcement activities and media enquires than for the human application and post mortem sectors.

1.5.4 Public display sector

THESE FIGURES ARE ILLUSTRATIVE ONLY

Current fees

Main fee:	£3,750
Satellite fee:	£560
Less than 20 items:	£1,000

Proposed fees

	Site visit included*	Site visit separate*
Application fee: (main licence)	£1,750	£1,750
Application fee: (satellite licence)	£350	£350
Annual fee: (main licence)	£3,600	£2,900
Annual fee: (less than 20 items)	£1,000	£1,000
Annual fee: (per satellite for first 3 satellites)	£540	£440
Annual fee: (per satellite for 4-10 satellites)	£270	£220
Annual fee: (per satellite for over 10 satellites)	£135	£110
Site visit fee: (very simple - 1 day, 1 person)	-	£2,800
Site visit fee: (simple - 1 day, 2 people)	-	£5,100
Site visit fee: (complex - 2 days, 2 people)	-	£7,500
Site visit fee: (very complex - 3+ days, 2 people)	-	£9,900

Temporary public display licence: This fee would be calculated on a case by case basis, but can be expected to be in the region of £8,000-£15,000, reflecting the amount of HTA resource required.

* We wish to consult on whether or not stakeholders would like to see the cost of site visits included in their annual fee or charged for separately.

Further Comments

- Licence fees for permanent displays of 20 items or over would decrease slightly
- The reduced fee of £1,000 for displays with less than 20 items would remain in place
- There would be the introduction of a temporary public display fee which would be set on a case by case basis. This would cover temporary displays and exhibitions which require a large amount of regulatory assistance in a short space of time. Fees would be calculated on a case by case basis, but can be expected to be in the region of £8,000-£15,000.

1.5.5 Anatomy sector

THESE FIGURES ARE ILLUSTRATIVE ONLY

Current fees

Main fee:	£6,500
Satellite fee:	£975

Proposed fees

	Site visit included*	Site visit separate*
Application fee: (main licence)	£1,750	£1,750
Application fee: (satellite licence)	£350	£350
Annual fee: (main licence)	£4,600	£3,500
Annual fee: (per satellite for first 3 satellites)	£700	£520
Annual fee: (per satellite for 4-10 satellites)	£350	£260
Annual fee: (per satellite for over 10 satellites)	£175	£130
Site visit fee: (very simple - 1 day, 1 person)	-	£2,800
Site visit fee: (simple - 1 day, 2 people)	-	£5,100
Site visit fee: (complex - 2 days, 2 people)	-	£7,500
Site visit fee: (very complex - 3+ days, 2 people)	-	£9,900

* We wish to consult on whether or not stakeholders would like to see the cost of site visits included in their annual fee or charged for separately.

Further Comments

- Licence fees in the anatomy sector would decrease
- The total amount of money to be recovered from the anatomy sector has decreased due to a lower number of site visits being carried out than previously assumed, and a lower requirement from the sector for advice and guidance. There has also been a slight increase in the number of licenses held.

1.6 CONSULTATION QUESTIONS

The HTA would be particularly interested in views on the following questions and you can add comments on any part of the proposals in your response. Please respond using the online response form available on the HTA website:

<http://www.hta.gov.uk/consultations/htaconsultations.cfm/843-Licence-fee-consultation-2011-12.html>

1. Are the activities it is proposed to charge for separately the appropriate activities?
2. Has the correct balance been achieved between charging for activities and incorporation in an annual fee? (Costs have been included in the annual fee where the same costs apply to all)
3. Should those establishments selected for site visits bear the cost of their inspection, rather than costs being spread amongst all establishments in the sector, as part of the annual fee?
4. Is the categorisation of site visits (simple, complex etc) appropriate?
5. Are the annual fee charging bands, reflecting the number of satellites, appropriate?
6. In the human application sector:
 - a) Are the annual fee charging bands, reflecting the amount of licensable activity and tissue types, appropriate?
 - b) Do the fee proposals properly take account of your activity?
7. Are the proposals for staggered payment helpful?
8. Are the proposals for part year payment for new licence holders fair?