

Human Tissue Authority: Proposal for 2011/12 fee structure

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Developing the 2011/12 proposed fee structure

While working on the fee structure for 2011/12 we worked to the following principles:

- The HTA needs to recover the full costs of regulatory activity through licence fees
- There should be no cross subsidisation between sectors
- Any fee structure should align with the principles of better regulation
 - Proportionality
 - Consistency
 - Targeting
 - Accountability
 - Transparency

During this exercise we have taken into account feedback from stakeholders gathered during previous fees consultation and workshops. In particular the following issues were raised and have been considered when developing the fee structure for 2011/12:

- *“Licence fees should reflect the differing sizes of establishments and reflect the different 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”*

Three work streams supported the development of the 2011/12 fee proposals

Developing a Cost Model

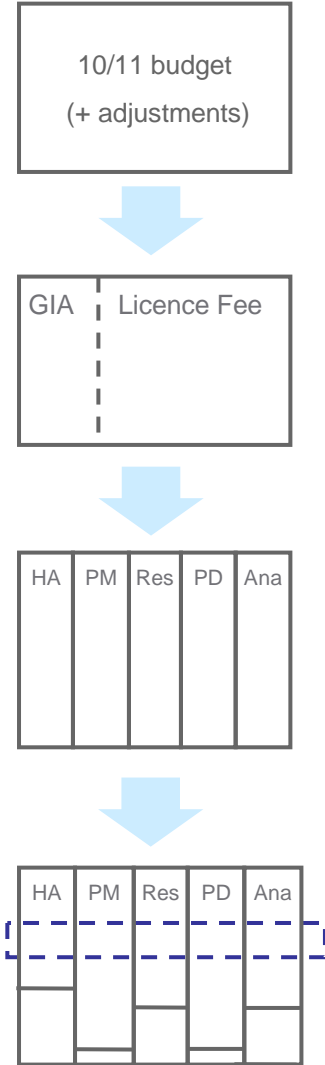
- Determine the amount to be recovered in 2011/12 based on adjustments to the 2010/11 budget and Grant in Aid allocation
- Understand how activity was broken down across the HTA and in particular the regulation directorate
- Develop “allocation keys” to apportion HTA costs across the five fee-paying sectors.

Developing the Fee Structure

- Determine how the fees could be structured based on industry best practice, stakeholder feedback and HTA assessment
- Investigate the options for activity based costing

Modelling the indicative fees

- Model the impact of the cost model and fee structure on the fees for 2011/12
- Develop suitable proposals and/or options to take to consultation with key stakeholders

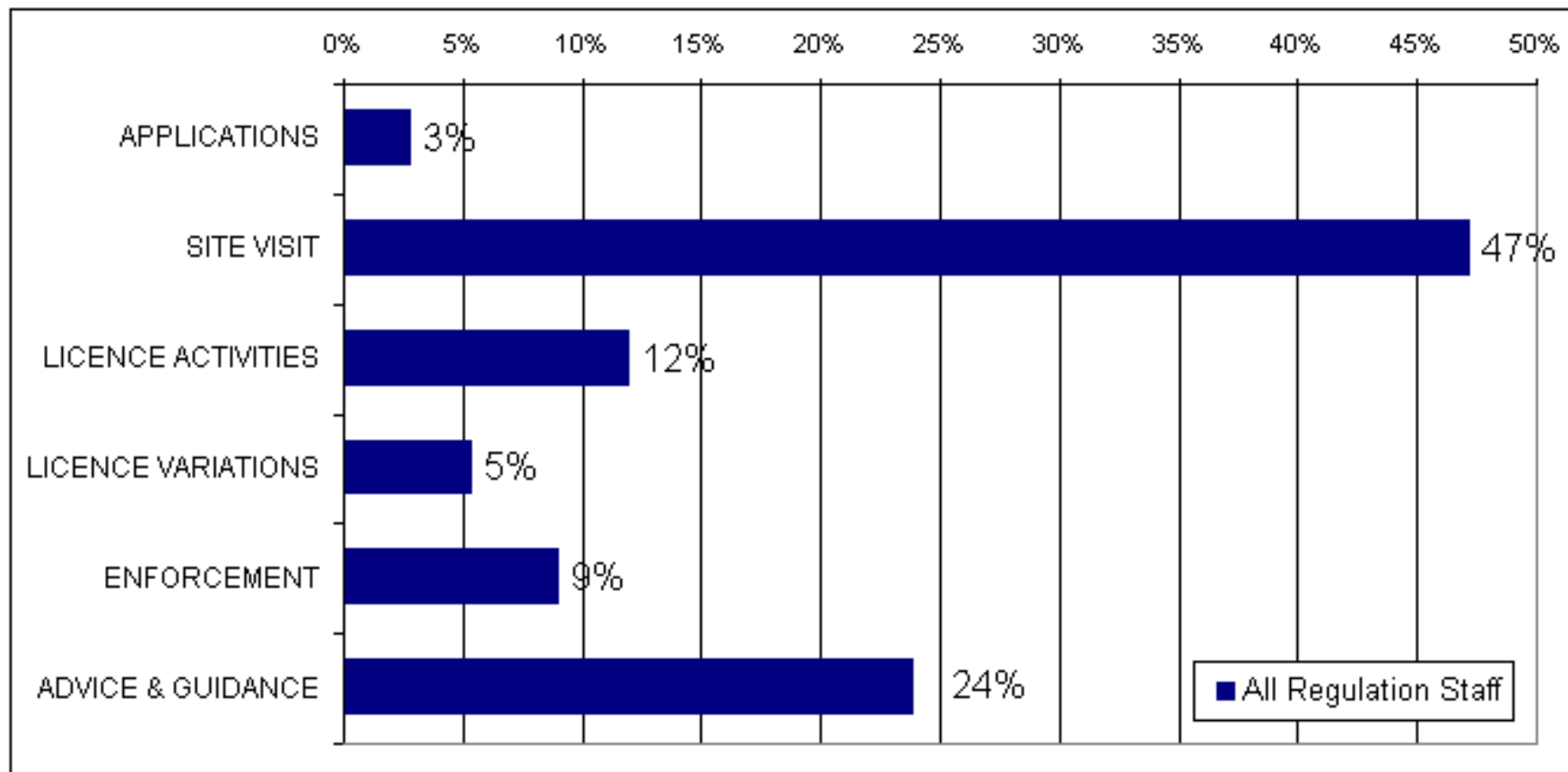


Developing the Cost Model

A full understanding of HTA activity was necessary for this piece of work

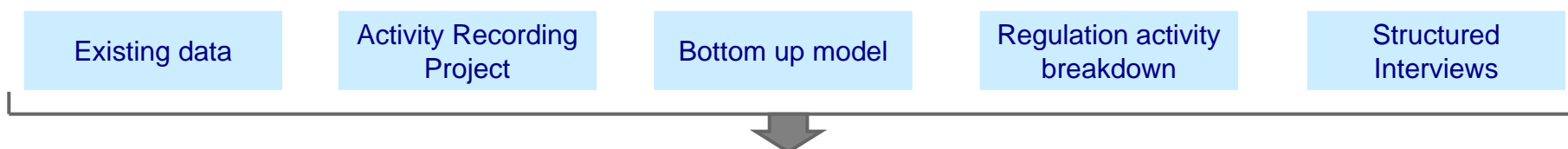
Stakeholders fed back that they would like to see fees based on activity undertaken, either through separate charging or a breakdown on invoices. We undertook an exercise to determine how effort was focussed across different activity in the regulation directorate. This informed where there was potential for separate activity based fees as well as allowing a more rigorous approach to the sector cost breakdown.

Proportion of regulation staff time spent on direct licensing activities



Allocating costs across the five sectors prevents cross subsidisation

A number of different methods were used to develop robust “allocation keys” for the cost model. An allocation key allocates a particular element of cost across the five sectors. Allocation keys are maintained as parameters to the cost model meaning they can be updated when HTA activity changes.



NAME	Allocation Keys					Source Data					Source	
	HA %	PM %	Res %	PD %	Anat %	HA	PM	RES	PD	Anat		
Main Licences	30%	38%	24%	3%	6%	179	222	140	16	34	Number of main licences (Supplied by AW - Feb 2010)	2%
Satellite Licences	31%	26%	36%	1%	5%	80	67	92	3	13	Number of satellite licences (Supplied by AW - Feb 2010)	
Total Licences	31%	34%	27%	2%	6%	259	289	232	19	47	Total number of licences (Supplied by AW - Feb 2010)	
Communications	37%	36%	22%	2%	3%	33	32	20	2	3	from comms lead - excludes 10% transplant	8%
Media	31%	50%	13%	4%	3%	25	40	10	3	2	from media lead - excludes 20% transplant	4%
Overall Communications Activity	35%	41%	18%	3%	3%	35%	41%	18%	3%	3%		
Policy	35%	40%	20%	2%	3%	35	40	20	2	3	use number of licenses with adj for research	6%
Legal	44%	44%	10%	1%	2%	218	218	48	4	10	use Enforcement Assumption	
Strategy	42%	37%	16%	1%	4%	0.42	0.37	0.16	0.01	0.04	use Regulation Activity	
Overall Policy Activity	39%	40%	16%	2%	3%	39%	40%	16%	2%	3%		
Application Assumption	37%	15%	36%	4%	8%	29	12	28	3	6	based on 2008 & 2009 applications	3%
Site Visit Assumption (10/11)	41%	43%	12%	1%	4%	915	950	260	25	80	based on 2010/11 site visit plan & visit complexity	47%
Licensing Activity	42%	41%	13%	1%	3%	268.5	266.4	84	8	17	based on compliance info submission & complexity	11%
Advice & Guidance	45%	24%	25%	2%	4%	45	24	25	2	4	based on Enquiries Database and HoR judgement	5%
Enforcement Assumption (All)	44%	44%	10%	1%	2%	218	218	48	4	9.5	based on past enforcement activity & judgement	14%
Overall Regulation Activity	42%	37%	16%	1%	4%	33.6	30.0	13.0	1.2	3.0		
Overall CEO Activity	25%	70%	3%	1%	1%	25	70	3	1	1	from CEO	1%
Overall Direct Staff Activity	40%	38%	16%	2%	3%	40%	38%	16%	2%	3%		
Debtor Analysis	79%	14%	2%		5%	72.5	13.1	1.7		5.0	from accounts	1%

Applying these allocation keys gives an overall sector breakdown

Applying this set of allocation keys to the adjusted 2010/11 budget gives the following breakdown of HTA licence fee costs across the five sectors:

	Human Application	Post Mortem	Research	Public Display	Anatomy
Current Model	38.1%	38.0%	18.2%	1.3%	4.3%
Proposed Model	40.3%	38.3%	16.2%	1.6%	3.5%

Assuming a 2011/12 budget of £5.1m means that the amount of money required to be raised by licence fees in each sector is as follows:

	Human Application	Post Mortem	Research	Public Display	Anatomy
	(£ 000's)	(£ 000's)	(£ 000's)	(£ 000's)	(£ 000's)
Current Model	£1,943	£1,940	£931	£69	£220
Proposed Model	£2,055	£1,956	£828	£83	£177

Developing the fee structure

Two workshops were held to agree a proposed fee structure

Two workshops were held to decide on a proposed option for the fee structure. In each workshop a list of options was considered and then scored against pre agreed criteria to move from a “long list” of options to a “short list” in the first workshop and then from the “short list” to a “proposed option” in the second workshop. This approach provided a clear reasoning for selecting the proposed fee structure; it gave a clear audit trail of the decision process; and it also highlighted areas which could be considered to take out to consultation.

Long List



The long list consisted of 31 fee structure options. These were derived from:

- Feedback from 09/10 fee structure changes
- Stakeholder workshops held in July 09
- Interviews with the Heads of Regulation
- Research into other regulator’s fees modelling

Short List



The long list was moved to a short list by scoring the 31 options against the following criteria

- Cultural fit with HTA as a compliance based regulator
- Fairness and transparency of charging structure
- Ease of understanding of charging structure
- Ease of HTA implementation
- Ease of Licensee implementation

Proposed Option

The short list was moved to a proposed option by scoring against the five original criteria plus:

- The potential change in fees across organisations
- The risk of the HTA not recovering full costs

The following fee structure is proposed for 2011/12

- 1) To charge a separate application fee in addition to the annual licence fee
- 2) To introduce a banding system for satellite licence charging
- 3) To introduce a separate case-by-case fee for temporary public displays
- 4) To charge a separate fee for site visits, rather than incorporate this cost into the annual fee
- 5) To introduce a set of charges which breaks down fees according to licensed activity and tissue type for the Human Application sector.

Current Fee Structure	Human Application	Post Mortem	Research	Public Display	Anatomy
Main Licence	£11,000	£8,000	£6,000	£3,750	£6,500
Satellite Licence	£3,800	£2,000	£900	£560	£975
Procurement organisations	£6,000				
Public Display (< 20 Items)				£1,000	

Other options were considered but not taken forward

The following options were considered for activity based costing

- **Licence Variations.** It was decided to not charge separately for licence variations as this could; incentivise organisations to not update information, lead to an overly complex charging structure, and have a high risk of not fully recovering costs.
- **Advice & Guidance.** It was decided to not charge separately for advice & guidance, since we did not wish to deter organisations from seeking advice and guidance. Advice and guidance would be difficult to price fairly and accurately, and it could be seen as unfair if advice and guidance is offered without being requested.
- **Licensing Activity.** Licensing activity includes gathering data to support continuous licensing, updating compliance information, collating activity analysis data and serious & adverse event reporting. It was decided to not charge separately for these licensing activities since they would be complex to price fairly and accurately.

Indicative fees

We have modelled indicative fees for the proposed fee structure

Numbers are as accurate as possible however can only be considered indicative at this stage due to:

- Feedback being sought from stakeholders on some aspects of our proposed fee structure
- The HTA will be reviewing assumptions every year to ensure fees are as fair as possible, this will include a refresh for 2011/12
- There is potential for further adjustment to the 2011/12 budget and Grant in Aid allocation

1) Charge a separate application fee and annual licence fee

The HTA propose to move to charging a fee for new licence applications. This would enable the HTA to recover money when work is done on processing a licence application and the licence offer is not accepted. This would also serve to reduce the annual fee slightly for existing organisations.

The application fee would be similar across sectors as a similar process is followed in each sector, with a reduced fee for satellite licences as these take less time to process.

Main Site Application	Satellite Application*
£1,750	£350

* Satellite applications would not be banded, so each satellite applied for would be charged the full Satellite fee

Indicative numbers only

2) Introduce a banding system for satellite licence charging

Charges for satellite licences have been reviewed to understand the amount of HTA effort involved in dealing with these licences. After this review it is proposed to introduce a banding system to reflect economies of scale when dealing with an organisation with a large number of satellites. In addition the charge for satellites in the research sector would be adjusted to reflect the greater complexity of satellite arrangements in that sector than previously assumed.

Model	Satellites	Human Application	Post Mortem	Research	Public Display	Anatomy
Current	All Satellites	35%	25%	15%	15%	15%
Proposed	For each of the first 3 satellites	35%	25%	25%	15%	15%
Proposed	For each of the next 4-10 satellites	17.5%	12.5%	12.5%	7.5%	7.5%
Proposed	For each satellite over 10	8.75%	6.25%	6.25%	3.75%	3.75%

Percentages indicate the amount a satellite licence would cost in relation to the cost of a main site licence

3) Introduce a separate case by case fee for temporary Public Display

Currently temporary public displays pay the same amount as static display sites (either £3,750 or £1,000). It is estimated that at least half of all HTA staff effort in the Public Display sector is spent on 2 or 3 temporary exhibitions per year compared to 16 permanent licences.

The proposed option is to set a separate fee for temporary public displays on a case by case basis. This fee would reflect the amount of work carried out by the regulation directorate as well as the communications and policy directorates.

The fee would be based upon component parts.

Illustrative example for a large international exhibition:

Application fee

+ 2 person, 1 day site visit

+ 1.5 x annual fee (reflecting large amount of advice and guidance and a large communications effort).

This example would total £11,650

Indicative numbers only

These three changes to the fee structure imply the following fees

Proposed fee structure (without separate site visit charge)	Human Application	Post Mortem	Research	Public Display	Anatomy
Application fee	----- £1,750 main licences / £350 satellite licences -----				
Proposed Annual Fee	£11,000	£8,000	£4,900	£3,600	£4,600
For each of the first 3 satellites	£3,800	£2,000	£1,200	£540	£700
For each of the next 4-10 satellites	£1,900	£1,000	£600	£270	£350
For each satellite over 10	£950	£500	£300	£135	£175
Procurement Organisation	£6,000	-	-	-	-
Public Display (< 20 Items)	-	-	-	£1,000	-

An separate fee would be charged for temporary Public Display fees to reflect the amount of work undertaken. This charge would be set on a case by case basis but could typically be expected to be in the range of £8,000 to £15,000

Current fee structure	Human Application	Post Mortem	Research	Public Display	Anatomy
Main licence annual fee	£11,000	£8,000	£6,000	£3,750	£6,500
Satellite licence annual fee	£3,800	£2,000	£900	£560	£975

Indicative numbers only

4) Charge a separate fee for site visits

The HTA propose to charge organisations for site visits in a separate charge from the annual fee. In 2010/11 it is estimated that around 50% of HTA direct regulatory activity will be on site visits so this is a substantial component of the annual fee. Currently the charge for site visits is spread across all organisations in a sector. For example

- In Human Applications each organisation shares the costs of 79 Site visits (a mix of 1 day and 2 day visits)
- In Public Display each organisation shares the cost of 3 x 1 day visits

The HTA would like to consult with its stakeholders as to:

- 1) Whether organisations should pay for site visits only if they receive a visit rather than share the costs of site visits across all organisations in the sector
- 2) If organisations would like to see separate charging, whether they are happy with the granularity of simple / complex site visits. Please note site visit durations are predetermined in the HTA annual site visit plan.

	Very Simple	Simple	Complex	Very complex
Number of Regulation Managers on site	1	2	2	2
Number of days spent on site	1	1	2	3+
Estimated days of HTA total staff time	5.25	10.5	16	22
Site Visits to date	5%	70%	24%	1%

4) Charging separately for site visits would imply the following fees

The following fee structure is proposed. These fees take into account the cost of the staff time to prepare for the visit, to conduct the visit, to produce the report and to conduct any resulting licence activity or advice and guidance. The cost also includes all travel time and expenses.

Proposed site visit fee	Very Simple	Simple	Complex	Very complex
	£2,800	£5,100	£7,500	£9,900

In addition to being a more transparent approach, charging separately for site visits would have the effect of reducing the annual licence fee across the sectors.

Methodology	Range of fees	Revised Annual Fee				
		Human Application	Post Mortem	Research	Public Display	Anatomy
No site visit fee	£0	£11,000	£8,000	£4,900	£3,600	£4,700
Site visit fee	£2,800 - £9,900	£8,500	£6,250	£3,850	£2,900	£3,500

Indicative numbers only

4) A worked example for separate site visit charging

Example: Research Sector

We assume that 21 out of 147 Research establishments are scheduled to receive a site visit (as per 2010/11 plan)

- If site visit charges are incorporated in the annual fee then each establishment pays an annual fee of £4,900
- If site visits are charged for separately then
 - 126 establishments would pay a reduced fee of £3,750
 - 12 establishments would pay £8,850 (annual fee + simple site visit fee)
 - 8 establishments would pay £11,250 (annual fee + complex site visit fee)
 - and 1 establishment would pay £13,650 (annual fee + very complex site visit fee)

Indicative numbers only

5) Breakdown Human Application charges by licensing activity and tissue type

The HTA propose to charge organisations within the Human Application sector based on the amount of work undertaken by each establishment. The proposal would be to charge based on the number of licensable activities undertaken by an organisation, and the number of tissue types they deal with.

The HTA would like to consult with its stakeholders in the Human Application sector as to:

- 1) Whether this charging structure is considered fairer in principle
- 2) Whether the pricing points proposed for this approach are appropriate for stakeholders

8 Licence Activities

- Storage (Human Tissue Act)
- Procurement
- Testing
- Processing
- Storage
- Distribution
- Import
- Export

7 Tissue Type Groupings

- Skeletal tissue
- Haematopoietic stem cells
- Ocular tissue
- Cardiovascular tissue
- Skin
- Tissues or cells procured for ATMPs or IMPs
- Other tissues or cells

5) Charging by the Human Application breakdown implies the following fees

If site visit fees are not charged for separately the following fees would apply for annual fees for main licences in the Human Application sector

Licensed Activities	Tissue Types Handled		
	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

1-3 satellites	35%
4-10 satellites	17.5%
11+ satellites	8.75%

If site visit fees are charged for separately the following fees would apply for annual fees for main licences in the Human Application sector

Licensed Activities	Tissue Types Handled		
	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

1-3 satellites	35%
4-10 satellites	17.5%
11+ satellites	8.75%

Indicative numbers only

5) A worked example for the Human Application sector

Example1: An orthopaedic unit obtaining femoral heads from NHSBT and storing for trauma patients

2 licensed activities & 1 tissue type

> Currently paying £11,000

New HA structure with site visit costs included

> Would pay £6,000

New HA structure with site visit costs separated

> Would pay £4,600 + the potential cost of a site visit (£5,100) = up to £9,700

Example2: A large teaching hospital with 2 satellite sites

6 licensed activities & 5 tissue types

> Currently paying £17,600 (£11,000 + £3,800 + £3,800)

New HA structure with site visit costs included

> Would pay £25,500 (£15,000 + £5,250 + £5,250)

New HA structure with site visit costs separated

> Would pay £19,550 (£11,500 + £4,025 + £4,025)

+ the potential cost of a site visit (£7,500 or £9,900) = up to £29,450

Indicative numbers only

The proposed fee structure for 2011/12

The following fee structure is proposed for 2011/12

- 1) To charge a separate application fee in addition to the annual licence fee
- 2) To introduce a banding system for satellite licence charging *
- 3) To introduce a separate case-by-case fee for temporary public displays
- 4) To charge a separate fee for site visits *
- 5) To break down Human Application charges by licensing activity and tissue type *

* Specific consultation points

The proposed fee structure (site visits charged for separately)

Annual Fee	Human Application	Post Mortem	Research	Public Display	Anatomy
Main Licence		£6,250	£3,850	£2,900	£3,500
For each of the first 3 satellites		£1,560	£940	£440	£520
For each of the next 4-10 satellites		£780	£470	£220	£260
For each satellite over 10		£390	£235	£110	£130

Human Application charges

Activity fee	All sectors
Application fee for main site	£1,750
Application fee for satellite site	£350
Site Visit - 1 person 1 day	£2,800
Site Visit - 2 people 1 day	£5,100
Site Visit - 2 people 2 days	£7,500
Site Visit - 2 people 3+ days	£9,900

		Tissue Types Handled		
		1	2-3	4-7
Licensed Activities	1-2	£4,600	£5,400	£6,200
	3-4	£6,500	£7,700	£8,900
	5-8	£8,500	£10,000	£11,500
	For each of the first 3 satellites		35%	
For each of the next 4-10 satellites		17.5%		
For each satellite over 10		8.75%		

Proposed questions for consultation

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?