

Title: Increase the fees, in respect of the Animals (Scientific Procedures) Act 1986, for 2018 IA No: HO0302 RPC Reference No: N/A Lead department or agency: The Home Office Other departments or agencies: HM Treasury	Impact Assessment (IA)			
	Date: 28/11/2017			
	Stage: Final			
	Source of intervention: Domestic			
	Type of measure: Secondary legislation			
	Contact for enquiries: phoebe.stannard@homeoffice.gsi.gov.uk 0207 035 8625			
Summary: Intervention and Options				RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option				
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANDCB in 2014 prices)	One-In, Three-Out	Business Impact Target Status
-£0.0m	-£2.5m	-£0.2m	Not applicable	To be determined

What is the problem under consideration? Why is government intervention necessary?

The problem is ASRU's financial forecast is that expenditure will exceed income by about £360,000 in 2017/18 and by about £290,000 in 2018/19. Only government can provide the regulatory framework, The Animals (Scientific Procedures) Act 1986, which regulates the production, supply, care and use of animals for experimental and other scientific purposes. The administrative and inspectorate function which serves the public interest is provided by Animals in Science Regulation Unit (ASRU). Self-funding is required to maintain regulatory standards and service levels. If this is not achieved, incomplete information on these activities may result.

What are the policy objectives and the intended effects?

The primary objective is for ASRU to cover their costs through the fee increase. Investment in IT to provide a more efficient service has already been made. The objectives include:

- ASRU breaking even in the next five financial years.
- ASRU maintaining the current regulatory standards.
- Minimising the negative effects the fee rise has on business.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Non-regulatory options were only considered briefly because this is a tightly regulated activity. Raising the fee does not increase or decrease the amount of regulatory activity that takes place.

Option 1: Is to do nothing. This option does not achieve the Government's objective. It does not allow ASRU to operate effectively on a full cost recovery basis.

Option 2: Is to increase the licence fees. **The preferred option** achieves the Government's objective and allows ASRU to operate effectively on a full cost recovery basis.

Establishment Licence:	Current fee	£631	Increase to	£757	Increase of	£126 (20%)
Personal Licence:	Current fee	£242	Increase to	£257	Increase of	£15 (6%)
Project Licence:	Current fee:	£0	Maintain at	£0	No change	

Will the policy be reviewed? It will not be reviewed. If applicable, set review date: 2018 (informal review)						
Does implementation go beyond minimum EU requirements?			No			
Are any of these organisations in scope?			Micro Yes	Small Yes	Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded: N/A		Non-traded: N/A	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister: Williams of Trafford Date: 13th December 2017

Summary: Analysis & Evidence

Policy Option 2

Description: Increase the fees, in respect of the Animals (Scientific Procedures) Act 1986, for 2018

FULL ECONOMIC ASSESSMENT

Price Base Year 2017	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -£0.0	High: -£0.0	Best Estimate: -£0.0

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	£0.0	£0.3	£2.4
High	£0.0	£0.3	£2.7
Best Estimate	£0.0	£0.3	£2.5

Description and scale of key monetised costs by 'main affected groups'

There are some very small familiarisation costs to the private and public sector in Year 1 only. These lie in a range of £100 to £2,800 whereas the public sector familiarisation costs are negligible, even in the High scenario.

The ongoing costs to the private sector lies in a range of £2.4 million to £2.7 million (PV) over 10 years with a central estimate of £2.4 million (PV) over the same period.

Other key non-monetised costs by 'main affected groups'

There are no other significant costs to business or the public sector of this change. Licence holders already pay a fee for a licence and it is only the level of the fee that has changed.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A	£0.3	£2.4
High	N/A	£0.3	£2.6
Best Estimate	N/A	£0.3	£2.5

Description and scale of key monetised benefits by 'main affected groups'

The increase in the licence fee paid is part of a payment from the private sector to the public sector for regulatory services provided. The investment in IT has already been made and the fee increase is to cover this cost. The benefit to the public sector is estimated to be in the range £2.4 to £2.6 million (PV) over 10 years, with a central estimate of about £2.5 million (PV) over the same time period.

Other key non-monetised benefits by 'main affected groups'

The main benefit to the private sector is the maintenance of both the regulatory standard and the level of service provided by ASRU. There is also a benefit to the public where ASRU provide complete information on a yearly basis to society. Without the fee increase the level of service may fall and incomplete information may result. It was not possible to monetise either of these benefits.

Key assumptions/sensitivities/risks Discount rate (%) 3.5

The estimates are sensitive to the assumptions made about the number of establishments that require a licence and the volume of individuals who could hold a licence.

There is very little risk to this policy as it is a simple fee change that allows regulatory work to continue at the same standard without disrupting the current level of service to the private sector.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: £0.3	Benefits: £0.0	Net: -£0.3	
			N/A

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

The Animals (Scientific Procedures) Act 1986¹ (as amended) (ASPA) regulates the production, supply, care and use of animals for experimental and other scientific purposes. The regulatory system issues establishment licences to places where such work can be undertaken, requires project licences be issued for programmes of work, and that those who perform the regulated procedures are the holders of personal licences. The Act was amended in 2013 following an EU Directive, 2010/63/EU². The Animals in Science Regulation Unit (ASRU) is the regulator and provides the administrative and inspectorate function on behalf of the Home Office for England, Wales and Scotland but not for Northern Ireland. There are 40 staff based in Croydon, 2 Marsham Street and spread across the UK. There are currently 162 licensed establishments. The majority are universities and pharmaceutical companies (or contract research organisations undertaking research on their behalf). At any time there are approximately 2,650 live project licence licences, with 500 to 600 new applications and over 1,100 licence amendment requests received by ASRU each year. There are more than 15,000 personal licences live at any time, with more than 3,000 new applications and 500 to 600 licence amendment requests received by ASRU each year.

A.2 Groups Affected

The ASRU licences apply to any **establishment, individual or programme** requiring the use of animals in research and testing. The licensing system ensures that animal research and testing is only undertaken where no practicable alternatives exist and under rigorous controls where animal welfare must be of the utmost priority. The place at which the work is carried out must hold an 'establishment licence' (PEL); the programme of work in which the procedures are carried out must be authorised in a 'project licence' (PPL); those carrying out procedures must hold a 'personal licence' (PIL), which ensures that those working with the animals are qualified and suitable.

A.3 Consultation

Within Government

In September a business case for an increase to fees was submitted to HM Treasury (HMT). This was approved by HMT with an email confirmation that they were content with the fee increases set out.

¹ Animals in Science Regulation Unit: Annual Report 2015;
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/582282/asru-annual-report-2015.pdf

² Animals in Science Regulation Unit: Annual Report 2015;
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/582282/asru-annual-report-2015.pdf

B. Rationale

Economic Rationale

The primary problem is a financial one. The business case outlines that the fee increase is required to ensure the regulator is able to recover all costs, on a break-even basis. The financial forecast for ASRU indicates that expenditure will exceed income by about £360,000 in 2017/18 and by about £290,000 in 2018/19. This is primarily due to increases in the IT costs per year, including the associated depreciation costs and the annual cost of hosting and supporting the system. The investment in improved IT has already been made. Increasing fees will also ensure that existing staffing levels can be maintained so establishments should not see any deterioration in the service provided.

The economic rationale for the continued intervention in this case is incomplete information. This information is needed for the market to operate efficiently, and it must be available to both sides of the market. Where it is not, the market may fail. The animal science market is an already regulated market. Previous economic assessments have identified that the market would not function on price alone and this position has not changed. ASRU's purpose as a regulatory body is to provide greater information to society about the safeguards for animals used in research. The economic argument is that if fees cannot be increased to a full cost recovery level, the service provided to the licence holders and society will be compromised. This means that without the fee increase, the scope of the information and monitoring gained, which is valued by society and consumers, will revert back to a form of incomplete information because of the inability to maintain the same regulatory standards. In 2016, over 99 per cent of licence applications were processed within the service target (40 days for project licence applications and 20 days for personal licence applications).

C. Objectives

The primary objective is for ASRU to cover their costs through the fee increase. The set of objective outcomes to measure policy success could be:

- ASRU breaking even in the next five financial years.
- ASRU maintaining the current regulatory standards.
- Minimising the negative effects the fee rise has on business.

ASRU maintaining a break-even position would be measured through actual income and expenditure, where the difference between these should be close to zero.

ASRU maintaining their current regulatory standards would be compared to the benchmark of 2016's figure of a 99 per cent licence application process target success rate. Other service level indicators could be used, for example, the amount of site visits a year and inspections a year. Success should mean no change in regulatory standards.

D. Options

Option 1

Option 1 is to make no changes (do nothing). However, this option does not achieve the Government's objective. It does not allow ASRU to operate effectively on a full cost recovery basis.

Option 2

Option 2 is to increase the licence fees. The proposed licence fees are:

- Establishment:
Current fee £631 Increase to £757 Increase of £126 (20%).
- Project:
Current fee: £0 Maintain at £0 No change.
- Personal:
Current fee £242 Increase to £257 Increase of £15 (6%).

Option 2 would allow ASRU to operate effectively on a full cost recovery basis. The full cost recovery would allow ASRU to maintain their level of regulation. No new regulation is proposed and there is no increase in regulatory activity as a result of the increase being proposed.

E. Appraisal (Costs and Benefits)

GENERAL ASSUMPTIONS & DATA

A social discount rate of 3.5 per cent is used to obtain present value, see HM Treasury (2003) Green Book. Any estimate quoted (PV) or the Net Present Value (NPV) is discounted using this rate. The appraisal is over a ten-year period.

Occupational wages are taken from the Annual Survey of Hours and Earnings (ASHE) for 2017, Table 14.5a published by the Office for National Statistics³. Gross median hourly wages are used in the estimate and these are grossed up using an uplift of 19.8 per cent⁴ for non-wage costs as recommended by HMRC and Department for Business Innovation and Skills.

³ Annual Survey of Hours and Earnings (ASHE) for 2017, Table 14.5a published by the Office for National Statistics, London. See: <https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashtable14>

⁴ Eurostat non-wage labour costs (2017) see: http://ec.europa.eu/eurostat/statistics-explained/index.php/Hourly_labour_costs

Preferred option

The preferred option (option 2 above) is to increase the fees charged for establishment and personal licences. The estimates are based upon the assumption that the current level of regulation will continue.

Set-up costs

Private sector familiarisation costs

Familiarisation costs apply to organisations as they need to know what their future fees are going to be. Familiarisation costs are estimated across the 10-year appraisal period. It has been assumed that 100 per cent of establishments (organisations that are in scope for payment of a licence fee) will read the guidance, which is approximately 350 words and includes the details of the fee changes.

Data for the volume of licences and the number of ASRU employees are taken from the ASRU Fees Business Case 2017/18, (2017).

Table 1: Familiarisation costs: staff volumes and gross wage for administrative staff, private and public sector (£), 2017.

Category	SOC ⁽³⁾	Gross wage ⁽³⁾	Low	Central	High
ASRU admin staff ⁽¹⁾	411	£13.66	40	40	40
Business admin staff ⁽²⁾	41	£13.23	444	820	1,800

Note: No veterinarian or practising staff are involved in the administration of the fees. For virtually all institutions, this is done by administrative staff.

Source: (1) Animal and Scientific Regulatory Unit (ASRU), Fees Business Case 2017/18, (2017) and internal management information.

(2) ASRU internal information and Annual Report (2016).

(3) Annual Survey of Hours and Earnings, Table 14.5a, 2017, October, ONS, London.

Table 2: Reading speed assumptions used for familiarisation costs, 2017.

Scenario	Number Words	Speed (wpm)	Time (mins)	Comp	Re-read time (mins)	Allowance (mins)	Total time (mins)
High	400	100	4.0	0.5	2.00	1.00	7.00
Central	350	200	1.8	0.6	0.70	0.50	3.00
Low	300	400	0.8	0.8	0.00	0.00	1.00

Notes: wpm = words per minute. Comp = comprehension. Units are minutes unless otherwise specified.

Source: readingsoft.com, see: <http://www.readingsoft.com/index.html>

The reading times were estimated using standard tables from readingsoft.com (see Table 2). Because of lower comprehension a slow reader may need to re-

read the guidance (column 5). An allowance has been made for a person who may be dyslexic or where English is not their first language. The volumes and wages used are given in Table 1.

The familiarisation costs are estimated as:

The number of private sector businesses x wage x time taken.

The familiarisation costs for private sector organisations are estimated to be in a range of £0.0 million to £0.0 million, with a central estimate of £0.0 million. There are very small familiarisation costs ranging from £100 to £2,800 and these occur in year 1 only.

Public sector familiarisation costs

Public sector familiarisation costs are estimated in the same way as private sector familiarisation costs. ASRU staff volume is reported as 40 FTEs (see Table 1).

The total familiarisation costs for the public sector are estimated to be in a range of £0.0 million to £0.0 million, with a central estimate of £0.0 million. The public sector familiarisation costs are negligible, with the high estimate only about £60 in year 1 only.

Total familiarisation costs

Total familiarisation costs are estimated to be in a range of £0.0 million to £0.0 million, with a central estimate of £0.0 million.

Ongoing costs

Private sector fee increases

As described in the 'Background' section establishments and individuals require a licence to undertake regulated work with animals. Licence applicants are charged a fee to cover the cost of administering the application, inspecting and monitoring the institution and to cover the other regulatory costs associated with the licence application.

Private sector fee changes are calculated as:

The proposed fee change (the difference between the current fee and proposed fee) x volume of expected applications for each type of licence fee (personal, project and establishment).

Private sector fee changes are detailed in Table 3 with the current fee, proposed fee, fee change and the estimated volume of application using the central estimate.

Table 3: Licence fee, summary impacts (£ and £ million), 2017.

Fee and Application Volume	Current Fee (£)	Proposed Fee (£)	Change in Fee (£)	Annual Impact Option 2	10 Year Impact £ million (PV)
Establishment Fee No. Applications:	£631	£757	£126 164	£20,700	0.2
Project Fee No. Applications:	£0	£0	£0 2,650	£0	0.0
Personal Fee No. Applications:	£242	£257	£15 18,000	£270,000	2.3
Total				£290,700	2.5

Note: Figures may not sum due to rounding.

The total ongoing cost to the private sector is estimated to be in a range of £2.4 million to £2.7 million (PV) over 10 years, with a central estimate of £2.5 million (PV) over the same period.

Total costs

The total cost of this proposal to increase the fees for establishment and personal licences required for undertaking regulated work with animals is estimated to be in the range of £2.4 million to £2.7 million (PV) over 10 years, with a central estimate of £2.5 million (PV) over the same time period.

BENEFITS

Public sector benefit

There is no direct monetised benefit to the private sector. The benefit to the public sector is the increase in the licence fee which is appraised over the 10 year period. While the fee is a transfer payment, the investment made by the public sector has consumed real resources. The fee increase simply is the private sector paying to cover the public sector costs of maintaining the level of service and the regulatory standard. This benefit allows ASRU to cover its costs of administering and inspecting establishments when licence applications are made.

The total ongoing benefit to the public sector is estimated to be in a range of £2.4 million to £2.6 million (PV) over 10 years, with a central estimate of £2.5 million (PV) over the same period.

Given there are no other monetised benefits the total benefit to this proposal to increase animal licence fees is the same as the public sector benefit, see above, so around £2.5 million (PV) over 10 years.

Non-monetised benefits

For the private sector the main benefits are that the standard of regulation is maintained at the very high standard that is currently provided by ASRU. Any drop in the regulatory standard may reduce the information available to society and potentially weaken the inspection regime which ensures the welfare of animals. It also maintains the service level agreements of the regulatory body.

Given this licence application and inspection regime would be maintained at a high standard, this also instils confidence in the public and other associated authorities, provides timely and accurate information, ensures that regulatory frameworks are transparent and accountability is clear.

NPV, BNPV and EANDCB

The Net Present Value (NPV) is defined as: the total benefit minus the total cost, both of which are discounted over the appraisal period. The NPV is estimated to be -£0.0 million over a 10 year period.

The Business Net Present Value (BNPV) is defined as: the total direct benefit to business minus the total direct cost to business, both of which are discounted over the appraisal period. The BNPV is estimated to be -£2.5 million over a 10 year period.

The Estimated Annual Net Direct Cost to Business (EANDCB): this provides a single average annualised estimate of the net direct cost to business in each year of the policy. The EANDCB is the metric used in scoring impacts for the Business Impact Target (BIT). The EANDCB is estimated to be £0.3 million every year, over a 10 year period.

Small and Medium Sized Business Assessment (SaMBA)

There are no official statistics⁵ that are available to indicate the population of small businesses that may be impacted by this policy change. A register of establishments is held by ASRU. After excluding government establishments and large employers, for example a university, ASRU estimate that there may be up to 12 micro or small establishments and a maximum of 15 medium businesses within the 164 licensed establishments.

Given the type of regulated work undertaken by licensed establishments, on the grounds of animal safety and welfare plus public re-assurance it is not possible to offer any form of exemption for small and medium sized businesses. All establishments (including micro, small and medium businesses) that work in this are already subject to regulation and pay an annual fee for their licence.

So the question of providing an exemption to micro, small and medium size businesses does not apply simply because there is a proposed fee increase. The micro, small and medium sized businesses already have to deal with a

⁵ Inspection of the Business Population Estimates, 2016, published by the Department of Business, Energy and Industrial Strategy (2017) show data on Higher Education (Group 854) and on Veterinary Activities (Group 750) but they do not indicate institutions that undertake work that is regulated by ASRU.

regulatory framework and administer their part in the scheme. The proposal is to simply increase the fee to allow ASRU to cover costs. There is no proposal to increase regulatory activity or to increase the administrative burden on micro, small and medium sized businesses.

F. Risks

OPTION 2 – To increase the establishment and personal licence fees.

There are few risks to this policy as there has been a robust assessment of costs carried by ASRU, Home Office Finance and validation of the business case by HM Treasury. The assumptions and estimates made are cautious and prudent so there is unlikely to be any significant deviation in cost from the estimates given. The only risk is that the actual volume of staff in the private sector who may have a familiarisation cost is not known with certainty. However, given the low cost of familiarisation cost in the private sector this is not a significant concern.

G. Enforcement

This policy will be enforced in line with the Hampton principles (HM Treasury, 2005). There is a long-standing relationship between ASRU and the licence holder and with ASRU and other interest groups. There is no new measure (apart from the fee increase) that the legislation introduces that places an enforcement burden on licence holders or new applicants. Any breaches of a condition of a licence will be dealt with in the same way that ASRU currently deal with any breaches.

H. Summary and Recommendations

Table 3 presents a summary of the impacts arising from Option 2 over the 10 year appraisal period. It is recommended that Option 2 should be implemented as it meets the Government's objective of having ASRU operate on a self-funding basis. There is no adverse impact on regulatory standards or on business (other than the fee increase itself).

I. Implementation

The Government plans to implement these changes on 1st April 2018. These changes will apply across the UK.

J. Monitoring and Evaluation

The effectiveness of the new regime would be monitored by ASRU staff. The data and any other factors noted by the regulator will be used in the monitoring and evaluation. After one year only a light touch evaluation is planned.

K. Feedback

The Home Office will maintain channels of communication with licensees. Feedback from licensees will be used. The feedback from these organisations will be used in the light touch evaluation after one year.

L. References

Department of Business, Energy and Industrial Strategy (2017) Business Population Estimates, 2016, Detailed Tables, London.

See: <https://www.gov.uk/government/statistics/business-population-estimates-2016>

Department of Business, Innovation and Skills (2016) *Better Regulation Framework Manual and Toolkits, Practical Guidance for UK Government Officials*, BETA version, Better Regulation Executive, July, London.

HM Treasury (2005) Reducing administrative burdens: effective inspection and enforcement, (known as 'The Hampton Report'), March, HMSO, London.

<http://webarchive.nationalarchives.gov.uk/20121205081213/http://www.bis.gov.uk/files/file22988.pdf>

HM Treasury (2003) *The Green Book, Appraisal and Evaluation in Central Government*, (2003 version includes amendments made in July 2011), London.

Home Office (2017) *Animals in Science Regulation Unit, Business Case: to increase fees in respect of The Animals (Scientific Procedures) Act 1986*. (unpublished).

Home Office (2016) *Animals in Science Regulation Unit, Annual Report 2015*, London

See: <https://www.gov.uk/government/publications/animals-in-science-regulation-unit-annual-report-2015>