

<b>Title:</b> Increase the fees, in respect of the Animals (Scientific Procedures) Act 1986, for Financial Year 2020/21 <b>IA No:</b> HO0358 <b>RPC Reference No:</b> N/A <b>Lead department or agency:</b> The Home Office <b>Other departments or agencies:</b> HM Treasury	<b>Impact Assessment (IA)</b>			
	<b>Date:</b> 6 March 2020			
	<b>Stage:</b> Final			
	<b>Source of intervention:</b> Domestic			
	<b>Type of measure:</b> Secondary legislation			
<b>Contact for enquiries:</b> Will Reynolds Tel: 0207 035 0454				

<b>Summary: Intervention and Options</b>	<b>RPC Opinion:</b> Not Applicable
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Cost of Preferred Option (in 2018 prices)			
Total Net Present Social Value	Business Net Present Value	Net cost to business per year	Business Impact Target Status
£0.0m	-£2.1m	-£0.4m	Non qualifying provision

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

ASRU's financial forecast highlights that expenditure will exceed income by £445,000 in 2020/21. Only government can provide the regulatory framework set out under 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, which could lead to a reduction in animal welfare.

**What are the policy objectives and the intended effects?**

The primary objective is for ASRU to continue to cover its costs through a fee increase and ensure the continued delivery of the statutory requirements of the Animals (Scientific Procedures) Act (1986). Investment in IT to provide a more efficient service has already been made and ASRU must meet the annual capital depreciation costs. The policy objectives include: ASRU breaking even in the next five financial years, ASRU maintaining the current regulatory standards and Minimising the negative effects that 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.

**Option 2:** is to increase the licence fees. **This is the Government's preferred option** as it meets the objective; ASRU to operate effectively on a full cost recovery basis.

The personal licence fee would rise from £275 to £299, an increase of £24 (10%).  
The establishment licence fee would rise from £826 to £915, an increase of £89 (9%).

**Will the policy be reviewed?** It will be reviewed. **If applicable, set review date:** 11/2020

Does implementation go beyond minimum EU requirements?		No		
Is this measure likely to impact on trade and investment?		No		
Are any of these organisations in scope?	<b>Micro</b> Yes	<b>Small</b> Yes	<b>Medium</b> Yes	<b>Large</b> Yes
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)		<b>Traded:</b> N/A		<b>Non-traded:</b> N/A

*I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.*

Signed by the responsible Minister: Williams of Trafford Date 6th March 2020

# Summary: Analysis & Evidence

# Policy Option 1

**Description:** Increase the fees, in respect of the Animals (Scientific Procedures) Act 1986 for Financial Year 2020/21

## FULL ECONOMIC ASSESSMENT

Price Base Year 2018	PV Base Year 2018	Time Period Years 5	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	1	£1.9
High	£0.0		£2.3
Best Estimate	£0.0		£2.1

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

There are some very small familiarisation costs to the private sector in Year 1 only. These lie in a range of £0 to £1,000 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 £1.9 million to £2.3 million (PV) over 5 years with a central estimate of £2.1 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	£0.0	N/A	£1.9
High	£0.0		£2.3
Best Estimate	£0.0		£2.1

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

The increase in the licence fee paid is a transfer payment from the private to the public sector for regulatory services provided. The increase is to continue to cover IT investment and ASRU staff costs. The benefit to the public sector is estimated to be in the range £1.9 to £2.3 million (PV) over 5 years, with a central estimate of about £2.1 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 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: £0.4	Benefits: £0.0	Net: £0.4	
			N/A

# Evidence Base (for summary sheets)

## A. Strategic Overview

### A.1 Background

The Animals (Scientific Procedures) Act 1986 (as amended 2012) (ASPA) regulates the production, supply, care and use of animals for experimental and other scientific purposes. The Act was amended in 2012 following an EU Directive, 2010/63/EU. The withdrawal of the UK from the EU will not change the requirement for administration and enforcement of ASPA and therefore related work requirement of the Home Office regulator.

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. Northern Ireland have separate regulatory arrangements under devolution. There are 46 staff based within 2 Marsham Street, Croydon and across the country.

The regulatory system issues establishment licences to places where such work can be undertaken, requires that project licences are issued for programmes of work and requires that those who perform the regulated procedures are the holders of personal licences.

There are currently 150 licensed establishments. The majority are universities and pharmaceutical companies (or contract research organisations undertaking research on their behalf). There are approximately 2,750 live project licence licences at any time, with 500 new applications and over 1,000 licence amendment requests received each year. There is a stock of approximately 15,500 personal licences live at any time, with a flow of approximately 17,900. There are approximately 1,000 personal licence amendment requests received each year.

Licensing and inspection costs are recovered through annual fees levied on establishments licensed under the terms of section 8 of ASPA. The charges levied on each establishment should be reflective of the resource required to provide the regulatory services.

ASRU charges the holders of a section 2C licence periodical fees that contain a fixed element to the fee (for the annual 2C licence) and a variable element to the fee (for each Personal licence held under the 2C licence); the latter of which represents the resource required to complete the work at the establishment and also reflects the administrative burden to the regulator.

### 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.

## B. Rationale for intervention.

On 1<sup>st</sup> April 2015, ASRU started operating on a full-cost recovery basis in line with HM Treasury fees and charges principles. The business case outlines that the fee increase is required to ensure the regulator continues to be able to recover all costs, on a break-even basis. The financial forecast for ASRU indicates that expenditure will exceed income by about £445,000 in 2020/21. This is primarily due to the recruitment of four new staff, increases in pension costs and investment in IT which has already been made and agreed through Cabinet Office / Government Digital, and other costs which have arisen. 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 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.

## C. Policy objective

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 that 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.. Success should mean no change in regulatory standards. The fees were last raised in April 2019. The objectives remain the same as the previous IA for the increase (reference no. HO0326<sup>1</sup>)

## D. Description of options considered.

### 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 £826      Increase to £915      Increase of £89 (10%).
- Project:  
Current fee: £0      Maintain at £0      No change.
- Personal  
Current fee £275      Increase to £299      Increase of £24 (9%).

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 fee increase being proposed. To

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<sup>1</sup> [http://www.legislation.gov.uk/ukia/2019/70/pdfs/ukia\\_20190070\\_en.pdf](http://www.legislation.gov.uk/ukia/2019/70/pdfs/ukia_20190070_en.pdf)

achieve true full cost recovery, ASRU has taken a staged approach to increasing the fees so as not to impose the entire cost on licence holders in a single increase. Fees were raised last year to facilitate this approach.

## E. Appraisal.

### General assumptions and data

A social discount rate of 3.5 per cent is used to obtain present value, see HM Treasury (2018) Green Book. Any estimate quoted Present Value (PV) or the Net Present Value (NPV) is discounted using this rate. The appraisal is over a five-year period.

Occupational wages are taken from the Annual Survey of Hours and Earnings (ASHE) for 2018, Table 14.5a published in 2019 by the Office for National Statistics. Gross median hourly wages are used in the estimate and these are grossed up using an uplift of 18.0 per cent for non-wage costs as taken from Eurostat Share of Non-Wage Costs.

**Table 1, Proposed changes to establishment and personal fees (£), 2020/21.**

#### Establishment Fee

Fee considered £	Fee Change £	Volume of licences expected	Revenue £	Expenditure £	Net surplus or deficit £
855	29	150	128,300	137,300	-9,000
870	44	150	130,500	137,300	-6,800
885	59	150	132,800	137,300	-4,500
900	74	150	135,000	137,300	-2,300
<b>915</b>	<b>89</b>	<b>150</b>	<b>137,300</b>	<b>137,300</b>	<b>0</b>
930	104	150	139,500	137,300	2,200
945	119	150	141,800	137,300	4,500

#### Personal Fee

Fee considered £	Fee Change £	Volume of licences expected	Revenue £	Expenditure £	Net surplus or deficit £
285	10	17,900	5,101,500	5,354,200	-252,700
289	14	17,900	5,173,100	5,354,200	-181,100
295	20	17,900	5,280,500	5,354,200	-73,700
<b>299</b>	<b>24</b>	<b>17,900</b>	<b>5,352,100</b>	<b>5,354,200</b>	<b>-2,100</b>
300	25	17,900	5,370,000	5,354,200	15,800
310	35	17,900	5,549,000	5,354,200	194,800
322	47	17,900	5,763,800	5,354,200	409,600

Note: the chosen fees (Establishment and Personal) are highlighted in bold. All figures are rounded to the nearest 100.

Table 1 shows that the volume of licences are held at 150 and 17,900 respectively for establishments and personal categories. Estimated expenditure was subtracted from the estimated income (volume of application x fee) and the fee that resulted in a positive figure closest to zero was accepted as the optimal fee level. For the personal fee, the fee chosen resulted in a net deficit of £2,100. This was accepted as ASRU are expecting employment run rate to fall owing to a number of staff members going part time or part retired. It was deemed preferable by the policy team to have a small net deficit, which will likely be recovered through reduction in employee

expenses, than a larger surplus, which may become larger through reduction in employee expenses.

## Preferred option

**The Government's 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 five-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 2019/20, (2019).

**Table 2, Familiarisation costs: staff volumes and gross wage for administrative staff, private and public sector (£), 2019.**

Category	SOC <sup>(3)</sup>	Gross wage <sup>(3)</sup>	Low	Central	High
<b>ASRU admin staff (41)</b> <sup>(1)</sup>	411	£14.57	46	46	46
<b>Stakeholder business admin staff (411)</b> <sup>(2)</sup>	41	£13.43	435	750	1,550

*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 2020/21, (2019) and internal management information.

(2) ASRU internal information

(3) Annual Survey of Hours and Earnings, Table 14.5a, 2018, October, ONS, London.

**Table 3, Reading speed assumptions used for familiarisation costs, 2019.**

Scenario	Number Words	Speed (wpm)	Time (mins)	Comp	Re-read time (mins)	Allowance (mins)	Total time (mins)
<b>High</b>	400	240	1.7	0.6	0.67	1.00	3.00
<b>Central</b>	350	400	0.9	0.8	0.18	0.50	2.00
<b>Low</b>	300	1000	0.3	0.85	0.00	0.00	0.00

*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 3). 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 2.

The familiarisation costs are estimated as:

*The number of private sector businesses x gross 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 £0 to £1,000 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 46 FTEs (see Table 2).

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 £34 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

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 4 with the current fee, proposed fee, fee change and the estimated volume of application using the central estimate.

**Table 4, Licence fee, Option 2, summary impacts (£ and, £ million PV), 2020/21.**

Application Volume	Current Fee (£)	Proposed Fee (£)	Change in Fee (£)	Annual Impact £	5 Year Impact £ million (PV)
<b>Establishment Fee</b> Applications: <u>150</u>	826	915	89	13,350 (150 x 89)	<b>0.06</b>
Project Fee Applications: <u>2,750</u>	0	0	0	0	<b>0.00</b>
<b>Personal Fee</b> Applications: <u>17,900</u>	275	299	24	429,600 (17,900 x 24)	<b>2.00</b>
<b>Total</b>				<b>442,950</b>	<b>2.07</b>

Note: Central estimate. Figures may not sum due to rounding.

The total ongoing cost to the private sector is estimated to be in a range of £1.9 million to £2.3 million (PV) over 5 years, with a central estimate of £2.1 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 £1.9 million to £2.3 million (PV) over five years, with a central estimate of £2.1 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 five-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 £1.9 million to £2.3 million (PV) over 5 years, with a central estimate of £2.1 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 £2.1 million (PV) over 5 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 five-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 -£2.1 million over a five-year period.

The Equivalent Annual Net Direct Cost to Business (EANDCB) provides an average 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 £0.4 million every year, over a five-year period.

### **Small and Medium Sized Business Assessment (SaMBA)**

There are no official statistics<sup>2</sup> 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

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<sup>2</sup> Inspection of the Business Population Estimates, 2018, published by the Department of Business, Energy and Industrial Strategy (2018) 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.



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 150 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.

Providing an exemption to micro-, small and medium size businesses does not apply. This is because micro-, small and medium sized businesses already have to deal with a regulatory framework and administer their part in the scheme. The proposal is to increase the fee to allow ASRU to cover costs. There is no proposal to increase regulatory activity or increase the administrative burden on micro-, small and medium sized businesses.

## **F. Proportionality.**

The level of analysis used in this IA is reasonable considering the risk of the fee change. The data used within this IA is robust and the analysis follows the method of prior years. The analysis carried out proportionate to the complexity and risk profile of the IA is sufficient.

## **G. Risks.**

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

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. Additionally, the assumption over the number of establishment licences of +/- 5 establishments from the central estimate was based on expert advice. This was under the advice of the ASRU policy team using knowledge that this year there was a removal of old establishments on the system, therefore the central estimate is lower than the previous year. The variation of 10 per cent used previously was deemed too wide ranging for establishments, where there is little fluctuation.

## H. Direct costs and benefits to business calculations

<b>Summary of Costs and Benefits</b>	<b>Low 5 yr impact (£m)</b>	<b>Central 5 yr impact (£m)</b>	<b>High 5 yr impact (£m)</b>
<b>Costs</b>			
<b>Set-up costs</b>			
Private sector set-up costs	0.0	0.0	0.0
Public Sector set-up costs	0.0	0.0	0.0
<b>Total set up costs</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
<b>Ongoing costs</b>			
Private sector ongoing costs	1.9	2.1	2.3
Public sector ongoing costs	0.0	0.0	0.0
<b>Total ongoing costs</b>	<b>1.9</b>	<b>2.1</b>	<b>2.3</b>
<b>Total costs</b>	<b>1.9</b>	<b>2.1</b>	<b>2.3</b>
<b>Benefits</b>			
Private sector benefits	0.0	0.0	0.0
Public sector benefits	1.9	2.1	2.3
<b>Total benefits</b>	<b>1.9</b>	<b>2.1</b>	<b>2.3</b>
<b>Net Present Social Value</b>			
<b>Business Net Present Value</b>	-1.9	-2.1	-2.3
<b>Equivalent Annual Net Direct Cost to Business</b>	0.40	0.44	0.49

## I. Trade Impact.

This policy will not have any impact on trade.

## J. Implementation date, monitoring and evaluation (PIR if necessary), enforcement principles.

The Government plans to implement these changes on 6<sup>th</sup> April 2020. These changes will apply across Great Britain. 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. ASRU will reassess the level of increase for FY 2021/22.

## Economic Impact Tests

<p><b>Small and Micro-business Assessment (SaMBA)</b></p> <p>Providing an exemption to micro-, small and medium size businesses does not apply. This is because micro-, small and medium sized businesses already have to deal with a regulatory framework and administer their part in the scheme. The proposal is to increase the fee to allow ASRU to cover costs. There is no proposal to increase regulatory activity or increase the administrative burden on micro-, small and medium sized businesses.</p>	Yes
<p><b>Statutory Equalities Duties</b></p> <p>A Policy Equality Statement will be provided prior to introduction of the new policy</p>	Yes