Title: **UK implementation of European Directive 2010/63/EU on the protection of animals used for scientific purposes** **Lead department or agency: Home Office** **Other departments or agencies: Department of Health, Social Services and Public Safety Northern Ireland (DHSSPSNI)**	Impact Assessment (IA) **IA No:** **Date:** 28/02/2011 **Stage:** Consultation **Source of intervention:** EU **Type of measure:** Secondary legislation **Contact for enquiries:** Martin Walsh, Animals Scientific Procedures Division 02070350746

Summary: Intervention and Options

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

European Directive 2010/63/EU on the protection of animals used for scientific purposes was adopted in September 2010 and came into force on 9 November 2010. Directive 2010/63/EU replaces Directive 86/609/EEC which is transposed into current UK legislation by the Animals (Scientific Procedures) Act 1986. In common with other Member States, the UK has Treaty obligations to transpose the provisions of the new Directive into UK legislation and must complete this process by 10 November 2012. The provisions of the new Directive must be implemented in the UK and other Member States from 1 January 2013.

What are the policy objectives and the intended effects?

The principal policy objective is to comply with UK Treaty obligations to transpose the provisions of Directive 2010/63/EU into UK legislation fully and appropriately. Additional objectives are to do so adopting measures which are proportionate; provide for efficient and effective regulation and appropriate standards of animal welfare and protection; promote the use of alternatives to animal use; avoid unnecessary administrative and regulatory burdens; and support the success, sustainability and competitiveness of the UK research and science base.

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

Option 1: Do nothing – Do not transpose the Directive; retain the Animals (Scientific Procedures) Act 1986.

Option 2: Transpose the minimum requirements of Directive 2010/63/EU.

Option 3: Transpose the Directive retaining current higher UK standards and requirements, where appropriate, as allowed under Article 2 of Directive 2010/63/EU.

Option 3 is the preferred option at this stage.

Will the policy be reviewed? Yes. **If applicable, set review date:** 10/2017 **What is the basis for this review?** PIR. **If applicable, set sunset clause date:** n/a	
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

Ministerial Sign-off:

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: LYNNE FEATHERSTONE Date: 3 MAY 2011

Summary: Analysis and Evidence

Policy Option 2

Description: Transpose the minimum requirements of Directive 2010/63/EU

Price Base Year 2010	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: -** £35.7m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	5	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	£19.6m		£2.5m	£37.4m

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

Transitional costs (establishments): to adopt new care and accommodation standards (£16 million - £3.2m per annum 2012-2016); to renew certificates of designation (£0.02m); to adopt new humane killing methods (£0.2m). Transitional costs (government): to prepare training guidelines (£0.03m) and a code of practice for humane killing (£0.03m); Annual average running costs of retrospective assessment of projects (£0.1m). Total costs of setting up and running the local systems of controls on individuals £21.4m of which £3.3m transitional costs and £2.4m annual average cost.

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

Potential loss of public confidence in the regulatory system arising, for example, from transfer of responsibility for the control of individuals using animals from central government to establishments and lower standards of care and accommodation set out in Annex III to the Directive; less frequent inspections; and reduced transparency arising from publication of substantially fewer project abstracts (non-technical summaries).

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	1	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		£0.19m	£1.6m

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

Annual saving to government from reduction in administrative functions arising from replacement of personal licences with a system of local registration of individuals: Annual Average £0.175m, Present Value £1.5m. Saving to establishments from a reduction in the number of non-technical summaries of projects required: Annual Average £0.015m, Present Value £0.125m.

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

Positive impact on public confidence arising from provisions designed to promote the development and validation of alternative approaches to animal testing.

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

The main risk is that the adoption of the minimum requirements of the directive will result in lower standards of control, animal welfare and transparency in some areas of activity than currently apply in the UK and lead to a loss of public confidence in the regulatory system. There is also a risk that adoption of the minimum requirements of the directive will result in increased costs for establishments regulated under the revised UK legislation arising from a transfer of functions from central government to establishments.

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs: £4.44m	**Benefits: £0.02m**	**Net: - £4.43m**	**No**	**N/A**

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			1 January 2013		
Which organisation(s) will enforce the policy?			Home Office/DHSSPSNI		
What is the annual change in enforcement cost (£m)?			£0.2 m		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** 0	**Non-traded:** 0	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** n/a	**Benefits:** n/a	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	Annex 2
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	Annex 2
Small firms Small Firms Impact Test guidance	No	Annex 2
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	Annex 2
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	Annex 2
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	Annex 2
Human rights Human Rights Impact Test guidance	No	Annex 2
Justice system Justice Impact Test guidance	No	Annex 2
Rural proofing Rural Proofing Impact Test guidance	No	Annex 2
Sustainable development Sustainable Development Impact Test guidance	No	Annex 2

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

No.	Legislation or publication
1	European Directive 2010/63/EU on the protection of animals used in scientific research
2	Animals (Scientific Procedures) Act 1986
3	Consultation and impact assessment on a proposal for a new directive on the protection of animals used in scientific research (May 2009) http://webarchive.nationalarchives.gov.uk/20100418065544/http://www.homeoffice.gov.uk/documents/cons-2009-animals-research/cons-2009-animals-research2835.pdf?view=Binary Summary Report http://tna.europarchive.org/20100413151426/http://scienceandresearch.homeoffice.gov.uk/animal-research/legislation/summary-report.html
4	Summary report on the public consultation on the revision of Directive 86/609/EEC (April 2010)

+ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs	6.8	3.2	3.2	3.2	3.2	0	0	0	0	0
Annual recurring cost	0	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Total annual costs	6.8	5.7	5.7	5.7	5.7	2.7	2.7	2.7	2.7	2.7
Transition benefits	0	0	0	0	0	0	0	0	0	0
Annual recurring benefits	0	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Total annual benefits	0	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2

* For non-monetised benefits please see summary pages and main evidence base section

Summary: Analysis and Evidence

Policy Option 3

Description: Transpose the Directive retaining current higher UK standards and requirements, where appropriate, as allowed under Article 2 of Directive 2010/63/EU.

Price Base Year 2010	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** - £15.9m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	5	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	£16.2m		£0.1m	£15.9m

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

Transitional costs (establishments): to adopt new care and accommodation standards (£16 million - £3.2 million per annum 2012-2016); to renew certificates of designation (£0.02m). Transitional costs (government): to prepare training guidelines (£0.03m) and a code of practice on humane killing (£0.03m); to gather evidence to support retention of current UK methods of humane killing (£0.1m). Annual average running costs (establishments and government): retrospective assessment of projects (£0.1m).

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

Retention of current legislative prohibition on disclosure of information (limiting transparency) would potentially harm public confidence.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	1	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	0

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

None.

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

Positive impact on public confidence from maintenance of current standards of control, animal welfare and transparency and adoption of provisions designed to promote the development and validation of alternative approaches to animal testing.

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

The main risk is that the UK adopts a framework that places the UK science-base at a competitive disadvantage because other Member States adopt compliant, but less stringent, measures. Whilst we have not attempted to estimate the likely level of disinvestment arising from any specific impacts, we estimate (based on figures prepared for the May 2009 consultation and impact assessment) that for each 1% disinvestment UK annual spending on research and development would fall by £50 million, and 1,000 highly skilled or highly paid jobs would be lost. We propose to reduce this risk by maintaining an active dialogue with the Commission and other Member States to coordinate our approach with theirs and promote harmonisation.

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs: £1.84m	**Benefits: £0m**	**Net: - £1.84m**	**Yes**	**IN**

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			1 January 2013		
Which organisation(s) will enforce the policy?			Home Office/DHSSPSNI		
What is the annual change in enforcement cost (£m)?			0		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			Yes		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** 0	**Non-traded:** 0	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** n/a	**Benefits:** n/a	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
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Economic impacts		
Competition Competition Assessment Impact Test guidance	No	Annex 2
Small firms Small Firms Impact Test guidance	No	Annex 2
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	Annex
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	Annex 2
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	Annex 2
Human rights Human Rights Impact Test guidance	No	Annex 2
Justice system Justice Impact Test guidance	No	Annex 2
Rural proofing Rural Proofing Impact Test guidance	No	Annex 2
Sustainable development Sustainable Development Impact Test guidance	No	Annex 2

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

No.	Legislation or publication
1	European Directive 2010/63/EU on the protection of animals used in scientific research
2	Animals (Scientific Procedures) Act 1986
3	Consultation and impact assessment on a proposal for a new directive on the protection of animals used in scientific research (May 2009) http://webarchive.nationalarchives.gov.uk/20100418065544/http://www.homeoffice.gov.uk/documents/cons-2009-animals-research/cons-2009-animals-research2835.pdf?view=Binary Summary Report http://tna.europarchive.org/20100413151426/http://scienceandresearch.homeoffice.gov.uk/animal-research/legislation/summary-report.html
4	Summary report on the public consultation on the revision of Directive 86/609/EEC (April 2010)

+ Add another row

Include the links to relevant legislation and publications, such as public impact assessments of earlier stages (e.g. Consultation, Final, Enactment) and those of the matching IN or OUTs measures.

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs	3.4	3.2	3.2	3.2	3.2	0	0	0	0	0
Annual recurring cost	0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Total annual costs	3.4	3.3	3.3	3.3	3.3	0.1	0.1	0.1	0.1	0.1
Transition benefits	0	0	0	0	0	0	0	0	0	0
Annual recurring benefits	0	0	0	0	0	0	0	0	0	0
Total annual benefits	0	0	0	0	0	0	0	0	0	0

* For non-monetised benefits please see summary pages and main evidence base section

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

European Directive 2010/63/EU on the protection of animals used for scientific purposes was adopted in September 2010 and came into force on 9 November 2010. Member States have until 10 November 2012 to transpose the provisions of the new Directive into national legislation. National legislation must be implemented from 1 January 2013.

The new Directive replaces Directive 86/609/EEC adopted in November 1986, which is transposed into UK legislation by the Animals (Scientific Procedures) Act 1986 (ASPA). ASPA has a three-level licensing system. Those carrying out the scientific procedures must hold:

- personal licences, which ensures that they are qualified and suitable (15,500);
- the programme of work must be authorised in a project licence (2,700);
- the place at which the work is carried out must hold a certificate of designation (188).

The Commission's objectives in revising and replacing Directive 86/609/EEC were to rectify wide variations in its implementation in different Member States; to strengthen the measures required to protect animals used in scientific procedures; and to promote the development, validation, acceptance and implementation of means to replace, reduce and refine such animal use.

This Consultation Stage Impact Assessment has been prepared to inform consideration of options for the transposition and implementation of the revised directive.

We estimate that the following components of the new Directive generate costs and savings. Analysis of articles that are cost neutral is provided in Annex 3.
(Where referring to annexes within this document, an annex denoted by roman numerals refers to an annex of the European Directive 2010/63/EU, e.g. Annex IV: Permissible methods of killing. Annexes denoted by a standard number refer to an annex of this impact assessment document, e.g. Annex 2: Specific Impact Tests.)

Article 6 & Annex IV: Methods of killing animals

Article 6 requires that animals are killed humanely and Annex IV lists the mandatory methods of killing to be used for specified animals. The principles set out in Article 6 are consistent with UK policy and practice. There are, however, significant differences in the list of permissible methods and Annex IV methods may impose a higher welfare cost than the methods currently permissible under Schedule 1 to the 1986 Act. For example, the use of inert gases for rodents, the use of CO_2 for birds, and the requirement for prior sedation before overdosing with anaesthetic. Potential costs include staff training and purchase of equipment for methods not listed in Schedule 1 to the 1986 Act and the generation and evaluation of evidence required to justify retaining methods currently on Schedule 1 to the 1986 Act and not listed in Annex IV of the revised directive.

Article 20: Authorisation of breeders, suppliers and users

Article 20 requires that all breeders, suppliers and users are authorised by and registered with the competent authority. Authorisation is dependent on compliance with the requirements of the Directive. The authorisation must specify the person responsible for compliance and the persons referred to in Articles 24(1)[1] and 25[2]. Significant changes in the structure or functions of the establishment will require re-authorisation and changes to named persons must be notified to the competent authority. Authorisation will be of corporate users, breeders and suppliers rather than establishments, as is currently the case under ASPA. It is assumed this will require existing certificates of designation to be re-issued on the revised basis.

[1] Persons responsible for the care and welfare of animals and for training and supervision of staff
[2] Named veterinary surgeon

Article 23 & Annex V: Competence of personnel

The Directive requires that each breeder, supplier and user has sufficient staff on site and that they have been adequately educated and trained before carrying out procedures on animals; designing procedures and projects; taking care of animals; or killing animals. Those designing procedures and projects must have received instruction in a scientific discipline relevant to the work being undertaken and have species-specific knowledge. Staff carrying out procedures on animals, designing procedures and projects and taking care of animals must be supervised until they have demonstrated the requisite competence.

Member States can choose to ensure these requirements are met either through a system of authorisation or by other means. This provides an opportunity to simplify the current personal licensing system or to transfer responsibility for the control of individuals applying procedures to animals from central government to designated establishments. The Directive requires that Member States publish their minimum requirements with regard to education and training, based on the elements listed in Annex V. Member States must also publish their minimum requirements for obtaining, maintaining and demonstrating requisite competence.

Articles 26 & 27: Animal Welfare Body & Tasks of the Animal Welfare Body

Article 26 requires that each breeder, supplier and user sets up an animal welfare body (AWB) including, as a minimum, the person(s) responsible for the welfare and care of the animals and, in the case of a user, a scientific member. The animal welfare body must also receive input from the designated veterinary surgeon or the expert referred to in Article 25. Member States may allow small breeders, suppliers and users to fulfil the tasks laid down in Article 27(1) by other means. The AWB is to advise staff dealing with animals on matters related to the welfare of animals, the application of replacement, reduction and refinement, establish and review relevant internal operational processes, follow the development and outcome of projects and advise on re-homing schemes. Records of AWB decisions and advice are kept for at least three years and made available to the competent authority upon request.

The requirements for AWBs are less stringent than those relating to the operation of the similar requirement for local ethical review processes in the UK. Fewer persons are involved (in theory in some places a minimum of two might suffice) and there are fewer functions (for example no involvement is required in the pre-authorisation phase of project authorisation). We believe some establishments are likely to retain current more extensive arrangements where this better meets their operational needs.

Article 33 & Annex III: Care and accommodation

Article 33 sets out the requirements for the care and accommodation of animals kept in establishments. Annex III sets out detailed accommodation and care standards, both general and species-specific. These standards differ in a number of respects from the current UK requirements mostly involving the application of higher standards. However, some lower standards are also specified. Annex III standards are to be applied from 1 January 2017.

The areas where Annex III requirements are lower may have a negative impact on animal welfare. For example rat rearing behaviour may be restricted by lower cage heights and reduced trough space allowances may lead to fighting and inequalities in food rations. Conversely, retention of current UK standards providing more space is likely to have additional cost implications for users, breeders and suppliers, particularly for rats where large numbers of animals are bred and used. It is likely that cage manufacturers will charge a premium for cages made for a restricted market. In addition larger cages will reduce the capacity of animal holding facilities. This is particularly likely to affect breeders.

Article 34: Inspections by the member state

The directive requires that competent authorities carry out regular inspections of all breeders, suppliers and users to verify compliance. The frequency of inspections is to be based on a risk analysis for each establishment. In addition, at least one third of users are to be inspected each year and breeders, suppliers and users of non-human primates are to be inspected at least once a year.

Under ASPA, there are currently 188 designated establishments to which just under 2000 visits were carried out by Home Office inspectors in 2010. About half of these visits were unannounced. We

estimate implementation of the minimum requirements of the Directive would require a total of 80 inspections per year in the UK with between 3 and 5 years between inspections for some designated establishments.

To ensure compliance we assume these inspections would involve a detailed and formal audit of all relevant aspects of compliance at the relevant establishment and that occasional follow up and thematic inspections would also be required. We estimate that an inspection of this nature involving one of the larger establishments may require between 16 and 20 days of inspector input, including 3 or 4 days on site, and that most would need to be conducted by appointment, rather than unannounced.

We estimate that this approach would be broadly cost neutral compared with current inspection arrangements. Separate arrangements would need to be made to provide advice on applications, animal welfare and the 3Rs between inspections.

Article 39: Retrospective assessment

Article 39 creates a requirement for the retrospective assessment of all projects using non-human primates and projects involving procedures classified as "severe" and allows Member States the option of requiring retrospective assessment of projects involving ‘moderate’ procedures (to be decided on a case by case basis). There is no current legislative requirement in the UK for projects to be retrospectively assessed. However a form of retrospective assessment is undertaken for the 75% projects that are renewed on expiry (approximately 375 of the 500 or so project licences issued each year). Under the Directive, retrospective assessment may only be required for fewer than 20% of projects (100 per year).

Article 43: Non-technical project summaries

Article 43 creates a legislative requirement for the provision and publication of non-technical summaries (abstracts) of a subset of authorised projects. The UK currently operates a voluntary system, publishing abstracts of over 80% of authorised projects (about 400 per year).

Article 54: Reporting

Article 54 requires Member States to collect and publish annual statistics on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures. The content and format of the statistics will be finalised by May 2012 after further discussions between the Commission and Member States. The UK currently collects and publishes detailed annual statistics of animal use under ASPA. These do not include information on the actual severity of the procedures carried out.

A.2 Groups Affected

There are currently about 15,500 individuals holding ASPA personal licences, 2,700 project licences in force and 188 designated establishments. The breakdown between sectors is set out in Table 1, below.

Table 1: Breakdown of designated establishments between economic sectors

As at 31/12/2010	No.	%
Commercial concerns	64	34
Higher Education	74	39
NDPBs	22	12
Government laboratories	8	4
Non profit organisations	14	7
NHS research facilities	3	2
Public Health Laboratories	3	2
Total	188	100

The sectors dependent on the use of animals for experimental and other scientific purposes have an estimated 100,000 employees, many in highly-skilled and highly-paid jobs, and a total annual research

and development spend in excess of £5 billion. These sectors make a significant contribution to the UK economy. Animal use is funded by the private and public sectors, and the third sector.

A.3 Consultation

Within Government

An inter-departmental group has been consulted extensively during the negotiation of the new directive. The group was led by the Home Office and comprised officials from the Departmental for Business, Innovation and Skills (BIS), the Department for the Environment, Food, and Rural Affairs (Defra), the Foreign & Commonwealth Office (FCO), the Department of Health, the Ministry of Defence and the Department of Health, Social Services and Public Safety Northern Ireland (DHSSPSNI).

Public Consultation

In preparation for the negotiation of the new directive, the previous Government held a formal, public consultation to inform the UK negotiating position. Responses were received from 87 organisations and over 1000 individuals. A breakdown of responding organisations by type is provided in table 2 below.

Table 2: Breakdown of responses to 2009 consultation

Category	Responses	%
Academic institution	33	38
Animal welfare groups	19	22
Representative bodies	17	19
Charities	3	3
NDPBs	4	5
Practitioners	6	7
Others	5	6
Total	**87**	**100**

B. Rationale

The EU has the authority to legislate to make provision for the protection of animals used for experimental and other scientific purposes. Directive 86/609/EEC made provision for regulating these activities on the basis of the Treaty Establishing the European Economic Community, and in particular Article 11. Directive 2010/63/EU relies upon the Treaty on the Functioning of the European Union (TFEU), and in particular Articles 114 and 294.

Current UK legislation and administrative controls are not fully compliant with the revised directive. Under the TFEU, and in common with other Member States, the UK has Treaty obligations to transpose the provisions of the new Directive into national legislation. UK Government intervention is essential to comply with these obligations, and to ensure the resulting regulatory and administrative frameworks deliver the required provisions.

C. Objectives

The principal policy objective is to comply with UK Treaty obligations to transpose the provisions of Directive 2010/63/EU into UK legislation fully and appropriately. Additional objectives are to do so adopting measures which are flexible and proportionate; provide for efficient and effective regulation; appropriate standards of animal welfare and protection; promote the use of alternatives to animal use; avoid unnecessary administrative and regulatory burdens; ensure a level economic playing field and the free movement of skilled labour; and support the success, sustainability and competitiveness of the UK research and science base.

D. Options

Option 1: No change

Option 1 is the no change option, retaining the Animals (Scientific Procedures) Act 1986, current licensing requirements, housing and care standards, humane killing methods, etc. It provides the baseline for the calculation of any additional costs and savings arising from other options. In view of the UK's Treaty obligations, Option 1 is not a viable option for the implementation of Directive 2010/63/EU as ASPA does not fully transpose its requirements.

Option 2: Transpose the minimum requirements of Directive 2010/63/EU

Option 2 assumes that the UK will transpose Directive 2010/63/EU by 'copying out' its provisions into revised UK legislation. 'Copy out' would entail transposing the requirements of the directive faithfully and without including more stringent measures unique to the UK. Key potential impacts might be a transfer of responsibility for control of individuals using animals from government to establishments (Article 23) and adoption of a minimum frequency programme of audit-style inspections (Article 34).

Option 3: Transpose the Directive retaining current higher UK standards and requirements, where appropriate, as allowed under Article 2 of Directive 2010/63/EU

Under Option 3, it is envisaged that the UK will implement the requirements of Directive 2010/63/EU, where they are more stringent than those of the Animals (Scientific Procedures) Act 1986. Option 3 would also retain current UK requirements in force on 9 November 2010 where they are more stringent and/or provide better welfare than the Directive, such as some current higher UK care and accommodation requirements (Annex III); the current more stringent UK personal licensing system (Article 23); and some more humane killing methods (Annex IV).

E. Appraisal (Costs and Benefits)

Evidence is drawn from published information relating to animal use in the UK; operational information from the Home Office inspection programme and other activities; information from other published sources; and information provided by stakeholders.

General Assumptions and Data

Every effort has been made to avoid 'double-counting' of potential costs and benefits. No monetary value has been assigned to the benefits associated with increased transparency, improved animal welfare, or increased development and use of alternative methods. Evidence on these will be sought through a formal public consultation. Similarly, the impact on stakeholder confidence is not included.

The breakdown between sectors is shown in Table 1, above. Where appropriate, and unless otherwise stated, we assume costs and benefits to establishments will be allocated between the sectors in the same proportions. If costs and benefits are to be shared between the competent authority and the establishments, then this is made clear within the relevant analysis.

The analysis is based on 190 establishments (taking the 188 existing, and allowing for growth in the industry).
Unless stated otherwise, the average administrative staff salary is taken to be £30 per hour (based on Home Office administrative staff costs), and costs of inspectors and equivalent grades are assumed to be £60 per hour (based on Home Office Grade 6 and equivalent rates).
Where necessary the cost of developing guidance and training is estimated to be £30,000 based on previous Home Office experiences of similar activities[3].

For the purposes of this impact assessment it is assumed that transitional costs associated with implementation of Directive 2010/63/EU will be incurred in Year 0 (2012), except for those relating to implementation of Annex III of the Directive which will arise in Years 0 to 4 (2012-2016). On going annual costs will be incurred in Years 1 to 9 (2013-2021).

[3] eg, code of practice on the care and accommodation of ferrets and gerbils

Further assumptions relating to the minimum standards of care and accommodation required by Annex III to the Directive are that:

- a proportion of the costs of meeting the minimum standards can be discounted as relevant 'business as usual costs' as equipment wears out and is replaced;
- breeders' estimates of the impact on capacity and costs of the Annex III requirements are generally accurate, and that new UK infrastructure and capacity will be provided to ensure that sufficient purpose-bred animals are produced to meet UK demand;
- the capital and operating costs of the additional breeding infrastructure would be recovered in costs passed on to the end user;
- compliance with Annex III will not result in improved welfare or cashable savings;
- the new minimum requirements for avian species will make it uneconomical to conduct some forms of testing in the UK or EU and the work will be displaced.

The sectors dependent on the use of animals for experimental and other scientific purposes have an estimated 100,000 employees, many in highly-skilled and highly-paid jobs, and a total annual research and development spend in excess of £5 billion. As regards competitiveness, we have not attempted to estimate the likely level of disinvestment arising from any specific impacts. However, we expect (based on figures prepared for the May 2009 consultation and impact assessment[4]) that for each 1% disinvestment, UK annual spending on research and development would fall by £50 million, and 1,000 highly skilled or highly paid jobs would be lost.

The proposal is considered over a ten year time frame for the purposes of calculating present values.

Option 2: Transpose the minimum requirements of Directive 2010/63/EU

Policy Costs (excluding OIOO)

Article 20: Authorisation of breeders, suppliers and users

We estimate that resubmitting certificates of designation for re-issue on the revised basis will entail costs for establishments and the competent authority. Assuming 2 hours of preparation time by administrative staff, at a rate of £30 per hour, and 2 hours processing by the competent authority at an Inspector grade rate, for 190 designated establishments, there is an expected transitional cost of £34k. We assume that this cost is split equally between the establishment and the competent authority. We assume that the Home Office processing time can be treated as a 'business as usual' cost.

Transitional cost (establishment)[5]: £0.02m; Annual Average cost: N/A; Total costs (PV): £0.02m.

Article 23 & Annex V: Competence of personnel

It is an existing requirement that designated establishments have sufficient staff on site and that key persons are trained, and adequately supervised until competent. These, therefore, represent business as usual costs.

We estimate the additional costs for establishments associated with a system of local control of personnel would comprise transitional set-up costs of £35K and on-going annual costs of £25K[6] for each user, breeder and supplier. However, as well run establishments will have significant elements of a system of local control already in place, a proportion of these costs will be business as usual costs in many cases. From recent stakeholder discussions, we estimate these at 50% of the total, but will seek further and better estimates from the public consultation.

[4] Consultation on EU proposals for a new directive on the protection of animals used for scientific purposes http://webarchive.nationalarchives.gov.uk/20100418065544/http://www.homeoffice.gov.uk/documents/cons-2009-animals-research/cons-2009-animals-research2835.pdf?view=Binary (pages 39 and 48)

[5] (2hrs x £30ph x 190 establishments + 2hrs x £60ph x 190 establishments) x 0.5

[6] Set up and running costs based on figures provided by a single, medium sized establishment, but thought to be realistic and representative.

Transitional costs (establishments)[7]: £3.3m; Annual average costs(establishments)[8]: £2.4m; Total cost (PV): £3.3m + £18.1m = £21.4m

Articles 26 & 27: Animal Welfare Body & Tasks of the Animal Welfare Body

Although there appear to be potential savings to establishments if the minimum EU specification is implemented, in practice it is likely that many of the additional members and functions of the local ethical review processes would be retained by establishments. Our assumption is, therefore, that, in practice, Option 2 would not provide savings and would be cost neutral.

Transitional costs: £0; Annual average costs: £0; Total cost (PV): £0.

Article 33 & Annex III: Care and accommodation

Option 2 envisages the adoption of the lower standards set out in Annex III, as well as the higher standards, where applicable. We assume that where Annex III requires lower standards establishments will retain current caging and other facilities until such time as they require replacement or refurbishment and will then adopt the lower standard. We further assume that any costs and savings incurred in their replacement should be treated as business as usual costs.

The major additional costs arising under Option 2 relate to the housing of rats, mice, guinea pigs and rabbits, for the short period from post-weaning until they are used in procedures. Relevant space requirements are increased by approximately one third. This is likely to have a significant impact, on breeders in particular and to a lesser extent on users. It is likely that either additional capacity will need to be built to house the same number of animals, or that production will decrease as fewer animals can be kept in the current space. We estimate[9] that the required additional UK capital investment would be between £10 and £16 million in the period Year 0 to Year 4 (2012-2016), with the commercial sector passing on the costs to users with a potential increase in the cost per animal of up to 30%.

Transitional costs (establishments): £16m; Annual average costs: N/A ; Total cost (PV): £15m.

Article 34: Inspections by the member state

Just under 2000 visits were carried out by Home Office inspectors in 2010 to 188 designated establishments involving over 10,000 hours inspector input. To meet the minimum requirements of the directive we estimate would require a total 80 inspections per year in the UK with between 3 and 5 years between inspections for some establishments. We assume these inspections would entail a detailed audit of all relevant aspects of compliance at the relevant establishment and that occasional follow up and thematic inspections would also be required. We further assume that such inspections would require the involvement of two inspectors and between 16 and 20 days inspector input, comprising 3 or 4 days on site, 4 or 5 days preparation and report writing and 1 or 2 days travelling and that most would be conducted by appointment, rather than unannounced. We estimate this would require between 10,000 and 12,000 hours (1300 to 1600 days) inspector input per year[10] and would be broadly cost neutral compared with the current inspection arrangements.

The impact on public confidence of adopting this approach to inspection will be assessed as part of the forthcoming consultation on transposition of the directive. A more audit style format for inspections may be welcomed in some quarters, but any benefit is likely to be offset by concerns about the much reduced frequency of visits this would entail.

Transitional costs: £0; Annual average costs: £0; Total cost (PV): £0.

Article 54: Reporting

[7] (£35k x 190 establishments x 50%)

[8] (£25k x 190 establishments x 50%)

[9] Based on evidence provided by a single stakeholder with relevant and detailed operational knowledge.

[10] (3days on-site+ 4days preparation + 1day travelling) x 8 hrs per day x 2 inspectors x 80 inspections = 10,240 hrs

Although the nature of the information to be reported has yet to be determined it is likely that the minimum EU information requirements will be less extensive than current UK requirements. This may provide some minor annual savings for project licence holders. There will, however, be transitional costs of implementing the new reporting requirements arising from the need to make changes to recording arrangements and the introduction of arrangements to record and report the actual severity of procedures applied to animals. It is not possible to estimate these. Further information will be sought on the impact of the expected changes in the public consultation.

Transitional costs: £unknown; Annual average costs: £unknown; Total cost (PV): £unknown.

Administrative Burdens (excluding OIOO)

Article 6 & Annex IV: Methods of killing animals

The provisions of the revised directive Annex IV will require investment in training and equipment for methods not listed in Schedule 1 to ASPA, estimated from stakeholder contacts to represent one-off transitional costs of £100-200K (assuming there is convergence on overdose of anaesthetic as the generally preferred method).
Based on the preparation of similar documents[11], the estimated cost to the competent authority of producing a code of practice is £30K.

Transitional costs (establishments): £0.2m; Transitional costs (competent authority): £0.03m; Annual average costs: N/A; Total cost (PV): £0.23m

Article 23 & Annex V: Competence of personnel

The competent authority is expected to incur transitional costs of £30K developing training guidelines.

Transitional costs (competent authority): £0.03m; Annual average costs: N/A; Total cost (PV): £0.03m

Article 39: Retrospective assessment

There is currently no legislative requirement in the UK for projects to be retrospectively assessed. We estimate that 100 projects would require retrospective assessment each year (from Year 2 onwards) and envisage that parent establishments would prepare and submit dossiers providing all relevant data to enable the competent authority to complete the assessment. We further estimate each assessment would require a minimum of 2 days input split evenly between the relevant establishment and the competent authority (costed at £60 per hour[12]).

Transitional costs: N/A; Annual average costs (establishments)[13]: £0.05m; Annual average costs (competent authority):0.05m; Total cost (PV): £0.7m

Policy Costs (OIOO)

Not applicable.

Administrative Burdens (OIOO)

Not applicable.

TOTAL COSTS

Transitional costs: £0.02m + £3.3m + £16m + £0.23m + £0.03m = £19.6m;
Annual average costs: £2.4m + £0.1m = £2.5m.
Total cost (PV): £0.02m + £21.4m + £15m + £0.23m + £0.03m + £0.7m = £37.4m

[11] eg, code of practice on the care and accommodation of ferrets and gerbils
[12] Calculated at Home Office Inspector (Civil Service Grade 6) rates. We assume work at establishments will be carried out by staff of similar seniority.
[13] (2 days x 8hrs per day x 100 projects x £60ph)

Policy Benefits (excluding OIOO)

There is expected to be a positive impact on public confidence arising from provisions designed to promote the development and validation of alternative approaches to animal testing. These effects could not be quantified; however evidence on these will be sought through a formal public consultation.

Administrative Savings (excluding OIOO)

Article 23 & Annex V: Competence of personnel

Under a local accountability system we estimate Home Office administrative costs would reduce by about £200K (6,500 personal licence transactions[14] taking 1 hour charged at £30/hour[15]) leading to an equivalent reduction in fee income.

Transitional saving: N/A; Annual Average Saving (Competent Authority)[16]: £0.175m; Total saving (PV): £1.5m.

Article 43: Non-technical project summaries

The directive requires publication of non-technical summaries for 20-25% of projects (leading to a volume of 125-150 per year in future). The UK currently operates a voluntary system which produces around 400 project summaries per year. Thus we can assume 250-275 fewer summaries are required each year. Assuming that each summary currently takes one hour to prepare and one hour to process by the Competent Authority this would provide cashable annual savings of £15k[17] per year. It is assumed that this saving can be passed on to the establishments in the form of savings.

Transitional saving: N/A; Annual Average Saving (establishments)[18]: £0.015m; Total saving (PV): £0.125m.

Policy Benefits (OIOO)

Not applicable.

Administrative Savings (OIOO)

Not applicable.

TOTAL BENEFITS

Transitional saving: N/A
Annual Average Saving: £0.175m + £0.015m = 0.19m;
Total saving (PV): £1.5m + £0.125m = £1.6m.
Further anticipated benefits from impact on public confidence arising from provisions designed to promote the development and validation of alternative approaches to animal testing, however these effects could not be quantified.

Option 3: Transpose the Directive retaining current higher UK standards and requirements, where appropriate, as allowed under Article 2 of Directive 2010/63/EU

Policy Costs (excluding OIOO)

Article 6 & Annex IV: Methods of killing animals

[14] Figure drawn from Home Office operational records
[15] The average hourly cost of Home Office administrative staff.
[16] (6500 licences x 1hr to process x £30ph)
[17] Assuming average salary costs of £30 per hour (equivalent to HO administrative staff).
[18] (250 fewer licences x 1hr to prepare x £30ph + 250 fewer licences x 1hr to process x £30ph)

Retaining some methods listed in Schedule 1 to the 1986 Act which are not included in Annex IV will ensure current UK animal welfare standards and public confidence are maintained and reduce or eliminate the need for additional training and equipment. Should the Commission require justification for the retention of methods the transitional cost of producing dossiers identifying and analysing available supporting evidence would be of the order of £80-100K[19]. We judge this to be low/medium likelihood.

As at Option 2, there is a likely cost to the competent authority of about £30K to produce a code of practice on how the methods should be applied and on the provision that should be made for types of animal not identified in Annex IV.

Transitional costs (Competent Authority): £0.1m + £0.03m = £0.13m; Annual Average Cost: N/A
Total cost (PV): £0.13m.

Article 20: Authorisation of breeders, suppliers and users

We estimate that reissuing certificates of designation will entail costs of 34K split evenly between establishments and the Home Office. The requirement to notify changes or amend the authorisation under specified circumstances is consistent with current UK practice, but appears to allow more flexibility (notification of some changes, rather than revised authorisations). However, it is not believed that this will result in significant cashable savings. We assume that the Home Office processing time can be treated as a 'business as usual' cost.

Transitional cost (establishment)[20]: £0.02m; Annual Average cost: N/A; Total costs (PV): £0.02m.

Articles 26 & 27: Animal Welfare Body & Tasks of the Animal Welfare Body

Option 3 would entail incorporating current UK arrangements for local ethical review processes into legislation but would, in effect, be cost neutral.

Transitional costs: £0; Annual average costs: £0; Total cost (PV): £0.

Article 34: Inspections by the member state

Option 3 retains the current system and frequency of inspection and current arrangements for the provision of advice and is assumed to be cost neutral.

Transitional costs: £0; Annual average costs: £0; Total cost (PV): £0.

Article 54: Reporting

It is assumed that retention of the current UK reporting requirement will be cost-neutral. There will, however, be transitional costs of implementing the new reporting requirements arising from the need to make changes to recording arrangements and the introduction of arrangements to record and report the actual severity of procedures applied to animals. It is not possible to estimate these. Further information will be sought on the impact of the expected changes in the public consultation.

Transitional costs: £unknown; Annual average costs: £unknown; Total cost (PV): £unknown.

Administrative Burdens (excluding OIOO)

Article 23 & Annex V: Competence of personnel

The competent authority will incur transitional costs developing training guidelines

Transitional costs: £0.03m; Annual average costs: £0; Total cost (PV): £0.03m.

Article 39: Retrospective assessment

[19] Based on experience of previous, similar exercises.
[20] (2hrs x £30ph x 190 establishments + 2hrs x £60ph x 190 establishments) x 0.5

There is currently no legislative requirement in the UK for projects to be retrospectively assessed. We estimate that 100 projects would require retrospective assessment each year (from Year 2 onwards) and envisage that parent establishments would prepare and submit dossiers providing all relevant data to enable the competent authority to complete the assessment. We further estimate each assessment would require a minimum of 2 days input split evenly between the relevant establishment and the competent authority (costed at £60 per hour[21]). Total annual cost £100k.

Transitional costs: £N/A; Annual average costs (establishments)[22]: £0.05m; Annual average costs (competent authority):0.05m; Total cost (PV): £0.7m

Policy Costs (OIOO)

Article 23 & Annex V: Competence of personnel

Retention of the current personal licensing system is expected to be cost neutral. However, some administrative cost savings may be achievable through further refinement of the application process, simplification of personal licences and adoption of an e-licensing system. An IT pilot study currently under way will provide a basis for calculating these savings when it reports in late spring/summer 2011.

Transitional costs: £0; Annual average costs: £0; Total cost (PV): £0.

Article 33 & Annex III: Care and accommodation

Implementation of the higher space standards required for rats, mice, guinea pigs and rabbits would incur the same costs as Option 2. We estimate[23] that the required additional UK capital investment would be between £10 and £16 million in the period Year 0 to Year 4 (2012-2016), with the commercial sector passing on the costs to users with a potential increase in the cost per animal of up to 30%.

Transitional costs (establishments): £16m; Annual average costs: N/A; Total cost (PV): £15m.

Article 43: Non-technical project summaries

We assume Option 3 would be cost-neutral if we implement the mandatory requirements of Article 43 and the provision of non-technical summaries (abstracts) for other categories of project remains voluntary as at present in the UK. This would maintain current levels of transparency and public confidence.

Transitional costs: £0; Annual average costs: £0; Total cost (PV): £0.

Administrative Burdens (OIOO)

None

TOTAL COSTS

Transitional costs: £0.13m + £ 0.02m + £16m + £0.03m = £16.2m
Annual average costs: 0.01m;
Total cost (PV): £0.13m + £0.02m + £15m + £0.03m + £0.7m = £15.9m

Policy Benefits (excluding OIOO)

Positive impact on public confidence from maintenance of current standards of control, animal welfare and transparency and adoption of provisions designed to promote the development and validation of alternative approaches to animal testing. . These effects could not be quantified; however evidence on these will be sought through a formal public consultation.

[21] Calculated at Home Office Inspector (Civil Service Grade 6) rates. We assume work at establishments will be carried out by staff of similar seniority.
[22] (2 days x 8hrs per day x 100 projects x £60ph)
[23] Based on evidence provided by a single stakeholder with relevant and detailed operational knowledge.

Administrative Savings (excluding OIOO)

None.

Policy Benefits (OIOO)

None.

Administrative Savings (OIOO)

None.

TOTAL BENEFITS

Positive impact on public confidence from maintenance of current standards of control, animal welfare and transparency and adoption of provisions designed to promote the development and validation of alternative approaches to animal testing. These impacts could not be quantified.

Comparative Analysis

	Option 2		Option 3	
	Establishments	**Competent Auth.**	**Establishments**	**Competent Auth.**
Transitional Costs				
Article 20: Authorisation of breeders, suppliers & users	17,100	-	17,100	-
Article 23: Competence of Personnel	3,325,000	-	-	-
Article 23: Competence of Personnel	-	30,000	-	30,000
Article 33 & Annex III: Care and Accommodation	14,953,853	-	14,953,853	-
Article 6 & Annex IV: Methods of Killing	200,000	30,000	-	130,000
	18,495,953	**60,000**	**14,970,953**	**160,000**
On going Costs				
Article 23: Competence of Personnel	18,068,255	-	-	-
Article 39: Retrospective Assessment	365,169	365,169	365,169	365,169
	18,433,424	**365,169**	**365,169**	**365,169**
Transitional Benefits				
	-	**-**	**-**	**-**
Ongoing Benefits				
Article 23: Competence of Personnel	-	1,483,499	-	-
Article 43: Non-Technical Project Summaries	125,527	-	-	-
	125,527	**1,483,499**	**-**	**-**
Net	**- 36,803,851**	**1,058,330**	**- 15,336,122**	**- 525,169**
Total	**-35,745,521**		**-15,861,291**	

Establishments (as at 31/12/2010)			**Net Burden Option 2 (£m)**	**Net Burden Option 3 (£m)**
Commercial Concerns	64	34%	-12.5	-5.2
Higher Education	74	39%	-14.5	-6.0
NDPBs	22	12%	-4.3	-1.8
Government Laboratories	8	4%	-1.6	-0.7
Non Profit Organisations	14	7%	-2.7	-1.1
NHS Research Facilities	3	2%	-0.6	-0.2
Public Health Laboratories	3	2%	-0.6	-0.2
Total for Establishments	**188**	**100%**	**-36.8**	**-15.3**
Competent Authority	1	100%	**1.1**	**-0.5**

One In One Out - Impacts on Establishments (£m)	**Option 2**	**Option 3**
Present Value of Costs (establishments)	36.9	15.3
Present Value of Benefits (establishments)	0.1	-
Discount Rate	3.50%	3.50%
Appraisal Length (years)	10	10
Annuity Rate	8.32	8.32
Equivalent Annual Cost (establishments)	4.44	1.84
Equivalent Annual Benefit (establishments)	0.02	-
Net Equivalent Annual Value	**-4.43**	**-1.84**

The Net Equivalent Annual value was calculated by using the following formula[24]:

$$\text{Net Present Value}/\text{Annuity Rate} = (\text{Present value of benefits to establishments} - \text{Present value of costs to establishments})/\text{Annuity Rate}$$

$$\text{For option 2} = ([£0m + £0.13m] - [£18.50m + £18.43m])/8.32 = -£4.43m$$

$$\text{For option3} = ([£0m + £0m] - [£14.97m + £0.37m])/8.32 = -£1.84m$$

F. Risks

Option 1: Do nothing.

Does not deliver compliance with the new EU provisions or deliver the relevant policy objectives, and may disadvantage the UK science-base.

Option 2: Transpose the minimum requirements of Directive 2010/63/EU

The main Option 2 risk is that the adoption of the minimum requirements of the directive will result in lower standards of control, animal welfare and transparency in some areas of activity than currently apply in the UK and lead to a loss of public confidence in the regulatory system.

There is also a risk that adoption of the minimum requirements of the directive will result in increased costs for establishments regulated under the revised UK legislation arising from a transfer of functions from central government to establishments.

Option 3: Transpose the Directive retaining current higher UK standards and requirements, where appropriate, as allowed under Article 2 of Directive 2010/63/EU

The main Option 3 risk is that the UK adopts a framework that places the UK science-base at a competitive disadvantage because other Member States adopt compliant, but less stringent, measures when transposing the Directive. It is proposed to minimise this risk by maintaining an active dialogue with the Commission and other Member States.

G. Enforcement

The policy objective is to rely on a system of proportionate and dissuasive administrative and non-criminal penalties, reserving the option of prosecution for only the most significant instances of non-compliance where these alternative sanctions would not be appropriate or acceptable.

H. Summary and Recommendations

Table H.1 Costs and Benefits

Option	Costs	Benefits
2	£37.4m (PV)	£1.6m (PV)
	Potential loss of public confidence in the regulatory system arising, for example, from transfer of responsibility for the control of individuals using animals from central government to establishments and lower standards of care and accommodation set out in Annex III to the Directive; less frequent inspections; and reduced transparency arising from publication of substantially fewer project abstracts (non-technical summaries)(not quantified).	Positive impact on public confidence arising from provisions designed to promote the development and validation of alternative approaches to animal testing. (not quantified)

[24] Annuity rate = $(1/r) * (1-(1/(1+r))^t)$ where r = 3.5% and t = 10

3	£15.9m (PV)	£0m (PV)
	Retention of current legislative prohibition on disclosure of information (limiting transparency) may harm public confidence (not quantified).	Positive impact on public confidence from maintenance of current standards of control, animal welfare and transparency and adoption of provisions designed to promote the development and validation of alternative approaches to animal testing (not quantified)..
Source: see above.		

Although it does not provide savings, Option 3 is our preferred option (at this stage) based on its lower overall cost compared with Option 2 (which entails significant additional transitional and on-going annual costs) and our expectation that it will have a more positive impact on public confidence and animal welfare because it maintains current Home Office control of places and individuals using animals and retains existing higher UK care and accommodation standards and more humane killing methods.

I. Implementation

Member States have until 10 November 2012 to transpose the provisions of the new Directive into national legislation. National legislation must be implemented from 1 January 2013. We plan to have new UK legislation in place by the summer of 2012 and prepare for implementation in the second half of 2012. We will start preliminary preparations for implementation earlier in 2012, where possible. New care and accommodation standards set out in Annex III to the Directive must be implemented by designated establishments by 1 January 2017. We envisage implementation of these standards will be phased over the five year period 2012-2016.

J. Monitoring and Evaluation

The operation of the new regime will be monitored using operational information generated continuously by the regulator; regular liaison with those affected by and with a legitimate interest in the protection of animals used for experimental and other scientific purposes; periodic reviews of the effectiveness and efficiency of regulatory system, through scrutiny by the national committee for the protection of animals used in scientific procedures (Article 49); and by periodic reviews by the European Union (Article 58).

K. Feedback

Feedback will be obtained from those affected by the implementation of the Directive and with others with a legitimate interest in the protection of animals used for experimental and other scientific purposes, through regular liaison meetings and periodic reviews.

L. Specific Impact Tests

See Annex 2.

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

Basis of the review: Article 58 requires the Commission to review the Directive by 10 November 2017.
Review objective: To carry out a proportionate check that regulation is operating as intended to protect animals used in scientific research without imposing unnecessary bureaucracy and to ensure a level economic playing field across the Union.
Review approach and rationale: [The review will consider data on the implementation of the legislation relating to project evaluation, inspections, compliance and non-compliance by licensees, implementation of the 3Rs and of mandatory care and accommodation standards. It will also consider stakeholder views on the impact of regulation and available data on implementation in other Member States. This approach is considered most suitable to meet the review objectives.
Baseline: The regulatory system under the Animals (Scientific Procedures) Act 1986 will provide the baseline for the review.
Success criteria: The review will look for evidence of measures which are flexible and proportionate; provide for efficient and effective regulation; appropriate standards of animal welfare and protection; promote the use of alternatives to animal use; avoid unnecessary administrative and regulatory burdens; ensure a level economic playing field and the free movement of skilled labour; and support the success, sustainability and competitiveness of the UK research and science base.
Monitoring information arrangements: The operation of the new regime will be monitored using operational information generated continuously by the regulator and through regular liaison with those affected by and with a legitimate interest in the protection of animals used for experimental and other scientific purposes. Information on implementation in other Member States will be sought through the Commission and direct contact with other national competent authorities.
Reasons for not planning a review: N/A.

Annex 2: Specific Impact Tests

Statutory Equality Duties

Equality Impact Assessment

Author / editor / assessor	Martin Walsh Head of Division Animals Scientific Procedures Division Home Office Email: martin.walsh@homeoffice.gsi.gov.uk Tel: 020 7035 0746
Partners / decision-makers / implementers, etc	The Home Office is responsible for implementation in England, Wales and Scotland. DHSSPSNI – has responsibility for implementation in Northern Ireland.
Start date	November 2010: in preparation for changes to take effect in UK law 1 January 2013.
End date	Transposition/implementation of revised EU requirements to take effect 1 January 2013 – with planned initial review of outcomes 2016.
Relevance	The revision of Directive 86/609/EEC will result in changes to the way the use of live animals for experimental and other scientific purposes is regulated in the UK. The revised regulatory system impacts on those who produce or use animals for these purposes.
Policy aims	Why is the policy needed? The current regulatory framework must be revised to comply with revised EU legislation. What does the authority hope to achieve by it? The national competent authority seeks to comply with the revised EU requirements and to regulate the use of animals for experimental and other scientific purposes efficiently and effectively, and to deliver the relevant policy objectives - without damaging the success, sustainability and competitiveness of the UK science-base. How will the authority ensure that it works as intended? In addition to the normal checks and balances that exist with respect to legislation (including EU scrutiny), and public sector policies and decision making, the regulatory outcomes will be periodically reviewed.
Available evidence	The operation of the current UK legislative system (which the revised EU provisions resemble) has not resulted in significant diversity or equality issues. Although provision is made within the current system for accommodating those with special needs (e.g. language problems or physical disabilities), it has never proved necessary in practice to bring these into play (e.g. foreign language, Braille or audio-book copies of documentation).
Evidence gaps	A formal public consultation is planned of 'options for change' – and within this process feedback will be invited on equality issues.
Involvement and consultation	EU public and expert consultations on revised EU requirements did not identify any significant equality issues. A previous UK consultation on European Commission proposals for changes to Directive 86/609/EEC did not identify any significant equality issues. Ongoing interest group liaison (which indirectly includes patient groups) have not identified significant equality issues.

What is the actual/likely impact?	The legislative and policy changes will be designed so as not to create equality issues. The administrative processes (e.g. access to services, documentation/information and forms design) will comply with Home Office policies and systems to take account of the need to ensure that issues arising from race, gender, disability are avoided or identified and resolved.
Address the impact	Serial consultations and impact assessments, and ongoing external liaisons all focus on the costs and benefits of how a revised legislative framework will operate – including identifying and remedying equality issues. All findings, including comments and evidence, will be considered within the programme for the transposition and implementation of the revised directive.
Monitoring and review	It is proposed to review the outcome of revised legislation and policies in 2017: in addition, outcomes of and feedback on administrative practices will be continuously reviewed.
Action plan	An action plan will be developed to monitor and review outcomes. This will include an active dialogue with other Government Departments and those affected by the legislative and administrative changes from the time the changes take effect. Problems will be promptly investigated and remedied.
Decision-making and quality control	Equality issue analysis is reviewed within the larger Impact Assessment process for the implementation of Directive 2010/63/EU, with key documents signed-off by the Home Office Chief Economist.

Economic Impacts

Competition Assessment (Options 2 and 3)

Checklist

In any affected market, would the proposal:

1. Directly limit the number or range of suppliers? NO

- Not if the suppliers of types of animals not covered by the current UK legislation which must in future be purpose bred operate to acceptable standards, register and are approved.
- It is expected all current reputable breeders will apply, and will be approved.

2. Indirectly limit the number or range of suppliers? NO

- Not if the suppliers of types of animals not covered by the current UK legislation which must in future be purpose bred are approved.
- It is expected all such reputable breeders will apply, and will be approved.

3. Limit the ability of suppliers to compete? NO

- No: indeed they will be able to supply user establishments throughout the EU.

4. Reduce suppliers' incentives to compete vigorously? NO

- No: all EU operations will be required to operate to the same standards.

Explanatory Text

For the purposes of this Competition Assessment there is no net effect on places already regulated by the Animals (Scientific Procedures) Act 1986: see above. The new provisions most relevant to this Assessment are those with increase the range of protected animals that must be bred or supplied from approved breeders/suppliers. The majority of such animals are already produced/supplied by designated establishments – and it is anticipated that all reputable breeders/suppliers not currently designated who wish to register will be approved under the new provisions. For user establishments, the relaxation of the current requirement to use only UK designated sources (unless a specific exemption has been granted) will provide more choice and competition between providers.

Otherwise, the main risk is that the UK adopts a framework that places the UK science-base at a competitive disadvantage because other Member States adopt compliant, but less stringent, measures when transposing the Directive. We propose to reduce this risk by maintaining an active dialogue with the Commission and other Member States to ensure the UK approach is as closely coordinated with that of other Member States as possible.

Small Firms Impact Test

Checklist

A. At an early stage in the Impact Assessment preparation make a preliminary assessment of businesses likely to be affected:

□ Does the regulation apply to small businesses or affect the business environment in which they operate

It applies to all business regulated by ASPA, less than 5% of which are small businesses.

□ What are the characteristics of small businesses likely to be affected

They are small-scale breeders of laboratory animals, and small biomedical research organisations – most of which are already known to be compliant.

B. Consider alternative approaches for regulating smaller firms:

□ Consider whether alternative approaches (including, but not limited to, exemptions, simplified inspections, less frequent reporting) might be appropriate for firms with fewer than 20 employees[27].

The revised directive does not allow exempting small businesses from the regulatory requirements, but it does allow a proportionate "risk based" approach to be taken.

□ Consider whether a complete or Consultation Stage exemption would be appropriate for micro and small businesses (those with fewer than 50 employees).

The revised directive does not allow exempting small businesses from the regulatory requirements, but it does allow a proportionate "risk based" approach to be taken.

C. Scope issues with a representative sample of small businesses:

□ Contact a reasonable number (e.g. 10) of representative businesses.

The Home Office has maintained an active dialogue with the trade associations/umbrella organisations representing the relevant small business as the revision has progressed– and all business to be affected had the opportunity to contribute to the preliminary written consultation, and all have had visits by HO staff.

□ Obtain feedback about the likely effects of the proposal:

- How serious is the problem the proposal seeks to address in relation to smaller firms?

  For the UK to comply with the revised directive it is essential all designated establishments operate in compliance with the revised EU requirements.

- What changes will smaller firms have to make to the way their business operates?

  The changes to administrative practices and staffing are minor – and in some cases may result in a net reduction in costs.

  The changes in the cost of supplies, equipment and infrastructure are phased in over time, with many of the resulting costs largely absorbed as business as usual costs.

- Is there likely to be a greater impact on the operations and performance of smaller business than others[28]?

  No.

- What are the likely approximate costs and benefits of the proposal for small business?

  The cost are minor (the main costs being changes to administrative practices – and in many cases there may be savings rather then costs), and the benefits are continued authorisation when the revised EU directive is implemented.

- Will exempting smaller firms from the policy materially affect the potential benefits from the policy?

[27] For all regulations that affect business, policy makers are now required to consider whether alternative approaches (e.g. flexibilities or exemptions) are appropriate for firms with up to 20 employees. This requirement was announced in the Government's 2008 Enterprise Strategy -.see http://www.berr.gov.uk/whatwedo/enterprise/enterprisesmes/enterprise-framework/index.html

[28] It is normal for the impact of measures to bear more heavily on small businesses because they do not enjoy the economies of scale of larger firms.

Yes: the UK would not be in compliance with revised EU legislation.

- Are there alternative approaches for smaller firms, which would not materially affect the potential benefits from the policy?

  No.

D. Determine if there is likely to be a greater impact on the operations and performance of small business than others:

□ If yes, proceed with the next stage of the small businesses analysis, based on the information received from the sample of businesses and other research, where appropriate. (Note it is normal for the impact of measures to bear more heavily on small businesses because they do not enjoy the economies of scale of larger firms).

No, the impact is not disproportionate.

□ If no, prepare the draft impact assessment for public consultation, including details of preliminary soundings. Note that you will still need to consider:

- Whether alternative approaches (including, but not limited to, exemptions, simplified inspections, less frequent reporting) are appropriate for firms with fewer than 20 employees; and

- Whether exemptions are appropriate for small firms (those with up to 50 employees).

  See above.

E. Gather detailed data about likely impacts on small businesses as part of the wider consultation including costings:

□ Contact a wider sample of representative businesses. Contact with trade associations/umbrella organisations will be maintained, and full written consultation is planned.

The Home Office has maintained an active dialogue with the trade associations/umbrella organisations representing the relevant small business as the revision has progressed– and all business to be affected had the opportunity to contribute to the preliminary written consultation and all have had visits by HO staff.

□ Obtain feedback about likely effects of the proposals, including estimates of costs and benefits that can withstand external scrutiny.

Contact with trade associations/umbrella organisations will be maintained, and full written consultation is planned.

See above.

□ Consider again if the proposal will have a greater effect on small business.

That will be done when the consultation has been completed, and will take account of the feedback received.

□ Consider alternative approaches for smaller firms.

See above.

Environmental Impacts

Greenhouse Gas Assessment

No net effect.

Wider Environmental Issues

1. Will the policy option be vulnerable to the predicted effects of climate change?

No.

2. Will the policy option lead to a change in the financial costs or the environmental and health impacts of waste management?

No: the proposed changes produce no net change to current practices or outcomes.

3. Will the policy option impact significantly on air quality?

No.

4. Will the policy option involve any material change to the appearance of the landscape or townscape?

No.

5. Will the proposal change 1) the degree of water pollution, 2) levels of abstraction of water or 3) exposure to flood risk?

No.

6. Will the policy option change 1) the amount or variety of living species, 2) the amount, variety or quality of ecosystems?

No: indeed the regulatory regiment will permit research and testing to better protect the environment.

7. Will the policy option affect the number of people exposed to noise or the levels to which they're exposed?

No.

Social Impacts

Health and Well-being

1. Will your policy have a significant impact on human health by virtue of its effects on the following wider determinants of health?

Income	No
Crime	No
Environment	No
Transport	No
Housing	No
Education	No
Employment	No
Agriculture	No
Social cohesion	No

NB – the revision makes provision for the effective regulation of biomedical research.

2. Will there be a significant impact on any of the following lifestyle related variables?

Physical activity	No
Diet	No
Smoking, drugs, or alcohol use	No
Sexual behaviour	No
Accidents and stress at home or work	No

Consider risk factors that influence the probability of an individual becoming more or less healthy.

N/A in this case.

3. Is there likely to be a significant demand on any of the following health and social care services?

Primary care	No
Community services	No
Hospital care	No
Need for medicines	No
Accident or emergency attendances	No
Social services	No
Health protection and preparedness response	No

Human Rights

Check List - HRA Act requirements:-

Absolute rights:-

Article 2 – Right to life	Compliant.
Article 3 – Prohibition of torture	Compliant
Article 4 – Prohibition of slavery and forced labour	Compliant.
Article 5 – Right to liberty and security	Compliant.
Article 6 – Right to a fair trial	Compliant.
Article 7 – No punishment without law	Compliant.

Qualified rights:-

Article 8 –Right to respect for private and family life	Compliant.
Article 9 – Freedom of thought, conscience and religion	Compliant.
Article 10 – Freedom of expression	Compliant.
Article 11 – Freedom of assembly and association	Compliant.
Article 12 – Right to marry	Compliant.
Article 14 – Prohibition of discrimination	Compliant.

Protocol 1, Article 1: Protection of property	Compliant.
Protocol 1, Article 2: Right to education	Compliant.
Protocol 1, Article 3: Right to free elections	Compliant.

Justice Checklist Does the policy involve:

Creating or amending a criminal offence.

- No: at this stage the preferred option is to follow the model used with the Animals (Scientific Procedures) Act 1986, relying predominantly on administrative sanctions.

Creating a new civil sanction or fixed penalty.

- No: at this stage the preferred option is to follow the model used with the Animals (Scientific Procedures) Act 1986, relying predominantly on administrative sanctions.

Creating a civil order or injunction breach of which may lead to further proceedings or criminal sanctions.

- No: at this stage the preferred option is to follow the model used with the Animals (Scientific Procedures) Act 1986, relying predominantly on administrative sanctions.

New, or amendments to, sentencing/penalty guidelines

- No: at this stage the preferred option is to follow the model used with the Animals (Scientific Procedures) Act 1986, relying predominantly on administrative sanctions.

New, or amendments to, court or tribunal procedure rules?

- No: at this stage the preferred option is to follow the model used with the Animals (Scientific Procedures) Act 1986, relying predominantly on administrative sanctions.

Or is the policy likely to:

Result in, create or increase applications to the courts or tribunals, including judicial review

- No: at this stage the preferred option is to follow the model used with the Animals (Scientific Procedures) Act 1986, relying predominantly on administrative sanctions.

Establish a new tribunal jurisdiction

- No: at this stage the preferred option is to follow the model used with the Animals (Scientific Procedures) Act 1986, relying predominantly on administrative sanctions.

Require an appeals mechanism

- No: at this stage the preferred option is to follow the model used with the Animals (Scientific Procedures) Act 1986, relying predominantly on administrative sanctions and established appeals procedures.

Require enforcement mechanisms for civil debts, civil sanctions or criminal penalties

- No: at this stage the preferred option is to follow the model used with the Animals (Scientific Procedures) Act 1986, relying predominantly on administrative sanctions.

Result in an increase in the number of offenders being committed to custody or probation

- No: at this stage the preferred option is to follow the model used with the Animals (Scientific Procedures) Act 1986, relying predominantly on administrative sanctions.

Result in an increase in the length of custodial sentences?

- No: at this stage the preferred option is to follow the model used with the Animals (Scientific Procedures) Act 1986, relying predominantly on administrative sanctions.

Rural Proofing

Will the policy affect the availability of public and private services?	NO
Will the policy rely on existing service outlets, such as schools, libraries and GP surgeries?	NO
Will the policy rely on the private sector or a public-private partnership?	NO
Will the cost of delivery be higher in rural areas where clients are more widely dispersed and economies of scale can be harder to achieve?	NO
Will the policy rely on local institutions for delivery?	NO
Will the policy affect travel needs or the ease/cost of travel?	NO
Does the policy rely on infrastructure (e.g. broadband ICT, main roads, utilities) for delivery?	NO
Will delivery of the policy be challenging at the 'edges' of administrative areas?	NO
Is the policy dependant on new buildings or development sites?	NO
Does the policy rely on communicating information to clients?	NO
Will the policy impact on rural businesses, including the self employed?	NO
Will the policy affect land-based industries and, perhaps, rural economies and environments? change.	NO
Will the policy affect people on low wages or in part-time or seasonal employment?	NO
Will the policy target disadvantaged people or places?	NO

Sustainable Development

Stage 1

1. Environmental Standards

1a. Are there are any significant environmental impacts of your policy proposal (see Wider Environment Specific Impact Test)?
No
~~If the answer is 'yes' make a brief note of the impacts below:~~

~~1b. If you answered 'yes' to 1a., are the significant environmental impacts relevant to any of the legal and regulatory standards identified?~~
~~Yes No~~
~~If the answer is 'yes' make a brief note of the relevant standards below:~~

~~If you answered 'yes' to 1b, have you:~~
~~1c. Notified the Government Department which has legal responsibility for the threshold and confirmed with them how to include the impacts appropriately in the analysis of costs and benefits?~~
~~1d. Informed ministers where necessary?~~
~~1e. Agreed mitigating or compensatory actions where appropriate?~~

2. Intergenerational impacts

2a. Have you assessed the distribution over time of the key monetised and non-monetised costs and benefits of your proposal? This assessment can be included in your Evidence Base or put in an annex.
Yes

N/A

2b. Have you identified any significant impacts which may disproportionately fall on future generations? If so, describe them briefly.
No

~~If you answered 'yes' to 2b. , have you:~~
~~2c. Informed ministers where necessary? If so, provide details.~~
~~2d. Agreed mitigating or compensatory actions where appropriate? Provide details.~~

Annex 3: Evidence and analysis

Other Articles and Annexes

The following Articles and Annexes are cost neutral or have limited or no impact.

Article 1: Subject Matter and Scope

Animals bred for organs and tissues

The revised directive extends protection to animals bred and killed by technically competent persons to supply organs and tissues for scientific use. This activity is not covered by the current UK legislative framework.

This provision potentially protects an additional one million plus animals/year. These animals are already bred and used at authorised establishments and no additional personal or project authorisations will be required. Provided places where animals are killed primarily for other purposes (for example licensed slaughter houses) do not require dual-authorisation, it is assumed that this requirement will result in no net costs or savings. Option 2 and Option 3 are assumed to be cost-neutral.

Animals and stages covered

Fewer **immature forms** of animals are protected by the provisions of the revised directive. Only immature mammals during the last third of normal development are protected. This removes protection for other classes of immature animals (e.g. embryonated avian eggs, and immature mammals between half and two thirds through normal development).

With respect to protection being broadened to all **cephalopod species**: this is more stringent than the current UK requirement which protects only Octopus vulgaris.

Option 2

There are no additional costs and the savings are small. It is estimated (based on what is currently licensed) that there will be no reduction in the number of authorised establishments, a reduction of fewer than 5 project licences, and a reduction of fewer than 15 authorised persons. The savings to the competent authority are not significant (well under 0.5% of current resource costs).

With respect to the extension of protection to all **cephalopod species**, a previous survey of cephalopod use in the UK (undertaken in the margins of evaluating APC advice to extend protection under the 1986 Act to these classes of animal) suggests this work takes place almost exclusively at academic establishments already authorised, that less than10 projects are ongoing at ongoing at any one time, involving about 12-20 persons (all known or believed to be competent). These users are believed to operate to a voluntary code of practice that is likely to be deemed sufficient to ensure appropriate welfare standards. There are no savings. The transitional costs are those of efficiently inducting persons/projects into the regulatory system. The main costs relate to staff training and authorisation of 20 persons, and production of 10 simple project authorisations.

The ongoing costs to Government relate to maintaining the licence authorities, and the related inspection programme (at a small marginal cost – as the places at which the work is undertaken are already within the scope of the national inspection programme). For the purposes of the Impact Assessment the assumption is the savings arising from less stringent requirements with respect to immature forms, and the costs of regulating work on cephalopod species, effectively cancel each other out.

Option 3

See Option 2 above. With respect to the less stringent protection of immature forms, there are no scientific or welfare benefits in retaining the current UK provision, and no reason to believe political or public confidence would be damaged by this being seen as a significant weakening of the regulatory system.

Article 2: Stricter National Measures

Article 2 allows Member States to maintain provisions in force at the time of entry into force of this Directive aimed at ensuring more extensive protection of animals than those contained in this Directive, providing the measures in question are not deemed to have the potential to distort the internal market.

This Article forms the legal basis for the Option 3 analysis. Associated costs are shown under the relevant articles.

Article 3: Definitions

No issues.

Article 4: Principle of Replacement, Reduction and Refinement

The provisions of Article 4 are consistent with current UK requirements and practice.

Option 2 and Option 3 are therefore assumed to be cost neutral.

Article 5: Purposes of Procedures

Article 5 defines and limits the purposes for which animals may be used. These are similar to current UK legislative requirements provided Article 5(f) does not require the dual authorisation of training of stockmen under the Agriculture Miscellaneous Provisions regulation. Option 2 and Option 3 are therefore assumed to be cost-neutral.

Article 7: Endangered Species

The Directive prohibits the use of the endangered species listed in Annex A to Council Regulation (EC) No 338/97[29] except for specified purposes. These provisions are consistent with current UK legislation, policy and practice. There are, therefore, no resulting costs of savings from Option 2 or Option 3.

Article 8: Non-Human Primates

Article 8 prohibits the use of non-human primates except where there is a scientific justification and the procedure has certain specified purposes. It is assumed that non-human primate use currently permissible in the UK will still be permissible under these provisions.

The Directive also prohibits the use of great apes, except in research aimed at the preservation of those species and where action is warranted in relation to a life-threatening or debilitating condition endangering human beings and no other species or alternative method would suffice (see also 'safeguard clause' at Article 50). This provision is weaker than the current UK policy and administrative prohibition of the use of great apes.

Option 2

The only significant change is a potential relaxation allowing the use of Great Apes under exceptional circumstances. There are no suitable approved facilities for such work in the UK, and no requests to use Great Apes have been received under the Animals (Scientific Procedures) Act 1986. It is assumed that there would no costs or savings if UK legislation were to be aligned to the revised EU requirement.

Option 3

See Option 2 above. There may be a case for retaining the current UK policy prohibition on the use of great apes to maintain public and political confidence. There are no relevant costs or savings if this is done.

[29] The most recent consolidated version of the EU reference document can be found at http://eurlex. europa .eu/LexUriServ/LexUriServ. do ?uri=CON S LE G: 1997R0338:20080411 : EN: PDF

Article 9: Animals taken from the wild

Article 9 prohibits the use of animals taken from the wild, subject to exemptions based on scientific justification. These provisions are consistent with current UK legislation, policy and practice.

Option 2, and Option 3 are therefore assumed to be cost neutral.

Article 10/Annex I: Animals bred for use in procedures[30]

Subject to exemption on the basis of scientific justification, the Directive limits the use of the species listed in Annex II to those which have been bred for use in procedures. The list differs from the current UK requirements.

Annex II does not protect common quail, ferrets, genetically modified pigs, and genetically modified sheep. The GM pigs and sheep are not currently bred in the UK except under project licence authority; and deregulating the breeding of common quail and ferrets produces no costs or savings. The common quail is not in common use (the Japanese and bob-white quail are the commonly used quail species). High-health status ferrets will still be required for research use, both to provide suitable scientific subjects, and for bio-security reasons to maintain the health status of the animal facilities.

Protection will now extend to Frog and Rana (the most commonly used amphibians), and Zebra Fish. These are already largely bred at authorised establishments or specialist breeders, and only minor administrative adjustments will be required to authorise the breeding facilities.

Option 2 is assumed to be cost neutral. There may be a case under Option 3 for adding ferrets to the list of purpose-bred animals. This is also essentially cost-neutral.

Article 11: Stray and Feral Animals of Domestic Species

The Directive prohibits the use of stray and feral animals of domestic species except where (a) there is an essential need for studies concerning the health and welfare of the animals or serious threats to the environment or to human or animal health, and (b) there is a scientific justification that the purpose of the procedure can be achieved only by the use of a stray or a feral animal. These provisions are consistent with current UK legislation, policy and practice.

Option 2, and Option 3 are assumed to be cost neutral.

Article 12: Procedures

The Directive requires that procedures are always carried out in authorised user establishments, unless an exemption is granted on the basis of scientific justification, and that procedures are only carried out within the framework of a project. These provisions are consistent with current UK legislation, policy and practice. Option 2 and Option 3 are therefore assumed to be cost-neutral.

Article 13: Choice of Methods

Article 13 prohibits the use of animals in a procedure if a scientifically satisfactory, non-animal method, or testing strategy, is recognised by EU legislation. It further specifies that where more than one animal method is available, the method to be used is that which achieves the best combination of the following considerations: using the minimum number of animals; involving animals with the least capacity to experience pain, suffering, distress or lasting harm; causing the least pain, suffering, distress and lasting harm; and being most likely to provide satisfactory results.

Article 13 also requires that death as an endpoint is avoided and replaced by early and humane end points, but where this is not possible, that the procedure results in as few deaths as possible and minimises suffering.

[30] The current UK legislation favours UK based approved breeders: it is believed that this protection of UK based business will not be permissible under the legal basis for the revised directive.

The provisions of Article 13 are consistent with current UK requirements and practice.

Option 2 and Option 3 are therefore assumed to be cost neutral.

Article 14: Anaesthesia

Article 14 requires that all procedures are carried out under general or local anaesthesia except where anaesthesia would be more traumatic than the procedure itself; or is incompatible with the purpose of the procedure (other than where the procedure involves serious injuries that may cause severe pain).

Article 14 also requires that where a procedure is carried out without anaesthesia, analgesia or other appropriate methods are used to ensure that unavoidable pain, suffering and distress is minimised. Also, that analgesics, or other appropriate pain-relieving methods, are administered to animals which may suffer considerable pain when anaesthesia has worn off and that appropriate action is taken to minimise suffering when the purpose of the procedure has been achieved.

Article 14 also makes provision regarding the use of neuromuscular blocking agents, requiring that appropriate anaesthesia or analgesia is used in conjunction with such agents.

Article 14.1, 14.2, and 14.5 describe the current UK regulatory system, and are therefore assumed to be cost neutral.

Article 14.3 is cost/saving neutral. However, it presents provisions for the use of neuromuscular blocking agents slightly less stringent than in the current UK system of controls. The revised EU requirements would allow the administration of neuromuscular blocking agents with analgesics instead of general anaesthetics (the current UK policy). As analgesics alone do not remedy any non-pain related distress associated with the use of neuromuscular blocking agents, there is a welfare case for retaining current UK provision.

Article 14.4 requires the pre-emptive use of intra-operative analgesia to animal which might otherwise experience pain once the anaesthesia has worn off. This is current good practice, and is therefore assumed to be cost neutral.

Option 2

Save for the derogation with respect to the option to use analgesics rather than anaesthetics in conjunction with neuromuscular blocking agents, the revised directive sets out the current UK policy and practice. That derogation (effectively a minor technical procedural change), if exercised, would be cost-neutral.

Option 3

There is strong welfare case for maintaining the current UK prohibition on the systemic use of neuromuscular blocking agents without general anaesthesia in mature forms of protected animals.

Article 15 & Annex VIII: Severity Classification of Procedures

The Directive requires that Member States ensure that all procedures are classified in one of four categories: ‘non-recovery’, ‘mild’, ‘moderate’ or ‘severe’ using criteria set out in annex VIII. Article 15 also requires that no procedures are to be carried out involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated. This latter provision may be overridden using the safeguard clause at Article 52(3).

The severity classification system is, for practical purposes, equivalent to current UK arrangements, assuming humane killing is accepted as a means of limiting severity and that surgical preparation will typically require a procedure of moderate severity. Option 2 and Option 3 are therefore assumed to be cost neutral.

Article 16: Re-Use

Article 16 sets out the circumstances in which animals may be re-used. Re-use is generally limited to mild, moderate or non-recovery procedures, but may be allowed after use in a severe procedure in exceptional circumstances after veterinary examination.

The decision making framework differs from that currently incorporated in UK legislation. However, we believe that in practice it will not prove significantly different in terms of outcomes, costs, savings and benefits to the system already in use in the UK. Option 2 and Option 3 are therefore assumed to be cost-neutral.

Article 17: End of the procedure

The Directive defines the end of a procedure as the point at which no further observations are to be made or, for new genetically modified lines, when adverse effects are no longer observed or expected. It requires a decision to be taken by a veterinarian or other competent person at the end of a procedure whether the animal is to be kept alive or killed by a humane method and specifies that an animal must be killed when it is likely to continue to experience moderate or severe pain, suffering, distress or lasting harm. Where an animal is to be kept alive, it is to receive the care and accommodation appropriate to its state of health.

It is assumed that these provisions reflect current UK good practice. Option 2 and Option 3 are therefore assumed to be cost-neutral.

Article 18: Sharing Organs and Tissues

Article 18 requires that Member States shall, where appropriate, facilitate the establishment of programmes for the sharing of organs and tissues of animals killed. The aim is to minimise animal use and costs.

Promoting the sharing of organs and tissues, where it is known to reduce welfare costs without significantly increasing the regulatory burden, is existing UK good practice, and the provision is assumed to be essentially cost neutral for the UK. Option 2 and Option 3 are therefore assumed to be cost-neutral.

Article 19: Setting free of animals and re-homing

The Directive permits Member States to allow the setting free or re-homing of animals used, or intended for use, in procedures providing they are healthy, present no danger to the public, and appropriate measures have been taken to safeguard the well-being of the animal.

These provisions are consistent with current UK requirements and practice. Option 2, and Option 3 are therefore assumed to be cost neutral.

Article 21: Suspension and withdrawal of authorisation

The Directive requires competent authorities to withdraw authorisation where an establishment ceases to comply with the requirements of the Directive. Where authorisations are withdrawn or suspended, Member States will be required to ensure the welfare of animals housed at an establishment is not adversely affected. These requirements are consistent with current UK legislative provision.

Option 2, and Option 3 are therefore assumed to be cost neutral.

Article 22: Requirements for installations and equipment

The Directive requires Member States to ensure that all breeding, supplying and user establishments have installations and equipment suited to the species housed and, where relevant, to the performance of procedures, and that their design, construction and method of functioning is such that the procedures are carried out as effectively as possible and obtain consistent results using the minimum number of animals and causing the minimum pain, suffering, distress or lasting harm.

The changes required to implement the mandatory standards of animal care and accommodation set out in Annex III are discussed below. Otherwise the provisions of Article 22 are consistent with current UK requirements and practice. Option 2 and Option 3 are therefore assumed to be cost neutral.

Article 24: Specific requirements for personnel

Article 24 requires that each breeder, supplier and user has one or more persons on site who shall be responsible for overseeing the welfare and care of the animals in the establishment; ensure that the staff dealing with animals have access to information specific to the species housed in the establishment; and be responsible for ensuring that the staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competence.

Option 2 and Option 3

The requirements of Article 24 are somewhat broader than current UK legislative provisions, but it is assumed functions (a) and (b) are already discharged at establishments and represent business as usual costs. It is further assumed that function (c) is also carried out, but that additional resource may be required to fully meet the requirement in some establishments. To avoid double-counting, these are included in the costs of administering a local registration scheme set out under Article 23 in Part A, above.

Article 25: Designated Veterinarian

The revised directive sets out provisions consistent with current UK policy and good practice.

Option 2 and Option 3 are assumed to be cost neutral.

Articles 26 & 27: Animal Welfare Body & Tasks of the Animal Welfare Body

Article 26 requires that each breeder, supplier and user sets up an animal welfare body (AWB) including at least the person(s) responsible for the welfare and care of the animals and, in the case of a user, a scientific member. The animal welfare body must also receive input from the designated veterinary surgeon or the expert referred to in Article 25. Member States may allow small breeders, suppliers and users to fulfil the tasks laid down in Article 27(1) by other means.

The AWB is to advise staff dealing with animals on matters related to the welfare of animals, the application of replacement, reduction and refinement, establish and review relevant internal operational processes, follow the development and outcome of projects and advise on re-homing schemes.

Records of AWB decisions and advice are kept for at least three years and made available to the competent authority upon request.

The requirements for local Animal Welfare Bodies are less stringent than those relating to the operation of local ethical review processes in the UK. Fewer persons are involved (in theory in some places a minimum of two might suffice) and there are fewer functions (for example no involvement is required in the pre-authorisation phase of project authorisation).

Although there appear to be potential savings to establishments if the minimum EU specification is implemented, in practice it is likely that many of the ‘redundant’ functions would be retained by establishments. Our assumption is, therefore, that Option 2 would be cost neutral.

Option 3 would entail incorporating current UK arrangements for local ethical review processes into legislation but would, in effect, be cost neutral.

Article 28: Breeding Strategy for Non-Human Primates

The Directive requires establishments breeding and supplying non-human primates to have a strategy for increasing the supply of F2 animals. Establishments will be required to provide proof to the competent authority, on request, that the establishments from which they have acquired non-human primates have such a strategy in place.

UK breeders operating under the Animals (Scientific Procedures) Act 1986 already only produce F2+ animals. Option 2 and Option 3 are therefore assumed to be cost neutral.

Article 29: Scheme for re-homing or setting free of animals

Under Article 19 above, Member States may allow the setting free or re-homing of animals used or intended for use in procedures. Where they do so, relevant establishments will be required to have a re-homing scheme that ensures socialisation of the animals to be re-homed.These provisions are generally consistent with the current UK requirements and practice.

Option 2 and Option 3 are therefore assumed to be cost neutral.

Article 30: Animal Records

Article 30 sets out the records to be kept by establishments on animals. These are the number and species of animals bred, acquired, supplied, re-homed. humanely-killed or that have died; the dates on which animals were acquired, supplied, released or re-homed; and the name and address of the supplying establishment, or recipient, and date of arrival. These records are to be kept for three years and submitted to the competetent authority on request.

These requirements are consistent with current UK requirements and good practice.

Option 2 and Option 3 are therefore assumed to be cost neutral.

Article 31: Information on Dogs, Cats and Non-Human Primates

Under the Directive, all establishments will be required to keep a range of information on each dog, cat and non-human primate. These records are to be kept for three years and submitted to the competetent authority on request.

These requirements are consistent with current UK requirements and good practice.

Option 2 and Option 3 are therefore assumed to be cost neutral. Option 4 has the potential to produce additional costs by introducing more stringent requirements, that is, additional record keeping requirements. Without the detail of any potential additional requirements, it is not possible to monetise the potential costs or savings.

Article 32: Marking and Identification of Dogs, Cats and Non-Human Primates

The Directive requires that dogs, cats and non-human primates are given an individual identification mark, before weaning, in the least painful manner possible. Unmarked animals taken into establishments must be marked as soon as possible after first receipt. If a dog, cat or non-human primate is moved to another establishment before weaning, and it is not practical to mark it beforehand, a full documentary record must be maintained by the receiving establishment until it is marked. If asked, establishments must explain to the competent authority why an animal is unmarked.

These requirements are consistent with current UK requirements and good practice.

Option 2 and Option 3 are therefore assumed to be cost neutral.

Article 35: Controls of Member State Inspections

This is a new requirement, a responsibility placed on the Commission but also affecting the Competent Authority, but unlikely to require additional national resource. Option 2 and Option 3 are therefore assumed to be cost neutral.

Article 36: Project Authorisation

The revised directive sets out provisions consistent with current UK policy and good practice.

Option 2 and Option 3 are assumed to be cost neutral.

Article 37 and Annex VI: Application for Project Authorisation

Article 37 requires that an application for project authorisation must be submitted by the user or the person responsible for the project and as a minimum include a project proposal; a non-technical project summary; and information on the elements listed in Annex VI. These requirements are broadly similar to current UK requirements.

Option 2 and Option 3 are assumed to be cost neutral.

Annex VI: List of elements referred to in Article 37(1)

These provisions closely resemble current UK policy and practice. The requirement to list information relating to the competence of persons involved in the project is new: assuming this responsibility can be discharged by referring to trained and competent persons (see Article 23) at the user establishment there need be no significant additional costs.

Option 2 and Option 3 are assumed to be cost neutral.

Article 38: Project Evaluation

Article 38 sets out the requirements for project evaluation by the competent authority. It is assumed these will not require any significant changes to the current UK system in which the Secretary of State has access to the relevant expertise through the Animals Scientific Procedures Inspectorate, the Animal Procedures Committee, and independent experts. Option 2 and Option 3 are therefore assumed to be cost neutral.

Article 40: Granting of Project Authorisation

Article 40 specifies the content of project authorisations. These provisions are consistent with current UK arrangements. Option 2 and Option 3 are assumed to be cost neutral.

Article 41: Authorisation Decisions

Article 41 requires that Member States ensure that authorisation decisions are taken and communicated to the applicant at the latest 40 working days (or in certain circumstances 55 working days) from the receipt of a complete and correct project application.

The current UK processing target is to deal with 85% of applications within 35 working days. This target is currently being met and exceeded, with a mean processing time of less than 20 days. It is assumed compliance with Article 41 can be achieved without additional resource.

Option 2 and Option 3 are assumed to be cost neutral.

Article 42: Simplified Administrative Procedure

This Article makes provision for a simplified administrative procedure for evaluating and processing subsets of project applications (potentially 60% of the projects currently licensed in the UK). It is discretionary. There are minor reductions to the standard information requirements, and a need to amend authorities only if changes with a negative impact on animal welfare need to be considered.

It is assumed for the purposes of the Impact Assessment that the UK will with respect all project applications require only the minimum information, and endeavor to minimise the need for amendments. The impact of this Article is therefore considered to be cost neutral.

Option 2 and Option 3 are assumed to be cost neutral.

Article 44: Amendment, Renewal and Withdrawal of a Project Authorisation

Under Article 44, amendment or renewal of the project authorisation is required for any change of the project that may have a negative impact on animal welfare.Any amendment or renewal of a project authorisation shall be subject to a further favourable outcome of the project evaluation.

In addition, the competent authority may withdraw the project authorisation where the project is not carried out in accordance with the project authorisation. Where a project authorisation is withdrawn, the welfare of the animals used or intended to be used in the project must not be adversely affected.

Member States must also establish and publish conditions for amendment and renewal of project authorisations.

These provisions are consistent with current UK arrangements. The production of guidance is assumed to be a business as usual cost for the competent authority. Option 2 and Option 3 are assumed to be cost neutral.

Article 45: Documentation

Article 45 requires that all relevant documentation, including project authorisations and the opinion on the project evaluation, are kept for at least three years from the expiry date of the project or, where relevant, until any retrospective assessment has been completed. This is consistent with current UK policy and good practice.

Option 2 and Option 3 are assumed to be cost neutral.

Article 46: Avoidance of duplication of procedures

Under Article 46, each Member State is required to accept from another Member State data that are generated by procedures recognised by the legislation of the Union, unless further procedures need to be carried out regarding that data for the protection of public health, safety or the environment. This provision is assumed to be consistent with the existing Mutual Acceptance of Data agreements and current UK practice, and to be cost-neutral. Option 2 Option 3 are therefore assumed to be cost neutral.

Article 47: Alternative Approaches

Article 47 requires the Commission and the Member States to contribute to the development and validation of alternative approaches to animal testing. Member States are to assist the Commission in identifying and nominating suitable specialised and qualified laboratories to carry out validation studies.

At national level Member States are to ensure the promotion and dissemination of information on alternative approaches. Member States must also nominate a single point of contact to provide advice on the regulatory relevance and suitability of alternative approaches proposed for validation.

Current UK arrangements provide most of what is required and Option 2 and Option 3 are assumed to be cost neutral.

Article 48: Union Reference Laboratory & Annex VII: Duties and tasks Of Union Reference Laboratory

Article 48 and Annex VII set out requirements for a Union reference laboratory to coordinate and promote the development, validation and use of alternatives. The Article and Annex impose obligations on the Commission and are cost neutral for the purposes of this impact assessment,

Article 49: National Committees for the Protection of Animals used for Scientific Purposes

Article 49 requires each Member State to establish a national committee for the protection of animals used for scientific purposes to advise the competent authorities and animal welfare bodies in matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practices. The national committee is to exchange information on the operation of animal welfare bodies and project evaluation and share best practices within the Union.

Although the consultation may produce feedback on a range of options to meet the requirement, for the purposes of the impact assessment it is assumed that that it can be satisfied without adding to the resources currently provided to the Animal Procedures Committee and National Centre for the 3Rs.

Option 2 and Option 3 are assumed to be cost neutral.

Article 50: Adaptation of Annexes to Technical Progress

This is an obligation placed on the Commission: there are no costs or savings to Member States.

Article 51: Exercise of Delegation

This Article deals with the Commission's obligations: it is not relevant to this Impact Assessment.

Article 52: Revocation of Delegation

This Article deals with the Commission's obligations: it is not relevant to this Impact Assessment

Article 53: Objections to Delegated Acts

This Article deals with the Commission's obligations: it is not relevant to this Impact Assessment

Article 55: Safeguard Clause

The safeguard clause provides a mechanism by which provisional decisions by Member States to allow derogations from specific prohibitions set out elsewhere in the directive may be confirmed or reversed following consideration by the Commission and a committee of Member States.

Article 56: Committee

This is an obligation placed on the Commission: there are no costs or savings to Member States.

Article 57: Commission Report

This is an obligation placed on the Commission: there are no costs or savings to Member States.

Article 58: Review

This is an obligation placed on the Commission: there are no costs or savings to Member States other than minor administrative costs relating to thematic reviews.

Article 59: Competent Authorities

This is consistent with current UK practice. Although various options might be considered, all are considered to be cost neutral. Option 2 and Option 3 are assumed to be cost neutral.

Article 60: Penalties

This provision is consistent with the operation of the Animals (Scientific Procedures) Act 1986, and the principles of good regulatory practice.

Option 2 and Option 3 are assumed to be cost neutral.

Article 61: Transposition

This places a cost on Member States: however it is customarily considered to be a business as usual cost with respect to transposing and implementing EU legislation.

Article 62: Repeal

This is an obligation placed on the Commission: there are no costs or savings to Member States.

Article 63: Amendment of Regulation (EC) 1069/2009

This is an obligation placed on the Commission: there are no costs or savings to Member States.

Article 64: Transitional Provisions

This is an obligation placed on the Commission: there are no costs or savings to Member States.

Annex II: NHPS referred to in Article 10

Annex II provides the timetable for requiring non-human primates used for experimental and other scientific purposes are the offspring of non-human primates that have been bred in captivity (termed F2+) or are sourced from self-sustaining colonies. NB: these requirements do not come into effect until feasibility studies have been undertaken by the Commission, and even then Member States may permit exceptions based upon scientific justification.

All marmosets currently used in the UK are already F2+: as are all UK purpose-bred macaques and almost all macaques imported for scientific use.

F2+ non-human primates are already the preferred animal in the UK, and it is assumed that the Commission report and timelines (additional safeguards not present in the original EU Proposal) will ensure continuity of supply with no significant increase in price. This component is therefore assumed to be cost-neutral. It is also assumed (see above) that all currently justified non-human primate use in the UK will be permissible under the terms of the revised directive. Therefore this element is also assumed to be cost neutral.

This provides a legislative basis for the current UK policy, practice and outcomes. As the UK already effectively complies with these new provisions, and it is assumed that consideration of the EU feasibility studies will ensure the eventual lead times will ensure a sustainable supply of suitable animals at prices similar to those current paid by UK users, it is assumed to be cost neutral.

Annex 4: Summary of monetised costs and benefits

(£m)	Option 2	Option 3
Net Present Value	-35.7	-15.9
Total Transitional Costs	19.6	16.2
Annual Average Costs	2.5	0.1
Total Costs (PV)	37.4	15.9
Total Transitional Benefits	0.0	0.0
Annual Average Benefits	0.2	0.0
Total Benefits (PV)	1.6	0.0

Variables	
PV Base Year	2011
Year 0	2012
Discount Rate	3.50%

Assumptions

General

190 establishments
£30 per hour for average staff salary
£60 per hour for inspector (Grade 6 or equivalent)
£30,000 to develop guidelines

Article 6 & Annex IV: Methods of Killing

£200,000 investment in equipment for methods of killing
£100,000 Cost to produce dossiers to support alternative methods of killing

Article 20: Authorisation of breeders, suppliers & users

2 hours of work to reissue certificates at average rate (est)
2 hours of work to reissue certificates at inspector rate rate (comp auth)
50% recoverable as business as usual

Article 23: Competence of Personnel

£35,000 per establishment to set up a system of local control
£25,000 per establishment per year to run a local system of control
50% of this infrastructure already exists
6500 personal licences
1 hour to prepare personal licence fee application at average rate

Article 33 & Annex III: Care and Accommodation

£16,000,000 investment to establish appropriate standards of care

Article 39: Retrospective Assessment

100 projects require retrospective assessment
2 days per assessment
8 hours per day at inspector rate

Article 43: Non-Technical Project Summaries

275 Fewer Non Technical Summaries
1 hour to prepare at average rate
1 hour to process at average rate

Present Value Table (£m)	Option 2	Option 3
Transition cost		
Article 20: Authorisation of breeders, suppliers & users	0.0	0.0
Article 23: Competence of Personnel	3.3	0.0
Article 23: Competence of Personnel	0.0	0.0
Article 34: Inspections by the member state	0.0	0.0
Article 39: Retrospective Assessment	0.0	0.0
Article 43: Non-Technical Project Summaries	0.0	0.0
Article 54: Reporting	0.0	0.0
Article 33 & Annex III: Care and Accommodation	15.0	15.0
Article 6 & Annex IV: Methods of Killing	0.2	0.1
Total transition costs	**18.6**	**15.1**
On going Costs		
Article 20: Authorisation of breeders, suppliers & users	0.0	0.0
Article 23: Competence of Personnel	18.1	0.0
Article 23: Competence of Personnel	0.0	0.0
Article 34: Inspections by the member state	0.0	0.0
Article 39: Retrospective Assessment	0.7	0.7
Article 43: Non-Technical Project Summaries	0.0	0.0
Article 54: Reporting	0.0	0.0
Article 33 & Annex III: Care and Accommodation	0.0	0.0
Article 6 & Annex IV: Methods of Killing	0.0	0.0
Annual Average recurring cost	**2.5**	**0.1**
Total recurring costs	**18.8**	**0.7**
Total Costs	**37.4**	**15.9**
Transition benefits		
Article 20: Authorisation of breeders, suppliers & users	0.0	0.0
Article 23: Competence of Personnel	0.0	0.0
Article 23: Competence of Personnel	0.0	0.0
Article 34: Inspections by the member state	0.0	0.0
Article 39: Retrospective Assessment	0.0	0.0
Article 43: Non-Technical Project Summaries	0.0	0.0
Article 54: Reporting	0.0	0.0
Article 33 & Annex III: Care and Accommodation	0.0	0.0
Article 6 & Annex IV: Methods of Killing	0.0	0.0
Total Transitional Benefits	**0.0**	**0.0**
Article 20: Authorisation of breeders, suppliers & users	0.0	0.0
Article 23: Competence of Personnel	1.5	0.0
Article 23: Competence of Personnel	0.0	0.0
Article 34: Inspections by the member state	0.0	0.0
Article 39: Retrospective Assessment	0.0	0.0
Article 43: Non-Technical Project Summaries	0.1	0.0
Article 54: Reporting	0.0	0.0
Article 33 & Annex III: Care and Accommodation	0.0	0.0
Article 6 & Annex IV: Methods of Killing	0.0	0.0
Annual Average recurring benefits	**0.2**	**0.0**
Total Recurring Benefits	**1.6**	**0.0**
Total Benefits	**1.6**	**0.0**
Net Outcome	**-35.7**	**-15.9**

OPTION 2		2012	2013	2014	2015	2016	2017	2018	2019	2020	2021			
	Policy/Admin	Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Total	Annual Average	Present Value
Transition cost														
Article 20: Authorisation of breeders, suppliers & users	Policy	17,100										17,100		17,100
Article 23: Competence of Personnel	Policy	3,325,000										3,325,000		3,325,000
Article 23: Competence of Personnel	Admin	30,000										30,000		30,000
Article 33 & Annex III: Care and Accommodation	Policy	3,200,000	3,200,000	3,200,000	3,200,000	3,200,000						16,000,000		14,953,853
Article 6 & Annex IV: Methods of Killing	Admin	230,000										230,000		230,000
Total transition costs		**6,802,100**	**3,200,000**	**3,200,000**	**3,200,000**	**3,200,000**	**-**	**-**	**-**	**-**	**-**	**19,602,100**		**18,555,953**
Annual recurring cost														
Article 23: Competence of Personnel	Policy	-	2,375,000	2,375,000	2,375,000	2,375,000	2,375,000	2,375,000	2,375,000	2,375,000	2,375,000	21,375,000	2,375,000	18,068,255
Article 39: Retrospective Assessment	Admin	-	96,000	96,000	96,000	96,000	96,000	96,000	96,000	96,000	96,000	864,000	96,000	730,338
Total recurring costs		**-**	**2,471,000**	**2,471,000**	**2,471,000**	**2,471,000**	**2,471,000**	**2,471,000**	**2,471,000**	**2,471,000**	**2,471,000**	**22,239,000**	**2,471,000**	**18,798,593**
Total Costs		**6,802,100**	**5,671,000**	**5,671,000**	**5,671,000**	**5,671,000**	**2,471,000**	**2,471,000**	**2,471,000**	**2,471,000**	**2,471,000**	**41,841,100**		**37,354,547**
Transition benefits														
Total Transitional Benefits		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**		**-**
Annual recurring benefits														
Article 23: Competence of Personnel	Admin	-	195,000	195,000	195,000	195,000	195,000	195,000	195,000	195,000	195,000	1,755,000	175,500	1,483,499
Article 43: Non-Technical Project Summaries	Admin	-	16,500	16,500	16,500	16,500	16,500	16,500	16,500	16,500	16,500	148,500	14,850	125,527
Total Recurring Benefits		**-**	**211,500**	**211,500**	**211,500**	**211,500**	**211,500**	**211,500**	**211,500**	**211,500**	**211,500**	**1,903,500**	**190,350**	**1,609,026**
Total Benefits		**-**	**211,500**	**211,500**	**211,500**	**211,500**	**211,500**	**211,500**	**211,500**	**211,500**	**211,500**	**1,903,500**		**1,609,026**
Net Outcome		**-6,802,100**	**-5,459,500**	**-5,459,500**	**-5,459,500**	**-5,459,500**	**-2,259,500**	**-2,259,500**	**-2,259,500**	**-2,259,500**	**-2,259,500**	**-39,937,600**		**-35,745,521**

Net Present Value	**-35,745,521**
Total Transitional Costs	19,602,100
Annual Average Costs	2,471,000
Total Costs (PV)	37,354,547
Total Transitional Benefits	-
Annual Average Benefits	190,350
Total Benefits (PV)	1,609,026

OPTION 3		2012	2013	2014	2015	2016	2017	2018	2019	2020	2021			
	Policy/Admin	Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Total	Annual Average	Present Value
Transition cost														
Article 20: Authorisation of breeders, suppliers & users	Policy	17,100										17,100		17,100
Article 23: Competence of Personnel	Admin	30,000										30,000		30,000
Article 33 & Annex III: Care and Accommodation	Policy	3,200,000	3,200,000	3,200,000	3,200,000	3,200,000						16,000,000		14,953,853
Article 6 & Annex IV: Methods of Killing	Policy	130,000										130,000		130,000
Total transition costs		**3,377,100**	**3,200,000**	**3,200,000**	**3,200,000**	**3,200,000**	**-**	**-**	**-**	**-**	**-**	**16,177,100**		**15,130,953**
Annual recurring cost														
Article 39: Retrospective Assessment	Admin	-	96,000	96,000	96,000	96,000	96,000	96,000	96,000	96,000	96,000	864,000	96,000	730,338
Total recurring costs		**-**	**96,000**	**96,000**	**96,000**	**96,000**	**96,000**	**96,000**	**96,000**	**96,000**	**96,000**	**864,000**	**96,000**	**730,338**
Total Costs		**3,377,100**	**3,296,000**	**3,296,000**	**3,296,000**	**3,296,000**	**96,000**	**96,000**	**96,000**	**96,000**	**96,000**	**17,041,100**		**15,861,291**
Transition benefits														
Total Transitional Benefits		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**		**-**
Annual recurring benefits														
Total Recurring Benefits		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Total Benefits		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**		**-**
Net Outcome		**- 3,377,100**	**- 3,296,000**	**- 3,296,000**	**- 3,296,000**	**- 3,296,000**	**- 96,000**	**- 96,000**	**- 96,000**	**- 96,000**	**- 96,000**	**17,041,100**	**-**	**15,861,291**

Net Present Value	**-**	**15,861,291**
Total Transitional Costs		16,177,100
Annual Average Costs		96,000
Total Costs (PV)		15,861,291
Total Transitional Benefits		-
Annual Average Benefits		-
Total Benefits (PV)		-