Title:	Impact Assessment (IA)
Impact Assessment of The Diseases of Animals Approval for Disinfectants **Lead department or agency:** Defra **Other departments or agencies:** Veterinary Laboratories Agency	**IA No:** **Date:** **Stage:** Development/Options **Source of intervention:** Domestic **Type of measure:** Primary legislation **Contact for enquiries:** John O'Rourke

Summary: Intervention and Options

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

In the event of certain disease outbreaks there is a statutory requirement for cleansing and disinfection. Only certain disinfectants can be used which must be approved by Defra. The testing of disinfectants is carried out by the Veterinary Laboratories Agency (VLA) to confirm they are effective against specific viruses and bacteria. Disinfectant approvals are renewed by the VLA every two years and during a recent renewal exercise it was found that several disinfectants had changed their composition, affecting the efficacy of the product. In order to ensure that all disinfectants are efficacious it has been decided to implement more regular testing of the disinfectants which would be paid for by an annual subsistence charge levied on manufacturers.

What are the policy objectives and the intended effects?

The policy objective is to ensure that Government and users have confidence that disinfectants approved by Defra will work as intended in the event of a disease outbreak. This will help prevent disease spread during an outbreak and help promote sales of disinfectants abroad.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

Option 1: Do nothing - Leave the current disinfectants system as it is, only allow for a charge for new applicants to the approval system. This would not generate sufficient funds for regular checks of the approved disinfectants, undermining both effective disease control in the event of a disease outbreak and the credibility of the Approval system.

Option 2: Reduce the current fee for new applicants and introduce an annual fee per approved disinfectant per year. This would allow the VLA to undertake a 2 year paper test plus a 5 year laboratory test of all approved disinfectants. This option provides stability of charges for manufacturers and the disinfectant tests will improve the credibility of the approvals system and enhance disease control in the event of an outbreak.

Option 3: Charge the disinfectant manufacturer in full for each test when the test is conducted. This option doesn't provide stability for manufacturers as testing and therefore payment could occur at any time and is dependent to some extent on laboratory availability.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will be reviewed November 2011
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

SELECT SIGNATORY Sign-off For consultation stage Impact Assessments:

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 SELECT SIGNATORY:..... Date:.....

Summary: Analysis and Evidence

Policy Option 1

Description: Undertake additional testing of Defra approved disinfectants and impose an annual fee on manufacturers

Price Base	PV Base	Time Period	Net Benefit (Present Value (PV)) (£m)		
2010	**2010**	**Years** 10	**Low:** Optional	**High:** Optional	**Best Estimate: -£0.8m**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate			£0.1m	**£0.8m**

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

The costs of the VLA undertaking a 2 year paper test plus a 5 year laboratory test of all approved disinfectants is £0.8m in PV terms over a 10 year appraisal period. To fund these tests an annual fee of £350 will be charged to manufacturers of approved disinfectants however, this is partly offset by a reduction in the cost for new applicants. The net cost imposed on business is approximately £0.8m in PV terms over the appraisal period.

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

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

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

There are no quantifiable benefits from an increase in testing.

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

Provides assurance that approved disinfectants will be effective during a disease outbreak and will help prevent disease spread. Consumers have imperfect information about the quality of disinfectants, a credible approval system ensures confidence that a product is effective. The disinfectants scheme is recognised internationally and the industry estimates that the sales for the industry that depend on a robust Defra approval scheme are likely to exceed £1 million in the UK and to exceed £10 million internationally.

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

It is assumed that the number of successful new applicants for approval orders is offset by those leaving the scheme as a result of failed check tests.
It has been assumed that the costs incurred by the VLA of testing disinfectants does not increase above the rate of inflation and therefore the fees charged to business also do not need to rise above inflation.
There is a risk that disinfectant manufacturers will not apply for Defra approval of their disinfectants if they believe the costs are too high

Impact on admin burden (AB) (£m): N/A			Impact on policy cost savings (£m):		In scope
New AB:	**AB savings:**	**Net:**	**Policy cost savings:**	N/A	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England Scotland and Wales		
From what date will the policy be implemented?			01/04/2011		
Which organisation(s) will enforce the policy?			VLA		
What is the annual change in enforcement cost (£m)?			0		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			N/A		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	
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	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	Yes/No	Yes/No	Yes/No	Yes/No	Yes/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	8
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	8
Small firms Small Firms Impact Test guidance	No	8
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	8
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	8
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	8
Human rights Human Rights Impact Test guidance	No	8
Justice system Justice Impact Test guidance	No	8
Rural proofing Rural Proofing Impact Test guidance	No	8
Sustainable development Sustainable Development Impact Test guidance	No	8

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB 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

Include the links to relevant legislation and publications, such as public impact assessment of earlier stages (e.g. Consultation, Final, Enactment).

No.	Legislation or publication
1	The Diseases of Animals (Approved Disinfectants) (England) Order 2007
2	The Diseases of Animals (Approved Disinfectants) (Fees) (England) Order 2010
3	
4	

+ 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										
Annual recurring cost		0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Total annual costs		0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Transition benefits										
Annual recurring benefits										
Total annual benefits										

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

Microsoft Office Excel Worksheet

Evidence Base (for summary sheets)

Problem Under Consideration

The testing and approval of disinfectants is carried out on behalf of DEFRA by the VLA and IAH ("Institute for Animal Health") so that in the event of a disease outbreak (such as foot and mouth) disinfectants are efficacious to work on specific viruses and bacteria. There is a statutory requirement for cleansing and disinfection and only approved disinfectants can be used in the event of an outbreak and these must be approved by DEFRA. Disinfectant approvals are renewed by the VLA every two years and during a recent renewal exercise several disinfectants were found to have changed their composition, changing the efficacy of the product. In order to ensure that all disinfectants are efficacious it has been decided to implement regular testing of approved disinfectants which will be funded by an annual subsistence charge payable by disinfectant manufacturers.

While in theory the industry could set up and operate a quality standard for disinfectants there are two reasons why this is not acceptable. The first is that we have a legal obligation to operate an official scheme under the various EU control directives for the notifiable exotic animal diseases. The Defra approval scheme fulfils that obligation. The second reason is that changes are sometimes made to the disinfectant formulations and these are not always notified to the VLA. Ministers must have confidence that disinfectants used under statutory conditions in a disease outbreak are reliable during an outbreak.

Following previous problems, a bi-annual paper renewals exercise was established whereby manufacturers are required to resubmit their formulations with a view to a simple check to monitor for a change in formulation. This provides a certain degree of comfort. Nevertheless, the VLA do know from experience that check tests on product bought off the shelf do expose failures even where previous paper checks have been ok and these need to be explored with the manufacturer. For example, there may be an issue with a particular batch exposing a quality control problem or it may be that some other change has taken place, perhaps with a non active ingredient that has an effect under biological conditions. We are therefore increasing the test frequency from once in 30 years to once in 5 years together with a paper check every two years. We have challenged industry representatives as to whether they consider the level is adequate and they are content it will meet their needs in providing an adequately robust system.

Rationale for the Intervention

The quality of a disinfectant is difficult to observe. Consumers and Government therefore have imperfect information about the quality of a disinfectant and laboratory tests are required to determine their efficacy. Defra oversees the approval of disinfectants and part funds the VLA in order to make sure that the disinfectants that are approved will work as intended during a disease outbreak. Intervention is appropriate in order to make sure that the disinfectants regime is robust thus ensuring that Government and consumers are confident in the quality of their product. Manufacturers rely on the approval system in order to sell their produce on a domestic and international level. Should approved disinfectants not be available during a disease outbreak consumers would be unable to use approved products which would prove financially damaging for disinfectant manufacturers as well as the economy in general, through disease not being controlled and managed effectively.

Policy Objective

The policy objective is to ensure that the Government and consumers have confidence that disinfectants approved by Defra will work as intended in the event of a disease outbreak.

Description of Options Considered

Option 1

To leave the current disinfectants system as it is. The current administration fee charged to new applicants does not cover the two year paper check exercise, other administrative costs and only funds check tests at a frequency of about one test for each disinfectant every thirty years. Leaving the current system as it is would mean that disinfectants cannot be checked on a more regular basis with the possibility of them not being suitable for use during a disease outbreak. The industry depends on disinfectant approvals to enhance the sales of their products. If the integrity of the approvals system is compromised then the implications for disinfectant sales would have serious consequences for the industry.

Option 2

Reduce the current administration fee for new applications (that is, remove the check test element of current administration fee for new applications), and introduce an annual subsistence fee payable per approved disinfectant per test each year – this annual fee would allow the VLA to undertake the two year paper renewal scheme and check test products at a frequency of about once every five years. This revised system would provide government with greater confidence in disinfectants being capable for use during a disease outbreak. This is the preferred option.

Option 3

Introduce a fee for each disinfectant test conducted, payable by the manufacturer when the test takes place. This system would cover the costs of the tests and provide Government with confidence that the disinfectants will be suitable for use during a disease outbreak. However, as the tests could take place at any time dependent upon laboratory availability, it does not give manufacturers stability in charges. Further, it also may not create a consistent revenue stream for the VLA as the tests may only occur at certain periods.

Risks and Assumptions

The analysis assumes that the VLA is able to cover its testing costs with an annual subscription fee of £350 alongside a joining fee of £1000. If these fees do not cover the costs of the VLA then it is possible that the fees analysed here will need to change. It has also been assumed that the growth in new products listed and approval orders will be offset by those products leaving the scheme as a result of failed check tests. It is likely that the number of failed check tests will be higher early on in the scheme as manufacturers will not be accustomed to the new level of scrutiny. As a policy of this type hasn’t previously been implemented in this market it is unknown what the reaction of manufacturers will be. There is therefore the risk that disinfectant manufacturers will not apply for Defra approval of their disinfectants if they believe the costs are too high. Nevertheless, we assume that the extra profit generated from being an approved disinfectant will outweigh the cost of the new subsistence fee.

Costs and benefits of preferred option

Costs to Government

The VLA will undertake a two year paper renewal scheme of disinfectants and check test products at a frequency of about once every five years. This will be funded by annual fees payable by disinfectant manufacturers. The estimated annual cost of conducting the required number of tests is outlined in the table below:

Table 1: Costs to VLA of conducting testing regime

Procedure	Quantity	Unit Price (£)	Total Cost (£)
Foot and Mouth Disease	14	1920	26,880
Swine Vesicular Disease	11	1920	21,120
Diseases of Poultry Order, Avian Influenza & Influenza of Avian Origin in Mammals	22	1040	22,880
Tuberculosis	3	1300	3,900
General Orders	19	715	13,585
Test Co-ordination	37hrs 45mins	48.51 per hour	1,831
Distribution and witness of sub-sampling	40hrs	51.14 per hour	2,046
Disinfectant purchase	30	150	4,500
Results Processing	83hrs 45mins	48.51 per hour	4,063
Total			**100,805**

Notes: It has been implicitly assumed here that all products which are tested pass the tests and no fails are recorded. While this assumption is likely to be incorrect and is inconsistent with previous assumptions that the number of new applicants is offset by the number of check tests failed. The difference in costs incurred by the VLA in passing and failing check tests is marginal, so for simplicity it is assumed that there are no failed check tests.
Source: VLA

There are additional costs incurred by the VLA in administering the disinfectant approval order system, however, these costs are existing costs and do not arise as a result of the new testing procedure. These costs are therefore present in Policy Option 1 as well as Policy Option 2 and so are not appraised here.

Option 3 which is not the preferred option, involves the same testing regime however it replaces the annual fee to manufacturers with a fee payable when the testing takes place. Given that there are no changes to the cost of the testing regime and manufacturers will still have to pay the same amount, albeit at different times, it is assumed that Option 3 incurs the same costs and benefits as Option 2.

Costs to business

To fund the VLA testing procedure a new annual fee of £350 per annum for all Defra approved disinfectants will be introduced. The fee for joining the Defra approval scheme will fall from £1,770 to £1,000. There are currently 326 approval orders, which each require an annual fee. The scheme averages around 19 new successful applicants per year however, it is assumed

that these new applicants are offset by the number of disinfectants failing the check tests and therefore leaving the scheme so there is no assumed growth in the number of approval orders in existence over time. The full costs and benefits to the disinfectant industry are outlined in the table below. The costs to business have been treated as a transfer from business to Government so therefore they are not included in the NPV calculation.

Table 2: Transfer from disinfectant manufacturers to Government

Year (£)	0	1	2	3	4	5	6	7	8	9	10
Costs											
Approval Orders	326	326	326	326	326	326	326	326	326	326	326
Annual Fee	-	350	350	350	350	350	350	350	350	350	350
Costs		**114,100**	**114,100**	**114,100**	**114,100**	**114,100**	**114,100**	**114,100**	**114,100**	**114,100**	**114,100**
Benefits											
New Approval Orders		19	19	19	19	19	19	19	19	19	19
Reduction in fee		770	770	770	770	770	770	770	770	770	770
Benefits		14,630	14,630	14,630	14,630	14,630	14,630	14,630	14,630	14,630	14,630
NPV		**-96,106**	**-92,856**	**-89,716**	**-86,682**	**-83,751**	**-80,919**	**-78,183**	**-75,539**	**-72,984**	**-70,516**
										Total	**-827,253**

Source: VLA

Benefits

It is extremely difficult to quantify the potential benefits from a more stringent disinfectant testing regime however, ensuring that the disinfectant approval scheme remains robust will lead to significant benefits for Government, the disinfectant industry and consumers.

This policy will help ensure that a robust and reliable disinfectant approval system is in place. It will therefore provide assurance to Government and businesses that approved disinfectants will be effective during a disease outbreak and will help prevent disease spread. Consumers have imperfect information about the quality of disinfectants, a credible approval system ensures consumer confidence that a product is effective.

The disinfectant approval scheme is recognised internationally and generates a substantial amount of business for manufacturers who may be unable to sell their product without approval from a credible scheme. While sales figures are confidential, the industry estimates that the sales for the industry that depend on a robust Defra approval scheme are likely to exceed £1 million in the UK and to exceed £10 million internationally.

Administrative Savings and Policy Burden Calculator

There will be negligible administrative costs for businesses limited to confirming whether they wish to keep the current approval for their product and sending the annual fee to the VLA.

Wider Impacts

No Wider Impacts are forseen.

Specific Impact Tests

Impact on Competition

The annual fee applies uniformly to all Defra approved products and does not differentiate in any way between different disinfectants. The most it will cost to keep one product listed is £1750 per year (if all 5 Orders are renewed) and the least, £350 (one Order), it is therefore unlikely to discourage firms from entering or leaving the market. Non-approved disinfectants are prohibited from use during a disease outbreak which limits the potential for non-approved disinfectants to compete. However, this is currently the status-quo and this Impact Assessment

is only intended to cover the impact of the introduction of an annual fee rather than the regulation as a whole.

Small Firms
The disinfectant market is made up of a mixture of large and smaller firms. The larger firms will generally have more products and therefore will pay for more approval orders. Despite the existence of smaller firms the charges are still relatively small and are therefore unlikely to have a disproportionate impact on smaller firms. It is unclear how firms of varying size will react to the policy, furthermore the exact composition of the market isn't entirely understood therefore we have not been able to quantify the impact on firms of varying size.

Rural Proofing
Disinfectant manufacturers are predominantly located in industrial areas so in this context the policy does not have a disproportionate impact on the rural community. While the disinfectants are predominantly used by rural agricultural producers, the charges to disinfectant manufacturers are relatively small and will therefore have only a negligible impact on the price they charge for their products.

Summary and Preferred Option with Description of Implementation Plan

An initial discussion has been held with representatives of the industry. Initial industry views are that while they will be reluctant to pay an annual subsistence fee, they recognise that the scheme must be properly maintained and they and their customers must have confidence in it. They do consider that it is fair that those in the scheme should contribute to its maintenance.

The proposed changes only affect the disinfectant manufacturing industry and we will consult with those concerned.

We aim to then revise the disinfectants fees order in time for implementation in April 2011.

It is expected that the Fees will be reviewed annually and an annual increase should be anticipated to be at least in line with inflation.

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

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: N/A
Review objective: N/A
Review approach and rationale: N/A
Baseline: N/A
Success criteria: N/A
Monitoring information arrangements: N/A
Reasons for not planning a PIR: The fees will be reviewed on an annual basis therefore it is no necessary to conduct a formal PIR.