EXPLANATORY MEMORANDUM TO

THE DISEASES OF ANIMALS (APPROVED DISINFECTANTS) (FEES AND AMENDMENT) (ENGLAND) ORDER 2011

2011 No. 1509

1. This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before the House of Commons by Command of Her Majesty.

2. Purpose of the instrument

2.1 The instrument revokes and replaces the Diseases of Animals (Approved Disinfectants) (Fees) (England) Order 2010. It reduces the fee for administrative services relating to an application for approval of a disinfectant but otherwise the table of application fees remains the same as in the 2010 Order. An annual fee is introduced by the instrument, and the Diseases of Animals (Approved Disinfectants) Order 2007 S.I. 2007/448 ("the 2007 Order") is amended so that non-payment of that annual fee can result in suspension and ultimately revocation of the approval of the disinfectant.

3. Matters of special interest to the Select Committee on Statutory Instruments

The instrument introduces a new annual fee payable by the disinfectant manufacturers on 1 September in every year to cover the costs of the Secretary of State ensuring that disinfectants remain efficacious and the formulae is not changed from that which was originally approved.

4. Legislative Context

EU animal disease legislation requires competent authorities in each member state to set up a process for approval of disinfectants that are efficacious in cleansing and disinfecting infected premises and other potentially contaminated things. The 2007 Order is made under section 1 of the Animal Health Act 1981 and provides for the Secretary of State to approve disinfectants for use in certain circumstances and against certain animal diseases if they can demonstrate efficacy during laboratory testing. Section 84 of the Animal Health Act 1981 provides legislative power to charge for testing and related matters. The instrument replaces the Diseases of Animals (Approved Disinfectants) (Fees) (England) Order 2010 to reduce the administration fee for applications for approvals whilst introducing a new annual fee to cover the actual costs of post-approval monitoring of approved products related administrative costs and maintenance of the scheme/list.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

What is being done and why

7.1 In the event of animal disease outbreaks there is a statutory requirement for cleansing and disinfection. Only disinfectants approved by a member state may be used for this purpose. The initial testing of disinfectants is carried out by the department's executive agency, the Animal Health and Veterinary Laboratories Agency (AHVLA) to confirm they are effective against specific viruses and bacteria and can therefore be approved under the 2007 Order. That Order provides for disinfectant approvals to be renewed by the AHVLA every two years and the Secretary of State may re-test marketed product at any time. There are no fees currently charged to cover the cost of renewals or re-tests.

7.2 During recent post-approval testing it was found that several manufacturers had changed the composition of their approved disinfectants since the original application for approval, affecting the efficacy of the product. In order to ensure that all disinfectants are efficacious it is necessary to implement more regular post-approval testing of the disinfectants. The annual charge on manufacturers will cover the administrative costs and check tests required to verify that our approvals scheme is sufficiently robust.

7.3 Manufacturers apply for approval on a voluntary basis. Disinfectants will only be added to the list of 'approved' disinfectants if they demonstrate at the time of application efficacy of their product during laboratory testing. Applications will only be progressed on receipt of the administrative fee for dealing with the application and the relevant test fees as set out in the Schedule of the instrument dependent on the proposed use of the product.

8. Consultation outcome

8.1 There has been a one month consultation by communicating directly with the 61 disinfectant manufacturers who will pay these fees. Ministers agreed that because of the small numbers affected, and the earlier discussions that had already taken place with the key industry representatives where it was clear that the reason for introducing more regular post approval testing was an appropriate way forward, it would not be necessary to conduct a full 12 week public consultation. Of the 61 companies that were contacted during the consultation only 6 responded and 5 of these respondents were in agreement with the principle and rationale of the changes to the fee structure in order to protect the overall integrity of the disinfectants approval scheme.

8.2 Industry stakeholders are already aware of the proposed changes to the fees and will be individually informed in April of the date for payment of the annual fee that is payable on 1 September. Following the consultation exercise it was decided that the annual fee of £375 would be appropriate in order for the AHVLA to be able to recover their actual costs of operating and maintaining a more robust approvals scheme.

9. Guidance

The AHVLA will be writing to each of the 61 disinfectant manufacturers to explain the new fee structure and when the annual fee will be payable (by 1 September). The VLA will update its internet pages to provide further guidance to this small group of affected manufacturers.

10. Impact

10.1 The impact on businesses, charities or voluntary bodies is considered to be minimal. The annual fee will apply uniformly to all approved products and does not differentiate between different disinfectants. Manufacturers apply for approval of their product on a voluntary basis which is test and fee based. The fees are unlikely to discourage firms from entering or leaving the market. The approval and post-approval monitoring mechanism maintains a level competitive playing field; all disinfectant manufacturers have equal access to take advantage of the approval scheme if they wish to market their product for the specific purpose of protecting premises and equipment against certain animal diseases. The scheme therefore maintains equity and fairness.

10.2 This policy will help ensure that a robust and reliable disinfectant approval system is in place. It will provide assurance to Government and businesses that approved disinfectants will be effective during a disease outbreak and will help to prevent disease spread. The cost to the taxpayer from paying compensation to keepers of farm animals that have to be killed during an outbreak can be very substantial and therefore it is vital that effective disinfectants are used to lessen the financial impact of such a disease outbreak. Users have imperfect information about the quality of disinfectants, and therefore a credible approval system ensures consumer confidence that a product will be effective.

10.3 The Defra disinfectant approval scheme that is run by the AHVLA is recognised internationally and generates a substantial amount of business sales for manufacturers. The devolved Administrations do not operate their own schemes and rely on the Defra scheme for disinfectant approvals in their territories.

10.4 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

11. Regulating small business

11.1 The legislation applies equally to all manufacturers of disinfectants wishing to seek approval for their product. 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 more in fees for a higher number of tests. Despite the existence of smaller firms that also manufacture disinfectants our assessment is that the introduction of this annual fee is unlikely to have a disproportionate impact on smaller firms.

11.2 Interested trade representatives of both the large and smaller producers were involved in pre-consultation discussions with the department regarding the need for more post-approval testing and hence the need to introduce an annual fee. Those representatives did not identify serious concerns and neither did they propose any alternative solution.

12. Monitoring & review

12.1 The AHVLA manages the disinfectants scheme and will oversee the proposed changes. The fees for operating the scheme are reviewed annually.

13. Contact

John O'Rourke at the Department for Environment, Food and Rural Affairs, Tel: 020 7238 3185 or e-mail: john.orourke@defra.gsi.gov.uk can answer any queries regarding the instrument.

Title:	Impact Assessment (IA)
Impact Assessment of The Diseases of Animals Approval for Disinfectants	**IA No:** Defra 1135
Lead department or agency: Defra	**Date:**
Other departments or agencies: The Animal Health and Veterinary Laboratories Agency	**Stage:** Final
	Source of intervention: EU
	Type of measure: Secondary 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 Animal Health and Veterinary Laboratories Agency (AHVLA) to confirm they are effective against specific viruses and bacteria. Disinfectant approvals are renewed by the AHVLA 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 at home and abroad.

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

3 options were considered, further details are in the Evidence Base. Option 1: Retain the current system, 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 AHVLA to undertake a 2 year paper test plus a 5 year laboratory test of all disinfectants. This option provides stability of charges for manufacturers and the disinfectant tests will improve the credibility of the system and enhance disease control in the event of an outbreak. This is our chosen option. A consultation with industry was completed in January 2011. Of the 62 companies consulted only 6 responded. Whilst all 6 responses said industry would have to take on extra costs 3 of the returns agreed that it was important to retain faith in the disinfectants system.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 11/2011	
What is the basis for this review? Please select. **If applicable, set sunset clause date:** Month/Year	
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

SELECT SIGNATORY Sign-off For final proposal stage Impact Assessments:

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

Signed by the responsible SELECT SIGNATORY: Jim Paice Date: 25th May 2011

Summary: Analysis and Evidence

Policy Option 1

Description:

Price Base Year 2010	PV Base Year 2010	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	**High:**	**Best Estimate: -£0.9m**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate			£0.1m	**£0.9m**

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

The AHVLA will undertake a 2 year paper test plus a 5 year laboratory testof all approved disinfectants. To fund these tests as well as associated administration costs an annual fee of £375 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 £0.9m in NPV 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'

Provide assurance that disinfectants will be effective during an outbreak and will prevent disease spread. Consumers and Govt have imperfect information on the quality of disinfectants used for exotic disease, a credible approval system ensures confidence that a product is effective. The disinfectants scheme is recognised internationally, industry estimates that sales for the industry of disinfectants which are dependent on having the Defra approval label are likely to exceed £1m in the UK and £10m 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 AHVLA 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 some disinfectant manufacturers will not apply for Defra approval of their disinfectants if they believe the costs are too high.

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0.1	**Benefits:**	**Net:** -0.1	No	NA

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			01/04/2011		
Which organisation(s) will enforce the policy?			N/A		
What is the annual change in enforcement cost (£m)?			£0m		
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:**		**Non-traded:**
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	9
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	9
Small firms Small Firms Impact Test guidance	No	9
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	9
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	9
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	9
Human rights Human Rights Impact Test guidance	No	9
Justice system Justice Impact Test guidance	No	9
Rural proofing Rural Proofing Impact Test guidance	No	9
Sustainable development Sustainable Development Impact Test guidance	No	9

[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

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.

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	Thttp://www.defra.gov.uk/corporate/consult/disinfectants/index.htm
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

Problem Under Consideration

The testing and approval of disinfectants is carried out on behalf of DEFRA by the AHVLA (N.B. Animal Health and the Veterinary Laboratories Agency merged on 1 April 2011 to create the Animal Health and Veterinary Laboratories Agency - AHVLA) 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 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 AHVLA 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 AHVLA. 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 AHVLA do know from experience that check tests on products 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 AHVLA 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 and our EU obligations are fully met. Manufacturers rely on the approval system in order to sell their produce on a domestic and international level. If approved disinfectants are marketed but are not fully effective, our ability to control outbreaks of exotic animal diseases will be reduced risking a longer outbreak and extra costs to government, the farming industry and rural economy.

Policy Objective

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

Description of Options Considered

The following three options were considered while developing a proposal to reform the disinfectants approval system. During the informal discussions and meetings to develop ideas we asked industry representatives to consider whether there were any other options they wanted to put forward. Industry was content that these were the three key possibilities. Therefore we consulted formally with all industry contacts on these options which were included in the consultation impact assessment in December 2010. The consultation ended in January 2011. Sixty two companies affected by the proposals were consulted and six companies responded to the consultation. Although all six responses made reference to the industry having to shoulder additional costs three of the returns agreed that it was important to have faith in the disinfectants regime and that the system needed to be robust and to retain credibility. The consultation indicated that option 2 was the preferred proposal and this was agreed by industry.

Detailed options on which we consulted were:

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. Officials and industry did not support this way forward.

Option 2 – Preferred Option

Reduce the current administration fee for new applications (that is, remove the inadequate check test element of the 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 AHVLA to undertake the two year paper renewal scheme and check test products at a frequency of about once every five years. The decision to test every five years was agreed after discussions with industry and was based on a number of considerations key of which were:

- To balance the need for increased check testing without overburdening industry with increased costs.
- The five year test schedule is the maximum throughput each laboratory can manage without incurring the need to invest in additional laboratory facilities or other resources. Any additional costs would have to be charged to industry as the AHVLA must operate full cost recovery.
- A five year check test will increase the chances of the AHVLA identifying a failed disinfectant by about five or six times each year.

- Other possibilities (e.g. test every batch at every two year renewal) would impose disproportionate burdens on industry and would also require the AHVLA to invest in additional resources, the cost of which would have to be passed on to industry.

The decision to go for five years is based on a number of factors. We recognise the need to monitor the scheme and will review this with industry after two years to see whether the revised scheme is meeting its objectives. Officials and industry agree that this is the preferred option.

Option 3

Introduce a fee at the time each disinfectant check test is conducted, payable by the manufacturer when the test takes place (once every five years). This system would cover the predicted actual costs of the tests and provide Government and industry with confidence that the disinfectants will be suitable for use during a disease outbreak. However, the existing cycle of testing would have resulted in some manufacturers paying significant sums in some years and nothing in others. This would have particularly adversely affected the smaller manufacturing businesses. It would also not create a consistent revenue stream for the AHVLA to operate all parts of the scheme each year. Only one manufacturer preferred Option 3 however once the disadvantages of this proposal were explained they opted not to pursue this proposal any further. Officials and industry did not support this way forward.

Risks and Assumptions

The analysis assumes that the AHVLA is able to cover its testing costs with an annual subscription fee of £375 alongside a joining fee of £1,000. If these fees do not cover the costs of the AHVLA 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 some disinfectant manufacturers will not apply for Defra approval of their disinfectants if they believe the costs are too high. However, we think this is unlikely; during consultation industry stated that the disinfectants approval scheme generates a substantial amount of business for them relative to those who try to market without such approval certification.

Costs and benefits of preferred option

Costs to Business

The AHVLA 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 AHVLA 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	22	1040	22,880

of Avian Origin in Mammals			
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 AHVLA in passing and failing check tests is marginal, so for simplicity it is assumed that there are no failed check tests.
Source: AHVLA

In line with Treasury policy the AHVLA must operate full cost recovery however there are also existing costs incurred by them in administering the disinfectant approval order system that are currently not covered. These costs include processing fees, renewing approvals and processing new applications. The fees charged to industry are expected to cover these existing costs as well as the new testing costs. These costs outside of the testing regime were not fully recovered in recent years so the changes to fees payable by manufacturers are also planned to cover these costs in full as well as the cost of the new tests.

To fund the AHVLA testing procedure a new annual fee of £375 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 337 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.

Table 2: Cost to industry of changes to disinfectant approval fees

Year (£)	0	1	2	3	4	5	6	7	8	9	10
Costs											
Approval Orders	337	337	337	337	337	337	337	337	337	337	337
Annual Fee	-	375	375	375	375	375	375	375	375	375	375
Costs		**126,375**	**126,375**	**126,375**	**126,375**	**126,375**	**126,375**	**126,375**	**126,375**	**126,375**	**126,375**
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		**-107,966**	**-104,315**	**-100,788**	**-97,379**	**-94,086**	**-90,905**	**-87,831**	**-84,860**	**-81,991**	**-79,218**
										Total	**-929,339**

Source: VLA

Benefits

A revised disinfectant testing regime 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 and fully complies with EU obligations.

The Defra disinfectant approval scheme is recognised internationally and generates a substantial amount of business from third countries where the GB scheme is seen as being the "gold standard". 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. It is this business that will be jeopardised if the scheme loses credibility.

We have consulted on this point with the disinfectants industry who agree that the disinfectants scheme (whereby they are entitled to place a Defra approval certification on their label) generates a substantial amount of business for them as opposed to those who try to market without such approval certification. They agree that this scheme must remain credible both domestically and internationally in order for their customers to continue to choose to buy their disinfectants over those that are not similarly certified. They see this as a distinct benefit that assists with their sales.

If the scheme falls into disrepute and loses credibility, industry may lose business opportunities to sell to third countries and particularly Middle Eastern countries who have great faith in the Defra approval system and who may then turn to disinfectants manufactured and approved by other Community member States. Northern Ireland and the Republic of Ireland also require their manufacturers to have Defra Approval. Through these proposed changes we are enabling business to continue to benefit from these big market opportunities abroad.

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 AHVLA.

Wider Impacts

No Wider Impacts are foreseen.

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 £1875 per year (if all 5 Orders are renewed) and the least, £375 (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. These views were born out in a recent consultation where the majority of the responses to the consultation agreed that it was important to retain confidence in the disinfectants approval regime.

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

One In One Out

This proposal is out of scope of one in one out as the Diseases of Animals (Approved Disinfectants) (Fees) (England) Order implements requirements in Community legislation and EU measures are out of scope of one in one out. There are Community requirements in a number of control directives that say that the "disinfectants used (for the relevant disease) must be approved by the competent authority". The approved disinfectants Order implements those obligations. In most instances the community requirements also require the disinfectants to be of a certain quality or "concentration" in order to deal with infection. The current revision to the Disinfectants Fees Order also ensures that the quality and concentration of disinfectants is maintained. Relevant EU Directives include:

Council Directive 92/40 on the control of Newcastle disease – Article 11:

> Member States shall ensure that:
> (a) the disinfectants to be used and their concentrations are officially approved by the competent authority;

Council Directive 92/119 on a range of diseases including swine vesicular disease – Article 16

> 1. Member States shall ensure that:
> (a) the disinfectants and insecticides to be used and, where appropriate, their concentrations, are officially approved by the competent authority;

Council Directive 2001/89 on the control of classical swine fever – Article 12:

> 1. Member States shall ensure that:
> (a) the disinfectants to be used and their concentrations are officially approved by the competent authority;

Council directive 2002/60 on the control of African swine fever – Article 12:

> Member States shall ensure that:
> (a) the disinfectants and insecticides to be used and their concentrations are officially approved by the competent authority;

Council Directive 2003/85 on the control of foot and mouth disease – Annex IV

> Paragraph 1.2:
>
> The disinfectants to be used and their concentrations shall be officially recognised by the competent authority to ensure destruction of foot-and- mouth virus.
>
> Paragraph 2.1.3:
>
> As soon as the carcasses of the animals of susceptible species have been removed for processing and disposal, those parts of the holding in which these animals were housed and any parts of other buildings, yards, etc. contaminated during killing, slaughter or post-mortem examination should be sprayed with disinfectants approved for this purpose.

Council directive 2005/95 on the control of avian influenza and influenza of avian origin in mammals – Article 48

> Member States shall ensure that the disinfectants to be used and their concentrations are authorised by the competent authority.

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. If the policy is subject to a sunset clause, the review should be carried out sufficiently early that any renewal or amendment to legislation can be enacted before the expiry date. 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: [The basis of the review could be statutory (forming part of the legislation), i.e. a sunset clause or a duty to review , or there could be a political commitment to review (PIR)];
Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]
Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]
Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]
Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review]
Reasons for not planning a review: [If there is no plan to do a PIR please provide reasons here] The fees will be reviewed on an annual basis therefore it is not necessary to conduct a formal PIR.