

**EXPLANATORY MEMORANDUM TO THE
DISEASES OF ANIMALS (FEES FOR THE TESTING OF DISINFECTANTS)
ORDER**

2005 No. 379

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

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 Replacement of the Diseases of Animals (Fees for the testing of Disinfectants) Order 1991. The new Order increases the fees payable for the testing of disinfectants.

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

3.1 The Order increases the fees payable for the testing of disinfectants. These fees have not been increased since 1991.

4. Legislative background

4.1 The Animal Health Act 1981 and the Diseases of Animals (Approved Disinfectants) Order 1978 (made under the 1981 Act) provide 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 tests. The Animal Health Act 1981 provides legislative power to charge for testing.

5. Extent

5.1 This instrument applies to England.

6. European Convention on Human Rights

6.1 Not applicable.

7. Policy background

7.1 Veterinary disinfectants are a vital component of animal disease control strategies, both in the everyday prevention of disease and in controlling disease spread during epidemic outbreaks. Defra has put in place a statutory mechanism under the Diseases of Animals (Disinfectants Approvals) Order 1978. This allows disinfectants to be placed on an approved list for control of different diseases if they can be demonstrated to be efficacious in laboratory tests.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

8.2 During the consultation exercise comments were invited on the regulatory impact assessment. Some support was received for the increase in charges and for this regulatory mechanism to be self-financing. No serious objections or evidence was received to suggest that the increase in fees would have a disproportionate impact on the industry.

9. Contact

Ivy Wellman at the Department of Environment, Food and Rural Affairs, Telephone 020 7904 6041 or e-mail ivy.wellman@defra.gsi.gov.uk can answer any queries regarding this instrument.

Regulatory Impact Assessment

Revision of The Diseases of Animals (Fees for the Testing of Disinfectants) Order 1991

1. Purpose and intended effect of measure:

To amend the Diseases of Animals (Fees for the Testing of Disinfectants) Order 1991 to recover the increased costs of statutory tests of veterinary disinfectants under the Diseases of Animals (Approved Disinfectants) Order 1978. The Fees Order was last amended in 1991 and is in urgent need of updating.

2. The objective:

It is Defra policy that regulatory and approval regimes should be cost-neutral, and that regulatory bodies charge appropriate fees to recover the costs of processing applications for consent or approval. The current Fees and Charges, set out under the The Fees Order, are now out of date and the costs of testing the disinfectants are now higher than the amount charged to the disinfectants industry. In order to address this increasing shortfall, it is necessary to increase our fees in a revised Order

The objective of this proposal, therefore, is to amend the Fees Order to recover the costs of the statutory testing carried out by the two laboratories on Defra's behalf. At this stage, no increase in fees to cover Defra's administrative costs is proposed. Defra will be shortly issuing proposals for an overhaul of the approvals scheme. Once the running costs of the scheme have been calculated, consideration will be given to whether the Fees Order needs to be amended again.

3. Background

Veterinary disinfectants are a vital component of animal disease control strategies, both in the everyday prevention of disease and in controlling disease spread during epidemic outbreaks.

There are disease-specific EU Directives that require Member States to use only approved disinfectants in a disease outbreak.

Defra has put in place a statutory mechanism under the Diseases of Animals (Disinfectants Approvals) Order 1978. This allows disinfectants to be placed on an approved list for control of different diseases if they can be demonstrated to be efficacious in laboratory tests.

The statutory testing of veterinary disinfectants is carried out for Defra by two laboratories: the Veterinary Laboratories Agency and the Institute of Animal Health. Test methodologies vary in their complexity depending on the disease. All methodologies must be rigorous, provide consistent and accurate results and be conducted by experts in *appropriate facilities where testing* can be carried out safely. For example, the Institute of Animal Health at Pirbright is the only laboratory in the UK equipped to undertake efficacy testing of disinfectants against Foot and Mouth Disease. Test methodologies have been enhanced with experience and to make effective use in advancements in laboratory equipment technology.

4. Risk assessment

To do nothing would result in a continued discrepancy between actual costs of testing (paid by Defra) and those charged to the manufacturer. No action means that the taxpayer subsidises the cost of testing for the disinfectant industry. A revision to the

Fees Order would result in the approval system operating on a full cost recovery basis.

5. Options

The charge for each of the tests is based on the actual hours by graded staff needed to perform the test, together with the materials used, the complexity of the test and difficulty of the methodology. For example, the bacterium used to test the efficacy of a disinfectant against Tuberculosis is difficult to maintain in laboratories. Also, a high risk is posed by some pathogens; for example, the virus causing Foot and Mouth Disease and therefore testing needs to be carried out in high containment conditions.

There are three options:

1. The fees could remain at 1991 prices. However, it is not considered appropriate for Defra to continue to subsidise product testing when manufacturers profit from the sale of their products;
2. The fees could be revised to recover the full cost of the testing. As the price increases are relatively modest, despite the time lapse since the last revision, it seems reasonable to recover the full cost of the tests from the manufacturer;
3. The fees could be revised to recover the full cost of the testing and the increase in administrative charges. The administrative cost for each submission for testing of a disinfectant is £1,033.00

It is proposed that The Fees Order is amended along the lines of Option 2. Defra intends to issue proposals for a fundamental overhaul of the veterinary disinfectants approval process in due course. It is anticipated that administrative costs will be reduced under the new mechanism. So, for now, it is proposed to revise the fees to reflect the actual cost of the tests. It is considered that, given the complexity of the tests and their importance in ensuring efficacy, fee increases are reasonable.

In practice, the proposal means the fee for each test will be as follows:

Table 1:

	Current fee (£)	Revised fee (£)	Price increase (£)
Administration	134.00	134.00	-
Efficacy test against:			
Foot and Mouth Disease	381.00	750.00	369.00
Swine Vesicular Disease	381.00	750.00	369.00
Diseases of Poultry - single dilution test.	385.00	659.00	274.00
Diseases of Poultry - triple dilution test.	508.00	874.20	366.20
Tuberculosis	247.00	1,110.00	863.00
General Orders	247.00	606.00	359.00

6. Costs and Benefits

Economic

There are marketing benefits to manufacturers from having their disinfectants approved by Defra. The Defra Approval mechanism has international recognition and provides opportunities for domestic manufacturers to market their products abroad.

The fee charged to manufacturers is for each application for a product to be approved and is therefore paid only once. It is probable that the charges manufacturers face in having their products approved are already passed to customers as part of the selling price. It is also likely that the manufacturers will transfer all or part of the increase in fees to the consumer as an increase in selling price. This is a decision for the manufacturers. The veterinary disinfectant market is large and its customer base varied with products used on farms, marketplaces, slaughterhouses, show grounds and during the transport of animals.

A working assumption is that thousands of litres of disinfectants are sold annually. It is reasonable to assume that any price increase for a given unit of disinfectant would be a minor one.

Environmental

Not applicable as the amendment to the Order relates to recovery of costs for testing only.

Social

Not applicable as the amendment to the Order relates to recovery of costs for testing only.

Issues of equity and fairness

All disinfectants must be tested in order to gain approval for specific uses. Defra's approvals mechanism maintains a level competitive playing field; all disinfectant manufacturers have access to the tests and then the marketplace if the disinfectant is granted approval. The scheme therefore maintains equity and fairness.

The cost of the approval mechanism is relatively low compared to other regulatory regimes, for example pesticide approvals.

7. Consultation with small business: the Small Firms' Impact Test

Interested stakeholders from the manufacturing industry have been involved in preliminary discussions since July 2003. Formal consultation with these and a wider range of interested parties is in progress.

8. Competition Assessment

The approval system is already test and fee based. Approval is only granted based on efficacy. This scheme does not affect competition. All companies have equal access to the approval mechanism if they wish to gain approval for their product to be used for the control of specific diseases.

9. Enforcement and Sanctions

Manufacturers apply for approvals on a voluntary basis. Defra currently administers the Approval system and will continue to do so. Disinfectants will only be added to the 'Approved List' for specific diseases if they have passed Defra efficacy tests. Testing will not be carried out without an advanced fee. This approach has been used for a sufficient period to show that it already achieves adequate enforcement of the system.

10. Monitoring and Review

The Fees Order will be reviewed regularly to ensure that it operates on a cost recovery basis.

11. Consultation

Within Government: appropriate Divisions within Defra, Agencies and the Devolved Administrations have been consulted.

Public Consultation: industry stakeholders have been consulted informally. Defra is in the process of formal consultation with a wider range of interested parties.

12. Summary and Recommendation

This Regulatory Impact Assessment supports and recommends option 2 for the revision of The Diseases of Animals (Fees for the Testing of Disinfectants) Order 1978, in that for now fees will only be increased to recover the costs of testing. This does not cover development of tests or related activities. As administrative arrangements are being reviewed, it is not appropriate to amend fees for this at this time.

13. Declaration

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed : Ben Bradshaw

Date : 10 February 2005

**Ben Bradshaw,
Parliamentary Under-Secretary of State
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