

**EXPLANATORY MEMORANDUM TO
THE DISEASES OF ANIMALS (APPROVED DISINFECTANTS) (FEES) (ENGLAND)
ORDER 2010**

2010 No. 739

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

2. Purpose of the instrument

2.1 The Statutory Instrument replaces the Diseases of Animals (Approved Disinfectants) (Fees) (England) Order 2009. 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 and the administration fee to ensure that the approval regime operates on a cost recovery basis. These fees were last increased in April 2009.

4. Legislative Context

4.1 The Animal Health Act 1981 and the Diseases of Animals (Approved Disinfectants) Order 2007 (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 testing. The Animal Health Act 1981 provides legislative power to charge for testing.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

The Department of Environment, Food and Rural Affairs has made the following statement regarding 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 Veterinary disinfectants are a vital component of animal disease control strategies, both in the everyday prevention of disease and in controlling diseases spread during epidemic outbreaks. Defra has put in place a statutory mechanism under the Diseases of Animals (Approved Disinfectants) Order 2007. This allows disinfectants to

be placed on an approved list for the control of different diseases if they demonstrate efficacy during testing.

- 7.2 It is Government policy that regulatory and approval regimes should be cost neutral and that regulatory bodies charge appropriate fees to recover the cost of processing applications for consent or approval. A revision to the fees Order would result in the approval system operating on a full cost recovery basis.

7.3 The 2010 Order will revoke and replace the 2009 Order.

8. Consultation outcome

8.1 Industry are aware, through consultation, that fees associated with the approval mechanism are subject to regular review to ensure the scheme operates at full economic cost recovery to avoid any burden on the taxpayer. Fees have been revised annually in recent years.

8.2 Industry stakeholders will be informed of the proposed fees for the 2010 financial year.

9. Guidance

9.1 Manufacturers apply for approval on a voluntary basis. Disinfectants will only be added to the list of 'approved' disinfectants if they demonstrate efficacy during laboratory testing and testing will only be carried out after payment of the appropriate fee. This approach has been used for a sufficient period to show that it achieves adequate enforcement.

10. Impact

10.1 The impact on businesses, charities or voluntary bodies is considered to be minimal. Manufacturers apply for approval on a voluntary basis and it is already test and fee based. The approval mechanism maintains a level competitive playing field; all disinfectant manufacturers have equal access to the approval process if they wish to gain approval for their product 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.

10.2 The impact on the public sector is beneficial; by maintaining the operation of the approval mechanism on a cost recovery basis the public sector (and therefore the taxpayer) does not incur costs where industry benefit from the profits of the sale of their products.

10.3 An Impact Assessment has not been prepared for this instrument

11. Regulating small business

11.1 The legislation applies equally to all manufacturers of disinfectants wishing to seek approval for their product.

11.2 Interested stakeholders from the manufacturing industry were involved in preliminary discussions and formal consultation about the regular review of fees.

12. Monitoring & review

12.1 Efficacy testing is only completed after the payment of the appropriate fee so the instrument will achieve full recovery of costs. VAT will be paid in addition as the Veterinary Laboratories Agency must charge this to their commercial customers. The Institute of Animal Health also charge the Veterinary Laboratories Agency VAT on the tests they do for FMD and SVD.

13. Contact

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