EXPLANATORY MEMORANDUM TO

THE DISEASES OF ANIMALS (APPROVED DISINFECTANTS) (ENGLAND) ORDER 2007

2007 No. 448

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. Description

2.1 The Statutory Instrument provides for:

- compliance with the Biocidal Products Directive;
- a more responsive and efficient mechanism to approve disinfectants

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

3.1 None

4. Legislative Background

4.1 Disease specific EU Directives and domestic legislation requires that only approved disinfectants are used in particular circumstances and during a disease outbreak.

4.2 Currently, disinfectants are approved when they appear on Schedule 1 of an Amendment Order updating the Diseases of Animals (Approved Disinfectants) Order 1978.

5. Territorial Extent and Application

5.1 This instrument applies to England.

5.2 Scotland and Wales are preparing parallel legislation.

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

7.1 The objective of the 2007 Order is to ensure continued compliance with the Biocidal Products Directive while supporting a more efficient and responsive approval mechanism.

7.2 Approximately 90 interested parties were consulted on the draft instrument and 10 responses were received, all giving broad support to the proposals.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum

9. Contact

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

An alternative contact is Karen Skelton at the Department for Environment, Food and Rural Affairs, Tel: 020 7904 6035 or e-mail: karen.e.skelton@defra.gsi.gov.uk

Regulatory Impact Assessment

Revision of The Diseases of Animals (Approved Disinfectants) Order 1978

Defra is consulting with interested parties about changes to the legislation and mechanism for approving disinfectants.

The current mechanism operates under the Diseases of Animals (Approved Disinfectants) Order 1978. It needs to be amended to ensure that products approved by Defra comply with European legislation currently being phased into force and impacting upon disinfectants. The mechanism also needs to change to make it more responsive when product details and approvals change.

New legislation is needed to regulate the proposed changes to the system. I am writing to invite views and comments on Defra's proposals for changing the mechanism for approving disinfectants.

Purpose of revising the legislation

To revise the Diseases of Animals (Approved Disinfectants) Order 1978 to remove the need for disinfectants to be approved using the Statutory Instrument (SI) procedure and support a streamlined administrative process.

An SI is a piece of 'secondary' legislation. SIs are made under powers conferred by primary legislation; in this case the primary legislation is the Animal Health Act (1981), as amended. The proposed change will remove the requirement to make changes to the approved list through the SI procedure, but a revised SI is required to implement the policy. The proposed SI will also

ensure compliance with EU Regulations, namely the Biocidal Products Directive (BPD).

Objectives

A fundamental review of the procedure for approving disinfectants is needed.

Defra must ensure that its own legislative framework for the overall administration of the approvals process is transparent and effective. It is vital that an up-to-date and accurate list of approved and effective disinfectants is readily available in the event of a disease outbreak; this list will be issued on the Defra website. The list will be amended on the basis of results from laboratory efficacy tests and compliance with requirements of the approval mechanism.

The objectives of this proposal are to:

- introduce a streamlined and simplified administrative process;
- provide a swifter and more efficient system for granting or removing approval for disinfectants;
- meet requirements of the BPD.

Disinfectants will be approved if they appear on the list of approved disinfectants on the Defra website. In addition to information already held on the list of approved products (product name, disease Order it is approved for use under and the dilution rate at which the product is approved for use at), it is proposed that the website listing holds details of the approval holder. This will combine the information from the already published web-based 'manufacturers and distributors' list with the details of approved disinfectants.

It is also proposed that the website includes information about the active substance(s) in a product, but **not** its full formulation. This may enable the user to make a more informed decision about the environmental impact of their chosen product. Commercial information supplied to Defra and laboratories as part of the approval mechanism is treated as confidential and is not disclosed to third parties. This consultation exercise seeks your views as to whether information about the actives should be made available as a matter of course, only if consent if given by particular manufacturers or not at all.

Background

Disinfectants make a vital contribution to animal disease control strategies, both in everyday disease prevention and controlling spread of disease during epidemic outbreaks. Disease-specific EU Directives require Member States (MS) to use only approved disinfectants during a disease outbreak. Only disinfectants that have passed rigorous testing for efficacy against a specific disease are approved by Defra for use during a disease outbreak.

Currently, disinfectants used for statutory animal disease prevention and control purposes are approved by Defra when they appear on Schedule 1 of an Order updating the Diseases of Animals (Approved Disinfectants) Order

1978. Any amendments (adding or removing products or amending dilution rates) to the Order must be made using the SI procedure to produce an amendment Order; the current one is Diseases of Animals (Approved Disinfectants) (England) Order 2006. Making amendments to the list of approved disinfectants using the SI procedure is a lengthy process; under the current mechanism, it takes at least eight months for a disinfectant to gain approval for a product following its submission for testing or for any changes to be made to the list of approved disinfectants.

Approval will continue to be granted for disinfectants for the purposes of the Foot and Mouth Disease, Swine Vesicular Disease, Bovine Tuberculosis and Diseases of Poultry Orders. Approval will also continue to be granted for 'general' Orders; these are Orders (other than the specific disease Orders already mentioned) which include a provision for disinfection. Under the current approval mechanism, manufacturers submit application forms to Defra and samples of the disinfectant to be tested to the Veterinary Laboratory Agency. The rigorous testing of disinfectants on which approval is currently based will continue; only disinfectants that have passed independent testing for efficacy against a specific disease are approved by Defra for use during a disease outbreak. Defra will continue to inform manufacturers of the outcome of the efficacy test as notified by the laboratory. Defra uses suspension tests as the basis of its disinfectant approval mechanism. Defra recognises that new products are being developed for use in the field of disinfectants and the need to evolve, as far as practically possible, an approval mechanism that meets the demands of consumers and industry alike. To meet the changing demands of consumers and industry, Defra intends to review the test protocols underpinning the approval mechanism for disinfectants. This will involve a further and separate consultation with the industry and other interested parties.

Defra administers and legislates the approval of disinfectants for England. The Devolved Administrations of Wales and Scotland will continue to prepare their own legislation.

It is proposed that provision for 'trade names' approvals (called 'back-to-back' approvals) will continue to be made in the revised approval mechanism. As with the current mechanism, it is proposed that only manufacturers of approved disinfectants may submit products for testing and make representation against approval for their products being revoked. It is also proposed that manufacturers continue to be part of the approval process for 'back-to-back' approvals and that, if approval for a 'parent' product is revoked, all products approved as 'back-to-back' and 'trade' name products will also be revoked.

Approval is currently subject to certain conditions, for example, the composition, manufacturer and plant must remain unchanged from the time of testing and when tested, the product must be efficacious for use under the Order(s) for which it is approved. A change in these conditions results in the revocation of approval for the product and its trade name products. It is proposed that future approvals will be granted for a period of 2 years. At the

end of each 2 year period manufacturers will be required to reconfirm compliance with the conditions of the approval.

The legislation explained
Below is an explanation of the legislation and Defra's associated proposals on which you are invited to comment:

- article 1: this states that the proposed legislation applies to England. It is proposed that Defra continues to administer the approval mechanism and continues to work with the Devolved Administrations of Scotland and Wales in order for them to prepare their own lists of approved disinfectant;
- article 2: in practice, correspondence between Defra and manufacturers is in writing and is provided for by this section of the legislation;
- article 3: Defra approves disinfectants to support domestic and European legislation which requires that an approved product must be used. It is proposed that the current fee based efficacy test regime will remain in place until research into alternative methodologies is complete; Defra will continue to approve trade-name products without testing if the 'parent' product formulation is approved, has the same formulation as the trade-name/back-to-back product and is produced by the same manufacturer as the approved disinfectants. Manufacturers will continue to be involved with the approval of 'back-to-back' products and Defra seeks your opinion of this proposal;
- article 4: the requirement to use a disinfectant in a particular situation was not included in the 1978 Order and is not included in the 2006 Order. The Diseases of Animals (Approved Disinfectants) Order exists to provide approved disinfectant products to support legislation which does include the requirement to use one. Defra proposes to continue to approve disinfectants for use under Foot and Mouth Disease, Swine Vesicular Disease, Bovine Tuberculosis and Diseases of Poultry Orders as well as for use under general Orders
- article 5: this article provides for the new proposal that Defra approval will initially be granted for 2 years and be subject to review and renewal every 2 years. This will support Defra having accurate product information in the event of an outbreak. It is intended that renewal will be by the completion of a simple form requesting information about changes to the product since approval was granted;
- article 6: Defra will continue to revoke approval, and proposes to refuse to renew approval, if manufacturers or products fail to comply with conditions of the approval mechanism, for example, efficacy and compliance with the requirements of Biocidal Products Directive and Regulations. It is also proposed that Defra introduces suspending approval of a product if there is doubt about it continuing to meet conditions of approval;
- article 7: under the 1978 Order manufacturers had the right to appeal against decisions made by Defra. This section of the legislation continues to provide that right of appeal;

- article 8: if there is a change in the approval of a product, manufacturers and distributors must notify the change to those within the UK to whom the product has been supplied within the previous 6 months. This is necessary to ensure accurate information about the product is available along the chain from manufacturer to consumer;
- article 9: it continues to be an offence to supply or offer a disinfectant for sale as approved by Defra if it is not approved under the Diseases of Animals (Approved Disinfectant) Order;
- article 10: this updates legislation
- article 11: approval is given on the basis of the product tested. As a change in formulation may impact on efficacy it is an offence to change the formulation of an approved disinfectant and continue to label or describe the product as approved if the new formulation has not been tested and granted approval by Defra;
- article 12: Local Authorities enforce the 1978 Order and will enforce the 2006 Order;
- article 13: the 2006 Order will replace the 1978 Order and make amendment Orders redundant because it is proposed that approved disinfectants will appear on the Defra website. The proposal to remove making amendments to the list of approved disinfectant products from the SI procedure will reduce the time it takes to gain Defra approval for a disinfectant from 8 months to less than months. This proposed change will support the approval mechanism being more responsive in the event of a disease outbreak with consumers having more choice of disinfectant products in the event of an outbreak. Manufacturers will also benefit from being able to market their products as 'approved' sooner than the current mechanism allows. Defra proposes to produce one list of approved disinfectants which will include the following details:
    - product name;
    - Order it is approved for use under;
    - approved dilution rate;
    - manufacturer/distributor details.

Summary of proposals and questions:
Below is a list of the proposals on which you are invited to comment and some specific questions which may help you when responding:

<u>Proposed changes to the approval mechanism:</u>

- Make the approval mechanism more responsive in the event of a disease outbreak. *What do you think about Defra's aim to make the approval mechanism more responsive?*
- Remove the requirement to amend the list of approved disinfectant products from the Statutory Instrument procedure. This will reduce the time it takes to gain Defra approval for a disinfectant from 8 months to less than months. *Do you have any comments about the reduced timeframe?*
- Publish the list of Defra approved disinfectant products on the Defra website. *Do you support the publication of the list of approved disinfectants on the Defra web site?*

- Produce 1 point of reference for approved disinfectants. The list will include the:
    - product name;
    - Order it is approved for use under;
    - approved dilution rate;
    - manufacturer/distributor details.

  Do you think it would be useful to have one point of reference rather than the two lists which currently exist?
- The website may include details of the active substance(s) in each approved disinfectant on the website. *What is your view on this?*
- Approved disinfectants must comply with European regulations relating to the marketing of biocidal products, will need to supply more comprehensive information on labels and meet more stringent safety and environmental regulations by complying with the Biocidal Product Directive and the Biocidal Products Regulations. *Are these measures with which you agree?*
- Approval will be subject to renewal every 2 years. *Do you agree that continued approval should be subject to continued compliance with the conditions of approval, for example efficacy, safety and environmental regulations?*
- Introduce the status of 'suspended' approval for products where there are significant doubts or concerns about its approval. *Do you agree that suspending approval while the circumstances of an approval of a product may be more helpful than immediately revoking approval?*
- Place a responsibility on manufacturers and distributors to inform those to whom they supply approved disinfectants if the status of their product changes. *Do you have any comments about this duty being placed on manufacturers and distributors?*

<u>Features of the approval mechanism which Defra proposes to retain:</u>

- Current fee based efficacy test regime remains in place until research into alternative methodologies is complete. *Do you agree that Defra should review test methodologies in consultation with interested parties?*
- Defra continues to approve disinfectants for use under specified disease and general Orders. *Do you support this proposal?*
- Defra will continue to approve trade-name products, without testing, if the 'parent' product/formulation is approved, has the same formulation as the trade-name/back-to-back product and is produced by the same manufacturer as the approved disinfectants. *Do you agree that trade-name products should continue to be approved without testing?*
- Manufacturers will continue to involved with the approval of 'back-to-back' products. *Do you think this is necessary and/or desirable?*
- Defra will continue to undertake regular efficacy testing of products at the point of sale. This will involve the testing of a different batch to the one originally submitted for approval to ensure the continued efficacy of the disinfectant as manufactured. *Are you in agreement that Defra continues to undertake regular efficacy testing of products at the point*

of sale to ensure continued efficacy in animal disease prevention and control?

- Defra will continue to work with the Devolved Administrations of Scotland and Wales in order for them to prepare their own lists of approved disinfectants. *Do you agree to one focal contact point for the purposes of administration?*
- Manufacturers retain the right to appeal against decisions made by Defra. *Do you support the continued provision of this right?*
- It will continue to be an offence to market or supply a product and describe it as 'approved' if it is not. *Do you agree that supplying or selling a non-approved product as 'approved' should be an offence?*

Risk assessment

To do nothing would risk Defra's regime not being in accordance with relevant domestic and EU legislation and policies, for example the Biocidal Products Directive (BPD). No action would perpetuate a lengthy and cumbersome approval system that does not meet the requirements of industry and consumers. New legislation will ensure, as far as practicable, that up-to-date information on approved disinfectants is readily available, particularly during a disease outbreak. It will also provide scope to test and provide controls for new and emerging diseases.

Options

Disease prevention and control in animals is improved by disinfectants, especially during a disease outbreak. Defra must ensure the timely provision of accurate information and with regard to environmental and health and safety obligations.

There are 3 options:

1. The Order could remain unchanged.

To continue with a lengthy approval mechanism that falls short of meeting demands of industry, consumers and EU legislation is not considered appropriate.

2. The Order could be revised for England to streamline the administrative process, increase responsiveness of Defra in being able to amend the approved list and to ensure domestic legislation is in line with current EU requirements.

It is reasonable to expect Defra to supply up-to-date information that is in line with current and related legislation.

3. The revision to the Order could include a review of testing.

Defra recognises the need to review how products are tested prior to approval and take account, as far as practicable, innovations within the chemical industry and the practical application of disinfectants in real conditions. This

was discussed during preliminary, informal consultations with industry and interested parties. The aims of the BPD now also need to be considered. The BPD aims to harmonise evaluation and authorisation of biocidal products by Member States. However, Defra needs to ensure absolute clarity with regard to proposed test methodologies. Given the importance of efficacy testing, it is considered that a separate exercise would be appropriate and, until this is satisfactorily concluded, the current testing mechanism will remain.

Costs and Benefits

Economic

The reduced time-frame in which a disinfectant will be able to gain Defra approval will support the swifter issue of accurate and up-to-date details of approved disinfectants to control animal diseases. This will benefit manufacturers, consumers and the wider public alike. Ready access to correct information about effective products and their uses will be particularly important in the event of a disease outbreak. A shorter time-scale may encourage manufacturers to submit an application to have their product(s) approved and increase the arsenal of approved disinfectants that is available.

The Defra approval mechanism has international recognition and provides opportunities for domestic manufacturers to market their products abroad. The BPD is being phased into force and the Directive's review programme is assessing active substances. The Health and Safety Executive (HSE) is the main lead contact for the BPD. Industry had to inform the EU Commission of their intentions for supporting substances under the Directive by 'notifying' the substance for review and informing the Commission of the product types they intended to support during review. Veterinary hygiene disinfectants fall within product type 3. Where a substance has been notified for review in product type 3, products containing that substance can remain on the EU market (subject to the requirements of national legislation) until the review has been completed and a decision made on listing the substance in the Directive's annexes. If industry did not want to support a substance through the review programme, they had the option to 'identify' the substance to the Commission. Products containing substances that were neither 'identified' nor 'notified' had to be removed from the market by December 2003. Products containing substances that were 'notified', but not for the relevant product type, can remain on the EU market, subject to any national rules, until 1st September 2006. Defra, as a UK Government Department, is obliged to comply with European legislation; one aim of the revision to the approval mechanism is to support this compliance. Under the proposed new Order, only products containing active substances that already comply with the requirements of the BPD will be approved, or considered for approval, by Defra. Further, specific information about the BPD may be obtained from the HSE at www.hse.gov.uk

As Defra's approval mechanism is recognised internationally, some Authorities sometimes require Defra approval of a product before allowing a manufacturer to market a product in a particular country. Manufacturers of disinfectants occasionally apply for Defra approval in order to market their products internationally rather than on the domestic market. The requirements

of the BPD do not apply outside of Europe. However, Defra legislates on behalf of England and must comply with EU legislation and will, under the new legislation, only include disinfectants on the approved list or efficacy test new products for inclusion on the approved list if they comply with the BPD. If you are a manufacturer of a Defra approved disinfectant and this measure impacts on the status of your approved product, you will be contacted by a member of Defra's disinfectant approval team.

Environmental

The revision of the 1978 legislation supports more stringent regulation of the safety of products. It is proposed that a future condition of approval will be that manufacturers and distributors comply with national and EU environmental regulations, including those of the BPD as they are brought into force.

It is proposed that approval will be granted for two years and that the period of approval is clearly stated on the product's label. Manufacturers will be required to reconfirm compliance with their approval by submitting key product details when requested; this will support measures to safeguard the environment.

Social

Disinfectants form an important part of everyday animal disease prevention and control. Disinfectants are only effective if used correctly. It is proposed that, as a condition of approval, manufacturers and distributors of approved disinfectants will be required to provide more information on the labels for their products, including optimum storage conditions, an expiry date and instructions to ensure the highest degree of efficacy and guidance on safe use of the product. Comprehensive labelling will enforce current best practice within the industry and meet customer needs.

Defra will continue to undertake regular re-testing of previously approved disinfectants to ensure their continued efficacy in animal disease prevention and control.

Issues of equity and fairness

Disinfectants gain approval subject to demonstrating efficacy against a particular disease during rigorous testing using reproducible test protocols. The approval system operates under a standard administrative process. The approval mechanism maintains equity and fairness as all disinfectant manufacturers have equal access to it, the laboratories approved by Defra to undertake disinfectant testing and then the marketplace.

Consultation with small business: the Small Firms' Impact Test

The HSE is the Authority acting on behalf of the UK with regard to the BPD. The HSE has been publishing fact sheets for manufacturers, suppliers and users of biocidal products since July 1997. The HSE have also produced guidance material, undertaken a series of 'road-shows' and seminars and undertaken Public Consultation.

Defra has included interested parties in preliminary, informal meetings to discuss the proposals in this document. Manufacturers and the Devolved Administrations accepted and expressed general support for the proposals put forward. Formal consultation with these and a wider range of interested parties is now taking place.

Competition Assessment

Defra believes that there are a few dominant suppliers of disinfectants and several smaller companies in the industry. The proposed changes aim to streamline the currently cumbersome approval mechanism and do not affect competition. The fundamental feature of the approval system, i.e., fee based efficacy testing, will remain unchanged. The costs of the legislation will not be higher for new (or potentially new) firms than for existing suppliers of disinfectants and it is not thought that the costs will disproportionately affect some firms more than others. All manufacturers of disinfectants have equal access to the approval mechanism and Defra approved laboratories if they want to gain approval for their product for use under a specified disease or general Order. The reduced approval period may increase the incentives for firms to develop new disinfectants, or apply for approval of existing products and so increase the number of approved products available during an outbreak.

Enforcement and Sanctions

Manufacturers apply for approval on a voluntary basis. Defra will continue to administer the approval mechanism. Disinfectants are, and will only be, added to the 'Approved List' if they comply with the standard requirements of the approval mechanism.

The current approval mechanism has been used for a sufficiently long period of time to show that it achieves adequate enforcement. The proposed mechanism retains fundamental features of the original; one of the main changes being to remove the requirement for a Statutory Instrument in order to make changes to the list of approved disinfectants and reduce the time-lag between testing and granting approval.

Monitoring and Review

The proposed mechanism will be reviewed regularly. Defra must ensure that relevant national and EU obligations continue to be met, particularly those relating to health, safety and the environment and also recognise the impact of the BPD.

Consultation

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

Public Consultation: industry has been consulted formally by the HSE. Defra has consulted with industry informally and is now in the process of formal consultation with a wide range of interested parties.

Summary and Recommendation

This Regulatory Impact Assessment supports and recommends option 2 for the revision of The Diseases of Animals (Approved Disinfectants) Order 1978, in that it is revised to move towards a more responsive mechanism.

Declaration

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

Signed ***Ben Bradshaw*.**

Date **29 August 2006**

Ben Bradshaw, Parliamentary Under-Secretary (Commons)

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