Department for Environment, Food and Rural Affairs
Scottish Government
Welsh Government

Animal & Plant Health Agency

Guidance on the Defra disinfectant approval scheme

The Diseases of Animals (Approved Disinfectants) (England) Order 2007 No. 448 (as amended) for the purposes of The Animal Health Act 1981 (as amended)

The Animal and Plant Health Agency (APHA) is an executive agency of the Department for Environment, Food and Rural Affairs (Defra), and approves disinfectants on behalf of Defra as set out in the relevant Disinfectant Approval Orders (as amended), namely:

- The Diseases of Animals (Approved Disinfectants) (England) Order 2007 No. 448, (referred to in this document as The 2007 Order)
- The Diseases of Animals (Approved Disinfectants) (Scotland) Order 2008 No. 219
- The Diseases of Animals (Approved Disinfectants) (Wales) Order 2007 No. 2803

The purpose of an approval under this legislation is to confirm the disinfectant is effective in controlling certain pathogens under laboratory conditions. Where legislation requires the use of a disinfectant approved by Defra, only a disinfectant listed as having been approved under these orders may be used.

Manufacturers marketing disinfectants in Great Britain have a duty to understand and comply with relevant legislation, including the GB-BPR and general chemicals legislation. The GB-BPR replaces the EU-BPR in England, Scotland and Wales, with arrangements for Northern Ireland covered in the Northern Ireland Protocol (please contact NI and the Health and Safety Executive). These Regulations:

- enable the GB-BPR to be enforced in Great Britain
- appoint a competent authority (the Health and Safety Executive (HSE))
- set maximum penalties for non-compliance
- recover, through a fees system, the costs of services the HSE provides from those who benefit from them

Transitional arrangements were also required to enable parts of legacy systems (EU-BPD and the UK Control of Pesticides Regulations (COPR) 1986) to remain in place until affected products are brought under the product authorisation requirements in the new GB-BPR.

In making an application for a disinfectant to be approved by Defra under the relevant Disinfectant Approval Order, the applicant is required to confirm by signing the DDA1 form that they have and will continue to execute their legal duties and comply with relevant legislation for the manufacture, sale, labelling and safety of their products. These legal duties will include as a minimum:

- ensuring the formulation complies with the GB-BPR for Product Type 3 (Veterinary Hygiene Products) or such transitional arrangements as required by HSE
- ensuring the product is compliant with any applicable general chemicals and consumer legislation including the Classification, Labelling and Packaging of Substances and Mixtures Regulation (CLP Regulation), where appropriate the General Products Safety Regulations (GPSR), and the requirements of the GB-BPR
- informing the National Poisons Information Service (NPIS)
- depending on the specific intended usage of the product, ensuring that they comply with any other relevant national requirements that apply before the products can be used

More information about the requirements of the GB Biocides Regulation can be obtained from HSE biocides team:

Chemicals Regulation Directorate (CRD)
Health and Safety Executive
4N.G Redgrave Court
Merton Road
Bootle
Merseyside
L20 7HS
United Kingdom

Department for Environment, Food and Rural Affairs
Scottish Government
Welsh Government

Animal & Plant Health Agency

Email: pa.biocides@hse.gov.uk

Website: http://www.hse.gov.uk/biocides/index.htm

The Animal and Plant Health Agency (APHA) has operational delivery responsibility for the disinfectant approval scheme on behalf of Defra.

The DDA1 application form is to be used:

- for submission of a disinfectant for efficacy testing for the purpose of Defra approval for use under the relevant Disinfectant Approval Order (numbered 1 to 5 in the 'Initial application' section)
- to request the approval of a back-to-back approved trade name of an already approved disinfectant
- to apply for the biennial renewal of an approved disinfectant

Disinfectant assessment process summary

1. Submit DDA1 form plus product material safety data sheet (MSDS) to Defra Disinfectants Approvals Administration at APHA, preferably by email to disinfectant@apha.gov.uk.
2. APHA assess whether the disinfectant described on the form is eligible for testing and confirms this to the applicant.
3. Applicant submits sample to APHA when requested, together with appropriate fees.
4. APHA schedule test.
5. Tests are undertaken (results are typically notified within 12 weeks depending on the number of tests requested).
6. Once all results are available, the applicant will receive a disinfectant efficacy test report.
7. If successful, the applicant may, subject to signing a document to confirm their compliance with labelling and other requirements, market their product as Defra approved under the relevant disease order at the approved dilution rate once the product name has been added to the approved disinfectants list.

Initial application

Defra approves disinfectants for use on inanimate surfaces only. Applications can only be accepted from the manufacturer of the disinfectant to be tested. Applications are made voluntarily, and Defra approval is not required before placing a disinfectant on the market.

For Defra approval purposes, there are 4 specific Animal Disease Orders and one category for other notifiable diseases, also known as 'General Orders':

- Foot and Mouth Disease (FMDV) (column i on the list)
- Swine Vesicular Disease (SVDV), (column ii on the list
- Diseases of Poultry Order and Avian Influenza and Influenza of Avian Origin in Mammals Order (DoP, AI&IAOM), (column iii on the list)
- Tuberculosis Order (TB), (column iv on the list)
- General Orders (GO) for approval for use where animal disease control orders (other than the 4 specific animal disease Orders) made under The Animal Health Act requires the use of an approved disinfectant, such as The Transport of Animals (Cleansing and Disinfection) (England) (No.3) Order 2003 No. 1724, and The Animal Gatherings Order 2010, Animal By-Products, Catering Waste

Please contact Defra Disinfectants Approvals Administration at APHA if you have any questions relating to approval categories: disinfectant@apha.gov.uk.

See the list of efficacy tests for disinfectant approval purposes and the associated fees.

Efficacy tests for the following approval categories are conducted at The Pirbright Institute under contract from APHA:

- Foot and Mouth Disease Orders
- Swine Vesicular Disease Orders

Efficacy tests for the following approval categories are conducted at APHA (Weybridge HQ):

- The Diseases of Poultry Order
- The Avian Influenza and Influenza of Avian Origin in Mammals Order
- Tuberculosis Orders
- General Orders

Defra does not accept test data or evidence of efficacy from other facilities for the purpose of Defra approval. For details of the test methods, download the APHA efficacy methodologies.

Please note, all tests are conducted at +4°C.

Applicants are required to state which approvals they are seeking and the dilutions at which the product should be tested. The applicant must notify APHA of the intended use and exact formulation of the product.

APHA will assess the application. A decision on whether or not the disinfectant can be accepted for efficacy testing for the purpose of Defra approval will usually be made within 5 working days of receipt of the DDA1 form. The applicant is notified of the decision by email to the representative named by the applicant on the DDA1 form.

Neither Defra nor APHA is able to offer consultancy on disinfectant formulations submitted for the purpose of Defra approval.

Sample submission

If the application is accepted, an invoice is raised and samples and payment may then be submitted as discussed in the email correspondence following the initial assessment. Payment of the invoice may be made by BACS, cheque or credit card.

There are strict conditions on how to submit samples. Please see the DDA1 form for these guidelines and inner and outer packaging labels, as well as this page.

It is a legal requirement to send samples in secure, leak and tamper-proof containers appropriate for the contents. In addition to other regulatory labelling requirements that you must meet, the labels provided on the final page of the DDA1 form must be used on the internal (inner label bagged and tied to vessel if small) and external surfaces of the parcel and container. A copy of the product material safety data sheet (MSDS) must accompany the sample in the parcel.

Failure to meet sample submission instructions may result in the sample being rejected and the application halted. See the following for the individual sample volumes required per test and the address to send them to. Please ensure you send the correct volumes as we do not take sub-samples from bulk unless exceptional circumstances apply.
Do not send a sample until APHA asks you to.

Send your samples to:

Bacteriology Department (Building 17)
Defra Disinfectant Approvals
Animal and Plant Health Agency
Woodham Lane
Addlestone
Surrey
KT15 3NB

Test	Sample size needed
FMDV	1 x 100ml liquid or 1 x 100g dry sample per test
SVDV	1 x 100ml liquid or 1 x 100g dry sample per test
DoP, AI&IAOM	1 x 500ml liquid or 1 x 500g dry sample per single or triple dilution test
TB	1 x 500ml liquid or 1 x 500g dry sample per single or triple dilution test
GO	1 x 500ml liquid or 1 x 500g dry sample per single or triple dilution test

APHA will contact you if additional samples are required.

Testing

Testing usually takes place within a few weeks and the results reported to the applicant within 12 weeks of receipt of samples and payment. This may be longer if resources are required for urgent statutory work, for example in the event of an outbreak of notifiable animal disease.

If the result is a pass, the applicant is offered to have the disinfectant added to the Defra list of approved disinfectants and for this the applicant is required to sign and return a letter outlining the conditions of the approval. For details of the conditions of approval and the mandatory labelling text, email disinfectant@apha.gov.uk.

Defra approval

Approval is granted for 2 years. Subsequent approval is subject to conditions including a biennial renewal procedure that does not incur a fee and does not usually include submission of samples, but does require the applicant to provide key information to the APHA.

Once a product is approved, any change in the formulation of the approved product (no matter how minor) must result in a fresh application for assessment of the new formulation. APHA will advise you about whether retests are required.

The applicant must ensure the product continues to comply with the conditions of its original approval. Failure to comply with any condition of the approval may result in revocation of the approval.

Approval is subject to an annual fee per approved Order per product. The fee is payable on 1 September annually and APHA issues invoices in advance for this. The fee is payable regardless of when a disinfectant is listed as approved.

Post-approval check tests

Approved disinfectants will be subject to random check tests. If the disinfectant fails the check test at the approved dilution, approval for use under that disease order may be immediately suspended and full revocation may follow in accordance with Article 6 of the 2007 Order.