Detailed guide: Get your disinfectant approved by Defra

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If there is an outbreak of a notifiable animal or zoonotic disease, only Defra approved disinfectants can be used for cleaning and disinfecting hard surfaces like buildings, farm equipment, crates, and vehicles.

You are breaking the law if you market and sell as Defra approved a disinfectant that has not been tested and listed as approved.

To get your product approved by Defra it must:

- conform to the **Biocidal Products Directive**
- pass efficacy tests at a Defra approved laboratory

Legislation

This scheme is underpinned by the <u>The Diseases of Animals (Approved</u> <u>Disinfectants) (England) Order 2007</u>

The costs are set out in <u>The Diseases of Animals (Approved Disinfectants)</u> (Fees and Amendment) (England) Order 2011

Before you apply

You need to decide which dilution of your product you want to have tested. Defra and Animal and Plant Health Agency (APHA) can't advise you which formulation or dilution will pass the tests.

You must make sure your product meets the following <u>Health and Safety</u> <u>Executive (HSE)</u> standards:

- chemicals legislation such as <u>Classification</u>, <u>Labelling and Packaging of</u> <u>Substances and Mixtures Regulation</u> (CLP Regulation)
- <u>General Products Safety Regulations</u> (GPSR)
- advertising requirements in the <u>Biocidal Products Regulations</u> (BPR) 2001

You must also:

- inform the National Poisons Information Service
- check liability for the <u>General Industry Charge</u>

Apply for disinfectant approval testing

You must complete the DDA1 application form and post or email a signed copy to:

Defra Disinfectants Approvals Administration Office

Room SE175, Stewart Stockman Building

Animal and Plant Health Agency

New Haw

Addlestone

Surrey

KT15 3NB

Tel: 0208 026 9609

Email: disinfectants@apha.gsi.gov.uk

APHA will assess your application and decide if your product can be accepted for testing for Defra approval. They will let you know their decision within 5 working days.

Download details of the <u>APHA efficacy methodologies</u> (PDF, 348KB, 6 pages)

for more information.

Submit samples

If your product is accepted for testing you will be told where to send your samples and your purchase order for the tests you want.

See the application form for instructions on how to submit samples and packaging labels. You must not send any samples until APHA asks you to do so, or make a payment to APHA until you have received an invoice raised for your purchase order..

Approval testing fees

You must pay in advance for testing, but should wait until you know your product has been accepted for testing. You can pay by bank transfer, credit card or by cheque once APHA has sent you an invoice for your purchase order.

UK companies will have to pay VAT on the fees shown in the following table. Companies outside the UK do not have to pay VAT.

Approval tests

Fees per test (£) 1.920

Foot and mouth disease

Approval tests	Fees per test (£)
Swine vesicular disease	1,920
Diseases of poultry and the avian influenza and influenza of avian origin in mammals:	
– single dilution test	1,040
– triple dilution test	1,400
Tuberculosis:	
– single dilution test	1,300
– triple dilution test	1,620
General Orders:	
– single dilution test	715
– triple dilution test	815
Administrative charge	1,000

You should receive the results within 12 weeks of submitting your samples. This may take longer due to urgent statutory work (eg responding to a disease outbreak).

Product approval

You will get a 'conditions of approval' letter if your product passes the APHA tests.

This letter will include a text box with some wording specific to your disinfectant and you must add this to your label. Email <u>disinfectants@apha.gsi,gov.uk</u> for more information about this wording.

You need to sign and return the letter with a copy of your prepared label to Defra Disinfectants Approvals Administration at APHA before your product can be added to the list. Your product is usually listed within 5 working days of APHA receiving your signed letter.

You can only label, market and sell your product as Defra approved when it is on the approved list. You can find the complete list of Defra approved disinfectants on the <u>approved disinfectants list</u>.

Approval lasts for 2 years. There is a renewal procedure and conditions to extend approval. There is no fee and you may not need to submit samples but APHA will ask you to provide some information.

Application for Defra approval of a Tradename of an already approved disinfectant

The manufacturer of a Defra Approved disinfectant that is currently on the <u>approved disinfectants list</u> can sell their product to other companies who wish to rename and sell it as their own and with the same Defra Approval.

For this to be legally sold with the same Defra Approval as the already

approved product, the proposed new tradename must first be added to the list by APHA. Samples of the disinfectant under the proposed new name are usually not required for APHA to test, but there is an administrative fee for processing the application and listing the additional product name as Defra approved.

The manufacturer of the already approved product must complete the <u>DDA1</u> <u>application form</u>, following the <u>guidance notes</u> on which sections of the form to fill out.

Email the completed form to <u>disinfectants@apha.gsi.gov.uk</u>.

APHA will email an invoice to the applicant once the DDA1 application form has been assessed and the new tradename can be accepted. There is no fee for assessing applications that are subsequently declined (for example, if there is already a disinfectant under the same name on the list).

Application for a Trade Certificate in the name of a Defra Approved disinfectant

The importing authorities in some non-EU countries require documentation as proof of a disinfectant's Defra Approval.

Although the <u>approved disinfectants list</u> is the first point of reference, some countries do not accept it.

Manufacturers of a Defra Approved disinfectant can purchase a document from APHA which is letter-headed, signed and dated to confirm the Defra Approval of the named disinfectant.

There is an administrative fee for this service.

To make a request for a Trade Certificate, the manufacturer must sign the <u>Application for approved disinfectant trade certificate</u> (PDF, 139KB, 2 pages)

and email to <u>disinfectant@apha.gov.uk</u>.

APHA will email an invoice to the applicant for payment prior to issuing the certificates.

Application for a retrospective disinfectant efficacy test report in the name of a Defra Approved disinfectant

For manufacturers of Defra Approved disinfectants preparing dossiers for submission to the HSE (or EC) for product authorisation under the <u>BPR</u> (biocide product regulations), part of the assessment undertaken by the competent authority in each EU member state (e.g. for UK it is the HSE) is to assess proof of efficacy claims the manufacturer states on a product label

and in the product information literature.

For disinfectants that are Defra Approved, APHA can compile a report stating the efficacy of a Defra Approved disinfectant in the tests conducted for Defra Approval.

There is an administrative fee for this service.

To make a request for this report manufacturers must email <u>disinfectant@apha.gov.uk</u>.

APHA can only accept requests directly from the manufacturer of the Defra Approved disinfectant.

An invoice is raised upon receipt of the request and emailed to the applicant prior to issuing the report. APHA will email an invoice to the applicant for payment prior to issuing the report.

Administrative charges

You must pay administrative charges for:

- Defra approval of a tradename of an already Approved disinfectant
- Trade certificate in the name of a Defra Approved disinfectant
- Retrospective disinfectant efficacy test report in the name of a Defra Approved disinfectant

You can pay by bank transfer, credit card or by cheque once APHA has sent you an invoice for your purchase order.

Administrative charges	Fees (£)
Back-to-back approved tradename	292.85
Trade certificate (up to 10 copies in one disinfectant name	146.42
Retrospective disinfectant efficacy test report	512.48

Product changes

You must tell APHA if you change the formula of your approved disinfectant, or if any details you originally supplied have changed. APHA and Defra may decide to retest a product to make sure it is still effective. You will have to pay for these tests.

Product check tests

APHA runs random check tests on approved disinfectants. You will only know if your product has been chosen for check testing if it fails the tests.

You will be told the test results as soon as possible. Your product may be suspended from the list. You can re-submit the product for testing for which you have to pay the full test fees.

Fish farm disinfectant approval

To get your product listed as an approved disinfectant for fish farms, visit the <u>Centre for Environment</u>, <u>Fisheries and Aquaculture Science (Cefas) website</u>

Disinfectant enquiries

Email APHA for a list of frequently asked questions.