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**GUIDELINES ON THE EFFICACY DATA
REQUIREMENTS FOR APPROVAL OF NON-
AGRICULTURAL PESTICIDE PRODUCTS**

SURFACE BIOCIDES

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DEFINITION OF TERMS

Active ingredient	The component of a product which fits it for use as a pesticide.
Application	An application seeking approval to sell, supply, store, use or advertise a pesticide product in Great Britain.
Approval	An approval given jointly by Government Ministers under Regulation 5 of The Control of Pesticide Regulations
Committees	The Advisory Committee on Pesticides (ACP), established under SI 1985 No 1517, and the Interdepartmental Secretariat (IDS).
Evaluation	A written assessment of study reports or other data examined in the course of an appraisal by the Registration Authority.
Ministers	This refers to the Ministerial representatives of the following: Department of Environment, Food and Rural Affairs (DEFRA), Department for Work and Pensions (DWP), Department of Health, the Scottish Executive and the National Assembly for Wales.
Pesticide	As defined in The Food and Environmental Protection Act 1985 (FEPA) (part III., section 16. (15) + (16)) and COPR (section 3. (1)).
Quality Assurance	Those procedures and controls, including inspections and audits, designed to monitor studies to assure the quality of the data.
Raw Data	All original records and documentation, including verified copies thereof, which are the results of original observations and activities in a study.
Registration Authority	The Health and Safety Executive (HSE), Biocides and Pesticides Unit (BPU).

FOREWORD

1. As part of the commitment of FEPA and COPR, the Registration Authority (HSE) are obliged to look at the effectiveness (efficacy) of non-agricultural pesticide products submitted for approval.

Efficacy will be considered as part of the approval of non-agricultural pesticides on the basis of a flexible, cost effective framework that requires a sufficient amount of data necessary to:

- i) establish that a product is efficacious in relation to its conditions of approved use and that label claims are justified, and;
- ii) satisfy the requirement of Ministers who give approval on the basis of recommendations from the ACP and IDS.

In order to meet this obligation a structured approach towards the efficacy evaluation of products has been adopted whereby the efficacy will be addressed principally at a number of key stages (see section 2).

2. This document gives *guidance* on the nature and extent of the efficacy data required to gain a commercial approval for the sale, supply, use, storage and advertisement of a pesticide containing an active ingredient(s) intended for use as a surface biocide, or to support continuing approval of current products containing existing active ingredient(s) at review.

3. It embodies the efficacy policy outlined by HSE and endorsed by the ACP in January 1993, the basic framework of which is presented in the 'Consolidated Data Requirements for Non-Agricultural Pesticide Products and Their Active Substances' made available to approval holders in July 1993. It outlines and formalizes, but does **not** represent a change to, the methods which have been used in evaluations presented to, and endorsed by, the Committees in this time.

4. This document is prepared both for applicants who are routinely involved in efficacy testing strategies and those who may not be so familiar with such strategies. Therefore, it is hoped that the presentation style adopted in this document will be amenable to all current and potential approval holders of non-agricultural pesticides and other interested parties.

5. It is intended to be of use not only to companies, and staff within companies, involved in conducting efficacy tests and establishing efficacy strategies, but also companies' registration departments involved in preparing dossiers of efficacy data in support of product applications.

INTRODUCTION

This document gives guidance on the nature and extent of the efficacy data required to gain commercial approval of a pesticide containing active ingredient(s) for use as a surface biocide and also for continuing approval of current products containing existing active ingredients following review. The HSE is the Registration Authority to which such applications should be submitted.

These guidelines are designed to be as flexible as possible and will not specify rigid protocols to which tests must be conducted. Instead, applicants are encouraged to submit data generated to a sound scientific standard using their own testing strategies or studies conducted to national or international efficacy methods.

EACH STUDY PRESENTED WILL BE EVALUATED ON ITS OWN MERITS.

The assessment will be made solely in relation to the claims made on the product label for the effectiveness of the product. However, these claims will need to be sufficiently detailed to enable an assessment to be made; taking into account the organisms to be controlled, method(s) of application, application rates and use patterns of the product(s).

The data submitted should adequately demonstrate that the use of the active ingredient in the proposed products result in a measurable beneficial effect. To show such a beneficial effect, it is likely that the active ingredient's performance will need to be compared with that of a reference study (a test 'control') in which the pesticide is not applied.

Examples of typical efficacy claims which may be made for a product and the activity which may need to be shown through efficacy testing are described in Appendix 1.

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WHEN EFFICACY DATA ARE REQUIRED

To support the approval of non-agricultural pesticide products, HSE will not normally require efficacy data to support each and every product application. A structured approach has been adopted towards the efficacy assessment of product applications and HSE will request that data to be submitted at a number of key stages as outlined below:

a. In support of active ingredient(s) (and their products) and extensions of use of existing active ingredient(s) (and their products).

- i) e.g. to support applications for products containing an active ingredient yet to be assessed prior to first approval in the UK.
- ii) e.g. to support applications for products containing an active ingredient previously used in agricultural pesticides (e.g. an agricultural fungicide active ingredient now intended for use in non-agricultural pesticides as a surface biocide).
- iii) e.g. to support applications for products containing an active ingredient previously used in another sphere of non-agricultural pesticide use (e.g. an active ingredient currently used in wood preservative products now intended for use in surface biocides).
- iv) e.g. to support applications for products containing an existing active ingredient but incorporating novel formulation types and/or novel* application/delivery methods.
- v) e.g. to support applications for products containing an existing active ingredient targeted against novel* organisms.

b. To support existing active ingredient(s) (and their products) at review.**

c. To satisfy either post approval or post review data requirements set by the ACP arising from evaluation at submission times (a) or (b).

**Novel in this instance is considered to be a case where no precedent exists for formulation type, application method or target organism(s).*

***It should be noted that a review will consider all available existing data (both positive and negative) relevant to a particular active ingredient and its products. It is recognised that the nature of these data may not always conform to current testing practices and the data requirements outlined within this document. As all data are assessed on their own merits, such issues will be considered by the Registration Authority and the Committees at the review stage.*

3 FRAMEWORK OF THE ASSESSMENT PROCESS FOR COMMERCIAL APPROVAL

The five Government Department signatories to COPR are advised by the ACP after interdepartmental scrutiny of pesticides issues by the IDS.

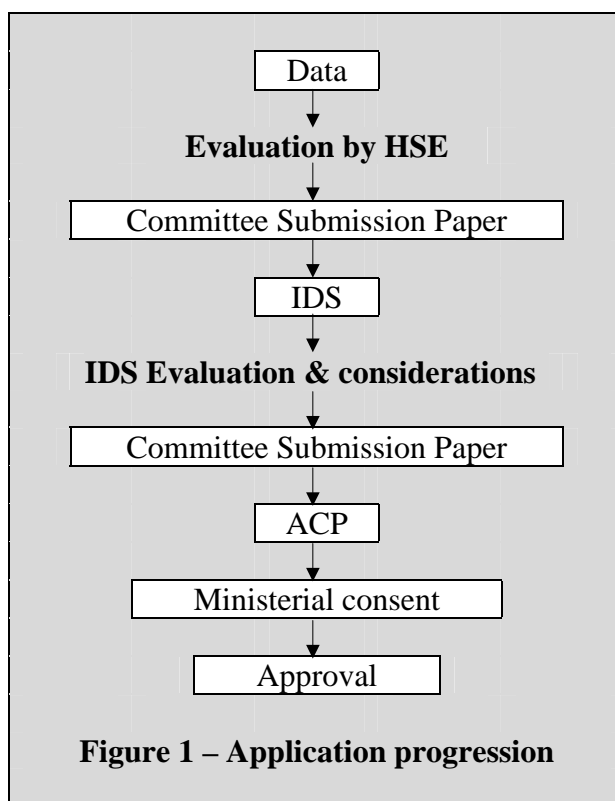
Data submitted by the applicant in support of new active ingredients (and their products), extensions of use of existing active ingredients (and their products) or existing active ingredients (and their products) at review are evaluated by HSE on behalf of the Committees and a presentation (tabled in the form of a committee submission paper) is made initially to the IDS. This presentation critically evaluates all aspects of the data submitted with the application (including chemistry data, toxicity, risk to human health, risk to the environment and efficacy data), and will include recommendations and possible further data requirements required to fill gaps or deficiencies in the data set. The IDS will consider the scientific data in relation to the application. Such considerations will be presented to the ACP alongside the committee submission paper. The ACP will then consider the application taking into account broader issues concerning pesticides.

The ACP's recommendations are then forwarded to the five Government Departments for Ministerial agreement and, where appropriate, the product's Notice and Schedule are forwarded to Ministers for signing; granting commercial approval.

The IDS/ACP process is summarised in Figure 1. At any of the Committee stages or during Ministerial agreement, the Registration Authority may be requested to further evaluate certain pieces of data or approach the applicant for additional data before the application can be progressed to the next stage of the process.

It must be stressed that the appropriateness of the data submitted to the Registration Authority has a major effect on the presentation of the application to the IDS and ACP, and ultimately whether or not commercial approval is granted.

4



DRAFT LABEL INFORMATION/LABEL CLAIMS

4.1 INTENDED LABEL CLAIMS

The efficacy data submitted in support of an application will be assessed to establish if the product containing the active ingredient(s) has a reasonable level of performing as claimed on the product label, when it is used as detailed in the label instructions.

Hence, for an evaluation to be undertaken, HSE will require a draft label or statements concerning the label claims which are proposed for the product. Such information will need to be sufficiently detailed to enable an assessment to be made, and will need to include:

- i) The pests which the product is to be used against.
- ii) The application methods and rates at which the product is to be applied.
- iii) The resulting activity which should arise from such pesticide application.

The use pattern is described in further detail below.

4.2 USE PATTERNS

With respect to label claims for a surface biocide application, a distinction between two use patterns may be made when evaluating a data package.

i) Surface biocides intended specifically for the control of dry rot

In this situation, the biocidal product (sometimes known as a masonry biocide/fungicide) is applied to masonry (or other mineral construction materials) in order to prevent the growth of dry rot fungi through or over the treated material.

ii) General surface biocide

In this situation, the biocidal product is applied to a wide variety of hard and/or soft surfaces to control organisms such as algae, yeasts, fungi, lichens, mosses and liverworts.

The possible efficacy label claims of both types of biocide use and testing strategy are outlined in Appendix 1. Appendix 2 contains examples of some common species of target organism that a surface biocide product may be used against.

5

DATA REQUIREMENTS

5.1 DATA SOURCES

Data from any source will be considered provided they are valid and relevant to the application. These data could represent nationally/internationally accepted standards, if these are available for the type of product for which an application is made. Sources of data may include:

- i) Well conducted studies carried out or commissioned by the applicant which are either laboratory, simulated use or field studies. Unpublished work from persons or organisations other than the applicant will only be accepted if accompanied by the appropriate authorisation e.g. statements that the work was conducted on behalf of the applicant or the right to access these data has been granted to the applicant.
- ii) Evidence, relevant to the product from published work in reputable journals. Scientific/technical papers in refereed journals are usually acceptable. It is recognised that published data in support of an application may often lack important detail. The applicant should explain whether the coatings referred to in a published paper are equivalent to those for which approval is sought. If this is not the case then the applicant should present a reasoned case, based on data, as to why and how the proposed coatings will behave similarly to that/those described in the published paper. Further advice on the preparation of a reasoned case is given in the Pesticides Newsletter No. 38, March 1998.
- iii) Data from outside the UK may also be acceptable.
- iv) Lack of complaints, customer testimonials and anecdotal evidence will not be acceptable.

5.2 TYPES OF DATA GENERATED

A number of methods of generating efficacy data within the development programme of a product containing an active ingredient(s) in question may be considered when producing an efficacy data package. These include laboratory/screening studies, simulated use tests and field trials.

Useful definitions of these three study types is given below.

Laboratory studies These may include screening studies performed with either the active ingredient itself or simple solutions of the active ingredient in a solvent carrier. Such tests are used to establish an innate toxic effect on the target organism(s) (dose response tests can additionally fall into this tier of testing category).

Simulated use studies These may be studies which are generated from test systems (including laboratory based situations) which are designed to reconstruct artificially the environment in which the product will be used.

Field studies These may be studies which are generated using the pesticide in the actual situation in which the proposed product will be used in the manner described in the product label.

A further distinction which can be made between these three types of studies is the nature of the formulation, application method and application rate used in these tests in relation to those of the likely product(s) for which approval is sought. For example, all of these parameters are likely to be the same as for the proposed product under field trial conditions. These distinctions are outlined in Table 1.

Table 1 Examples of the variability between efficacy study conditions conducted on a product containing a surface biocide active ingredient and actual use of the product should approval be granted

Nature of the study	Resemblance to the Product Application					Comments
	Active ingredient source	Formulation	Application method	Application rate	Organisms tested	
Laboratory/ Screening studies	✓	×	×	×	×/✓	These tests should provide an indication of the inherent biocidal activity and/or the range of concentrations over which such activity would be expected.
Simulated use tests	✓	×/✓	×/✓	✓	✓	These tests should introduce elements which reflect the environment in which the proposed product will be used.
Field Trials	✓	✓	✓	✓	✓	These studies should involve the use of the proposed product, formulated, applied and targeted as described on the product application form and draft label.

✓ - the same as that proposed in the product application

× - not always necessary to resemble/mirror that proposed in the product application.

This table illustrates the principle that efficacy studies generated before the final product formulation has been developed, where there have been different conditions used from those stipulated in the application for approval, have a part to play in the evaluation of an active ingredient in a surface biocide product.

The formulations used in laboratory studies may be simple solutions of the active ingredient whereas those used in simulated use studies may mirror the type of formulation for which approval is sought or may be the actual product formulation. It is recognised that field studies are more likely to be conducted on the actual product formulation.

To provide further guidance on the nature of laboratory and simulated use tests a number of examples are presented in Example Box 1.

Example Box 1 - Examples of possible studies that may be used to demonstrate surface biocide activity for use against dry rot or as a general surface biocide

Laboratory/Screening Studies

General surface biocide: (see Footnote 1)

Application of a range of concentrations of the active ingredient absorbed onto assay discs applied to a suitable nutrient agar medium seeded with either fungi or algae and following a suitable incubation period, determination of the zone of growth inhibition.

Simulated Use Tests

General surface biocide:

Laboratory tests employing actual building materials as substrates and permitting full substrate/organism/biocide interaction during testing. e.g., use of moist vermiculite-bed techniques to evaluate the efficacy of a biocide on a range of substrates.

Dry rot treatments:

Laboratory tests employing aged mortar which is treated with various concentrations or application rates of the test product and then exposed to challenge by *Serpula lacrymans* to determine the ability of the test fungus to grow over or through the treated substrate. One suitable method is described in ENV 12404 (1997) (See Appendix 4).

Field Trials

General surface biocide:

Natural exposure trials using samples from actual building material supported on an exposure rack in a region known to be vulnerable to establishment of biological growths, weathered and colonised by the organisms can be used to evaluate the efficacy of a biocide. Application of surface biocides to walls and other structures already colonised with lichens, mosses etc. may be used.

Dry rot treatments:

See footnote 2

Footnotes

1. At present, there are no laboratory methods for determining the efficacy of surface biocides against lichens, mosses and liverworts. These organisms are likely to colonise building materials placed on exposure racks but only after several years.
2. Field trials for dry rot control are difficult to establish because each outbreak is unique, so it is not possible to have 'untreated controls'. In treatments used to effect dry rot eradication, treatment requires major site works and the implementation of a 'package' of measures which together effect control. It is, therefore, difficult to design a field test which conclusively demonstrates that a product is efficacious, given that the level of actual biological challenge it is required to resist will be altered so much by the associated works and will vary greatly from building to building. The provision of a suitable simulated use test (e.g., one conducted to ENV 12404 (1997) or an equivalent) will normally be sufficient to give a good indication of field performance.

5.3 THE IMPORTANCE OF ‘CONTROLS’ IN EFFICACY STUDIES

The importance of control experiments for efficacy studies must be stressed with regard to the efficacy evaluation. Studies should be conducted alongside negative controls wherever possible to provide a reference point for the treatment results. A useful definition of this term is given below:

A negative control situation may be one in which the experimental design of the study is identical to that of the biocide challenge test except that the biocidal agent is not applied in the control study. A biocidal agent may be considered as the formulation or as the actual biocidal active ingredient itself.

It is recognised that generation of such control data can be relatively straightforward in well defined test situations such as laboratory and simulated use tests. However, it is also recognised that this can present a problem in field situations, where control sites may not be environmentally equivalent to the treatment site.

In such instances, there may be an alternative means of generating reference data other than collecting data from an untreated site. This method may involve pre-treatment monitoring of the site in question. This monitoring must be objective, e.g., assessment of numbers of trapped insects. In these instances, a ‘baseline’ infestation level would be established through such monitoring and then the effect of treatment on this baseline can be assessed. An example of a theoretical graph of such monitoring data is given in Example Box 2.

5.4 READ-ACROSS OF EFFICACY DATA TO DIFFERENT FORMULATION TYPES AND APPLICATION METHODS

It **will not** always be necessary to provide data on each and every individual product as wherever possible extrapolation between similar formulations within defined formulation types will be considered, provided such read-across is deemed appropriate. Justification of read-across may be provided through either the provision of a reasoned case *based on data* or through bridging arguments.

This is also the case when submitting a data package to support an application where the formulation type used in the study and the product for which approval is sought are not the same. A reasoned case *based on data* may be provided to justify why data from the study are relevant to that product application.

In the majority of cases, extrapolation will not be permitted between different formulation groups in the absence of supporting data.

For example, efficacy testing of a solvent based formulation will not support an application for a water based formulation.

However, the applicant may submit a reasoned case to read-across from one product application to another. Further information on possible surface biocide formulations and where read-across may be considered can be found in Appendix 3.

5.5 SUMMARY OF DATA REQUIREMENTS

The degree to which a product application is supported will depend upon the nature and extent of data presented in the efficacy data package.

In many situations, data based on simple laboratory/screening studies alone are unlikely to be enough to support the commercial approval of a product whereas the provision of other types (e.g., either simulated use tests or actual field (service) trials) are more likely to lead to a successful application.

Additionally, the acceptability of a test study is evaluated on the basis of all the relevant scientific information being available. Therefore, the Applicant's data submission should include all information necessary to provide a complete evaluation of the effectiveness of a candidate product. The Registration Authority will examine the submitted data package and a judgement will be made as to whether any data omissions are considered significant so as to delay assessment. Those so identified will be communicated back to the Applicant for supplemental data submission before the evaluation can be undertaken.

The next section of this document (Section 6) outlines the requirements of the Registration Authority with respect to details to be included in a test report and the standard of reporting.

6 DETAILS TO BE INCLUDED IN A TEST REPORT/STANDARD OF TEST REPORTING

The general information on the active ingredient(s) for which surface biocide activity is claimed and the level of detail required for each efficacy study submitted are presented in the following sections.

6.1 GENERAL INFORMATION WHICH SHOULD BE SUBMITTED ON THE ACTIVE INGREDIENT

For the activity of the product containing a new active ingredient(s), an active ingredient previously used in agricultural pesticides or an active ingredient used in a different sphere of non-agricultural pesticides to be assessed, a number of basic details are required to aid the initial stages of the efficacy evaluation. These are as follows:

- i) The chemical group of which the active ingredient is a member, e.g., quaternary ammonium compound, phenolic, chlorinated phenolic.
- ii) The mode of action of the active ingredient on the target organisms. This need only be a brief statement.

6.2 THE INFORMATION WHICH SHOULD BE SUBMITTED ON EACH STUDY

For a critical assessment of the efficacy data package to be undertaken, each study must be reported in sufficient detail to facilitate such an assessment.

The following requirements may exceed those expected in some of the standard tests available (see Appendix 4) and applicants commissioning work need to ensure that this information is supplied in full.

Each study must include details of the test protocol, end-use concentrations, controls, diluents, application rates and assessment criteria used in the particular test protocol. These should be relevant, wherever possible, to the product applications and their label claims.

A general checklist of information which it may be necessary to supply is given in Example Box 2 and the following is a more detailed examination of some of the elements raised in this example: -

Test reference

The submitted test should be provided with a full reference including the following (where appropriate): author(s), title, test house, year and a statement on whether these results have been published (if so a full journal reference should also be included whenever possible).

Study organisms	This is the full scientific name, and the culture collection strain number (where appropriate). In most instances, the test species must be representative of those encountered in practice and relevant to the product's draft label claims.
Active ingredient and formulation type.	<p>The active ingredient in the test formulation used in the study should be relevant to the product application submitted, i.e., the same specification as that stated for the proposed product. Therefore, the source should be presented in the study. In addition, the formulation type should be presented and where possible, complete formulation details should be stated (a list of typical surface biocide formulation types is given in Appendix 3).</p> <p>Ideally, studies should be conducted on formulations containing only the active ingredient(s) for which approval is sought. If other active ingredients are present, the full spectrum of their activity must be defined or it is difficult to interpret the results of the test with respect to the active ingredient in question.</p>
Application method(s)	The method(s) used to apply the active ingredient should be the same or similar (equivalent) to that proposed in the application for approval for at least simulated use and field tests.
Application rate	This should be reported in the test and should be able to support the proposed product application rate. Therefore, studies conducted at application rates lower than those proposed for the product may support a product application level but studies conducted at a higher rate than that proposed for the product may not be used to support an application
Study environment	Full details of the study environment should be provided with any test results. These should include temperature, humidity and lighting conditions, construction and dimensions of any test chambers/test structures.
Pesticide exposure details	All periods of exposure and methods of introducing the pests into the exposure scenario should be detailed in the test report. In addition, methods of recording/scoring the effect of exposure on the target pest should be given. In field studies, details of the monitoring regime adopted and any procedures to reduce human bias, e.g., reducing sampling bias from different operators during monitoring work, should be given.

EXAMPLE BOX 3 - A BASIC CHECKLIST FOR DETAILS TO BE INCLUDED IN A SUBMITTED STUDY

Test reports submitted to the Registration Authority typically should include the following details:

General

- The name and number of any standard protocol used (if applicable)
- Any deviations from standard protocols (if standard protocols are used)
- Test reference

Test organisms

- Species/strain of test organisms

Active ingredient and formulation details

- The nature and full details of the formulation(s) used (where relevant)
- The form in which the test product was used (e.g., RFU or diluted form)
- The solvent or diluent used
- The concentrations (expressed as % w/w) of the active ingredient present in the material tested.
- Application method for each test
- Application rates employed in the tests

Study details

- Nature of the substrates used in the test
- Conditions of test samples (e.g., ageing and/or natural/artificial weathering if applicable)
- Test chamber design/structure design
- Temperature, relative humidity and lighting during test
- Number of replicates
- Controls
- Duration of exposure (including start and finish dates for test)

Results

- Presentation of all results including tabulation or graphical presentation of the summarised results
- Scoring or other assessment system in the test
- Interpretation

NB. This checklist is not exhaustive and the items required on this list will vary between the test types that are reported in the efficacy data submission for a product. For example rearing of a pest species will not occur in field trials.

6.3 PRESENTATION OF RESULTS FROM EFFICACY STUDIES

The results for each study may be presented as tables, figures, photographs or graphs, as appropriate, but where graphs are presented, the data which have been used to construct the graph should also be provided where possible. Ideally, the results should be presented before correction for the control results and the corresponding control data should also be given. If detailed statistical analysis (e.g., analysis of variance, etc) are to be presented, it will not be accepted without the raw data on which these statistical analyses were performed. However, simple statistics such as mean and range, and regression analysis for graphical presentations may be presented.

The applicant's interpretation of these results should also be presented, although the evaluation and conclusions drawn from these data by the Registration Authority will be established before examining the applicant's statement.

Although efficacy data are not subject to the requirements of Good Laboratory Practice (GLP), the Registration Authority are aware that in the production of efficacy data applicants are likely to adopt standard Quality Assurance procedures (e.g., with respect to study personnel, methods, procedures, documentation, storage, archive and retrieval of data). Applicants are encouraged to continue this approach to ensure that if the Registration Authority requires further information (e.g., raw data), it will be readily available.

7

CONCLUDING COMMENTS

These guidelines are designed to be flexible and are intended to provide *advice* regarding the nature and type of efficacy data required to support the approval of non-agricultural pesticide products containing active ingredients intended for use as antifouling products. They do not set out a protocol to be followed exactly nor do they specify rigid protocols to which tests must be conducted in the process of generating efficacy data. They cannot give details on every possible evaluation situation, but outline the nature of the data required and the policy framework within which data will be evaluated. It is recognised that a wide diversity of products and their intended uses necessitates flexibility in the structure, layout and presentation of data.

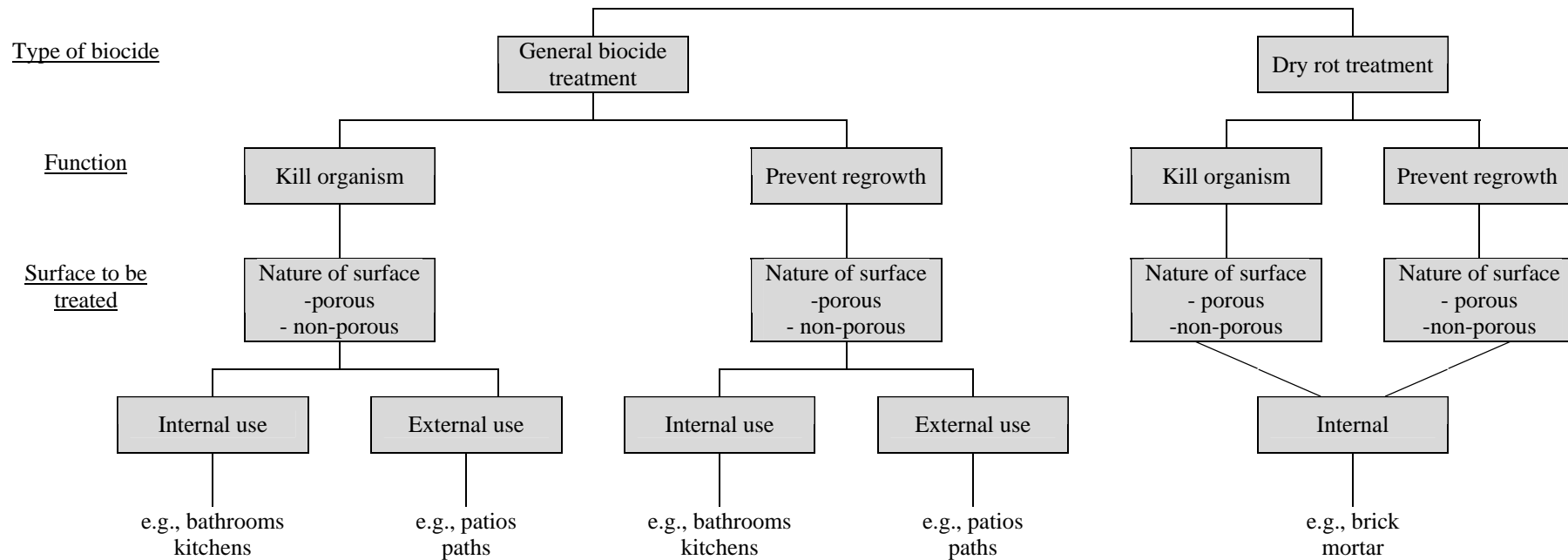
Applicants wishing to submit such products for approval, approval holders supporting active ingredients at review or addressing post approval data requirements, or interested parties requiring further guidance on efficacy requirements are encouraged to contact Biocides and Pesticides Unit (BPU) at their earliest convenience.

Biocides and Pesticides Unit
Health and Safety Executive
Magdalen House
Stanley Precinct
Bootle
Merseyside
L20 3QZ

Tel: (0151) 951 3535
Fax: (0151) 951 3317
E-mail: biocides@hse.gsi.gov.uk

APPENDIX 1

EXAMPLES OF POSSIBLE EFFICACY CLAIMS FOR SURFACE BIOCIDES: A BREAKDOWN OF THE INFORMATION WHICH MAY BE REQUIRED BY THE GENERATION OF EFFICACY DATA



APPENDIX 2

TARGET ORGANISMS AND POSSIBLE LABEL CLAIMS

The organisms selected for efficacy testing should be appropriate to the proposed product label claims for use on the United Kingdom market.

<u>Dry rot fungus</u>	<u>Mosses and liverworts</u>
<i>Serpula lacrymans</i>	<u>Mosses</u>
<u>Algae</u>	<i>Tortula muralis</i>
<i>Pleurococcus</i> spp.	<i>Barbula cylindrical</i>
<i>Stichococcus bacillaris</i> (green algae)	<i>Grimmia pulvinata</i>
<i>Gleocapsa alpicola</i> (green algae)	<i>Camptothecium sericeum</i>
<i>Nostoc commune</i> (blue-green algae)	<i>Rhynchostegiella tenella</i>
<u>Fungi/yeasts</u>	<u>Liverworts</u>
<i>Aspergillus versicolor</i>	<i>Lunularia cruciata</i>
<i>Aureobasidium pullulans</i>	<i>Marchantia polymorpha</i>
<i>Cladosporium caldosporioides</i>	
<i>Penicillium purpurogenum</i>	
<i>Phoma violacea</i>	
<i>Rhodotorula rubra</i>	
<i>Sporobolomyces roseus</i>	
<i>Stachybotrys atra</i>	
<i>Ulocladium atrum</i>	
<u>Lichens</u>	
<i>Lecanora dispersa</i>	
<i>Caloplaca</i> spp.	
<i>Candelariella</i> spp.	
<i>Buellia canescens</i>	
NB. This is not an exhaustive list of possible target organisms, it give some examples only from the major biological groups.	

It will not be necessary to test the entire range of organisms against which the biocidal product will be used. However, the test organisms chosen in laboratory studies should be representative of those encountered in practice.

The target organisms to be included in testing strategies can be confined to several broad groups as indicated above. Representative species from the above organism groups, e.g., lichens will have to be appropriate to the use pattern of the pesticide product, i.e., environment or areas to which the surface biocide is to be applied, e.g., indoor or outdoors, and will define the most appropriate species to be tested.

Where a broad label claim is made for a diverse range of target organisms and environments, at least one target organism from each group will need to be tested.

APPENDIX 3

TYPICAL FRAME FORMULATIONS CONSIDERED IN PRECEDENT SETTING OF PRODUCTS

These formulation types are placed into similar groups where read-across within the group may be considered. Read-across will only be considered when the application rates, areas of use etc. are equivalent.

This list is not an exhaustive one into which all product applications must be categorised. Applicants may submit novel formulation types not covered by this list or they may, in some cases, wish to submit a reasoned case *based on data* in support of their product application, if the product cannot readily be categorised into one of these groups.

Water based concentrate. Water based ready for use.	Water borne in-use systems which are not emulsion based systems.
Solvent based concentrate. Solvent based ready for use	Organic solvent based in-use systems
Liquid emulsion products.	Diluted emulsion in-use formulations in water
Paste formulations.	Solid/semi-solid preparations either water based or solvent based typically intended to be applied via trowel or caulking gun

APPENDIX 4

STANDARD TEST METHODOLOGY

There are, at present, only two standardised test methods which are relevant to this area of pesticides efficacy evaluation.

Standard	Date/Issue	Title
British Standard BS 3900. Part G6*	1989	Methods of test for paints. Part G6. Assessment of resistance to fungal growth.
European Prestandard ENV 12404	1997	Durability of wood and wood-based products – Assessment of the effectiveness of a masonry fungicide to prevent growth into wood of dry rot <i>Serpula lacrymans</i> – Laboratory method.

*The BS test has been published but only provides a methodology for production of a test surface for exposure by inoculation with mould growth. Therefore, this BS has to be modified to be used as a test method for assessing interior surface biocides.