

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

**INSECTICIDES  
AND ACARICIDES**

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## DEFINITION OF TERMS

<b>Active ingredient</b>	The component of a product which fits it for use as a pesticide.
<b>Application</b>	An application seeking approval to sell, supply, store, use or advertise a pesticide product in Great Britain.
<b>Approval</b>	An approval given jointly by Government Ministers under Regulation 5 of The Control of Pesticide Regulations (As Amended) 1986 (COPR).
<b>Committees</b>	The Advisory Committee on Pesticides (ACP), established under SI 1985 No 1517, and the Interdepartmental Secretariat (IDS).
<b>Evaluation</b>	A written assessment of study reports or other data examined in the course of an appraisal by the Registration Authority.
<b>Ministers</b>	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.
<b>Pesticide</b>	As defined in The Food and Environmental Protection Act 1985 (FEPA) (part III., section 16. (15) + (16)) and COPR (section 3. (1)).
<b>Quality Assurance</b>	Those procedures and controls, including inspections and audits, designed to monitor studies to assure the quality of the data.
<b>Raw Data</b>	All original records and documentation, including verified copies thereof, which are the results of original observations and activities in a study.
<b>Registration Authority</b>	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 an insecticide/acaricide, 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.

# **1 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 an insecticide/acaricide against pests in public hygiene situations (including stored product pests), 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.

In the context of this document, insecticide/acaricide products for use against public hygiene and stored product pests are deemed to include other products which also make claims for use against other arthropods, such as woodlice and millipedes.

*These guidelines are designed to be flexible 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 pests to be controlled, the 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(s) 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.

## **2 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 new active ingredients (and their products) and extensions of use of existing active ingredients (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 insecticide active ingredient now intended for use in non-agricultural pesticides as an insecticide/acaricide)
- 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 public hygiene insecticides)
- 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 ingredients (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**

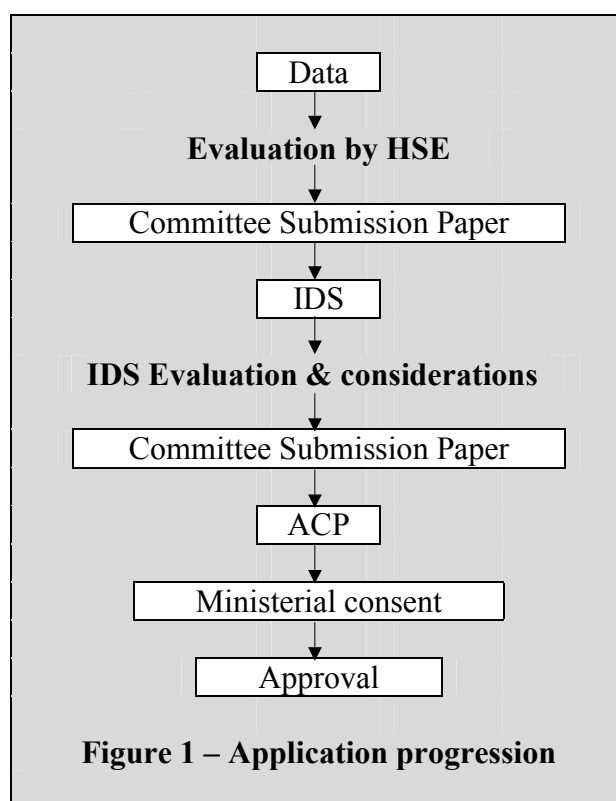
The five Government Department signatories to COPR are advised by the ACP after interdepartmental scrutiny of pesticides issues by the IDS.

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**

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 mode of action/effect
- iii) The area of use
- iv) Formulation type
- v) The application methods and rates at which the product is to be applied

Users of this guidance are again referred to Appendix 1 for further information on the examples of typical claims which may be made for a product and the activity which may need to be shown through efficacy testing, and Appendix 2 for further information on the label claims regarding target pest, mode of action and area of use. Some examples of formulation types are provided in Appendix 3.

## **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 this type of product. Current standard test methods available for efficacy testing of insecticides and acaricides are listed in Appendix 5. 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 formulation and application rate 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 formulation and application rate described in the published paper are relevant to the application. 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 provided it can be shown that the methods used, climatic conditions and pest(s) studied are relevant to the product application as used in a UK situation.

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 test, simulated use tests and field studies.

Useful definitions of these three study types is given below.

**Laboratory studies** These may include screening studies of the active ingredient, used to establish an innate toxic effect on the test pest species, dose response tests or simple laboratory studies, including surface contact tests, etc.

**Simulated use studies** These may be studies 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 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 the insecticidal/acaricidal product emphasising that each study submitted in a data package will be assessed on its own merit.*

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. Field studies should be conducted on the actual product formulation. Field studies provide the strongest support for product applications, if they are conducted to sufficient standards. Although a single field study is unlikely to be sufficient, on its own, to support a species/order.

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

**Table 1 Examples of the variability between efficacy study conditions conducted on a product containing an insecticide/acaricide 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	Pest tested	
Laboratory	✓	x/✓	x/✓	x/✓	x/✓	These tests should provide an indication of the inherent insecticide activity and/or the range of concentrations over which such activity would be expected.
Simulated use	✓	x/✓	x/✓	✓	✓	These tests should introduce elements which reflect the environment in which the proposed product will be used at the typical application rate etc. proposed for the product.
Field	✓	✓	✓	✓	✓	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

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

<b>Example Box 1 -</b>	<b><u>Examples of possible studies on cockroaches, fleas and a stored product pest in laboratory and simulated use types of test (the details of the product application these data could theoretically provide support towards are given in brackets).</u></b>
Laboratory -	<p>Direct cuticle application of active ingredient in solvent to Oriental cockroaches (<i>Blatta orientalis</i>) to assess contact toxicity (product application = public hygiene contact residual surface spray against cockroaches).</p> <p>Active ingredient present in a range of concentrations in flea rearing medium containing cat flea (<i>Ctenocephalides felis</i>) eggs (product application = residual surface spray against fleas).</p> <p>Sawtoothed Grain beetle (<i>Oryzaephilus surinamensis</i>) introduced into Petri dishes containing a surface coating of a dust formulation for a defined period of time (product application = contact dust against stored product beetles).</p>
Simulated use -	<p>Oriental cockroaches (<i>B. orientalis</i>) introduced into choice boxes, with one half of the base surface being sprayed with a test formulation (product application = public hygiene residual spray against cockroaches).</p> <p>Cat flea (<i>C. felis</i>) eggs are introduced onto treated carpet mat disc samples removed from a carpet mat which has been placed in a representative field site for a number of months (product application = residual surface spray against fleas).</p> <p>Sawtoothed Grain beetle (<i>O. surinamensis</i>) are introduced into a 0.06 m<sup>2</sup> container containing harbourages treated with a dust formulation (product application = contact dust against stored product beetles).</p>

### **5.3 THE IMPORTANCE OF ‘CONTROLS’ IN EFFICACY STUDIES**

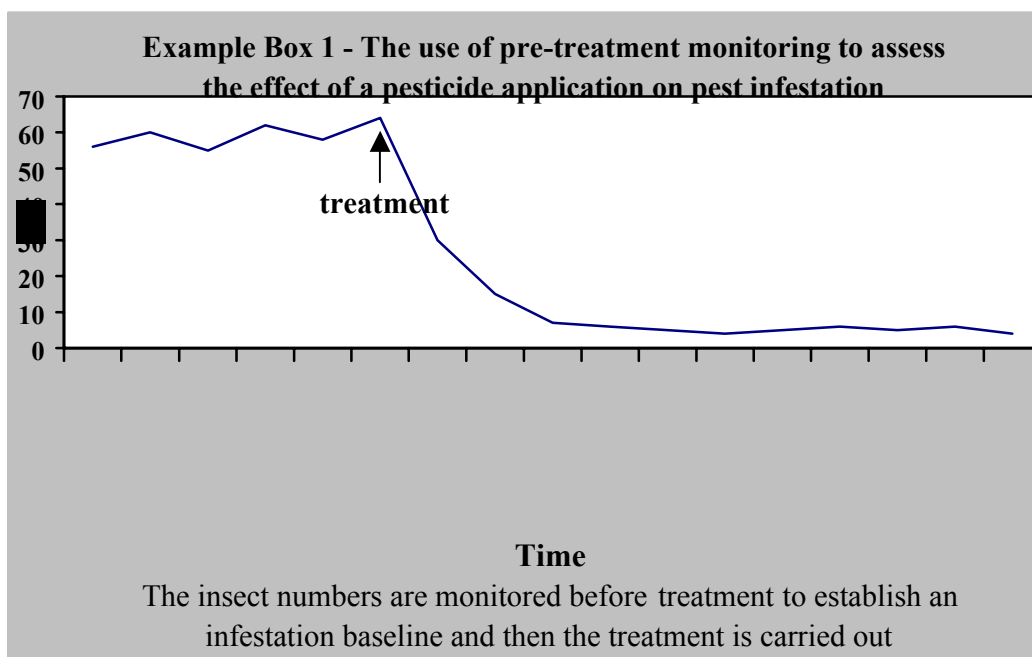
The importance of control experiments for efficacy studies must be stressed with regard to the efficacy evaluation. Studies should be conducted alongside negative controls wherever possible to provide a reference point for the treatment results. A useful definition of this term is given overleaf:

**A negative control situation may be one in which the experimental design of the study is identical to that of the pesticide challenge test except that the pesticidal agent is not applied in the control study. A pesticidal agent may be considered as the formulation or as the actual pesticidal 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 trial situations especially in public hygiene situations where leaving sites untreated to provide reference data can prove difficult if they present a health risk from the pest infestation. In addition, such control sites may not be environmentally equivalent to the treatment site and therefore direct comparison of the results through the treatment period may not be possible.

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.

Use of such a monitoring technique can still lead to some doubts as to whether such a drop in numbers is attributable to the pesticide treatment or other exogenous factors, e.g., a temperature drop, removal of food supply etc. One possible solution to such a validation problem may lie in repetition of such field trials across a number of sites representative of product use to show that this effect is due to the treatment, i.e., if a reduction in pest numbers is produced across a range of field sites tested, a pesticidal effect may be deduced.



## 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 suspension concentrate formulation.

Appendix 3 gives a list of possible insecticide formulation types and these are presented in the groups where read-across may be considered.

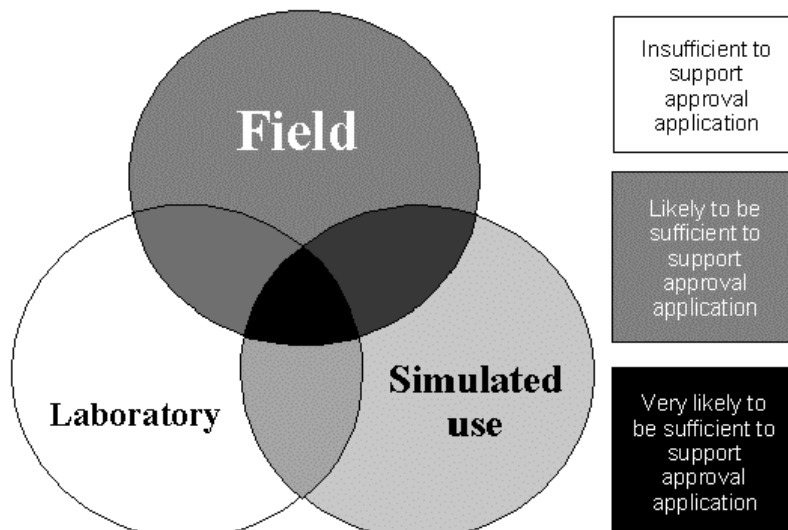
## 5.5 SUMMARY OF DATA REQUIREMENTS

The acceptability of data is judged on the quality of the data package as a whole. An overall judgement is made based upon the quality, number and scope of the studies submitted, as well as their relevance to the target pests and label claims. Ultimately, 1 or 2 good studies can provide more support to an application than several poor ones.

The degree to which a product application is supported will depend upon a number of factors, including the following:

- i) The quality of the data submitted
- ii) The extent of the data package
- iii) The balance of laboratory, simulated use and field data

With regard to iii) above, the possible interaction of elements of an efficacy data package and their potential of supporting a commercial approval is summarised in the diagram below.



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

The general information on the active ingredient(s) for which insecticide/acaricide 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 AND PRODUCT**

For the activity of the product containing a new active ingredient, 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., carbamate, synthetic pyrethroid, organophosphorus compound.
- ii) The mode of action of the active ingredient on the target pests. This need only be a brief statement but should give details such as the route and nature of the action, e.g., contact poison, and the nature of the effect, e.g., juvenile hormone analogue giving rise to sexually immature adults or supernumerary nymphs.

### **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. Each study must include details of the test protocol, which will include different elements depending on the nature of the study, i.e., whether it is a laboratory, simulated use or field trial study.

A general checklist of information which it may be necessary to supply is given in Example Box 3 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).

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

	<b>Yes</b>
<b>Test Reference</b>	<input type="checkbox"/>
<b>Test species</b>	
Stage of the life cycle	<input type="checkbox"/>
Age of the stadia	<input type="checkbox"/>
Collection and rearing conditions/source of test organisms	<input type="checkbox"/>
Any selection pressure	<input type="checkbox"/>
Numbers used in the test	<input type="checkbox"/>
Sex of those used in the test	<input type="checkbox"/>
<b>Active ingredient and formulation type</b>	
Source	<input type="checkbox"/>
Formulation type	<input type="checkbox"/>
Complete formulation	<input type="checkbox"/>
<b>Study details</b>	
Preconditioning of test species	<input type="checkbox"/>
Application method used	<input type="checkbox"/>
Application rate	<input type="checkbox"/>
Test chamber construction/measurements	<input type="checkbox"/>
Temperature, relative humidity and lighting during the test	<input type="checkbox"/>
Number of replicates	<input type="checkbox"/>
Controls	<input type="checkbox"/>
Nutrient supply conditions	<input type="checkbox"/>
Any additions or alterations to the test environment during the study	<input type="checkbox"/>
Duration of the exposure to the pesticide	<input type="checkbox"/>
Post-study monitoring of test species	<input type="checkbox"/>
<b>Results</b>	
Results/data	<input type="checkbox"/>
Interpretation	<input type="checkbox"/>

*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.*

**Pests used in the study**

This is the scientific name, stadia used, age of stadia, collection and rearing conditions and numbers and sexes used in the study. In most instances, the test species must be appropriate to the product's draft label claims but this need not be the case if the study is included to generally support the use of an active ingredient as an insecticide/acaricide (the choice of pest species used in efficacy studies is discussed further in Appendix 2 of this document).

If the pest used has been selectively reared under a pesticides stress to maintain a higher physiological resistance state to a particular group of pesticidal compounds, details should be given.

For any product claiming use against cockroaches in the UK, two species will be required and these should be the German cockroach (*Blattella germanica*) and the Oriental cockroach (*Blatta orientalis*). This does not preclude the submission of other cockroach species data.

It is recognised that, in instances such as when efficacy data are generated to support an application, containing a new active ingredient, originates from outside the UK or product development strategies have been initiated prior to the original guidance document being issued (16<sup>th</sup> February 1996), data on these two species of cockroach may not be available. In these cases, at least a confirmatory efficacy data requirement on the other species is likely to be required as a condition of approval and depending on the breadth of the cockroach efficacy package such data may be required before commercial approval is granted.

**Active ingredient and formulation type.**

The active ingredient in the test formulation used in the study should be relevant to 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 insecticide formulation types is given in Appendix 3).

**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.**

**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. This is summarised in Example Box 4.

**Study environment**

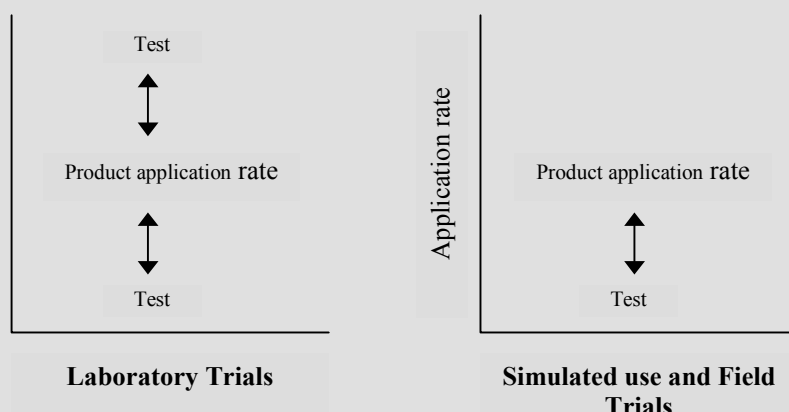
Full details of the study environment should be provided with any test results. These should include temperature, humidity and lighting conditions, construction and dimensions of any test chambers and the addition of any nutrients and water to such chambers. For field efficacy studies, the site environment should be described in enough detail to enable the Registration Authority to establish whether the situation is supportive of those proposed in the product label claims. In addition, appropriate observations, monitoring and recording of changes that might affect pest populations should be made.

**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.

Further specific elements which are required when submitting data from the use of bait stations and other similar formulation containment devices are detailed in Appendix 4.

**Example Box 4 – Acceptable application rates in efficacy studies to support proposed product application rates**



*N.B. Laboratory study data generated at rates greater than those proposed for the product may be acceptable when used to establish the dose effect range for an active ingredient against a target pest.*

## **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.

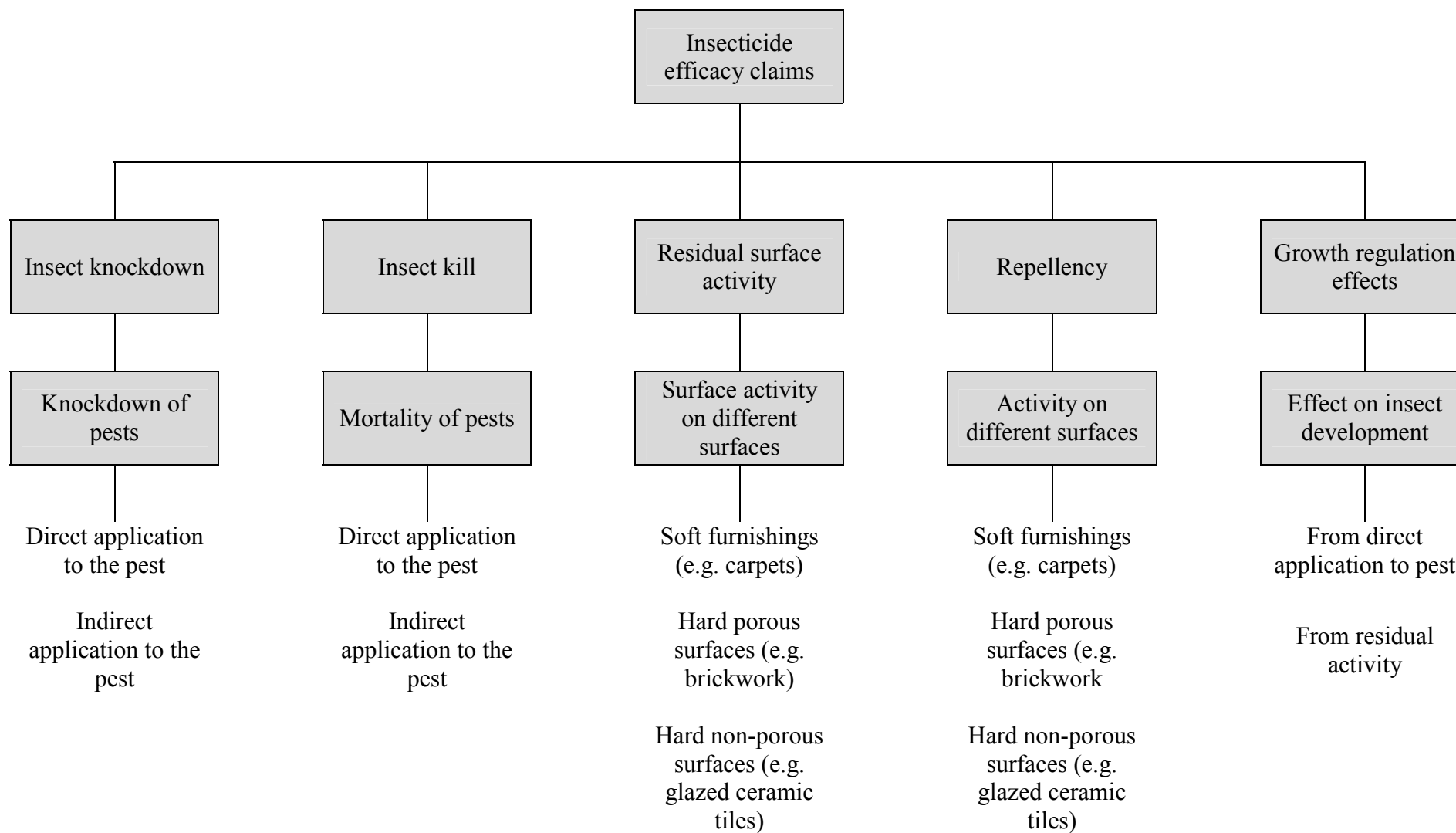
**Applicants wishing to submit such products for approval, approval holders supporting active ingredients at review or addressing post approval data requirements, or interested parties requiring further guidance on efficacy requirements are encouraged to contact Biocides and Pesticides Unit (BPU) at 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](mailto:biocides@hse.gsi.gov.uk)

## APPENDIX 1

### POSSIBLE INSECTICIDE EFFICACY CLAIMS: A BREAKDOWN OF THE INFORMATION WHICH MAY BE REQUIRED BY THE GENERATION OF EFFICACY DATA



## APPENDIX 2

### LABEL CLAIMS

#### Pests against which the product is to be used

The pest selected for efficacy testing should be appropriate to the proposed label claims for use in the UK market. When broad claims are made, tests on representative pest species need to be provided for the range of **pest orders** on the label. The typical orders for UK pests are shown below with the common or generic names by which these orders are known. Either common or generic names may be used on the label.

#### Insect orders

Thysanura	Silverfish and other bristletails
Dermaptera	Earwigs
Dictyoptera	Cockroaches
Psocoptera	Booklice
Hemiptera	True bug
Lepidoptera	Moths
Siphonaptera	Fleas
Coleoptera	Beetles
Hymenoptera	Wasps and ants
(Formicoid hymenoptera	Ants)
Collembola	Spring tails
Thysanoptera	Thrips
Orthoptera	Crickets
Isoptera	Termites
Diptera	True flies

#### Arachnid orders

Araneae	Spiders
<b>Parasitiformes</b>	Parasitic mites and ticks
<u>Suborders of Parasitiformes</u>	
Mesostigmata	Blood sucking mites e.g. red poultry mite
Metastigmata	Includes soft and hard ticks
<b>Acariformes</b>	Mites
<u>Suborders of Acariformes</u>	
Prostigmata	
Astigmata	e.g. house dust mite

#### Other orders

Isopoda	Woodlice
Myriapoda	Centipedes and millipedes

### **Data requirements for specific label claims**

For specific target pest claims where only efficacy against one insect/arachnid order or a certain family within that order is claimed, a limited number of test pest species will be required. To illustrate this point, a number of examples are given below:

FOR USE AGAINST DUST MITES – this may only require testing against a *Dermatophagoides* sp.

FOR USE AGAINST FLEAS – this may only require testing against the cat flea (*Ctenocephalides felis*) or the dog flea (*C. canis*).

FOR USE AGAINST COCKROACHES – this will require testing against the German cockroach (*Blattella germanica*) and the Oriental cockroach (*Blatta orientalis*).

### **Data requirements for broad label claims**

Broad label claims, such as “*crawling insect killer*” or “*flying insect killer*”, should be accompanied by qualification of the range of pests against which the product may be used. When broad claims are made, tests on representative pest species will need to be provided for the range of pest orders against which efficacy is claimed.

Representative pests from these pest orders will have to be appropriate to the use pattern of the pesticide product, i.e., the environment of the areas to which the pesticide is to be applied and the nature of the application (e.g., whether it is a space application or a surface application) will define the most appropriate pests to be tested.

For each order stated, at least the principal target species will need to be tested for public hygiene use. In more specific areas, such as use against stored product pests, at least two major representatives of the orders in question will require testing before a general claim is likely to be supported. Where such a claim covers a diverse range of pest habitats and pest morphology and biology, a greater number of representative species will be required.

### **The distinction between principal target and secondary/incidental target pests**

When a broad claim is made for a product, some pests will be defined as principal target pests and some as secondary/incidental target pests.

The following wording should be used on labels and other advertising literature for users to distinguish between primary and secondary target pests:

‘For the control of W, X\* and other crawling\*/flying\* insect targets such as Y\* and Z that may be encountered by chance during the main treatment.

W and X represent the ‘primary’ or ‘major’ pests and Y and Z represent the ‘minor’ or ‘secondary’ pests (\*delete as appropriate).

For example:

*For the control of ants, fleas, cockroaches, and other crawling insects such as silverfish, earwigs and spiders that may be encountered by chance during the main treatment.*

The principal target pests are ants, fleas and cockroaches, but silverfish, earwigs and spiders may be treated incidentally when applying the pesticide to the main target pests.

In such situations, where there is a clear distinction between the two target groups on a label, the secondary/incidental pests may only require simple but appropriate confirmatory laboratory-based testing, to supplement the extensive studies conducted on the major target pests.

**The Registration Authority will not impose such distinctions and hence the responsibility of deciding whether the principal and secondary/incidental targets exist within the claims made for product rests with the applicant.**

**The opportunity to use such discretion does not mean that Applicants may use such arguments to avoid thorough efficacy testing against public hygiene pests of significant importance, e.g., cockroaches.**

#### **Mode of action/Effect**

There are a variety of modes of action and possible effects on pests of insecticides/acaricides. The data submitted should give brief details to indicate the route and nature of the action (e.g. whether action is by contact or stomach poison), and the nature of the effect (e.g. cholinesterase inhibition, chitin synthesis inhibition, juvenile hormone analogue).

Additionally the available data should indicate what effect application of the product is expected to achieve. Examples could include:

- Knockdown
- Kill
- Residual activity
- Flushing activity
- Ovicidal, larvicidal or other developmental effects
- Ability to control strains of pests exhibiting resistance to other insecticides/acaricides

#### **Area of use and sites of application**

The label claim should clearly indicate the use pattern for the product. The most common areas of use for insecticides/acaricides fall into the following list of categories (N.B. products may often incorporate treatments using one or more of these areas of use. The list is not exhaustive):

- General surface treatments
- Contact (direct) spray treatments
- Crack and crevice treatments
- Space treatments
- Spot treatments
- Baits

Some illustrative descriptions of these areas of use are provided below:

### **General surface treatments**

These products are applied to broad expanses of surfaces such as walls, floors and ceilings or as an outside treatment to surfaces. This will normally include those products used for the control of pests on surfaces by treatments applied directly to the surfaces. Evaluation of products designed to be applied as surface treatments must be considered against the proposed label claims and the claimed effects (e.g. non-residual or residual). Examples include coarse sprays (including pressurised packs), dusts, lacquers, liquid water sprays or granular formulations applied as larvicides to permanent or temporary water bodies (e.g. for the control of mosquito larvae) or to solid and semi-solid manure (e.g. for the control of flies or beetles in animal houses/rearing units).

### **Crack and crevice treatments**

This refers to the application of small amounts of insecticide/acaricide into cracks and crevices where pests hide or through which they may enter the building. Such openings commonly occur at expansion joints, between different elements of construction and between equipment and floors. These openings may lead to voids such as hollow walls, equipment legs and bases, conduits and junction or switch boxes.

### **Contact (direct) spray treatments**

Application directly onto insects/mites is only likely to be possible when the insects are **visible** and **available** to a spray, and in practice this generally restricts direct application methods to controlling flying insects such as adult moths and houseflies. However, limited control of minor infestations of crawling insects such as ants or beetles may be possible in some situations.

### **Space treatments**

The control of flying insects can be achieved using non-residual space treatments with products dispersed in the atmosphere, e.g. fogs, mists, aerosols (including pressurised packs), vapourisers, smokes, etc., where small insecticide particles are applied into the air when insects are present. The very small particles (generally less than 80 µm volume medium diameter) will stay in the air for several hours in still conditions - but exposed insects should be contacted very quickly. Insecticide active ingredients, which have some residuality in structural sprays, are unlikely to demonstrate a residual effect when applied as a space treatment, due to the relatively low dosages applied with the latter.

### **Spot treatments**

These are products applied to limited areas on which insect pests are likely to occur, but which will not be in contact with food or utensils and will not ordinarily be contacted by workers. These areas may occur on floors, walls and bases or undersides of equipment. For this purpose a "spot" will not normally exceed an area of 0.19 m<sup>2</sup>.

### **Baits**

Bait products are intended for the control of pests by attracting them to a point where they will pick up the insecticide/acaricide by feeding or contact. These products usually utilise a palatable food base and sometimes incorporate an attractant (e.g. a pheromone), which may draw the pest to the bait over some distance.

## APPENDIX 3

### POSSIBLE INSECTICIDE/ACARICIDE FORMULATION TYPES

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. In some of these formulation types, the application method is an integral part of the formulation.

The list is not an exhaustive one into which all product applications must be categorized. Applicants may submit novel formulation types not covered in this list or they may, in some cases, wish to submit a reasoned case 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 solutions which are not emulsion based systems
Solvent based concentrate Solvent based ready for use	Organic solvent based in-use solutions
Emulsifiable concentrate	Diluted emulsion formulations in water
Microemulsion concentrate Microemulsion ready for use	Stable emulsion with very small droplets
Solid/powder concentrate Wettable powder Suspension concentrate Dusting powder Granules	Particle-based formulations which may be applied as water-based suspensions, likely to leave powder residues on the surfaces to which they are applied
Aerosol	Pre-pressurised active ingredient solutions dispersed as aerosols directly into the air or onto surfaces
Microencapsulated water suspension concentrate	Polymer encapsulated formulations diluted with water
Bait Gel	Liquid/solid/semi-solid preparations applied in baiting strategies, relying on consumption of the formulation by the target pest
Lacquer	Solvent based film forming composition
Plastic strip Coil Vapourising mat/tablet Impregnated sticker	Airborne active ingredients, vaporised or volatilised through delivery design or natural convection
Smokes	Airborne active ingredient present as particles generated by the combustion of the product

## APPENDIX 4

### BAIT STATIONS AND SIMILAR FORMULATION CONTAINMENT DEVICES – INFORMATION TO BE PROVIDED FROM SIMULATED USE AND FIELD TRIALS

The nature of this product type requires specific pieces of information be provided on each study submitted in support of such an application or approval. These details should be provided in each study report.

- **Treatment area**

The site of the study should be submitted in detail (Applicants may submit maps detailing monitoring sites, bait placement sites, etc.). This should include measurements of total area within the study, the nature of pest harbourages and environmental conditions whenever possible should be stated.

- **Monitoring strategy**

The nature/description of the devices used in the study to monitor the insect population should be reported. In addition, the positions and numbers of devices used, and details of the monitoring time periods should be recorded.

The numbers of pest individuals trapped using these monitoring devices should be presented. The format of the results (whether this number is the average per device or the total for all devices) should be clearly stated. The applicant may submit all trap data for each device. These numbers may be further divided into pest stadia or sex if these data are available.

If pre-treatment monitoring is carried out then these data should be submitted. The applicant should state any changes to monitoring positions, numbers of sites and monitoring strategy from that used in the pre-treatment part of the study. If all monitoring is consistent across the pre-treatment, treatment and post-treatment periods of the study then a statement should be made to this end.

- **Treatment strategy**

The number of treatment devices used and the baiting density in the study should be reported. The time intervals between replacing these devices should be stated and any changes to baiting density during the study should be recorded.

- **The device**

There should be a full description of the treatment device used in the study, including its dimensions and the number and dimensions of pest entrances into the device. The applicant should include a statement of whether this device is the same as that used in the product application or approval.

## APPENDIX 5

### CURRENT STANDARD TEST METHODS AVAILABLE FOR EFFICACY TESTING OF INSECTICIDES AND ACARICIDES

**Table 1. Available Standard Test Methods For Efficacy Testing Of Products Used In The Control Of Flying Insects**

Standard	Date/Issue	Title
AFNOR Norme Francaise – NF T 72-320	1977	Method for aerosol space sprays against houseflies
British Standard BS 4172 – Parts 1 and 2	1999	Aerosol space sprays – Houseflies (adaptable for other flying insects) Method and specification
South African Bureau Of Standards Method 807	1979	Methods for testing insecticides against flying and crawling insects
US ASTM E653-91 (2003)	2003	Standard Method for testing Effectiveness of Aerosol and Pressurised Space Spray Insecticides Against Flying Insects
US ASTM E652-91 (2003)	2003	Standard Test Method for Non-residual Liquid Household Insecticides Against Flying Insects
US CSMA Aerosol Guide 7 <sup>th</sup> Edition pp 129-134	1981	Test method for aerosol space sprays against flying insects
US EPA Guideline OPPTS 810.3000	1999	General considerations for efficacy of invertebrate control agents
US EPA Guideline OPPTS 810.3300	1999	Treatments to control pests of humans and pets
US EPA Guideline OPPTS 810.3400	1999	Mosquito, Black Fly and Biting Midge (Sand Fly) Treatments
US EPA Guideline OPPTS 810.3500	1999	Premises treatments
US EPA Guideline OPPTS 810.3700	1999	Insect repellents for human skin and outdoor premises
World Health Organisation WHO/VBC/81.805	1981	Instructions for determining the susceptibility or resistance of adult mosquitoes to organochlorine, organophosphate and carbamate insecticides – establishment of the baseline
World Health Organisation WHO/VBC/81.806	1981	Instructions for determining the susceptibility or resistance of adult mosquitoes to organochlorine, organophosphate and carbamate insecticides – diagnostic test
World Health Organisation WHO/VBC/81.810	1981	Instructions for determining the susceptibility or resistance of adult blackflies, sandflies and biting midges to insecticides
World Health Organisation WHO/VBC/81.813	1981	Instructions for determining the susceptibility or resistance of houseflies, tsetse flies, stableflies, blowflies etc. to insecticides

**Table 2. Available Standard Test Methods For Efficacy Testing Of Products Used In The Control Of Crawling Insects**

<b>Standard</b>	<b>Date/Issue</b>	<b>Title</b>
US CSMA Aerosol Guide 7 <sup>th</sup> Edition pp 135-139	1991	Test method for pressurised spray products against cockroaches
US ASTM E654-90	1990	Direct spray test method for spray insecticides against cockroaches
US ASTM E654-96 (2003)	2003	Standard test method for effectiveness of aerosol and pressurised spray insecticides against cockroaches
World Health Organisation WHO/VBC/75.593	1981	Instructions for determining the susceptibility or resistance of cockroaches to insecticides
US EPA Guideline OPPTS 810.3300	1999	Treatments to control pests of humans and pets
World Health Organisation WHO/VBC/81.809	1981	Instructions for determining the susceptibility or resistance of adult bed bugs to insecticides
World Health Organisation WHO/VBC/81.814	1981	Instructions for determining the susceptibility or resistance of adult ticks to insecticides
World Health Organisation WHO/VBC/81.815	1981	Instructions for determining the susceptibility or resistance of fleas to insecticides
South African Bureau of Standards Method 807	1979	Methods for testing insecticides against flying and crawling insects
US EPA Guidelines OPPTS 810.3500	1999	Premises treatments
EPPO PPP Efficacy Guidelines PP 1/202 (1)	1998	Space and structural treatments of store rooms
EPPO PPP Efficacy Guidelines PP 1/204 (1)	1998	Laboratory testing of plant protection products against insect and mite pests of stored plant products

**Table 3. Available Standard Test Methods For Efficacy Testing Of Fumigants**

<b>Standard</b>	<b>Date/Issue</b>	<b>Title</b>
EPPO, Paris	1982	EPPO Recommendations on fumigation standards (2 <sup>nd</sup> Edition)
EPPO Bulletin, <u>15</u> , p1-119, Paris	1983	The EPPO Conference on Fumigation, Paris, 1983
EPPO PPP Efficacy Guidelines PP 1/201 (1)	1998	Fumigants to control insect and mite pests of stored plant products

**Table 4. Available Standard Test Methods For Efficacy Testing Against Larvae**

<b>Standard</b>	<b>Date/Issue</b>	<b>Title</b>
British Standard BS 4797 ISO 3998	(1978) 1977	Test method for textiles to determine resistance to insect pests (e.g., moths, carpet beetles, etc.)
US AATCC Technical Manual Method 24	(1992) 1989	Test method for textiles to determine resistance to insects (e.g., moths, carpet beetles)
World Health Organisation WHO/VBC/81.807	1981	Instructions for determining the susceptibility or resistance of mosquito larvae to insecticides
World Health Organisation WHO/VBC/81.812	1981	Instructions for determining the susceptibility or resistance of mosquito larvae to insect development inhibitors
World Health Organisation WHO/VBC/81.811	1981	Instructions for determining the susceptibility or resistance of blackfly larvae to insecticides