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Transitional Guidance on the Biocidal Products Regulation

Transitional Guidance on Efficacy Assessment for Product Type 18, Insecticide, Acaricides & other Biocidal Products against Arthropods and Product Type 19, Repellents & Attractants

September 2016

TRANSITIONAL GUIDANCE

LEGAL NOTICE

This document aims to assist users in complying with their obligations under the Biocidal Products Regulation (BPR). However, users are reminded that the text of the BPR is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

Transitional Guidance on Efficacy Assessment for Product Type 18 Insecticide, Acaricides & other Biocidal Products against Arthropods and Product Type 19 Repellents & Attractants.

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PREFACE

This Transitional Guidance is to be applied to applications for active substance approval and product authorisation submitted under the Biocidal Product Regulation (EU) No 528/2012 (the BPR). This document describes the BPR obligations and how to fulfil them

This Transitional Guidance replaces part of Appendices to Chapter 7 (page 187 to 200) from the Technical Notes for Guidance (TNsG) on Product evaluation in support of Directive 98/8/EC (Biocidal Product Directive - BPD). This document deals with the evaluation of efficacy tests for biocidal products of product type 18 (insecticide, acaricides and other biocidal products against arthropods) and product type 19 (repellents and attractants) as far as invertebrates are concerned.

A "Transitional Guidance" is a document that has been initiated under the "old" Biocidal Products Directive 98/8/EC and because it has been finalised before the relevant new BPR guidance document has been fully developed, it is being made available as a Transitional Guidance document until such time as the relevant new document is ready for publication.

This Transitional Guidance document has had a Public Consultation by the Commission and this document is now finalised and waiting for inclusion into Volume II Efficacy Assessment and Evaluation (Parts B+C) of the new BPR guidance structure: there will be no further consultation on this document and it will be added to Volume II Efficacy Assessment and Evaluation (Parts B+C) following its consultation and before publication.

NOTE to the reader:

This Transitional Guidance will be reformatted when it is incorporated into the New Guidance Structure. When this is completed, the finalised version will be uploaded onto the website of ECHA. No consultation will be made to do this.

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1. Introduction

Depending on its field of use a product to control, repel or attract insects and other arthropods may be classified as a biocidal product or plant protection product. This section covers the products to control, repel or attract insects and other arthropods in the category of biocides, which are products against all pest arthropods except those that are plant parasitic.

Attractants used in monitoring traps to assess the necessity and the success of pest management measures are considered outside the scope of Biocides Directive (Manual of Decisions, "Traps for monitoring purposes").

This first section gives a general introduction. The following sections describe per insect or per type of use what the requirements for efficacy testing are. Information is missing on some of the organisms to be controlled with these products and also some of the uses and types of products. For instance, little information is provided on attractants (e.g. sex pheromones etc.) and treated articles (e.g. insecticide treated mosquito nets etc.). These data gaps will be filled in a future update of this guidance.

1.1 Aim

The aim is to assess the efficacy of biocidal products, to ensure that only effective products enter the market.

1.2 Global structure of the assessment

A full assessment of efficacy is conducted for applications for product authorisations.

Factors, which are taken into consideration during assessment of the efficacy for a biocidal product to control, repel or attract insects and other arthropods for which authorisation is sought, are:

- the target organism to be controlled, repelled or attracted;
- the physical state in which the product is applied (e.g. liquid/powder/bait);
- the areas of use, these may be:
- in and around residential homes and other spaces in which people are accommodated;
- in and around spaces in which animals are accommodated
- in spaces intended for the preparation, processing or storage of food and beverages;
- in empty stores, ship's holds, factories and silos.

Information on effectiveness and intended uses of the product, together with its active substances, must be sufficient to permit an evaluation of the product, including the nature and benefits that accrue following use of the product in comparison to suitable reference products or damage thresholds, and to define its conditions of use.

A combination of laboratory studies, rigorous simulated-use laboratory studies, or field studies can be used to evaluate whether the product is effective for the requested use(s) at the specified doses. Data from these studies are compared with the specified criteria.

Assessment will be made mainly in relation to the claims for the effectiveness of the product made on the product label. This assessment will take into account the pest(s) to be controlled, indoor or outdoor use, the method(s) of application, application rates and use patterns of the product, maximum storage period of the product, together with any other specific claims made for the product. More information on different aspects of the

label claim can be found in Appendix 1. Appendix 2 shows examples of possible label claims.

1.3 Dossier requirements

Data on efficacy are required for every application for authorisation.

The following guidance is designed to be flexible and does not specify rigid protocols to which tests must be conducted. Published or unpublished data from any source will be considered provided the data are valid and relevant to the application. In all cases, the methods and results have to be described in sufficient detail to make the data reproducible and to allow a full assessment. Anecdotal evidence will not be acceptable.

Ideally, data should be generated using internationally recognised testing methods (ISO, CEN, OECD, WHO etc.). Several international standard test methods currently exist for insecticide/acaricide products. A list of these is presented in Appendix 3 to this document.

If there are no guidelines available or guidelines are not suitable, the applicant may use their own methods (intra-company Standard Operating Procedures), on condition however, that the studies are scientifically robust, well reported and provide a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label. The use of existing guidelines, with revisions to make the guideline more suitable for the specific product or company conditions, is also possible.

For each test information such as the following should be available:

- the names of actives substances and their respective concentration in the tested formulation.
- as the formulation may be very important for the efficacy, if the test item differs from the product to be authorised, its composition should be provided.
- a statement about what is expected from the test, what should be determined and with which precision. Power and sample size considerations should be included as well.
- description of the test conditions (size of cage, floor area, presence of harbourages, presence of (alternative) food, water, temperature, photoperiod, location, weather conditions).
- are the test organisms allowed to acclimatise to the test conditions before the test? For how long?
- how many test organisms are present (sample size)?
- describe population composition (males, gravid or non-gravid females, nymphs, larvae, age of the population or generation number F1, fed or unfed) noting that the feeding behaviour of some insects (i.e. *Blattella*) changes during their life.
- are the test organisms starved prior to the test?
- are field strains or known insecticide-resistant strains tested (claim "effective against strains resistant to x")?
- a description of the history and origin of the test strain.
- is bait consumption determined? If so, a covered bait should be included to determine weight loss due to evaporation to correct weight loss of the exposed bait for actual consumption.
- are one or more alternative baits (e.g. registered reference products) or alternative food source present in the same test container or protocol?

- raw data should be available for each study, rather than just a summary of the results
- show the results of both tests (with biocide) and control (without biocide) treatment, preferably in a table
- size of the test population in the field before and after the test
- description of the monitoring methods used before, during and after the test
- statistical methods, if appropriate.

1.3.1 Test design

Although in general nationally or internationally recognised testing methods are preferred it is not always possible to use these. For some products no standard methods are suitable. In that case a test has to be designed.

Various factors must be considered when designing the tests, for example the number of test individuals (insects, mites, other arthropods) needed. The ultimate aim of relevant considerations should be to design experiments that economise on test individuals, but on the other hand generate sufficient power to detect effects of a magnitude considered important to demonstrate. To save test individuals, replicate tests are conducted. Another argument for using replicates is to account for the variation among test individuals in susceptibility and responses to the biocides. Numbers of test individuals per replicate group and dose level (treatment group) as well as the number of replicates in the entire study need to be established prior to conducting the tests. As the improvement in power wears off substantially as the number of replicates increases beyond five, it is usually sufficient to conduct four or five replicate tests at each dose level, employing 10 (or 20) test individuals each. The precise needs will depend on the size of the variances, relative and absolute, between and within the replicates. This can differ between insect species and test design. Sample size should be adequate to detect differences among groups (untreated vs treated) with a statistical power of at least 80%. Some details on these issues are outlined at the end of each section.

Useful information on the principles of test design, analyses end evaluation of efficacy trials can be found in the EPPO standards pp1/152(3) and pp1/181(3).

1.3.2 Test examples

In the following sections (2 to 15) examples are given of what kind of tests can be expected for efficacy testing. Sometimes these examples are a summary of a standard test, in other cases a company test is described or a general idea of what the test should be like is given. There is a great variation in how specific the description is. For instance, the number of replicates is given only when this was determined in the test described.

In all cases these tests are only meant as examples, not obligatory requirements. Since products against insects and other arthropods are so diverse in application method, mode of action etc. the guidance cannot possibly cover all possible ways of controlling arthropods.

1.3.3 Laboratory versus (semi) field trials

Laboratory and field trials with the test arthropods are normally needed to assess the efficacy of the product. Field trials are not mandatory in some cases, as outlined in the sections on specific groups of arthropods below. In some cases when robust field studies are available, laboratory studies can be waived. If the product is applied as a bait, the entire bait, including the bait-box if applicable, should be tested, not only the product which is contained in the bait. When efficacy against several insects or other arthropods

is claimed not all organisms have to be tested when appropriate bridging studies are available.

In the case of field trials where true replication is almost certainly impossible to achieve, a full description of any factors that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent areas, general levels of sanitation, treatment history etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

In the following sections (2 to 12) more specific dossier requirements are given per pest species. In most cases a general description of a proposed method is provided. This is only to give an idea of what kind of tests should be provided. More detailed descriptions of tests can be found in the standard test methods (norms) listed in Appendix 3. This is a list of all available methods (as far as we know now) without distinction on usefulness, repeatability, order of acceptability or robustness. Some norms might have a different approach than described in the section for that insect. If this approach is more suitable for the product under investigation the norm should be used.

1.3.4 The importance of controls on 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: "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 gredient itself."

The negative control trial should normally be of similar size (i.e. number of replications) as the test itself, to make statistical comparison possible and to get a fair impression of control mortality.

A relevant reference product (authorised, commercially available) can often be included at label rates in a protocol for laboratory and/or field studies as positive control. Unfortunately at this moment no standard reference products are available, however, an authorised reference can be included.

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 quantitative, 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. Post-treatment monitoring is required for this method.

1.3.5 Specific data to support label claims

In assessing the efficacy of a biocidal product to control, repel or attract insects and other arthropods competent authorities should in particular take the following parameters into account

- target organisms/spectrum of activity;
- mode of action/effect;
- use patterns/methods of application;

- dose rate.

The data provided in support of the efficacy claims must be sufficient to cover these key parameters.

1.3.6 Examples of specific label claims with respect to target organisms

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

- FOR USE AGAINST FLEAS - Data against the cat flea (*Ctenocephalides felis*) or the dog flea (*C. canis*) should normally be available.
- FOR USE AGAINST COCKROACHES - Data against two key species such as German cockroach (*Blattella germanica*) and the oriental cockroach (*Blatta orientalis*) should normally be available.
- FOR USE AGAINST DUST MITES - Data against *Dermatophagoides sp*. should normally be available.

In the European tropical overseas regions, the most common genus encountered could be different. A specific claim should therefore be proposed, with referred target organisms. This special request could concern for examples termites, cockroaches or mosquitoes

1.3.7 Examples of broad label claims with respect to target organisms

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, data on representative pest species will need to be provided for the range of pest orders against which efficacy is claimed.

Representative pests from these orders will have to be appropriate to the use pattern of the biocidal product i.e. the environment of the areas to which the biocide is to be applied and the nature of the application (e.g. whether it is a space application or 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, before a general claim is likely to be supported. In more specific areas, such as use against stored product pests, data on at least two major representatives of the orders in question will normally be needed 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, data from a greater number of representative species will need to be provided. Appendix 2 shows examples of possible label claims and the test species required.

When cockroaches are used as a reference species, it can only be used for the general claim “crawling insects”. If efficacy against other insects are claimed specifically (e.g. crawling insects including bed bugs) tests against these other insect should also be provided. Also if a company wants authorisation for more specific use with the same product they have to present specific data on the specific pest they are claiming. This is a consequence of the use of “reference species”, which should not be a way of short-circuiting the evaluation for efficacy.

1.3.8 The distinction between professional and consumer products

In some cases the dossier requirements and norms and criteria for the evaluation may differ between professional and consumer products. Products used by professionals must have a high level of efficacy since the objective is to eradicate the infestation. For consumer products an immediate knockdown or repellence is often more important than eradication, of course depending on the claim. For instance a spray against cockroaches does not necessarily have to eradicate the whole population but it should work fast. Consumers want to see that the insect/arthropod dies/knocks down immediately after they spray. For consumers it is difficult to eradicate a whole cockroach population since reinvasion from other premises will take place, therefore eradication does not always have to be proven. For each pest group it will be listed whether requirements differ for consumer and professional products.

1.3.9 The distinction between principal target and secondary/ incidental target pests

Screening tests (see sections below for details) can be used as bridging studies, showing similar effect of the product to different pest species, after which in some cases field studies can be waived for secondary target pest species.

1.3.10 Claims for residual efficacy

Most insect/arthropod pests are cryptic and/or nocturnal in behaviour and are unlikely to be contacted directly by a spray during application. For this reason many control programmes involve the use of relatively stable active substances applied to buildings and other surfaces to leave residual deposits. These compounds are intended to remain chemically active and therefore effective for periods of weeks up to several months following treatment, i.e. they have a high residuality. Residual life is a term to describe the period during which the biocide will be present in sufficient quantity to kill target pests, which walk upon it for a sufficient period of time to pick up a lethal dose.

Thus the amount of biocide residue deposited on treated surfaces is critical to the effectiveness of many treatments against crawling (and flying) pests. Ideally, the amount of residue deposited should be determined for instance by calculation or under actual or simulated use conditions. The method(s) of determination must be available with the test data.

Residual efficacy must be proven in tests. Usually, laboratory testing is performed to establish the efficacy direct after application and at the end of the residual life of the product.

The types of surfaces to which residual products are applied must be reported since surface type has a pronounced effect on the amount of active residue available to pests. In general a selection of both absorptive and non-absorptive surfaces, related to the label claim, should be tested when supporting a residuality claim for crawling (and flying) pests. These could include vinyl tile or linoleum, stainless steel, painted and unpainted wood, carpet, concrete and ceramic tile.

Efficacy data submitted to the competent authority in support for residual treatments should indicate the appropriate dosage and the utility of the formulation when used as directed.

1.3.11 Claims relating to storage of a bait product

Residual treatments may also involve the use of palatable baits. When a bait product is claimed to be effective after a long period of storage, it is necessary to demonstrate that the product will still be effective and attractive after the stated storage period. The applicant must either submit data for palatability of the product at the end of maximum

storage or alternatively (in case of a new product) data for a stress test with 'accelerated ageing', i.e. a palatability test with the product which is stored under challenging conditions (see FAO accelerated test).

1.3.12 Claims relating to outdoor use

When products are intended for outdoor use, tests should normally demonstrate efficacy under outdoor conditions. Changes in temperature and rainfall can have effect on the efficacy of the products. In general field trials cover this outdoor use. In some cases a field trial can be waived when a laboratory test can be done under worse case conditions.

1.3.13 Mode of action

There are a variety of modes of action and possible effects on target organisms derived from the proposed use of a product to control, repel or attract insects and other arthropods. The available data 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 inhibitor, chitin synthesis inhibition, juvenile hormone analogue giving rise to sexually immature adults or supernumerary nymphs).

A variety of molecules exist which control invertebrate pests by preventing successful completion of the insect's life cycle, rather than being acutely toxic to the insect. Examples of such molecules include chitin synthesis inhibitors (CSI) and juvenile hormone analogues (JHa). The CSI act by disrupting the deposition of chitin during the formation of the insect’s larval cuticle after moult, whereas JHa aim to interfere with the hormone based control of metamorphosis and reproduction. These two types of molecules are often referred to as insect growth regulators (IGR) to distinguish them from conventional insecticides with neurotoxic action.

Consequently molecules that affect the developmental cycle of insects may be effective without resulting in the immediate death of the insect and therefore efficacy trials should be designed to address the most appropriate life cycle stage of the insect sensitive to the molecule of interest and also to measure any long term effects (e.g on the fertility and fecundity of females or any effects on the embryonic development in the egg stage).

For example, in measuring the effectiveness of JHa, trials should be designed to record the number of adults produced from treated nymphs/larvae, the number of adults with deformed wings or terminalia and the mortality of insects prior to and at metamorphosis. Additionally a number of newly moulted females should be selected randomly from each treatment dose/formulation and their ability to produce viable eggs/oothecae after pairing with untreated males should be recorded.

IRAC, the Insecticide Resistance Action Committee, has developed a classification of insecticides based on mode of action (www.irac-online.org).

1.3.14 Resistance

Information on resistance and the likelihood of its development is required for BPR Annex I inclusion and is also important for product authorisation.

For insecticides resistance can be a problem. Some pests are more capable of building up resistance then others. For instance flies, with multiple generations and multiple females that can lay many eggs, resistance can be expected to build up easily. In ants on the other hand, with one or few queens who lay eggs for a long period, and a biocide that kills the whole colony most of the time, it is not to be expected that resistance will build up. Therefore, a resistance management strategy has to be provided for flies but not for ants for evaluation at product authorisation.

A resistance management strategy is generally based on the use of two modifiers, the frequency of use and the rotation with other active substances. For instance, for products against house flies, a label could state that the product should not be used more than five times per year and should only be used in rotation with at least one other product with a different mode of action.

For consumer products it is necessary to make clear that there might be a risk of building up resistance and that this can be reduced. Since consumers have no knowledge of resistance the label claim should contain information to prevent it. For instance, the following sentence could be added to the label: "When the product is not used according to the label resistance of insects might occur. When the infestation persists contact a professional."

More information on resistance can be found in Chapter 6.2 of this TNG on Product Evaluation and the Insecticide Resistance Action Committee (IRAC: www.irac-online.org).

1.4 Methodology of assessment

Methods of application and dose rates

When considering the overall evaluation of a proposed label claim competent authorities should ensure that the data presented are relevant not only to biological challenge and treatment environment but also that the method of application and application/dose rate(s) used in the test(s) are appropriate to the label claims and proposed use of the product.

The application technique should therefore reflect the claims proposed on the label, whether crack and crevice, spot, space spray, contact spray or total release.

General considerations

The efficacy data submitted should demonstrate that the biocidal product, when used as directed by the product label, will result in a measurable beneficial effect. The data supplied should demonstrate that an acceptable, consistent level and duration of control or other intended effect will result from the use of the product at the recommended dose rate.

This may, depending on the individual product, be measured as a reduction of the pest population to an acceptable level or a reduction in damage. The acceptable level may vary depending on the purpose of the proposed use.

Competent authorities should evaluate available data to determine whether they are sufficient to support a label claim.

The competent authority will examine the submitted data package and a judgment will be made as to whether any data omissions are considered significant as to delay assessment. Those so identified will be communicated back to the applicant. The applicant can then supply additional data or modify their label claims in line with whatever has been supported.

Any known limitations on efficacy (including resistance) should be considered during the assessment.

- possible restrictions or recommendations concerning the use of the product in specific environmental or other conditions. State possible factors that can reduce the efficacy, for instance hot, cold or humid environments or the presence of other substances, in addition to the grounds for these. Possible recommendations concerning the avoidance of the continuous use of the product in order to prevent the development of resistant strains and the grounds for these (see also TNsG on product authorisation Chapter 6.2). State if the product cannot be mixed with, for

example, other biocidal products or if the use of the product with other biocidal products is recommended;

- the guidance given on resistance for the corresponding data requirement of the active substance also applies here.

1.4.1 Assessment of specific claims

Sometimes a claim will include specific properties of the product, for instance:

- kills within 15 minutes;
- residual effect up to 3 months;
- storage period up to 5 years;
- control of tropical ants.

Where a particular property is claimed the data submitted to support the product should show that the product actually has these properties. If data do not support this claim, the product may still gain authorisation with amended label claims, provided that the product still shows acceptable efficacy.

For example: If a product claims complete control of ants within 2 weeks of application, the data submitted must show a high level of mortality (approximately 100%) within two weeks of application in order for these claims to be acceptable.

However, if the submitted data showed 90% mortality within 2 weeks and 100% mortality within 3 weeks, the product may still gain authorisation provided that the product claims were amended to 'complete control of ants within 3 weeks of application'.

Situations such as the example above will require each study to be evaluated on its own merits, taking into account what the data is actually showing. Evaluators must use scientific judgement to determine when authorisation would not be acceptable.

For example:

> If a product claims to kill ants within 15 minutes of application, the data submitted must show sufficient mortality within 15 minutes of application in order for these claims to be acceptable.

However, if the submitted data showed 50% mortality within 15 minutes but 90% mortality within 2 hours, the product would still not be granted authorisation on the basis that for claims such as 'kills ants', the average user would expect a rapid visual effect following application (unless the product label clearly states how long the product takes to have an effect).

1.5 Assessment of authorisation

When considering the overall evaluation of proposed label claims, competent authorities should ensure that the data and the method of application and application/dose rates used in the tests are appropriate to the label claims and proposed use of the product.

1.5.1 Norms and criteria

The test results are compared directly with the norms and criteria for efficacy described below per insect/arthropod pest. The performance criteria set in this guidance ask for high levels of efficacy, which is of course what we aim for. However, some products that do not fully meet the criteria can still be valuable in some cases.

When a product does not perform to the criteria it should be justified in the application why this product is still recommended for authorisation. For example, in a field trial the criteria may not be met because of immigration of insects from untreated areas (e.g.

flies, mosquitoes). When this is explained well in a justification the product might still be accepted for authorisation, depending on the results of other field trials, simulated use and laboratory trials.

Special attention should be paid to resistance, since under low insecticide pressure resistance can build up more easily. Moreover, it should be taken care of that no placebo's or misleading products are registered. If the efficacy level is significantly lower than the criteria state it should be mentioned on the label.

The justification will be evaluated case by case. The product should not be authorised, unless there is a good reason for having a product of lower effectiveness.

1.5.2 Assessment

The assessor/expert assesses on the basis of the label claim and the above criteria. If the product was assessed to be sufficiently effective in laboratory and/or field tests, it will be authorised as far as efficacy is concerned.

2. General Claims: Crawling Insects, Flying Insects, Acaricide

2.1 Introduction

Some products have a very broad claim: against crawling insects, against flying insects, insecticide-acaricide spray, etc. In these cases it is not possible to test the product against all claimed target pests. For each group claimed tests should be performed on a few relevant species, of significant importance, and on the species specifically claimed on the label.

General claims (e.g. insecticide, crawling insects) cannot be used for bait products, since the bait differs per insect species.

2.1.1 Crawling insects

A crawling insect is defined as an insect that generally moves on the ground. These include amongst others cockroaches, ants, fleas, crickets, silver fish, bed bugs and carpet beetle larvae. The effect of biocides on these insects is primarily based upon contact. The products involved can be sprays, dusts, etc. Amongst the crawling insects, cockroaches are the most difficult to control.

2.1.2 Flying insects

A flying insect is defined as an insect that generally flies from one spot to the other. These include flies, mosquitoes, wasps and moths. The products involved can be sprays, strips, paints, etc.

2.1.3 Insecticide, acaricide and other arthropods

A general claim for insecticides includes all insects. A general claim for acaricides includes ticks and mites. Other arthropods could include spiders (Araneae), harvestmen (Opiliones), centipedes (Chilopoda), millipedes (Diplopoda), woodlice (Isopoda) and scorpions (Scorpiones).

2.2 Dossier requirements

A clear label claim should be submitted. The study results of trials should demonstrate the efficacy of the product based on the submitted label claim. Laboratory, simulated-use tests and field trials with the test organisms are needed to assess the efficacy of the

product. Ideally, the studies should be performed according to established guidelines where these are available. These may be international, EU or national guidelines. Ideally, data should be generated using national or international recognised testing methods (ISO, CEN, OECD, etc.) where available and appropriate. See appendix 3 for a list of available guidelines. If there are no guidelines available or guidelines are not suitable, the applicant may use their own methods (intra-company Standard Operating Procedures), on condition however, that the study is scientifically robust, well reported, provides a clear answer to the question and demonstrates the efficacy claimed. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label. A control treatment without biocide (negative control) should be included in all laboratory trials.

In the case of field trials where true replication is almost certainly impossible to achieve and where normal control methods are not restricted to use of a single biocidal product, a full description of any factors that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent areas, general levels of sanitation, treatment history, season, etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

2.2.1 Test species

Claim: crawling insects. In case of an application for authorisation of a product with a claim of "killing crawling insects" a product, which has demonstrated sufficient effectiveness against cockroaches, may also be authorised to control other crawling insects. However, if also population control and/or nest kill is claimed both cockroaches and ants have to be tested.

Tests with cockroaches should normally be performed with two key species, one small, one large, such as the German cockroach (*Blattella germanica*) and either the oriental cockroach (*Blatta orientalis*) or the American cockroach (*Periplaneta americana*). Tests with ants should normally be performed with the Black garden ant (*Lasius niger)*.

Claim: flying insects. In case of an application for authorisation of a product with a claim of "killing flying insects" tests should be provided with flies, mosquitoes and wasps. Tests with flies should normally be performed with the house fly, *Musca domestica*. Tests with mosquitoes should normally be performed with *Culex* spp. Test with wasps should normally be performed with *Vespula* spp.

Claim: acaricide. If a product is claimed to be an acaricide tests should be provided with mites and ticks. What species should be used depends on the area of use (house dust mites in homes, flour mites in storage rooms, etc., for instance: *Dermatophagoides pteronyssinus, Tyrophagus putrescentiae, Acarus siro*). For mites and ticks relevant species can be found in sections 7 and 8.

Claim: other arthropods. For this claim the applicant should provide information on what organisms are relevant for the intended use. At least some example should be given and these should be tested.

Specific claim next to general claim:

Whenever efficacy against a specific organism is claimed next to a general claim or as specification of a general claim (e.g. crawling insects, including bedbugs), tests against this organism should be provided.

2.2.2 Laboratory tests and field trials

Test requirements for each test species can be found at the following sections dedicated to these insects/acarids. For other arthropods a field trial should be provided or a good justification why this is not appropriate.

2.3 Assessment of authorisation

2.3.1 Norms and criteria

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy". For products with general claims the performance criteria per tested organism are the same as those for products with a specific claim for the test species. I.e. for crawling insects the criteria are the same as for cockroaches and ants, for flying insect the same as flies, mosquitoes and wasps, etc. The criteria can be found in the sections dedicated to these insects/acarids.

3. Cockroaches

3.1 Introduction

Cockroaches are a common and persistent problem in many households. These crawling insects (although several species can also fly) are scavengers allowing them to readily adapt to changing food availability. Cockroaches can carry bacteria such as Salmonella in areas co-inhabited by humans. Cockroaches are also identified as a major cause of allergies and asthma, particularly in children. Amongst the crawling insects, cockroaches are the most difficult to control.

The effect of biocides on these insects is mainly based on either contact, both dermal and tarsal, or the ingestion of bait products.

3.1.1 Biology

Cockroaches belong to the (sub) order Blattodea. There are over 3500 species of cockroaches, but only a few are considered domestic pests in the EU. The German cockroach, *Blattella germanica*, is the most common.

Upon hatching from an egg capsule, cockroaches begin their nymphal stage (smaller version of adults minus fully developed wings and sex reproduction organs) and moult through various instars until reaching the adult stage. Time of development can take weeks or months depending upon the species and the surrounding environmental conditions. For instance the eggs of German cockroaches hatch after 3 to 5 weeks (depending on the temperature), the nymphal stage (5 to 7 moultings) can be 40 days to 6 months and the adults live about 6 month (longer under lab conditions).

In temperate European countries most cockroach species will almost never be found outside, with foraging activities almost entirely within human-made structures.

3.2 Dossier requirements

A clear label with comprehensive claims should be submitted. The study results of trials should demonstrate the efficacy of the product based on the submitted label claim. Requirements can differ for products for professional use and for consumer products. For professional use a field trial is always required, for consumer products in some cases laboratory and simulated-use tests are sufficient. If the product is applied as a bait, the entire bait (formulated, including the bait box if applicable) should be tested, not only the active substance which is contained in the bait.

Ideally, the studies should be performed according to established guidelines where these are available. These may be international, EU or national guidelines. See appendix 3 for a list of available guidelines. Appendix 4 gives an example of a test guideline that can be used. If the available guidelines are not suitable, industry standard or a company's own protocols are acceptable, on condition however, that the study is scientifically robust, well reported and provides a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address

the efficacy claim that appears on the product label. A control treatment without biocide (negative control) should be included in all laboratory trials.

In the case of field trials where true replication is almost certainly impossible to achieve and where normal control methods are not restricted to use of a single insecticidal product, a full description of any factor that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent areas, pest activity before the trial is initiated, general levels of sanitation, treatment history, season, etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

3.2.1 Test species

For use against cockroaches data against two key species, one small species normally German cockroach (*Blattella germanica*) and one large species either the Oriental cockroach (*Blatta orientalis*) or the American cockroach (*P. americana*), should normally be available for spray products (aerosol, space spray, residual spray) to support general claims against cockroaches. For bait products, the label can only claim efficacy against species that have been treated under field conditions.

3.2.2 Laboratory tests and field trials

For the evaluation of biocides against cockroaches different types of laboratory, simulated-use tests and field tests can be used. Examples of test are listed below.

3.2.2.1 Screening Studies (No- Choice Test)

The product is applied to representative surfaces or via direct cuticle application, in an arena with cockroaches, to assess inherent contact toxicity or knockdown effects of the active substance. Specify whether adults (male or female) or nymphs are used. Tests may be used to demonstrate basic efficacy or efficacy against insects, resistance to specific chemicals (LD50 versus a susceptible field strain) or insect growth regulator effects (nymphs are treated and subsequent effects are recorded such as inhibition of moulting, deformities, sterile adults).

Results support descriptions related to the mode of action (symptomology) or "effective against strains resistant to "x" class of insecticides", or similar efficacy claims.

For bait products dietary bioassay studies can be conducted using the biocidal bait as a food source. Replicate groups of test insects are exposed to either a continuous toxic diet, or a toxic diet for 24 hours and then a non-toxic diet for the rest of test period.

In all laboratory studies a treatment without biocide should be conducted as a negative control, with insects from the same insect population and with the same number of replicates.

Screening tests are not always necessary. When efficacy is demonstrated in residual tests, palatability tests or similar tests, this is deemed sufficient. Screening tests can sometimes be used as bridging studies: if tests involving a product result in similar effects in different target species, field studies can be waived for some insect species.

3.2.2.2 Determination of residual efficacy

Formulated product (spray, powder, dust, etc.) is applied to representative surfaces at a specified dose rate, or rates, including the recommended label rate(s). Cockroaches (adults) are exposed to the deposit at several time intervals after application (including the day of treatment and at the end of the claimed residual period). Exposure time should, preferably, be comparable to the time the cockroaches might reasonably be expected to be in contact with a treated surface under natural conditions (e.g. 10 min - 1 hour) and assessors will take this factor into consideration when evaluating the data.

Treated surfaces should include at least one porous and one non-porous substrate (or according to the label claim) representing surfaces that might, typically, be treated for cockroach control (e.g. ceramic tile, plywood, painted plywood, stainless steel, concrete). Mortality is normally assessed 1 day and up to 7 days post-exposure.

To substantiate a knockdown claim the number of cockroaches on their backs is counted at stated times after exposure (typically at 5 minute intervals until +30 min, then again at 45 and 60 min). The time until 50% (KT50) and 95% (KT95) of the insects are knocked down is derived statistically.

For insect growth regulators, exposure conditions can be as described above, but selection of the developmental stage (nymph, adult) and post-exposure assessment (deformities, moulting success, sterility, mortality) must be adapted to suit the mode of action of the active substance. Hence, assessments may continue to be made several weeks after exposure (sub-lethal or non-lethal effects on fertility, sterility for example may contribute to long term population control without short term mortality).

Groups of cockroaches of the target species should be of specified age/sex and number. Normally tests are performed with 5 or more replicates, with at least 10 cockroaches per replicate. When only 3 replicates are used, at least 20 insects per replicate should be used. Replicates should be conducted per applied dose, time point, surface, and a reference product (at registered rate) and untreated surfaces should be included as negative controls.

Environmental conditions must be specified for the test itself, and during storage of the treated substrates (temperature, humidity, photoperiod). Temperature would be expected to fall in the range 19-29°C. When efficacy at high temperatures is claimed 40°C would be a good test temperature.

3.2.2.3 Palatability tests with bait products

The aim of the bait choice feeding trials is to determine the palatability of the product for the test insect. If conducted on both fresh and aged product it may provide information on the storage stability of the product. In this test design, nymphs and adults of German and Oriental cockroaches have the choice between a non-toxic food source (challenge diet, either the non-toxic bait or a non-toxic food source known to be a strong feeding source for the test species) and the bait containing the active substance. Normally tests are performed with 5 or more replicate tests, with at least 10 cockroaches per replicate. When only 3 replicates are employed, at least 20 insects per replicate should be used. In all laboratory studies a treatment without biocide should be conducted with insects from the same insect population, as a negative control.

The test should demonstrate acceptable toxicity in competition with the alternative food source.

The population composition (males, gravid non-gravid females, nymphs) in these tests is of importance. Preferably mature insects should be used since immature stages do not need to feed every 24 hours. It should be noted that the feeding behaviour of German cockroach females, changes during 'pregnancy' and that early instar nymphs tend to forage less than older instars.

3.2.2.4 Simulated use

These tests are designed to mimic the practical use situation. The insects must have a choice to be in contact with the biocide or not. For example, cockroaches (*B. orientalis, B. germanica*) can be introduced into choice boxes with one half of the base surface being sprayed with a test formulation. Food and water is always on the non-treated area to be reached by the animals without crossing the treated area. Variations on this test would be to expose insects (voluntary contact) to a variety of different treated surfaces, e.g. plywood, cement, vinyl, ceramic tiles, glass etc.

For products claiming "population control" (eradicates cockroach population) an entire population or at least different life stages should be tested while there is a possibility that only a few individuals get in contact with the biocide.

For "secondary kill" (kills cockroaches that do not visit the bait, however, not always the whole population) claims at least different life stages should normally be tested where only a few individuals get in contact with the biocide directly. Life stage is dependent on a specific mode of action (necrophagy versus coprophagy) and the claim. Either nymphs or adults could be used.

In all laboratory studies a treatment without biocide should be conducted with insects from the same insect population, as a negative control.

3.2.2.5 Field trial

In field trials the product is tested in actual use situation, for instance in an infested home or warehouse and applied according to the direction for use on the label. An example of the results to be achieved in a field trial can be found in Appendix 4.

3.2.3 Requirements per type of claim

Per type of claim the requirements will be listed.

Products intended for use as general surface treatment or aerosol for consumers:

- a laboratory test showing mortality and/or knockdown and/or residual efficacy, depending on the claim;
- a simulated-use test showing mortality and knockdown according to the claim.

Products intended for use as general surface treatment or aerosol for professionals:

- a laboratory test showing mortality and/or knockdown and/or residual efficacy, depending on the claim;
- a simulated-use test showing mortality and knockdown according to the claim;
- a field trial according to the directions for use.

Products intended for use as general surface treatment or aerosol with a claim of population control or secondary kill:

- a laboratory test showing residual efficacy;
- a simulated-use test showing mortality according to the claim;
- a field trial according to the directions for use.

Products intended for use as baits:

- due to the specificity of baits, only effects against species of cockroach that have been tested in the field can be claimed on the product label;
- a laboratory test showing palatability, of fresh product and product at the end of the claimed maximum storage period;
- a simulated-use test showing mortality according to the claim;
- a field trial according to the directions for use and with the claimed cockroach species.

Simulated-use tests can be waived if a robust field trial is submitted

3.3 Assessment of authorisation

3.3.1 Norms and criteria

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy" (BPD). This is implemented in the following way.

An insecticidal product intended for the control of cockroaches is normally considered to be sufficiently "effective" if the following results can be achieved:

Products intended for use as general surface treatment or aerosol for consumers:

- required results in laboratory tests and simulated-use tests:
  - ≥ 90% knockdown within a few minutes after contact with the product (or according to the claim), direct after spray and at the end of the residual period claimed;
  - mortality according to the label claim, preferably ≥90% in 24 hour.

Products intended for use as general surface treatment or aerosol for professionals:

- required results in laboratory tests:
  - direct application: 100% mortality within 1 hour after spraying the cockroaches, mortality between 90 and 100% can be accepted provided a qualified explanation is given for the lack of total control;
  - residual test: 100% mortality within 24 hours after placing the cockroaches in the test area, direct after spray and at the end of the claimed residual period. Mortality between 90 and 100% can be accepted provided a qualified explanation is given for the lack of total control.
- required results in field test:
  - after a period of 2-10 weeks, the population reduction exceeds ≥90% relative to either untreated sites or pre-treatment levels. If retreatment is necessary 100% mortality should then be achieved.

Products intended for use as general surface treatment or aerosol with a claim of population control or secondary kill:

- required results in laboratory tests and simulated-use tests:
  - ≥ 90% mortality within the test period, direct after spray and at the end of the residual period claimed;
- required results in field tests:
  - after a period of 2-10 weeks, the population reduction exceeds 90% relative to either untreated sites or pre-treatment levels.

Products intended for use as baits:

- required results in laboratory palatability choice test (bait and alternative food):
  - at least 95% of the test insects have been killed at a given time point;
- required results in simulated-use tests:
  - ≥ 90% reduction of the population within a few weeks;
- required results in field tests:
  - after a period of 2-10 weeks, the population reduction exceeds 80% relative to either untreated sites or pre-treatment levels.

Products based in insect growth regulators (IGR):

- required results in laboratory tests:
  - at least 95% of the insects does not develop to the next instar;
- required results in simulated-use tests:
  - ≥ 90% reduction of the population within a few weeks;
- required results in field tests:
  - after a period of 6 -14 weeks, the population reduction exceeds 80% relative to either untreated sites or pre-treatment levels.

Deviation from these norms is possible but should be justified in the application.

Field trial data at the label application rate(s) must preferably be evaluated by an experienced assessor since performance can vary considerably, even from apartment to apartment in the same building. Number of trials, the complexity of the trials sites, the use (or not) of additional measures that can contribute to effective control, treatment history, etc. can all have a substantial effect upon the level of control that is achieved. The data must provide evidence of suitable levels of efficacy during the residual period claimed, relative to pre-treatment population assessments and/or performance of reference products under similar conditions, and/or assessments of cockroach populations in untreated areas under similar conditions. Where mean population reduction exceeds 90% relative to either untreated sites or pre-treatment levels, the product is considered effective, but the assessor has the discretion to view each data set on its merits and consider all factors before concluding whether the data support the claimed level of performance or not.

4. Ants

4.1 Introduction

Ants may cause inconvenience both indoors and outdoors.

In Europe the following ant species are common:

Black garden ant,	*Lasius spp,* most common *L. niger*
Pavement ant	*Tetramorium caespitum*
Red ant	*Myrmica rubra*
Erratic ant	*Tapinoma erraticum.*

Next to these native ant species tropical ants can cause inconvenience, mainly indoors.

Of the tropical ant species there are two species that are most commonly found causing inconvenience in buildings in Europe:

Pharaoh ant	*Monomorium pharaonis*
Argentine ant	*Linepithema humile.*

4.1.1 Biology

Ant development involves a complete metamorphosis that includes distinct egg, larval, pupal and adult stages. Most ant species form colonies comprised of complicated social structures that include infertile female workers, one or more specialised fertile queens and (at certain stages in nest development) sexually mature males. Some species have developed additional specialised workers that are responsible for guarding the nest and attacking intruders, whilst others perform domestic and foraging duties. These workers will actively forage on a wide range of foods

including sweet substances, seeds, insects and aphid secretions. A successful foraging ant also has the ability to communicate where to find food to her co-workers, using chemical signals (trail pheromones).

4.2 Dossier requirements

A clear label claim should be submitted. The study results of field trials should demonstrate the efficacy of the product, based on the submitted label claim.

Requirements can differ for products for professional use and for consumer products. For professional use products a field trial is always required, while laboratory and simulated use tests might be considered sufficient in some cases for consumer products. Requirements also depend on the use: for "nest kill" and bait products alike, both laboratory and field trials with the test insects are needed; for products that only claim to kill individual insects that are in contact with the biocide, laboratory and simulated-use tests are sufficient. If the product is applied as a bait, the entire bait (formulated, including the bait box if applicable) should be tested, not only the active substance which is contained in the bait.

Ideally, the studies should be performed according to established guidelines where these are available. These may be international, EU or national guidelines. See appendix 3 for a list of available guidelines.

If there are no guidelines available or the guidelines are not suitable, the applicant may use their own methods (intra-company Standard Operating Procedures), on condition however, that the study is scientifically robust, well reported and provides a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label. In the case of field trials where true replication is almost certainly impossible to achieve and where normal control methods are not restricted to the use of a single insecticidal product, a full description of any factors that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent areas, general levels of sanitation, treatment history etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

4.2.1 Test species

Table 1 below shows for this group of insecticides the possible combinations of target organisms, and the corresponding test organisms on which efficacy is tested in both laboratory and field tests. The selection of test species should be relevant to the label claim.

Table 1: Target organisms *versus* test organisms

Target organisms of the insecticide:	Test organisms:
Ants	Garden ant (*Lasius niger)*
Tropical ants	Pharaoh ant (*Monomorium pharaonis*), Argentine ant (*Linepithema humile*)

4.2.2 Laboratory tests and field trials

For the evaluation of biocides against ants different types of laboratory, simulated-use tests and field tests can be used.

4.2.2.1 Screening studies for direct spray or general surface treatments

In all laboratory studies a treatment without biocide should be conducted with insects from the same insect population, as a negative control. Examples of tests are:

Direct spray: 20 ants placed within a Petri dish and directly sprayed with material. Knockdown, time to death and total mortality is recorded. For insecticides with a "nest kill" claim the time to death will be longer (>1 day) since these ants have to live long enough to take the insecticide into the nest. Normally at least 5 replications and 5 non-treated controls should be used. Controls are very important in this case, as it often turns out to be very difficult to keep ants active in trials.

Residual spray: 20 ants placed on a surface treated with the product. Ants are placed in the arena directly after application, at several time intervals after application and also at the end of the period claimed for residual effect. The time to death of the ants and total mortality is recorded.

A control treatment without biocide should be included in all laboratory trials. Normally at least 5 replications and 5 non-treated controls should be used.

4.2.2.2 Palatability tests with bait products

The important factors relating to testing bait products are to establish the appropriate dosage and intrinsic palatability of the formulation in laboratory tests. Claims made for bait products should distinguish between ants and tropical ants, since the latter can be attracted by completely different baits than the more common European ant, *L. niger*. Data should be provided for all species, for which claims are made.

The most important factor involved in laboratory testing is to provide a free choice alternative food source to the test insects. This may be sugar-based materials for European ants and protein-based materials (meat, eggs, dead insects) for some tropical ants. The formulation should demonstrate acceptable toxicity in competition with the alternative food source. A control treatment without biocide of similar size as the test itself (i.e. number of replications) should be included in all laboratory trials.

When a product is claimed to be effective after a long period of storage, it is also necessary to demonstrate that the product will still be effective, and attractive, after the stated storage period. The applicant must either provide data on the palatability of the product at the end of maximum storage period or alternatively (in case of a new product) data gained in a stress test with 'accelerated ageing', i.e. a palatability test with the product which is stored under challenging conditions.

4.2.2.3 Simulated use studies

These tests are designed to mimic the practical use situation. The tests should be relevant to the use and label claims. A control treatment without biocide should be included in all laboratory tests. Control trials should be of similar size (i.e. number of replications) as the test itself, to make statistical comparison possible and to get a fair impression of control mortality.

Examples of tests are:

Direct general surface treatments without nest kill:

Ants (normally at least 20 worker ants) can be introduced into choice boxes/arenas with one half of the base surface being sprayed with a test formulation, at the correct application rate according to the product label. Food and water is always on the non-treated area to be reached by the animals without crossing the treated area. Variations on this test would be to expose insects (voluntary contact) to a variety of different treated surfaces, e.g. plywood, cement, vinyl, ceramic tiles, glass etc. Mortality is recorded.

Normally tests should be performed in triplicate.

Direct general surface treatments with nest kill:

In a double chamber trial an ant's nest (normally at least 20 (worker) ants) is placed within one arena, which is connected to another arena. Part of the second arena is treated with the insecticide at the correct application rate according to the product label. Adequate food and water is placed on the non-treated surface of this second arena. Ants must be able to reach the food without contacting the treated surface. Normally tests should be performed in triplicate. Efficacy is assessed e.g. length of time taken to result in control of the ant population (e.g. no foraging ants).

The nest should be opened at the end of the trial (e.g. 1 week), to check whether all ants within the nest are dead, especially the queen(s).

Bait products:

The efficacy of the entire formulated bait is tested, hence not only the active component within the bait. An ant's nest is placed within an arena trial under controlled conditions (e.g. with respect to temperature, relative humidity, photoperiod, etc.). Adequate food (bait without the active substance or and alternative food source) and water are placed opposite the nest. Insects are allowed to acclimatise for 7 days before introduction of bait. An additional fasting period of 4 days, providing them with water only, is recommended. At regular time intervals (in hours), the attractiveness of the bait for the ants is recorded (by observing whether they approach the bait or avoid it). Ant mortality is recorded at regular time intervals (in days). At the end of the trial the nest could be opened to check whether all ants within the nest, including the queen(s), are dead.

4.2.2.4 Field trials for all claims

The tests should be relevant to the use and label claims. Tests with *Lasius niger* are done preferably during the early spring. In the end of summer population decline might be due to natural causes instead of the insecticide. Non-treated nests should be used as a negative control, to test nest activity.

Monitor ant numbers at various locations around a building and locate the entrances of nests and "ant-trails" (routes taken by ants). Apply the insecticide according to the label instructions.

The efficacy tests against ants should normally be performed in a minimum of three objects. An object can be a place in or near the house, where ants cause inconvenience for the inhabitants. This may be in a house, on a balcony, a terrace or in a garden, depending on the field of use of the product. If the test is performed outdoors, records of temperature and rainfall should be kept.

Monitoring should be conducted at the same locations (as the pre-treatment) and at similar times during the entire trial (e.g. at 12.30, 13.00, etc.). Monitoring should continue (e.g. 1 day after treatment, 1 week after treatment, etc. at least once weekly) until control is seen. If no ants are seen during a post-treatment monitoring visit then the site should be re-visited once to ensure that re-infestation does not occur.

The effect on the ant population can be determined by counting. For this purpose, a fixed position on the 'ant-trail' is to be used and a count of the number of any ants that pass is made in 1 minute, at several time intervals during the test.

4.2.3 Requirements per type of claim

Per type of claim the requirements will be listed.

Products intended for use as general surface treatment for consumers:

- a laboratory test showing mortality and/or knockdown and/or residual efficacy, depending on the claim;
- a simulated-use test showing mortality and knockdown according to the claim.

Products intended for use as general surface treatment for professionals:

- a laboratory test showing mortality and/or knockdown and/or residual efficacy, depending on the claim;
- a simulated-use test showing mortality and knockdown;
- a field trial according to the directions for use.

Products intended for use as general surface treatment with a claim of nest kill:

- a laboratory test showing residual efficacy;
- a simulated-use test showing mortality;
- a field trial according to the directions for use.

Products intended for use as baits:

- Due to the specificity of baits, only effects against ant species that have been tested in the field can be claimed on the product label;
- a laboratory test showing palatability;
- a simulated-use test showing mortality;
- a field trial according to the directions for use and with the claimed ant species.

Simulated-use tests can be waived if a robust field trial is submitted.

4.3 Assessment of authorisation

4.3.1 Norms and criteria

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy" (BPD). This is implemented for ants in the following way.

An insecticide against ants is normally considered to be sufficiently "effective" if the following results can be achieved:

Products intended for use as general surface treatment for consumers:

- required results in laboratory mortality tests and simulated-use tests:
  - ≥ 90% knockdown in 5 -10 minutes (or according to the claim), direct after spraying the ants and at the end of the residual period;
  - mortality according to the label claim, preferably ≥90% after 24 hour.

Products intended for use as general surface treatment for professionals:

- required results in laboratory tests:
  - direct application: 100% mortality within 24 hours after spraying the ants, mortality between 90 and 100% can be accepted provided a qualified explanation is given for the lack of total control;
  - residual tests: ≥ 90% mortality within 24 hours after placing the ants in the

test area, direct after spray and at the end of the residual period;

- required results in field tests:
  - after a period of 2-8 weeks, the population reduction exceeds 90% relative to either untreated sites or pre-treatment levels.

Products intended for use as general surface treatment with a claim of nest kill:

- laboratory tests:
  - 100% mortality within the test period, direct after spray and at the end of the residual period;
- required results in simulated-use tests:
  - slow knockdown, ants must be able to reach the nest;
  - ≥ 90% mortality within the test period, including ants in the nest;
- required results in field tests:
  - after a period of 2-8 weeks, the population reduction 100% relative to either untreated sites or pre-treatment levels, in case of lower efficacy it has to be shown that the queen(s) in the test nests is killed.

Products intended for use as baits:

- required results in laboratory palatability choice test (bait and alternative food):
  - at least 95% of the test insects have been killed at a given time point;
- required results in simulated-use tests:
  - ≥ 90% reduction of the population within a few weeks;
- required results in field tests:
  - after a period of 2-4 weeks, the population reduction exceeds 90% relative to either untreated sites or pre-treatment levels.

Deviations from these norms is possible but should be justified in the application.

5. Termites

5.1 Introduction

Termites, in natural settings, work as beneficial insects by breaking down cellulose-containing materials, such as dead trees. However, termites can cause damage to living trees and many crop plants, but the fact that they can use dead wood makes them a major pest for timber used both outdoors and inside buildings. Termites become a problem to humans when they infest timber used in constructions (i.e. wood structures) in risk areas. Owing to their high moisture requirements, they usually nest in soils, but can invade buildings from underneath through cracks and seams or by building shelter tubes connecting the wood to their nest in the soil. In Europe and in the European tropical overseas regions, there are three main types of termites: subterranean, tree and drywood termites, the subterranean being the most destructive termites in construction. Due to their biological characteristics (subterranean termites), they live in the soil and must maintain contact with the ground or some other moisture source to survive.

Insecticides against termites can be divided into PT8 products, preventive treatments to protect the wood and curative treatments on the wood, and PT18 products, which are considered in this section.

5.1.1 Biology

Termites belong to the order of Isoptera. In Europe and in the European tropical overseas regions there are three main termite families; subterranean (*Rhinotermitidae*), drywood termites (*Kalotermitidae*) and tree termites (*Nasutitermitidae*).

Reticulitermes is the most common genus encountered from the Rhinotermitidae family in Europe. The main species registered are: *R. flavipes (former R. santonensis), R. lucifugus, R. lucifugus corsicus, R. grassei, R. banyulensis, R. balkanensis*.

They are widespread around the Mediterranean (Spain, France, Italy, Portugal, Balkans, and Greece) and Black Sea (Turkey, Rumania), though some termite spots in the UK and Germany have been reported. Several unanswered questions remain about the origin of these termites. While some Reticulitermes are native to Europe, others may be related to species from eastern North America and the Middle East (Israel, Asian Turkey, etc.).

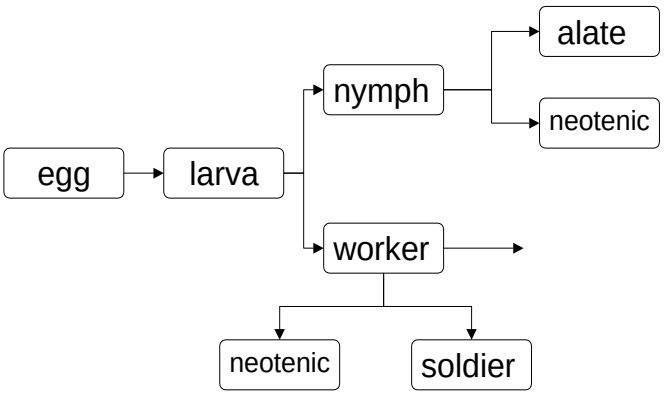
Coptotermes sp. and *Heterotermes sp.* are the main two species belonging to the *Rhinotermitidae* family found in European tropical overseas regions.

Nasutitermes sp. are the main species belonging to the *Termitidae* family (tree termites) encountered in the European tropical overseas regions.

Kalotermes flavicollis and *Cryptotermes brevis* are the main two species of drywood termites present in Europe (especially in the coastal areas of Mediterranean countries and Canary Islands). *Cryptotermes sp*. is a main genus belonging to drywood termites encountered in the European tropical overseas regions.

A brief explanation of the life cycle (figure 1) may help to clarify the difficulties involved in control of termites. There is a split after the larval stages into two lines, the sexual and the worker line. Individuals going down the sexual line develop into nymphs and then into either alates (which are the reproductive form most people are familiar with) or neotenics (supplementary reproductives). The alates do form queens (physogastrics), however, these are much more mobile than those found in tropical species. The alternative line of development, the neutral line, is the development of larvae into workers, which in turn can either remain workers or develop into neotenics or soldiers. Workers are approximately 4 to 6 mm in length. An important feature in the biology of termites that makes them very difficult to control is the ability of individuals in both lines to form sexual reproductives and, hence, give rise to a new, viable colony. In addition, supplementary secondary reproductives can be produced in very large numbers.

Figure 1: Life cycle of subterranean termites



5.1.2 Control methods

5.1.2.1 Preventive treatments

Traditionally, the methods used to fight termites were based upon treating infested or exposed wood with wood preservatives. This is valid for all termite types (subterranean, tree and drywood). Those products are included in product type 8 (wood preservatives) of the BPD, and are not considered in this section.

In addition to the preventive treatment of timber, a barrier can be used to isolate the paths used by subterranean termites to access the building from underneath where the nest is located. Barriers systems usually consist of a polymer membrane or other material and an insecticide (product type 18). The system is installed between the soil and the construction to keep subterranean termites outside and to eliminate those that come into contact with the insecticide.

5.1.2.2 Remedial treatments

Different methods are currently used in Europe:

5.1.2.2.1 Chemical barriers

Methods based on treating the infested wood with wood preservatives are included in product type 8 (wood preservative) of the BPD, and are not considered in this section.

In addition to the wood treatment, two types of chemical barriers are used to impregnate the walls of the construction and the soil around.

Considering the subterranean termites, this method aims to eliminate insects inside the construction and to protect it for several years. This method does not eliminate the nest (which is located in the soil).

5.1.2.2.2 Bait system

It consists typically of a cellulose-based matrix treated with a slow acting insecticide, which is consumed by workers and is spread through the colony by trophallaxis (one individual is fed by another). Consequently, this method may be useful to eradicate the whole colony.

5.1.2.3 Treatment of waste

In order to prevent termite contamination by waste infested and transported into an area not infested, it could be relevant to treat the waste with biocidal products.

5.2 Dossier requirements

A clear label claim should be submitted.

Laboratory and field trials with termites are needed to assess the efficacy of the products. Ideally, the studies should be performed according to established guidelines where these are available. These may be EU or national guidelines. European standardisation work is being conducted by several termite experts in Europe. At this moment, no European standard has been published yet, only French standards are available. However, due to the greater significance of termites as structural pests in countries outside Europe, such as the United States and Australia, a variety of standard test methods are published, together with extensive reports in the scientific literature which may prove useful references. Account should be taken of results obtained using such methods, especially where the same termite species are present as those in Europe including the French overseas territories. See appendix 3 for a list of available guidelines (guidelines outside EU not included yet).

If there are no guidelines available or guidelines are not suitable to evaluate the termiticide (e.g. if new products are developed), the applicant may use their own

methods, on condition however, that the study is scientifically robust, well reported and provides a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label. In the case of field trials a full description of any factors that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent areas, treatment history, etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

A control treatment without biocide should be included when testing any termite products in laboratory trials.

5.2.1 Test species

A product against termites in Europe should normally be tested on termites belonging to the genus Reticulitermes.

For European tropical overseas regions, the product should normally be tested at least against termites belonging to the genus *Coptotermes* and on every genus claimed by the applicant.

Remarks:

a) In any case, the termite species needs to be identified and all useful information about the colony collected (locality of origin, laboratory rearing conditions, characteristics of their natural environment if termites are collected in field);

b) For the evaluation of termite baits, the species referred to in the label claims should be used. If the claim refers generally to Reticulitermes species (without specifying the species), it is recommended to test, at least, two different European species in lab tests;

c) Due to the specificity of baits, only effects against species of termites that have been tested should be claimed on the product label.

5.2.2 Laboratory tests and field trials

The tests specified below are mainly for bait products. While laboratory tests can be conducted for all the termiticide products, field tests are addressed specially for bait products. For soil/wall barrier products and for physico-chemical systems the tests should be designed to mimic the practical use situation. The test should be performed according to the label claim.

Due to the specificity of baits, only effects against species of termites that have been tested should be claimed on the product label.

The important factors relating to testing bait products are to:

a) establish the appropriate dosage of the formulation in laboratory tests. This can be done in a mortality test (evaluation of the toxicity of the insecticidal formulation in a force-feed environment). The formulation should demonstrate acceptable toxicity;

b) test the palatability of the bait. The aim of the bait choice feeding trials is to determine the palatability of the product for the test insect. In this test design, insects have the choice between a non-poisoned food source (challenge diet) and the bait containing the active substance;

c) the test should demonstrate acceptable toxicity in competition with the alternative food source;

d) assess if a contaminated group of termites can transfer the insecticide to a group of termites that have never been exposed to it before. This transfer study should demonstrate acceptable toxicity of termites not exposed directly to the baits.

5.2.2.1 Laboratory/screening tests

No-choice test (A): test the termiticidal efficacy and the delayed effect of an insecticide formulation on a group of subterranean termites":

A group of termites is put into contact with an insecticide formulation. When testing baits, bait is the only source of food. For other types of termiticides the termites are exposed to the product according to the intended use (e.g. spray the surface and add the termites to the surface. The test is performed in assay containers. Mortality of the insects is assessed.

From this test the time "te" can be determined, necessary to perform the test B (te=time of exposure of the termites to the insecticide formulation which is required to observe a significant mortality compared with termites in an untreated control).

Transfer test (B): the transmission of the insecticide used in the baiting system to an uninfected group of termites:

Termites are exposed to the tested bait long enough to be contaminated with the active substance (time te). A group of termites is removed from the colony and put in contact with a healthy uncontaminated group. The mortality rate of both groups of termites (contaminated and uncontaminated) is assessed separately.

Choice test / palatability test (C): the suppression of a group of termites reared in laboratory under conditions of food competition; with the use of the same insecticidal bait formulation:

Add the insecticidal bait formulation to a group of termites already exploiting another source of food. The test is performed in assay containers. The aim is to assess the mortality after a given period of time.

5.2.2.2 Field trial

In field trials the product is tested in actual use situation and applied according to the direction for use on the label. The test method should evaluate the efficacy of the baits or barrier products in an experimental site where termite activity is reported.

The repellent termite barriers can be disposed in walls or soils, according to the claim. A common claim for a barrier product is the duration of "protection". This is normally in terms of a number of years and should be demonstrated by long-duration soil tests in field plots.

For bait products consumption of the tested bait must be registered at least in the first 6 months after the introduction of the baits. The elimination of termites in the experimental site should be registered maximum after 18 months (counted since the introduction of the first tested bait), excluding the winter period.

Table 2 gives an overview of available (French) guidelines for termites and how to use them.

Table 2: Overview guidelines on termites

Preventive treatment / Physico-chemical barrier		
	Protocol	**Ageing Test**
Laboratory test	NF X 41-550 after after after	 ENV 1250-2 (effect of water) CTBA-BIO-E-016 (effect of the natural light) CTBA-BIO-E-007 (effect of alkalinity)
Field test	CTBA-BIO-E-008	no
Remedial treatment / chemical barrier		
	Protocol	**Ageing Test**
Laboratory test	NF X 41-550 after	 NF X 41-542 (effect of water)
Field test Wall chemical barrier Soil chemical barrier	NF X 41-550 after after	 CTBA-BIO-E-001 (field ageing test) CTBA-BIO-E-002 (field ageing test)
Remedial treatment / Bait system		
	Protocol	**Ageing Test**
Laboratory test	XP X 41-543-1	no
Field test	XP X 41-543-2	no
Treatment of waste		
	Protocol	**Ageing Test**
Laboratory test	FCBA-BIO-E-38	no
Field test	FCBA-BIO-E-39	no

5.3 Assessment of authorisation

5.3.1 Norms and criteria

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy" (BPD). This is implemented in the following way.

An insecticidal product intended for the control of termites is normally considered to be sufficiently "effective" if the following results can be achieved (derived from standards NF XPX41-551, NF XPX41-543-3 and FCBA-BIO-E-041):

Products intended for use as baits:

- no-choice test: 100% mortality before the end of the test (16 weeks). Besides, if the 100% mortality is achieved too fast (less than 48 hours) the test bait should be rejected;
- transfer test: 100% mortality of all the termites, which have not been exposed directly with the tested bait;

- choice test / palatability test: more than 95% mortality;
- bait field test: No termite activity should be reported within the test period (max. 18 months, excluding the winter period). No termite activity should be reported in at least the following 3 months.

Products intended for use as termite barriers

- laboratory test: 100% mortality after the test (only for barriers with lethal activity);
- field test:
  - In soil barrier products, termites should not penetrate the soil more than 10 mm;
  - In wall barriers (i.e. thermoplastic films), termites should not be able to perforate the film after the duration of the test;
  - In other type of repellent barriers, termites should not be able to access to the other side of the barrier. Furthermore, any carrying of termite material (i.e. soil) to the other side of the barrier should not be reported.

6. Bed Bugs

6.1 Introduction

Bedbugs are small, wingless blood feeding insects. Of the many recognized species, only three are known to feed on humans. In temperate climate regions of the EU, *Cimex lectularius* is the dominant species. Bedbugs are not known to transmit disease in Europe, but infestations can cause painful and irritating bites on the skin while humans sleep. Once infested, treatment and control is very difficult.

A sign of bedbug presence include bites on the exposed skin (small red itchy bumps) of humans during sleep. If observed, confined locations such as mattress linings or furniture folds should be inspected for faecal spotting and the presence of bedbugs.

6.1.1 Biology

Bedbugs belong to the order of Hemiptera, Family Cimicidae.

Bedbugs harbour themselves in very confined areas in wall cracks, furniture joints, along lining of mattresses, behind pictures and in seams of furnishings. These insects generally confine themselves to these areas and leave them only to feed. Bedbugs are negatively phototactic and not usually seen outside the harbourage in the day or when the lights are on.

Female bedbugs can lay up to 500 eggs during their lifetime. Depending on frequency of blood meals, bedbugs can live for more than a year. They are able to survive for months without feeding (dependent upon temperature: at 16°C survival can be a year). The first nymph hatch from small white eggs after 7-10 days at room temperature (around 20°C) and earlier at higher temperatures. Each of the 5 nymphal stages need a blood meal to complete development to the next instar. The whole life-cycle from egg to egg takes a minimum of 28 days at 27°C or around 42 days at 22°C.

6.2 Dossier requirements

A clear label claim should be submitted. The study results of field trials should demonstrate the efficacy of the product, based on the submitted label claim.

Laboratory and field trials with bedbugs are needed to assess the efficacy of the product. Ideally, the studies should be performed according to established guidelines where these

are available. These may be international, EU or national guidelines. See appendix 3 for a list of available guidelines.

If there are no guidelines available or guidelines are not suitable, the applicant may use their own methods, on condition however, that the study is scientifically robust, well reported and provides a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label. In the case of field trials where true replication is almost certainly impossible to achieve and where normal control methods are not restricted to use of a single insecticidal product, a full description of any factors that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent areas, general levels of sanitation, treatment history etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

6.2.1 Test species

A product against bedbugs should normally be tested on the common bedbug (*Cimex lectularius*) or tropical bedbug (*Cimex hemipterus*).

6.2.2 Laboratory tests and field trials

For the evaluation of biocides against bedbugs different types of laboratory, simulated-use tests and field test can be used. Examples of tests are listed below.

6.2.2.1 Screening studies (no- choice test)

Testing should include application of the product to representative surfaces (e.g. plywood, painted plywood, textile fabric, wallpaper) or direct cuticle application of the product to bedbugs to assess inherent contact toxicity of the active substance. It should be specified whether adults or nymphs are used. A test may be used to demonstrate basic efficacy or efficacy against insects resistant to specific chemicals (LD50 versus a susceptible field or laboratory strain) or insect growth regulator effects (nymphs are treated and subsequent effects are recorded such as inhibition of moulting, deformities, sterile adults).

Results must support description related to the mode of action (symptomology) or "effective against strains resistant to "x" class of insecticides", or similar efficacy claims.

Screening tests are not always necessary. It is sufficient to demonstrated efficacy in residual tests or similar tests.

6.2.2.2 Determination of residual efficacy

Good residual efficacy is essential for insecticides used in bedbug control, as is impossible to treat all bedbugs directly or reach all of their hiding.

For the determination of residual efficacy, the formulated product (spray, powder, dust, etc.) should be applied to representative surfaces at the recommended label rate. Bedbugs (adults) should be exposed to the deposit at several time intervals after the deposit has dried (including the day of treatment, but after the deposit has dried completely and at the end of the claimed residual period). Exposure time should, preferably, be comparable to the time the bedbugs might reasonably be expected to be in contact with a treated surface under practical conditions (e.g. 10 min - 6 hours) and assessors will take this factor into consideration when evaluating the data. Treated surfaces should include at least two porous and one non-porous substrate, representing surfaces that might, typically, be treated for bedbug control (e.g. plywood, painted plywood, textile fabric, wallpaper, according to the label claim). Mortality is normally assessed after 1 day up to 14 days post-exposure.

For insect growth regulators, exposure conditions can be as described above, but selection of the developmental stage (nymph, adult) and post-exposure assessment (deformities, moulting success, sterility, mortality) must be adapted to suit the mode of action of the active substance. Hence, assessments may continue to be made several weeks after exposure (sub-lethal or non-lethal effects on fertility, sterility for example may contribute to long term population control without short term mortality).

Groups of bedbugs should be of specified age/sex and number. Tests should be performed in triplicate, with at least 20 bedbugs per replicate. When 5 or more replicates are used, 10 insects per replicate are adequate. Replicates should preferably be conducted per applied dose, time point, and surface. Untreated surfaces must be included as negative controls.

Environmental conditions must be specified for the test itself, and during storage of the treated substrates (temperature, humidity, photoperiod). Temperature would be expected to fall in the range 19-29°C. For use in Southern European countries higher temperatures (up to 40°C) might be necessary.

A control treatment without biocide should be included in all laboratory trials. The control trial should be of adequate size (i.e. number of replications and individuals), providing sufficient statistical power and a fair impression of control mortality

6.2.2.3 Simulated use

These tests are designed to mimic the practical use situation. The insects must have a choice to be in contact with the biocide or not. Due to the normal behaviour of the bedbugs, it seems to be very difficult to design simulated-use tests for the evaluation of products for bedbug control. Bedbugs do not leave their harbourage during daytime and without a host which attracts them.

6.2.2.4 Field trials

In field trials the product is tested in actual use situations, for instance in an infested home or hotel and applied according to the direction for use on the label.

It has to be considered that in bedbug infestations the aim of professional control operations must be the eradication of the population. It is not acceptable to have even very small remaining populations. Usually, pest control operations against bedbugs have to combine different measures. The documentation of the trial has to give all information on the products or other measures used.

6.2.3 Requirements per type of claim

Appropriate efficacy tests are needed for each claim.

<u>Products intended for use as general surface treatment for consumers:</u>

- a laboratory test showing mortality and/or knockdown and/or residual efficacy, depending on the claim.

<u>Products intended for use as general surface treatment for professionals:</u>

- a laboratory test showing mortality and/or knockdown and/or residual efficacy, depending on the claim;
- a simulated-use test showing mortality and knockdown according to the claim and/or;
- a field trial according to the directions for use;
- Simulated-use tests can be waived if a robust field trial is submitted.

6.3 Assessment of authorisation

6.3.1 *Norms and criteria*

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy" (BPD). This is implemented in the following way.

An insecticidal product intended for the control of bedbugs is considered to be sufficiently "effective" if the following results are achieved:

Products intended for use as general surface treatment for consumers:

- required results in laboratory tests (and simulated-use tests):
  - ≥ 90% knockdown within a few minutes after contact with the product (or according to the claim), direct after application and at the end of the residual period;
  - mortality according to the label claim, preferably ≥90% in 1 hour.

Products intended for use as general surface treatment for professionals:

- required results in laboratory tests:
  - direct application: 100% mortality within 24 hours after spraying the bedbugs;
  - residual test: ≥ 95% mortality within 24 hours after placing the bedbugs in the test area, direct after spray and at the end of the residual period.
- required results in field test:
  - after a period of 6-10 weeks, the population reduction exceeds 90% relative to either untreated sites or pre-treatment levels.
    Treatment repeats usually are necessary in bedbug control. At the end of a treatment, 100 % efficacy should be achieved.

Deviations from these norms is possible but should be justified in the application.

Data from field trials at the label application rate must preferably be evaluated by an experienced assessor since performance can vary considerably, even from apartment to apartment in the same building. The number of trials, the complexity of the trials sites, the use (or not) of additional measures that can contribute to effective control, treatment history etc. can all have a substantial effect upon the level of control that is achieved. The data must provide evidence of suitable levels of efficacy during the residual period claimed, relative to pre-treatment population assessments and/or performance of reference products under similar conditions, and/or assessments of bedbug populations in untreated areas under similar conditions. Where mean population reduction exceeds 90% relative to either untreated sites or pre-treatment levels, the product is considered effective, but the assessor has the discretion to view each data set on its merits and consider all the factors before concluding whether the data support the claimed level of performance.

7. Ticks

7.1 Introduction

Ticks are small arthropods classed along with mites and spiders in the Class Arachnida. All ticks are blood feeders. Certain tick species are known for carrying and transmitting many different pathogenic microorganisms including bacteria, viruses, parasites and fungi. Diseases associated with tick transmission in Europe include Lyme disease, tick-borne encephalitis, and human anaplasmosis, all transmitted by *Ixodes ricinus*. The tick

Hyalomma marginatum can transmit Crimean-Congo haemorrhagic fever, a viral disease common in East and West Africa. Mediterranean spotted fever is transmitted by the brown dog tick (*Rhipicephalus sanguineus*). Ticks also have an important role in animal health. They can cause anaemia, reduction of milk production and bodyweight gain of animals.

7.1.1 Biology

Ticks differ from insects morphologically having two main body parts (insects have three) and eight legs as nymphs and adults (six legs for insects). Ticks go through four stages to complete their lifecycle: egg, larva, nymph, and adult. Feeding will occur in both the immature and adult stages. After mating female hard ticks will feed once more followed by oviposition of hundreds to even thousands of eggs.

Ticks can be differentiated on their host choices:

- one host: developing stages and adults feed on one host (e.g. *Boophilus*)*;*
- two hosts: larvae and nymphs feed on the same host, adults feed on another host (e.g. *Rhipicephalus)*;
- three hosts: larvae, nymphs and adults feed on three different hosts. *(e.g. Ixodes, Haemophysalis, Dermacentor*).

Ticks can be classified into two main families: soft ticks (Argasidae) and hard ticks (Ixodidae). The hard ticks consist of many commonly known species such as the sheep tick (*Ixodes ricinus*), the brown dog tick (*R. sanguineus*) and *Dermacentor sp* . *H. marginatum* is also a hard tick. Hard ticks vary in host-tick relationship. Species may have one host, two different hosts or three different hosts. After mating female hard ticks will feed once more followed by oviposition of hundreds to even thousands of eggs.

Soft ticks have similar body parts as the hard ticks. Key differences are that soft ticks lack the sclerotized outer cuticle found in hard ticks and the mouthparts of soft ticks are located below the end of the body (hard tick mouthparts stick out the front of the protected hood). For example the bird ticks, *Argas reflexus* and *A. persicus*, are soft ticks which can be a pest in for instance poultry farms.

Hard ticks have to be fixed to their hosts and the meal can last five days, while soft ticks are not fixed and the meal is finished in 20 to 50 minutes.

When searching for a possible host, ticks generally remain stationary until a host passes by. Once attached, ticks crawl to locate a place to feed. Commonly, ticks will attach to human skin along pant or sock lines or other tight locations which are warm and humid. Feeding can take hours to days depending on the species.

The bird ticks, *Argas persicus* and *A. reflexus* have worldwide distribution in warm climates. *A. persicus* occurs in small poultry farms and feeds blood on chicken and other domestic fowls. *A. reflexus* occurs in pigeon farms and on urban pigeons and their surroundings in towns. They can get from the nests of pigeons to lofts and attic rooms and feed on sleeping humans for blood. *A. reflexus* is an urban pest parasitizing urban pigeons and may cause a wide range of allergic reactions.

Argas spp. hide in cracks and crevices of chicken houses, nests, wooden equipments etc. during the day and come out to blood feed at night. Males and females are both blood sucking. They are able to survive starvation for two years, which is why the protection against these mites is very difficult.

7.2 Dossier requirements

A clear label claim should be submitted. The study results of field trials should demonstrate the efficacy of the product, based on the submitted label claim.

Laboratory and, for some claims, field trials with ticks are needed to assess the efficacy of the product. The studies should normally be performed according to established guidelines where these are available. These may be international, EU or national guidelines. See appendix 3 for a list of available guidelines. If no guidelines are available, the applicant may use their own methods, on condition however, that the study is scientifically robust, well reported and provides a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label. In the case of field trials where true replication is almost certainly impossible to achieve and where normal control methods are not restricted to use of a single acaricidal product, a full description of any factors that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent areas, general levels of sanitation, treatment history etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

7.2.1 Test species

A product against ticks should normally be tested on the sheep tick *Ixodes ricinus*. When control or repellence of dog or bird ticks is claimed, tests with these ticks should be performed too (*Rhipicephalus sanguineus*, *A. reflexus*). When efficacy in the tropics is claimed or efficacy against *H. marginatum*, this tick should be tested too. *H. marginatum* behaves differently than *I. ricinus* since it is aggressive and it actively seeks the host to feed on and moves quickly on the ground. When the product is intended for use in poultry farms tests should be performed against *A. persicus*.

7.2.2 Laboratory tests and field trials

For the evaluation of biocides against ticks different types of laboratory and simulated-use tests can be used. Examples of tests are listed below.

7.2.2.1 Laboratory test to evaluate knockdown and kill effect (no-choice test)

A clear label claim should be submitted. The study results of field trials should demonstrate the efficacy of the product, based on the submitted label claim.

Laboratory and, for some claims, field trials with ticks are needed to assess the efficacy of the product. The studies should normally be performed according to established guidelines where these are available. These may be international, EU or national guidelines. See appendix 3 for a list of available guidelines. If no guidelines are available, the applicant may use their own methods, on condition however, that the study is scientifically robust, well reported and provides a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label. In the case of field trials where true replication is almost certainly impossible to achieve and where normal control methods are not restricted to use of a single acaricidal product, a full description of any factors that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent areas, general levels of sanitation, treatment history etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

7.2.2.2 Laboratory test for *repellents*

Candidate repellents are applied to human forearms from wrist to elbow. As a negative control untreated arm will be tested, preferably the other arm of the test person. A line is drawn 3 cm above the wrist. Disease free ticks are placed on the back of the hand with a forceps, 5 ticks per test. Fresh, starved ticks are required for each exposure. The arm is inverted to promote upward movement toward the treated surface (ticks are negatively geotropic). The first exposure is one hour post treatment and continues once

an hour for four hours. Each exposure is 5 minutes. Several criteria for repellence can be used. Either, a tick is considered non-repelled if it crosses the line 3 cm above the wrist or a tick is considered repelled when it drops down from the arm. A negative control treatment on an untreated arm, preferably the other arm of the same test person, should be performed.

Percentage repellence is calculated by recording the number of ticks crossing the line or dropping down from a treated arm as opposed to a control arm.

Normally, per repellent at least 10 persons are tested since repellence/attractiveness to ticks varies considerably between human individuals.

An alternative method could be using animals instead of humans to test the repellence against ticks. *I. ricinus*, *R. sanguineus* and *H. marginatum* will bite both humans and animals.

7.2.2.3 Simulated use tests

To prevent disease transmission ticks must be knocked down, killed or repelled before attaching to the skin. For repellents the test described in 7.2.2.2 is a "worse case" test, therefore there is no need to do a field trial with repellents. For products that knockdown and kill ticks a simulated-use tests should be performed in which the product is applied according to the instruction for use and then tested in the presence of a person or an arm or foot or animal. For some products this can be a similar test set up as described in 7.2.2.2. Then it has to be established that the ticks are knocked down or killed before they can attach to the skin and start feeding. This is compared to a control test.

7.2.3 Requirements per type of claim

- Repellent: laboratory test for repellents;
- Insecticide with knockdown or kill effect: laboratory and simulated-use tests.

Simulated-use tests can be waived if a robust field trial is submitted.

7.3 Assessment of authorisation

7.3.1 Norms and criteria

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy" (BPD). This is implemented for ticks in the following way.

An insecticide against ticks is normally considered to be sufficiently "effective" if the following results can be achieved:

- Repellent:
  - ≥ 90% repellence during the claimed efficacy period;
- Product with knockdown effect:
  - 100% knockdown before ticks start feeding and;
  - ≥ 80% kill within 24 hours;
- Product with kill effect:
  - ≥ 95% kill before ticks start feeding.

Deviations from these norms is possible but should be justified in the application.

8. Mites

8.1 Introduction

Mites, along with ticks, belong to the subclass Acarina (also known as Acari) and the class Arachnida. Mites are among the most diverse and successful of all the invertebrate groups. They have exploited an incredible array of habitats, and because of their small size (most are microscopic) most go totally unnoticed. Perhaps the best-known mite, is the house dust mite (family Pyroglyphidae), which can cause asthma and allergic symptoms. Mites are also important as vectors of microorganisms, transmitting rickettsiae and bartonellae. Flour mites (*Acarus siro*) and mould or storage mites (*Tyrophagus putrescentiae, T. longior*) are important pests in stored goods. Mites like the red mite, *Dermanyssus gallinae*, can be a pest in bird cages and poultry farms. The red mite can also feed on some species of mammals, including humans, but need an avian host to reproduce.

Part of the control of mites is covered in section 11 on stored goods. Often mites are only mentioned on a label as a secondary pest, while insects are the main pests.

8.1.1 Biology

The house dust mite is widespread in human habitation. House dust mites thrive in the indoor environment provided by homes, specifically in bedrooms and kitchens. Dust mites survive well in mattresses, carpets, furniture and bedding, with figures around 188 animals/g dust. Dust mites feed on organic detritus such as flakes of shed human skin and flourish in the stable environment of dwellings. The European house dust mite (*Dermatophagoides pteronyssinus*) and the American house dust mite (*Dermatophagoides farinae*) are two different species, but are not necessarily confined to Europe or North America; a third species *Euroglyphus maynei* also occurs widely. The average life cycle for a male house dust mite is 10 to 19 days. A mated female house dust mite can live for 70 days, laying 60 to 100 eggs in the last 5 weeks of her life.

The flour mite, *A. siro*, is the most common species of mite in foodstuffs. The males are 0.33 mm to 0.43 mm long and female are 0.36 mm to 0.66 mm in length. Flour mites contaminate grain and flour by allergens and they transfer pathogenic microorganisms. Foodstuffs acquire a sickly sweet smell and an unpalatable taste. When fed infested foodstuff, animals show reduced feed intake, diarrhoea, inflammation of the small intestine and impaired growth.

The red mite, *Dermanyssus gallinae,* is an ectoparasite of poultry and birds. They can be found in houses of laying hens, chickens and other fowls. The mites are blood feeders and attack resting birds at night. The optimal temperature is 27-28 °C. After feeding they hide in cracks and crevices away from daylight, where they mate and lay about 30-35 eggs in their lifetime. Their maximal lifetime is 8 weeks without starving and 6-10 months with starving. In spite of that these mites are ectoparasites, the main method of control is treating of the walls, bird cages, nests and hidden places in poultry farms with biocides.

8.2 Dossier requirements

A clear label claim should be submitted. The study results of laboratory or field trials should demonstrate the efficacy of the product, based on the submitted label claim.

Laboratory and/or field trials with mites are needed to assess the efficacy of the product. The studies should normally be performed according to established guidelines where these are available. These may be international, EU or national guidelines. See appendix 3 for a list of available guidelines. If no guidelines are available or guidelines are not suitable, the applicant may use their own methods, on condition however, that

the study is scientifically robust, well reported and provides a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label. In the case of field trials where true replication is almost certainly impossible to achieve and where normal control methods might not be restricted to use of a single acaricidal product, a full description of any factors that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent areas, general levels of sanitation, treatment history etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

8.2.1 Test species

Which test species should be used depends on the intended area of use and the label claim. In homes the European house dust mites, *D. pteronyssinus,* is the most important. In storage rooms the flour mite or storage mites, etc., for instance *T. putrescentiae, A. siro*. For use on poultry farms *D. gallinae* should be tested. When specific mite species are mentioned in the claim these should be tested.

8.2.2 Laboratory tests and field trials

For the evaluation of biocides against mites different types of laboratory and simulated-use tests can be used. Examples are given below.

8.2.2.1 Laboratory test to evaluate knockdown and kill effect (no-choice test)

The product is applied to representative surfaces or via direct cuticle application, in a container with mites, to assess inherent contact toxicity or knockdown effect of the active substance. For instance spray on a filter paper and put the filter paper in an aluminium dish. Specify whether adults (male or female) or nymphs are used. Normally tests are performed with 3 or more replicates, with normally 20 to 30 mites per replicate. Tests are done at 25°C and 70-75% R.H.. In all laboratory studies a treatment without biocide should be conducted with mites from the same population, as a negative control. The number of dead mites is counted at 24 hours after treatment.

8.2.2.2 Residual effect

For determination of residual efficacy, the formulated product should be applied to representative surfaces at a specified dose rate, or rates, including the recommended label rate. Mites should be exposed to the deposit at several time intervals after the deposit has dried (including the day of treatment, but after the deposit has dried completely and at the end of the claimed residual period). Exposure time should, preferably, be comparable to the time the mites might reasonably be expected to be in contact with a treated surface under practical conditions and assessors will take this factor into consideration when evaluating the data. Treated surfaces should include at least two porous and one non-porous substrate, representing surfaces that might, typically, be treated for mite control (e.g. plywood, painted plywood, textile fabric, according to the label claim). Mortality is normally assessed after 1 day up to 14 days post-exposure.

8.2.2.3 Simulated use tests

These tests are designed to mimic the practical use situation. For products that knockdown and kill mites simulated-use tests should be performed in which the product is applied according to the instruction for use. When products for general surface treatment are tested the mites must have a choice to be in contact with the biocide or not. The results should be compared to a control test, without biocide.

8.2.3 Requirements per type of claim

Specific mites: when specific mite species are mentioned in the claim (e.g. dust mite, red mite) both laboratory and simulated-use tests are required with the target species.

Mites as secondary pest: When mites are mentioned on the label claim only as a secondary pest, only laboratory tests with one mite species are required.

Acaricides: When mites are the main pest to control both laboratory and simulated-use tests are required with more than one mite species.

Space and structural treatments: requirements for these products are covered in section 11 on stored goods.

Simulated-use tests can be waived if a robust field trial is submitted.

8.3 Assessment of authorisation

8.3.1 Norms and criteria

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy" (BPD). This is implemented for mites in the following way.

A biocide against mites is normally considered to be sufficiently "effective" if the following results can be achieved:

- laboratory tests: ≥90% mortality in 24 hours;
- simulated-use tests: ≥90%mortality in 1 week;
- field trials for space and structural treatments: requirements for these products are covered in section 11 on stored goods.

Deviations from these norms is possible but should be justified in the application.

9. Fleas

9.1 Introduction

This section covers the assessment of efficacy of products used for treatment against cat and dog fleas. The application of these products is indoors on surfaces.

These biocides are divided into two groups, namely the adulticidal and ovicidal/larvicidal products. Adulticidal products are intended for use against fleas in the adult growth stage, and the ovicidal/larvicidal products for use against fleas in the egg and larval stages. This distinction is based on the very different modes of action of the product, which result in different criteria for assessment.

It should be emphasized that products against fleas, which are applied directly on dogs and cats and have a medical claim are covered by legislation on Veterinary Medical Products. The reader may refer to the borderline dossier available on the ECB website (www.ecb.jrc.it/biocides).

9.1.1 Biology

Of the over 2000 species of fleas (Siphonaptera), the cat flea (*Ctenocephalides felis*) and the dog flea (*C. canis*) are the most common in-home pests in the EU. Fleas undergo complete metamorphosis (egg, larva, pupa, adult) and the lifecycle begins when an adult female finds a suitable host. Once found, the female flea will remain on this host for the rest of its life. Females produce several eggs after each blood feeding and can produce several hundred eggs in its lifetime. Once laid, the eggs fall off the animal host and develop in the areas where the host animal spends its time. The eggs tend to

accumulate in the lowest areas such as deep in fibres of carpets, cracks in the floor, or crevices in furniture and furnishings.

Larvae require high protein food for their survival. This protein comes from feeding on the dry faeces of the adult fleas. The adult flea takes in more blood from the host than necessary for nourishment and excretes the remaining blood in almost pure form. Once dried, the faeces falls off the host animal where the larvae can feed. The larvae spin a cocoon and begin the pupal state.

An adult flea emerges from the pupae after stimulation from external cues that indicate an animal host is near. Once emerged, a flea must usually find a host (located using visual and thermal cues) within a week, or it risks death due to desiccation. Complete development from egg to adult occurs in as little as two weeks, but this can take much longer depending on environmental conditions.

9.2 Dossier requirements

A clear label claim should be submitted. The study results of laboratory. simulated-use tests and field trials should demonstrate the efficacy of the product, based on the submitted label claim.

Laboratory and field trials with fleas are needed to assess the efficacy of the product. Ideally, the studies should be performed according to established guidelines where these are available. These may be international, EU or national guidelines. See appendix 3 for a list of available guidelines. If there are no guidelines available or the guidelines are not suitable, the applicant may use their own methods, on condition however, that the study is scientifically robust, well reported and provides a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label. In the case of field trials where true replication is almost certainly impossible to achieve and where normal control methods are not restricted to use of a single insecticidal product, a full description of any factors that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent areas, general levels of sanitation, treatment history etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

9.2.1 Test species

A product against fleas should normally be tested on the cat flea (*Ctenocephalides felis*) or the dog flea (*C. canis*).

9.2.2 For claims made for products intended for use as general surface treatments

For the evaluation of biocides against fleas different types of laboratory, simulated-use tests and field tests can be used.

Examples of the types of data that may be available when considering the efficacy of insecticide products intended for use as surface treatments are given below.

9.2.2.1 Laboratory studies

The product is applied to representative surfaces (e.g. carpet discs). Information on the fibre length and density should be provided, as this has a bearing onto flea survival. Long fibres enable fleas to hide and, thus, protect fleas from getting their share of the insecticide applied, Fleas are transferred to the surface, either before (direct contact) or after (residual performance) application of the product, to assess inherent contact toxicity or knockdown effect of the active substance.

Alternatively, ovicidal or larvicidal products can be tested in flea rearing medium

containing flea eggs or larvae and the active substance in a range of concentrations, including the intended use concentration. Preferably, tests should be done in five replicates per treatment.

A control treatment without biocide with the same number of replicates should be included in all laboratory trials.

9.2.2.2 Simulated use studies

These tests are designed to mimic the practical use situation. The test should be performed according to the label claim.

Simulated-use tests can be waived if a robust field trial is submitted.

9.2.3 For claims made for products intended to be used as space spray treatments

Some insecticides against fleas can be used in foggers. For the evaluation of these insecticides different types of laboratory, simulated-use tests and field tests can be used.

The efficacy test design should be defined for the available treatment method.

9.3 Assessment of authorisation

9.3.1 Norms and criteria

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy". This is normally implemented for fleas in the following way.

For laboratory and simulated use:

An adulticidal product against fleas is considered to be sufficiently "effective" if:

- within 24 hours 100% knockdown of the adult fleas should occur (this norm only applies if the test fleas are sprayed directly or are placed immediately on a treated carpet) and;
- within 48 hours ≥90% mortality of adult fleas should occur.

An ovicidal/larvicidal product against fleas is considered to be sufficiently "effective" if:

- ≥80% inhibition should occur of the development of produced eggs/larvae into adult fleas during the claimed ovicidal/larvicidal duration of action of the product.

Deviations from these norms is possible but should be justified in the application.

10. Litter Beetles

10.1 Introduction

There are several species of "litter beetles" that inhabit poultry droppings and litter. Litter beetles belong to the order Coleoptera, family Tenebrionidae. The most important are the lesser mealworm (other names: darkling beetle), *Alphitobius diaperinus*, and two species in the dermestid genus *Dermestes*; the hide beetle (*D. maculatus*) and the larder beetle (*D. lardarius*). Other species of beetles that occasionally cause damage to poultry housing are *Dermestes ater, Tenebrio mollitor*, *Alphitobius laevigatus*, and *Trox* spp.

Litter beetles are of particular importance as a vector and competent reservoir of several poultry pathogens and parasites. The transmission of bacteria, (*Salmonella, Escherichia coli*) and protozoa (several Eimeria species which can cause coccidiosis) and different viruses can cause problems in livestock. This pest can also cause damage to poultry housing and is suspected to be a health risk to humans in close contact with larvae and

adults. Adults can become a nuisance when they move en masse toward artificial lights generated by residences near fields where beetle-infested manure has been spread.

Often these beetles are only mentioned on a label as a secondary pest, while other insects are the main pests (control of flies, cockroaches, and litter beetles in poultry houses). But when they are mentioned specifically on the label they should be tested.

10.1.1 Biology

Lesser mealworm adults lay their eggs in cracks and crevices in the poultry house, in manure or litter, and in grain hulls. Larvae hatch and complete development to the adult stage in 40-100 days depending on temperature and food quality. The larvae consume spilled feed, manure and, to a lesser extent, dead birds and cracked eggs. Beetle populations in broiler and turkey houses often are concentrated around lines of feeders, which provide the beetles with shelter and an opportunity to feed on spilled bird feed. Mature larvae disperse when they are crowded to find isolated pupation sites, and this behaviour is responsible for much of their destructive activity. Crowded larvae leave the litter and tunnel into thermal insulation materials where they construct pupal cells. Both larval and adult stages are omnivorous. The lesser mealworm is nocturnal, with greatest activity of both larvae and adults occurring shortly after dark. Populations of lesser mealworm often reach high densities, especially in deep-litter broiler and turkey houses and in high-rise caged layer operations. It is not unusual for the litter of a broiler house to move from beetle activity or for 70% of the surface of manure in a high-rise house to be covered with adult beetles.

10.2 Dossier requirements

A clear label claim should be submitted. The study results of laboratory, simulated-use tests and field trials should demonstrate the efficacy of the product, based on the submitted label claim.

Laboratory and simulated field trials with litter beetles are needed to assess the efficacy of the product. Ideally, the studies should be performed according to established guidelines where these are available. These may be international, EU or national guidelines. See appendix 3 for a list of available guidelines. If there are no guidelines available or the guidelines are not suitable, the applicant may use their own methods, on condition however, that the study is scientifically robust, well reported and provides a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label. In the case of field trials where true replication is almost certainly impossible to achieve and where normal control methods are not restricted to use of a single insecticidal product, a full description of any factors that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent areas, general levels of sanitation, treatment history etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

10.2.1 Test species

A product against litter beetles should normally be tested on the lesser mealworm, *A. diapernus*.

10.2.2 For claims made for products intended for use as general surface treatments

Examples of the types of data that may be available when considering the efficacy of insecticide products intended for use as surface treatments are given below.

10.2.2.1 Laboratory studies

The product is applied to representative surfaces, either before (persistence test) or after (direct contact) the insects are transferred to the surface, to assess inherent contact toxicity or knockdown effect of the active substance.

Preferably, test should be done in five replicates per treatment.

A control treatment without biocide should be included in all laboratory trials.

10.2.2.2 Simulated use studies

These tests are designed to mimic the practical use situation. The test should be performed according to the label claim.

Simulated-use tests can be waived if a robust field trial is submitted.

10.3 Assessment of authorisation

10.3.1 Norms and criteria

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy". This is normally implemented for litter beetles in the following way.

A product against litter beetles is considered to be sufficiently "effective" if:

For laboratory and simulated use:

- adulticide: ≥ 95% mortality;
- larvacide: ≥ 95% mortality;
- insect growth regulator: ≥ 90% mortality.

Deviations from these norms is possible but should be justified in the application.

11. Textile-attacking Insects (including fur and fabric attaching insects)

11.1 Introduction

Insecticides against textile-attacking insects can be used by professionals and non-professionals, use against beetle or moth larvae infested carpets for example.

Home user products may be used in vapour phase to prevent moth contact with stored clothing (via killing, repelling or attracting moth in traps) or insecticides may be applied to the surface of clothing to kill landing moths on contact.

Insecticides against textile-attacking insects can also be incorporated in the textile by industry for preventive treatments.

Other products made from textiles treated with insecticides are the so-called treated articles with an external claim (e.g. carpet with an insecticide not to protect the carpet but against fleas that are in contact with the carpet). These treated articles will not be considered specifically in this section since other than textile-attacking insects are the target insects.

11.1.1 Biology

The two main orders containing textile attacking insect species are Lepidoptera (moths) and Coleoptera (beetles). The webbing clothes moth (*Tineola bisselliella*), fur moth (*Tinea pellionella*), brown house moth (*Hofmannophila pseudospretella*) and carpet beetles (*Anthrenus* sp., *Anthrenocerus* sp.) are common in-house pests that feed on

clothing, drapery, carpet and other natural hair fibres. The larvae of these insects have a diet consisting of natural hair fibres, which provide protein from keratin in the hair. These insects have adapted to be able to digest keratin, which is not easily digested by other insects.

Clothes moths are distributed worldwide. They feed during the larval cycle within a silken cocoon attached to hair fibre. Clothes moths larvae that feed only on natural hair fibres such as wool, will not feed on, silk, cotton, linens or synthetic fibres. Adult clothes moths do not feed. These adults mate and the females lays eggs directly on the natural fibre food source.

Carpet beetle larvae (e.g. *Anthrenus* sp., *Anthrenocerus* sp.) attack woollens, rugs and upholstered furniture, etc.. The adult beetles, which feed on nectar and pollen, can usually enter the home on plants, flowers or other vegetation. Eggs are then laid on lint in protected areas such as behind baseboards. Once hatched, larvae begin feeding on a number of natural textiles or displays (animal horns, hoofs, insect collections, etc).

11.2 Dossier requirements

A clear label claim should be submitted. The study results of simulated-use tests or field trials should demonstrate the efficacy of the product, based on the submitted label claim.

For vapour based products the label should provide information on the volume that can be covered with the product (closet of x m^3, room of y m^3).

Laboratory and simulated-use trials with textile-attacking insects are normally needed to assess the efficacy of the product. Ideally, the studies should be performed according to established guidelines where these are available. These may be international, EU or national guidelines. See appendix 3 for a list of available guidelines. If there are no guidelines available or the guidelines are not suitable, the applicant may use their own methods, on condition however, that the study is scientifically robust, well reported and provides a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label. In the case of field trials where true replication is almost certainly impossible to achieve and where normal control methods are not restricted to use of a single insecticidal product, a full description of any factors that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent areas, general levels of sanitation, treatment history etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

11.2.1 Test species

A product against textile-attacking insects should normally be tested on:

- one of the following moth species:
  - the clothes moth (*Tineola bisselliella*);
  - the fur moth (*Tinea pellionella* L.);
  - the brown house moth (*Hofmannophila pseudospretella*);
- one of the following carpet beetle species:
  - *Anthrenus* sp;
  - *Anthrenocerus* sp.

Whether adults or larvae or both should be tested depends on the label claim.

11.2.2 Laboratory tests and field trials

For the evaluation of biocides against textile attacking insects different types of laboratory and simulated-use tests can be used. Examples of tests, mainly for cloths moth, are listed below.

11.2.2.1 Laboratory tests

Mortality test

Webbing clothes moths, adults, larvae (2^{nd}-3^{rd} instar) or eggs may be placed in a jar (e.g. 240 ml glass jars, brass-screened lid) containing a treated textile sample (e.g. circular, 4cm diameter, 100% wool sample).

Jars are periodically evaluated by recording mortality, egg laying and hatch (optional), and larval damage. A moth is considered inactivated when it is not able to walk or fly, in a spontaneous way or when stimulated with a brush or pin.

New moths are introduced into the jars periodically to test residual effects (depending on the label claims). Tests should normally be done in five replicates. A control treatment without biocide with the same number of replicates should be included in all laboratory trials.

Repellency test

Moth repellency can be tested in a choice test. Moths are placed in a clear tunnel between two dark boxes, both containing wool. One of the boxes contains the repellent product. The adult moths are released in the tunnel after which they can choose the treated or untreated box. The ratio of moths found in the treated vs. untreated box is a measure for the efficacy of the product.

11.2.2.2 Simulated use

These tests are designed to mimic the practical use situation. The study results should provide a clear picture of the efficacy of the product.

An example of tests that might match the proposed intended use of the product:

Simulated-use tests with moths added to drawers (minimum air volume: 0.016 m^3) or closets (minimum air volume: 0.5 m^3) can provide good information on home user products. In tests with vapour based products the door should be opened with a frequency resembling normal opening of a closet, to show that this does not reduce efficacy: once a day during completion of the assay, 5 seconds for drawers and 10 seconds for closets. Assessments of mortality would form the basis for efficacy claims. Additionally damage to the test material can be assessed. The damage will depend upon the number of insects, their developmental stage, the exposure time and the size and quality of the piece of carpet, etc. Therefore, damage should always be assessed in comparison to the control treatment.

Simulated-use tests can be waived if a robust field trial is submitted.

Test similar to the ones mentioned above can also be used to show efficacy against carpet beetles and the larvae of carpet beetles.

11.3 Assessment of authorisation

11.3.1 Norms and criteria

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy". This is implemented for textile attacking-insects normally in the following way.

At the end of an exposure period (e.g. 1 week):

- more than 90% of the adults and larvae should be killed (unless claimed different);
- a repellent should perform according to the label claim, preferably >90%.

Deviations from these norms is possible but should be justified in the application.

12. Stored Goods-attacking Insects and Mites

12.1 Introduction

The purpose of biocidal products against stored goods-attacking insects and mites is to control pests in storerooms, freight and alternative transport containers for products of plant origin etc. They should also protect the actual stored goods against insects and mites. The term "stored" in this regard refers specifically to: stored products (of plant origin) for human consumption, animal feed, industrial processing and propagation.

Products against stored goods-attacking insects can either be biocides or plant protection products. In general, where the stored products are protected, prior to processing, the use falls under plant protection and is not relevant in this guideline.

There are a number of different insects that attack stored goods. Common beetle invaders include grain beetles (*Tribolium castaneum, Oryzaephilus surinamensis,* etc.), confused flour beetles (*Tribolium confusum*), and rice weevils (*Sitophilus oryzae*). Indian meal moth (*Plodia interpunctella*) and flour mite (*Acarus siro*) are also very common pest. Infestations of these pests can occur at the packaging plant, the store, or in the home, making it difficult to determine where the source of the problem is. Sometimes these infestations are only noticed by the consumer once the insect leaves the food product and enters the home environment.

For professional and industrial use there are two classifications of such products:

- fumigation with gases, which is used for controlling pests in rooms used for the storage of products of plant origin (storerooms, freight structures and means of transport, gassing installations etc.);
- products other than gases, which are used for controlling pests in empty or full storerooms (including products which are applied by means of vaporisers).

12.2 Dossier requirements

A clear label claim should be submitted. The study results of simulated-use tests and field trials should demonstrate the efficacy of the product, based on the submitted label claim.

Laboratory and field trials with stored goods-attacking insects are needed to assess the efficacy of the product. Ideally, the studies should be performed according to established guidelines where these are available. These may be international, EU or national guidelines. See appendix 3 for a list of available guidelines. EPPO standards PP 201 to 204 are recommended (Appendix 3). If these guidelines are not suitable, the applicant may use their own methods, on condition however, that the study is scientifically robust, well reported and provides a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label.

In the case of field trials where true replication is almost certainly impossible to achieve and where normal control methods are not restricted to use of a single insecticidal product, a full description of any factors that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent

areas, general levels of sanitation, treatment history etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

12.2.1 Test species

A product against stored goods-attacking insects may be tested on beetles, moths or mites (more specifically mentioned in the relevant EPPO guidelines), or insects that are specifically identified in the label claim.

12.2.2 Laboratory tests and field trials

Depending on the application and the purpose of the product, one of the trials below (or equivalent trials) normally should be performed.

12.2.2.1 Consumer products

For consumer products laboratory or simulated-use tests are required. A direct spray test method can be used to evaluate performance against stored goods-attacking insects. A simulated use test can be a test, performed in a laboratory, where insects (either cultured or natural populations) are in contact with the stored goods (e.g. breakfast cereal, flour) and the biocide is applied according to the instructions for use.

Simulated-use tests can be waived if a robust field trial is submitted.

A control treatment without biocide with the same number of replicates should be included in all laboratory trials.

12.2.2.2 Gases for use in storerooms, freight and transport rooms and gassing installations with stored products present

Additional laboratory studies are not required, only field trials.

A field trial should normally be conducted according to the EPPO guideline PP 1/201(1) "Fumigants to control insect and mite pests of stored plant products".

The field of use of the gas are places where large supplies are stored, in particular cereal products, but also other food products such as dried nuts, processed vegetables, spices or meals.

The use of gas can be intended for controlling/fighting pests in spaces but also for controlling/fighting pests in or on the product itself.

12.2.2.3 Products other than gases for storerooms with or without stored products

Additional laboratory studies are not required, only field trials.

A field trial normally should be performed according to the EPPO guideline PP 1/202 (1) "Space and structural treatments of storerooms".

The products concerned exclude gases, but do include those applied by means of vaporisers (fogs, smokes, vapours, space sprays).

This trial focuses on the control of pests in full or empty storerooms (walls, cracks, etc.). The trial does not serve to test the efficacy of the treatment on pests in the stored products themselves.

The trial can be performed in two ways.

- the first possibility is conducting the trial in rooms where there is already an infestation. Using a trapping system, the effectiveness is determined by scoring the number of insects caught in the traps before and after the treatment;
- the second possibility is conducting the trial in a room where test organisms have

been introduced artificially (usually in small cages). The effectiveness is determined by scoring the number of alive, 'knocked down' and dead organisms in comparison with an untreated room.

12.3 Assessment of authorisation

12.3.1 Norms and criteria

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy". This is implemented for stored goods attacking-insect in the following way.

- consumer products: normally 100% mortality in direct spray tests, in simulated-use tests >90% knockdown and >70% mortality after 24 hours would be sufficient;
- gases: the duration of gassing (as specified in the label claim) should be such that at the end of gassing 100% of the insects/mites are dead or dying. It is possible to distinguish between dead and dying insects, which will not recover anymore, so these should also be counted;
- the duration of gassing should not be longer than necessary;
- all non-gases: the effect should be achieved within the duration of the treatment, as specified in the label claim. Normally >90% would be sufficient.

Deviations from these norms is possible but should be justified in the application.

13. Flies

13.1 Introduction

Flies are common pests in and around the house and in animal rearing facilities. Some of these insect species are merely a nuisance, others provide discomfort from irritating bites, and some potentially carry and transmit diseases.

The possible fields of use of the insecticides include: residential and other types of accommodation, public spaces, hospitals, storerooms, kitchens, waste dumps and stables and manure storage facilities.

13.1.1 Biology

House flies (*Musca domestica*) and other nuisance flies are common non-biting pests in the EU. The house fly lifecycle goes through four stages: egg, larvae (maggots), pupa, and adult. Eggs are laid on organic debris including faeces, decaying vegetation, etc. Once hatched, larvae feed by burrowing into the organic debris and filter decaying organic matter. In the pupal stage the fly is transformed into the adult. During this transformation, no feeding takes place. At the adult stage, house flies feed by regurgitating on food, then lap up the food in liquid form. The life cycle of house flies, from egg to fly, is 1 to 3 weeks, depending on the climate conditions. Males die soon after mating, females live temperature dependent normally one to several weeks in the field.

Flies regularly fly into and out of man-made structures. Outside, flies land on faecal material and other debris. Inside, flies land on human food and contact other substrates regularly touched by humans. Here, potential pathogens can be transferred on the flies' body (legs) or from inside the body (vomiting on potential food in order to feed) which are picked up in faecal or other decaying material. More than 100 germs have been documented as being transferred by house flies. Among them are *Salmonella* sp. and *E. coli* have been documented as being transferred by house flies.

The stable fly (*Stomoxys calcitrans*) is a pest often found in stables alone or together with the housefly. Rather unusual for a member of the family Muscidae is that it sucks blood from mammals. Under favourable conditions the stable flies develop from egg to fly in 3 weeks. The adults live several weeks.

Other biting flies include black fly (Simuliidae) and deer and horse flies (*Chrysops* and Tabanids), are also common pests in the EU. These insects can inflict a painful bite leaving an itchy welt. Some are also known to transmit disease. Apart from these species blow-flies can be of significance in a number of localities, including food producing facilities (Carrion flies, blue bottle fly, green bottle flies).

13.2 Dossier requirements

A clear label claim should be submitted. The study results of laboratory and simulated-use tests and field trials should demonstrate the efficacy of the product based on the submitted label claim.

Laboratory, simulated-use tests and field trials with the test insects are needed to assess the efficacy of the product, depending on the label claim. Ideally, the studies should be performed according to established guidelines where these are available. These may be international, EU or national guidelines. See appendix 3 for a list of available guidelines. If there are no guidelines available or the guidelines are not suitable, the applicant may use their own methods (intra-company Standard Operating Procedures), on condition however, that the study is scientifically robust, well reported and provides a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label. A control treatment without biocide with the same number of replicates should be included in all laboratory trials.

In the case of field trials where true replication is almost certainly impossible to achieve and where normal control methods are not restricted to use of a single insecticidal product, a full description of any factors that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent areas, general levels of sanitation, treatment history, season, etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

13.2.1 Test species

In case of an authorisation against flies the prescribed test insect is the housefly (*M. domestica*). When the product claim includes use in stables and animal housings (except poultry), for a general claim against flies both the housefly and the stable fly (*S. calcitrans*) should be tested. If efficacy against blow-flies is claimed tests have to be done with a blow-fly species (Calliphoridae). Skin repellents against flies should be tested against biting flies, for instance the stable fly. Spatial repellents against flies should be tested against the housefly or, when used in stables, against both housefly and stable fly. Products intended for use as repellent on horses (recreational and/or sport horses) should be tested against the claimed target organisms (see Appendix 2 Species grid PT19 3H to 3T).

13.2.2 Laboratory testing simulated use tests and field trials

For evaluation of biocides against flies different types of laboratory, simulated-use tests and field test can be used. Examples of tests are listed below.

13.2.2.1 Laboratory tests

Flies can be tested in the laboratory in small jars or Petri dishes. The surface can be treated or granules can be placed, after which insects can be added at different time

intervals. Alternatively, the flies can be sprayed directly. The knockdown percentages and mortality are determined.

A control treatment without biocide with the same number of replicates should be included in all laboratory trials.

13.2.2.2 Simulated use tests

For assessment of efficacy simulated-use tests should be conducted in a test chamber, for instance the Peet-Grady chamber. This is an airtight room of 1.8*1.8*1.8 m, into which a certain amount of product is introduced. Other chambers of similar or bigger size are acceptable, either airtight or with air exchanges. The chamber should be washed and dried between each replicate to avoid chemical contamination.

Environmental conditions must be specified during the test (temperature, humidity, photoperiod). Temperature would be expected to fall in the range 19-29°C, may be lower for use in stables. A control treatment without biocide with the same number of replicates should be included in all laboratory trials.

Simulated-use tests can be waived if a robust field trial is submitted.

Examples of tests for different products are listed below. For other types of products similar test can be performed.

13.2.2.2.1 Space treatment

In the case of an application of a liquid for space treatment, the aerosol test method is performed in the test chamber in the laboratory. A known number (50-100) test insects, including males and females, are exposed to the space treatment. The dose sprayed in the chamber should be comparable to the label directions. The test is performed in quadruplicate. A control treatment without biocide should be included. The knockdown percentages and mortality of flies in both insecticide treatment and negative control are determined.

13.2.2.2.2 Surface treatment

Products for surface treatment (including window stickers) act on the insect via contact with or feeding from the treated surface. The product can be applied by spraying, brushing, painting, etc. according to the label. These products are also tested in the test chamber.

In the test chamber the product is applied on a small surface or on the whole chamber, in a dose rate appropriate to the label claim. After the surfaces have been left to dry the test can commence. The insects are released in the test chamber at several time points after application (or at least at the maximum residual time claimed at the label), to show residual efficacy. At a suitable period of exposure (e.g. 24 hours) after each test time point mortality of the test insects is recorded. It is mandatory to report temperature and air humidity in the test room. These should agree as much as possible with practical use conditions.

13.2.2.2.3 Products to be vaporized or fogged

Only a French recognized guideline (NF T 72-321) is available for efficacy studies with products against flies that should be vaporized (heating element that heats a tablet or liquid, coils, fan driven devices, etc.) or products that should be applied in a fogging treatment. Recently WHO published a guideline for these types of products against mosquitoes. This guideline might be adapted for fly products. Further, the "Large room test" is generally accepted. Other methods are also acceptable if they are scientifically sound and provide a clear picture of the efficacy of the product.

The "Large room test" test can be performed in a non-ventilated room of 20 to 30 m^3. When a ventilated room is used (mimics in some cases reality better) the air exchange

should be measured (e.g. one air chamber renovation per hour). The product is applied according to the intended use, allowing it to evaporate over a specified time period (depending on the label claim e.g. 9 hours).

House flies (*M. domestica*) are exposed to the vapour/fog at different time points, e.g. at 0, 2, 4, 6 and 8 hours. The test insect to be used depends on the requested application. At every time point a known number of test insects (e.g. 50), including males and females, are exposed to the vapour. The test is performed in quadruplicate. A control treatment without biocide should be included.

The knockdown percentages (KD50, KD95, KD100), mortality and, if possible, the concentration of the active substance in the room are determined.

13.2.2.2.4 Larvicides

Larvicides are often applied to the floor of stables and to manure to prevent maggots and pupa from developing into the next stage. These products can be tested in naturally or artificially infested manure, in boxes covered with gauze. Adult flies emerging from the manure are counted and the difference between treated and untreated manure is analysed. Where IGRs (insect growth regulators) are used as larvicides, it is possible to additionally assess the deformation of larvae and pupae.

13.2.2.2.5 Bait products

For products formulated as baits the product should also be tested to establish the intrinsic palatability of the formulation.

The most important factor involved in laboratory testing is to provide a free choice alternative food source to the test insects. The formulation should demonstrate acceptable toxicity in competition with the alternative food source. A control treatment without biocide of similar size as the test itself (i.e. number of replications) should be included in all laboratory trials.

If conducted on both fresh and aged product it may provide information on the storage stability of the product.

13.2.2.2.6 Repellents

For products with a repellent effect against flies no agreed protocols are available. The tests should be designed to mimic the practical use situation. The study results should provide a clear picture of the efficacy of the product. The submitted data from studies are checked for completeness, based on the applied dose per treated area. It is also checked whether the duration of exposure is sufficient. If the formulation alone i.e. without the carrier (e.g. a product with a tissue as carrier) has been tested, data on release from the carrier are also required. The study data should provide a clear picture of the efficacy of the formulated product.

13.2.2.3 Field trials

For application in cattle houses, pigsties and/or treatment of pig and cattle manure for controlling flies, field trials are normally required, both for insecticides and repellents.

Tests are done preferably during spring and beginning of summer. At the end of summer and autumn population decline might be due to natural causes instead of the insecticide treatment. Apply the insecticide according to the label instructions.

During field trials in stables, special consideration should be given to the choice of the building material (concrete, wood etc.) of the walls and floors of the stables, as well as to the ventilation (number of total air changes per 24 hours), because the conditions should be representative of a practical situation. This can differ per EU country. It is possible to assess whether extrapolation to other types of accommodation is justified. If for example a general registration for poultry houses is requested, but studies conducted

in a house for laying hens have been submitted, a rational should be provided that extrapolation is justified.

The effect on the fly population can be determined by counting the numbers of flies (estimation of population size) before, during and after the treatment, or by the differences between treated and untreated objects in the same area. Various assessment methods are acceptable including visual assessments (fly density on a surface or animals is assigned to a category) or quantified measures such as using sticky fly papers, digital photographs of marked areas on walls, collecting dead flies from a defined floor or aisles area etc..

13.2.3 Requirements per type of claim

Per type of claim the requirements will be listed.

Products intended for use as general surface treatment, space treatment or vaporisers in houses:

- a simulated-use test showing mortality and knockdown and/or residual efficacy according to the claim.

Products intended for use as general surface treatment, space treatment or vaporisers in stables and waste dumps:

- a laboratory test showing mortality and/or knockdown and/or residual efficacy, depending on the claim;
- a field trial according to the directions for use.

Products intended for use as larvicides:

- a laboratory test showing larva mortality;
- a simulated-use test showing decrease in number of emerging flies.

Products intended for use as repellent:

- a laboratory or simulated-use test showing repellence;
- field test showing repellence (only required in some cases, for instance when a repellent is used to prevent flies from entering stables).

Products intended for use as repellent on horses (recreational and/or sport horses only):

- a laboratory test demonstrating repellence;
- a simulated use/ field test demonstrating repellence against the specific target fly species on target animals.

Simulated-use tests can be waived if a robust field trial is submitted.

13.3 Assessment of authorisation

13.3.1 Norms and criteria

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy". An insecticide against flies is considered to be sufficiently "effective" if the following results can be achieved:

Products intended for use as general surface treatment, space treatment or vaporisers in houses:

- required results in simulated-use tests:
  - the level of knockdown efficacy should be ≥80%;

- mortality after 24 hour should be >90%.

Products intended for use as general surface treatment, space treatment or vaporisers in stables and waste dumps:

- required results in laboratory tests:
  - the level of knockdown efficacy should be ≥80%;
  - mortality after 24 hour should be ≥90%;
- required results in field trials:
  - reduction in the amount of flies according to the claim (or compared to the control situation).

Products intended for use as larvicides:

- required results in laboratory tests:
  - >90% larva mortality;
  - showing decrease in number of emerging flies.

Products intended for use as skin repellent:

- required results in tests:
  - showing repellence, preferably >90%.

Products intended for use as spatial repellent:

- required results in tests:
  - showing repellence, preferably >80%.

Products intended for use as repellent on horses (recreational and/or sport horses only):

- a laboratory test demonstrating repellence;
- a simulated use/ field test demonstrating sufficient repellence against the specific target fly species on target animals.

Deviations from these norms is possible but should be justified in the application.

14. Mosquitoes

14.1 Introduction

Mosquitoes, including species in the Culex, Aedes, and Anopheles Genera are common pests in parts of the EU. As well as their annoying behaviour and itching bites, mosquitoes are well-known for transmitting diseases such as Malaria (Anopheles spp.), yellow fever, Dengue (Aedes spp.), West Nile (e.g. Culex spp.), blue tongue virus in animals, and various encephalitis. Although none of these diseases are endemic in Europe, occasional outbreaks occur and European travellers might encounter them, either in European tropical overseas regions or in the rest of the world. Biocides against mosquitoes can only claim to kill or repel the mosquitoes, not to prevent the diseases.

14.1.1 Biology

Like all Diptera, mosquitoes also go through four stages of development. The egg, larval and pupal stages take place in still aquatic environments such as floodplains, drainage ditches, natural and artificial water containers. Depending on the species, female mosquitoes will lay eggs directly in these aquatic environments or adjacent to locations in mud which typically have fresh water or tidal flooding events. Depending on the

genera, eggs are laid individually or in clumps called rafts.

Once larvae hatch, filter feeding begins near the top of the water. Typically, mosquitoes go through 4 larval instars before beginning the pupal stage. Once completed, mosquito adults emerge from the aquatic and enter the aerial environments. Mating usually begins a few hours to days after emergence. Once mated, the females begin to search for a blood meal. Humans and domestic animals are included as potential blood hosts, with some mosquito species preferring human blood to other animals.

Adult female mosquitoes locate potential blood hosts by detecting attractants such as carbon dioxide and skin emanations. Once located, the mosquito will attempt to bite, taking in a blood meal. This blood meal is partially digested and used for the development of eggs.

14.2 Dossier requirements

A clear label claim should be submitted. The study results of trials should demonstrate the efficacy of the product based on the submitted label claim.

Laboratory, simulated-use tests and field trials with the test insects are needed to assess the efficacy of the product. Ideally, the studies should be performed according to established guidelines where these are available. These may be international, EU or national guidelines. See appendix 3 for a list of available guidelines. Several WHO tests are available for mosquito testing. If the available guidelines are not suitable, the applicant may use their own methods (intra-company Standard Operating Procedures), on condition however, that the study is scientifically robust, well reported and provides a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label. A control treatment without biocide should be included in all laboratory trials.

In the case of field trials where true replication is almost certainly impossible to achieve and where normal control methods are not restricted to use of a single insecticidal product, a full description of any factors that might be expected to influence product performance should be given. These may include the risk of re-invasion from adjacent areas, general levels of sanitation, treatment history, season, etc. and are intended to provide the authorities with information to assist with the interpretation of the results obtained.

14.2.1 Test species

In case of an authorisation against mosquitoes insecticide testing should be performed with the house mosquito (*Culex* spp.) since this is the most common in Europe and a large mosquito, which makes it one of the most difficult to kill. Since *Aedes* spp. are the most aggressive mosquitoes repellents should be tested on this species too.

When use in tropical areas is claimed it should be specified against which mosquito spp. the product is effective and these should be tested (e.g. malarial mosquitoes: *Anopheles*).

Products intended for use as repellent on horses (recreational and/or sport horses) should be tested against the claimed target organisms (see Appendix 2 Species grid PT 19 3H to 3T).

14.2.2 Laboratory studies

For the evaluation of biocides against mosquitoes different types of laboratory, simulated-use tests and field test can be used. Examples of test are listed below. Mosquitoes used in all tests should be disease free.

14.2.2.1 Laboratory tests against adults

Insecticides against mosquitoes should normally be tested in the laboratory in WHO cones or WHO cylinders by force tarsal contact. The test is well described in WHO guidelines (methodology, number, age, nutritional status of the specimens and insecticide susceptibility of the strains). Only females have to be tested. First laboratory test (bio assay) can be conducted on a laboratory strain of well-known insecticide susceptibility. A second test can be conducted on field populations obtained by larval collection. Tests should be conducted on F1 generation adults. Mosquitoes are exposed during a few minutes to a treated surface and their evolution (knock down, death) is followed during 24 hours. The knockdown percentages and mortality are determined.

The cone tests can also be used to evaluate the efficacy of insecticide treated net. For netting evaluation the exposure time is only 3 minutes and mortality is also checked after 24 hours.

Tunnel tests baited with birds or little mammals could be conducted to assess the feeding inhibition, the repellent effect and the insecticide effect.

A control treatment without biocide with an adequate number of replicates should be included in all laboratory trials.

14.2.2.2 Laboratory tests: Larvicides

Larvicides are applied to water to prevent larva to develop into adult mosquitoes. These products can be tested in naturally or artificially infested water, in boxes covered with gauze. Tests are normally not performed in tap water but in water containing organic particles, especially where a claim for residual performance is made. Test is normally performed on late 3rd-early 4th larval stages only. Mortality is usually checked after 24 hours. For slow acting insecticides and insect growth regulators mortality has to be checked for several days. In that case food has to be supplied to larval stages. A control population susceptible to insecticide should be use as control in all bio-assays (positive control). A control treatment without biocide should be included as negative control. Adult mosquitoes emerging from the water are counted and the differences between treated and untreated boxes are analysed. The methodology of this bio-assay is described in WHO guidelines (WHO/CDS/WHOPES/GCDPP/2005.13).

14.2.2.3 Simulated use tests

For assessment of efficacy simulated-use tests should be conducted in a test chamber, for instance the Peet-Grady chamber. This is an airtight room of 1.8*1.8*1.8 m, into which a certain amount of product is introduced. Other chambers of similar or bigger size are acceptable.

The chamber should be washed and dried between each replicate to avoid chemical contamination.

Next to chambers experimental huts can be used. These huts are small buildings, several build next to each other, in which wild mosquitoes can enter but they have no way to escape. Volunteers are in the huts as attractants for mosquitoes. In each hut, the treatment of the hut (space or surface treatment) or the volunteers (skin repellents) should be different: test product, negative control (no biocide) or positive control (standard product e.g. DEET for repellents). At the end of a test period (e.g. one night) number of mosquitoes are counted by species, by status (death or alive), by engorgement (fed or unfed) and by position in the hut (hut or exit traps). Advantage of the hut is that wild populations can be used and that it is ventilated (mimics reality better in some cases).

Environmental conditions must be specified at the beginning and during the test (temperature, humidity, photoperiod). Temperature would be expected to fall in the range 19-29°C. When efficacy at high temperatures is claimed (use in the tropics) test at

temperatures >30°C should be provided. A control treatment without biocide should be included in all laboratory trials.

Simulated-use tests can be waived if a robust field trial is submitted.

14.2.2.3.1 Space treatment simulated use tests

In the case of an application for a liquid for space treatment, the aerosol test method is performed in the test chamber in the laboratory. A known number (e.g. 50-100) test insects (females) are exposed to the space treatment. The dose sprayed in the chamber should be comparable to the label directions. The test is replicated 3 or more times. The knockdown percentages and mortality of mosquitoes in both insecticide treatment and negative control are determined. Ideally, a ventilated room should be used to mimic the intended use better.

14.2.2.3.2 Surface treatment simulated use tests

Products for surface treatment act on the insect by tarsal contact with the treated surface. The product can be applied by spraying, brushing, painting, etc. according to the label. These products are also tested in a test chamber or an experimental hut. The WHO guideline for testing mosquito adulticides describes such a test.

In the test chamber the product is applied on small surface, or on the whole chamber, in a dose rate appropriate to the label claim. A negative control should be included. After the surfaces have been left to dry the test can commence. The insects are released in the test chamber at several time points after application (or at least at the maximum residual time claimed at the label), to show residual efficacy. After 24 hours mortality of the test insects is recorded. It is mandatory to report temperature and air humidity in the test room. These should agree as much as possible with practical use conditions.

14.2.2.3.3 Products to be vaporized or fogged simulated use tests

No officially recognized guidelines are available for efficacy studies with products that should be vaporized (heating element that heats a tablet of liquid, coils, fan driven dives, etc.) or products that should be applied in a fogging treatment. The "Large room test" is generally accepted. Other methods are also acceptable if they are scientifically sound and provide a clear picture of the efficacy of the product.

The "Large room test" test can be performed in a non-ventilated room of 20 to 60 m^3. When a ventilated room is used (mimics reality better in some cases) the air exchange should be measured (e.g. one air chamber renovation per hour). The product is applied according to the intended use, allowing it to evaporate over a specified time period (depending on the label claim e.g. 9 hours).

Mosquitoes are exposed to the vapour/fog at different time points, e.g. at 0, 2, 4, 6 and 8 hours. At every time point a known number of female test insects (50-100) are exposed to the vapour. The test is replicated 3 or more times. A negative control should be included.

The knockdown percentages (KD50, KD95, KD100), mortality and, if possible, the concentration of the active substance in the room are determined.

When the label claim says that the product should be used in ventilated rooms the opening of windows and doors should be simulated in the test.

14.2.2.3.4 Repellents

Repellents are products with a repellent effect and can drive away mosquitoes. These products are either applied on human or animal skin or on clothes (topical or skin repellent) or release the active ingredient to the air (spatial repellents).This is based on the biological activity of the evaporated active substance.

Products with a repellent effect, which are applied on the human skin or clothes, can be tested in an "arm-in-cage" simulated-use test. The repellent is applied in the specified dose on the (bare) forearm of the test person. The forearm is subsequently exposed to test mosquitoes in a cage for 5 minutes. This should be repeated every hour, at least up to the claimed efficacy period. If one bite is received during an exposure followed by another bite in the next exposure (confirming the first bite), the test should be stopped and the time of the first confirmed bite recorded as the length of repellence. If bites are not received in succession, then the test is continued and the first bite should be considered 'unconfirmed'. The same test is repeated with untreated forearms of, preferably, the same test persons. For the untreated forearm, a minimum of 5 lands in 5 minutes is required to qualify the test. Once 5 lands are received, the arm should be removed to prevent excess biting. If less than 5 lands are counted in 5 minutes, then the test should not proceed and the mosquito cage should be replaced with 'fresh' mosquitoes. The results of treated and untreated forearms are compared.

Alternative methods using rabbits are developed. The repellent solution could be applied directly on the skin of a rabbit on which a cage containing female mosquitoes is placed.

Skin repellents can also be tested in and experimental hut, as long as the number of mosquitoes entering the hut is not too low.

Similar tests can be used for cloth in which a repellent is incorporated (treated article).

Repellent effectiveness is based on protection time, that is, the time between repellent application and the time of 2 or more bites on the treated arm, or the first confirmed bite (a bite followed by another within 30 min.).

For products with a repellent effect, which are applied in another way (*not* on the human skin or clothes, for instance spatial repellents), no common protocols are available. These products can be tested in a simulated use test, for instance in an experimental hut. The submitted data from studies are checked for completeness, based on the applied dose per treated area. It is also checked whether the duration of exposure is sufficient. If the formulation alone i.e. without the carrier (e.g. a product with a tissue as carrier) has been tested, data on release from the carrier are also required. The study data should provide a clear picture of the efficacy of the product.

When the label claim says that the product should be used in ventilated rooms the opening of windows and doors should be simulated in the test.

14.2.2.3.5 Larvicides simulated use tests

In small scale simulated-use tests, insecticide formulation can be tested in natural breeding sites or simulated larval breeding sites. When natural larval populations are used pre-treatment assessments of the population should done at the site (larval count by dipping technique). Depending on the protocol, eggs or larvae can be regularly introduced in the treated sites to evaluate the residual efficacy. Breeding sites are kept uncovered to allow wild adults to lay their eggs. The methodology of this test is described in WHO guidelines (WHO/CDS/WHOPES/GCDPP/2005.13).

14.2.2.4 Field trials

For some products against mosquitoes, field trials are not required. Especially when field populations are used in the lab or in an experimental hut. However, for some products and uses a simulated-use test cannot mimic the practical situation sufficiently (e.g. larvicides used in large swamps and lakes, aerial applications). Especially with aerial applications the way the product is dispersed can make a difference for efficacy. In these cases the competent authorities should require a field test.

Tests are done preferably during spring and beginning of summer. In autumn population decline might be due to natural causes instead of the insecticide. Larvicides should normally be tested in July-August when sufficient levels of *Culex* spp. and *Aedes* spp.

can be found. In any field trial, the assessment of efficacy requires pre- and post-treatment assessments of the population. CDC light traps are one commonly used method to trap mosquitoes and can provide both quantitative (how many mosquitoes) and qualitative (which species are present) data. Other methods (exhauster, aspirator) can be used too. Apply the insecticide according to the label instructions.

14.2.3 Requirements per type of claim

Per type of claim the requirements will be listed.

Products intended for use as general surface treatment, space treatment or vaporisers in houses:

- a laboratory test showing adult mortality;
- a simulated-use test showing mortality and knockdown and/or residual efficacy according to the claim.

Products intended for use as larvicides:

- a laboratory test showing larva mortality;
- a simulated-use test showing decrease in number of emerging mosquitoes;
- depending on the claim (mandatory for use in natural waters) field test showing larval mortality or decrease in number of emerging mosquitoes.

Products intended for use as repellent on skin or clothes:

- a simulated-use test (arm-in-cage) showing repellence;
- a field study showing repellence in the field.

Products intended for use as repellent *not* on skin or clothes:

- a laboratory and/or simulated-use test showing repellence;
- depending on the claim field test showing repellence.

Products intended for use as repellent on horses (recreational and/or sport horses):

- a laboratory test demonstrating repellence;
- a simulated use/ field test demonstrating repellence against the specific target mosquito species on target animals.

Simulated-use tests can be waived if a robust field trial is submitted.

14.3 Assessment of authorisation

14.3.1 Norms and criteria

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy". An insecticide against mosquitoes is considered to be sufficiently "effective" if the following results can be achieved:

Products intended for use as general surface treatment, space treatment or vaporisers in houses:

- required results in simulated-use tests:
  - the level of knockdown efficacy should be >80%;
  - mortality after 24 hour should be >90%.

Products intended for use as larvicides:

- required results in laboratory tests:

- 100% mortality after 24 hours of contact is usually required. For slow acting insecticide 100% mortality after 48, 72 hours or more could be considered. Exceptionally a larval mortality >90% can be acceptable if all the surviving larvae died before or during emergence;

- required results in simulated-use or field tests:
  - >90% larva mortality;
  - showing decrease in number (usually 80%) of emerging mosquitoes.

Products intended for use as repellent on skin or clothes:

- required results in simulated-use test:
  - during the claimed protection period the protection should be ~100% (i.e. period to the second bite or the first confirmed bite is the claimed period);
  - if the claimed protection is less restrictions should be placed on these products preventing marketing as a way to prevent disease transmission.

Products intended for use as repellent *not* on skin or clothes:

- a laboratory and/or simulated-use test showing repellence;
- depending on the claim field test showing repellence (e.g. ~80% for repellents that are dispensed to protect an outdoor space (vaporisers, coils, etc).

Products intended for use as repellent on horses (recreational and/or sport horses):

- a laboratory test demonstrating repellence;
- a simulated use or field test demonstrating sufficient repellency over the time period claimed, preferably 90% OR provision of data that allow calculation of the 'complete protection time', i.e. the time till the first confirmed bite/landing.

Deviations from these norms is possible but should be justified in the application.

15. Wasps

15.1 Introduction

There are two types of wasp control: control of the wasps' nest and control of single flying wasps entering a home. The control of wasps' nests may be performed both indoors (in cavity walls or attics), as well as outdoors (in trees, under roof gutters).

15.1.1 Biology

The major pest wasps (Hymenoptera) are the social wasps in the family Vespidae. Yellow-jackets ((*Para)Vespula* spp., *Dolichovespula* spp.), paper wasps (*Polistes* spp.), and hornets (*Vespa* spp.) all belong to this family and are the greatest pests to homeowners. Wasps can be easily differentiated from bees by the fact that a wasp's body appears to be hairless and their hind legs thinner than a bees.

The vespid or social wasp lives in colonies in nests built of a paper-like material. Each nest is begun in the spring by a single queen who has mated the previous autumn. The queen builds a small nest in which she begins to lay eggs. It is only non-fertile female worker wasps that emerge from these initial eggs. These workers take over the nest building duties and forage for food to feed the larvae that emerge from subsequent eggs. Some of these eggs are fertile females and some are males.

Mature colonies are divided into a social order consisting of the queen, workers, males, and fertile females. In the autumn, the males and newly produced queens leave the nest to mate. The male's sole purpose is to inseminate the fertile females, which will become

next year's queens. The newly inseminated queens will then find a sheltered place where they will hibernate to begin the cycle with building a new nest the following spring.

Unprovoked, wasps are not aggressive stingers but will protect themselves and their nests making them an undesirable occupant of properties and buildings. Wasps commonly infiltrate in and around homes in search of nest sites and areas to hibernate causing problems for the homeowner. Some people are allergic to wasp venom, and can have life-threatening allergic reactions. Unlike bees, wasps can sting repeatedly.

For effective control of wasps, the entire wasps' nest should be treated. The control is aimed at exterminating all wasps that are within the nest that can fly. If this is achieved, the eggs and larvae that are still present cannot be taken care of and fed anymore, resulting in the elimination of the entire nest.

15.2 Dossier requirements

A clear label claim should be submitted. The study results of field trials should demonstrate the efficacy of the product based on the submitted label claim.

Laboratory and field trials with the test insects are needed to assess the efficacy of the product. Ideally, the studies should be performed according to established guidelines where these are available. These may be international, EU or national guidelines. See appendix 3 for a list of available guidelines. If there are no guidelines available or the guidelines are not suitable, the applicant may use their own methods (intra-company Standard Operating Procedures), on condition however, that the study is scientifically robust, well reported and provides a clear answer to the question. In addition, the test methods applied and the test conditions should be clearly and fully described and must address the efficacy claim that appears on the product label. A control treatment without biocide should be included in all laboratory trials.

In the case of field trials where true replication is almost certainly impossible to achieve and where normal control methods are not restricted to use of a single insecticidal product, a full description of any factors that might be expected to influence product performance should be given. These are intended to provide the authorities with information to assist with the interpretation of the results obtained.

15.2.1 Test species

A product for use against wasps should be tested on colonies and/or workers of *Vespula* spp. or *Dolichovespula* spp.

15.2.2 Laboratory simulated use tests and field studies

For the evaluation of biocides against wasps different types of laboratory and field test can be used. Examples of test are listed below.

15.2.2.1 Laboratory tests

Wasps can be tested in the laboratory in small jars or Petri dishes. The individual wasps should have sufficient access to food (e.g. sugar solution), since they can starve to death within hours when isolated from their nest without food. The surface can be treated, after which insects can be added at different time intervals. Alternatively, the wasps can be sprayed directly. Concentrations used must be in accordance with the claim. The knockdown percentages and/or mortality and/or residual effect are determined.

A control treatment without biocide with a similar number of replications should be included in all laboratory trials.

15.2.2.2 Repellents/attractants

For products with a repellent or attracting effect against wasps no agreed protocols are available. The tests should be designed to mimic the practical use situation. The study results should provide a clear picture of the efficacy of the product. Methods should be described well. The submitted data from studies are checked for completeness, based on the applied dose per treated area. It is also checked whether the duration of exposure is sufficient. If the formulation alone i.e. without the carrier (e.g. a product with a tissue as carrier) has been tested, data on release from the carrier are also required.

15.2.2.3 Field trials

Insecticides with a claim to kill wasps' nests should be tested in a field trial. The efficacy of the product should be tested in at least 5 nests. Depending on the label claim different nests (locations) should be tested (e.g. free hanging in trees or on buildings, hidden in the soil or in wall cavities, etc.). A few like size nests should be monitored over the same test period as untreated controls. A pre-treatment activity count should be taken over a pre-determined time interval of both treated and untreated nests. A well-established parameter for wasp colony activity is the traffic rate, which is defined as the number of wasps entering and leaving the colony in a given time. The traffic rate can be determined 7 days before the treatment for at least 5 minutes at two different times of day as well as on the day of treatment in order get a picture of the colony activity and development. The time interval between both observations must be at least 2 h. Treatment should be consistent with label instructions. When the nest is visible it can be treated directly. In some cases the nest is hidden, for instance in between walls or ceiling of houses. In those cases normally all the openings through which the wasps enter the space in which the nest is hidden should be treated. Nest position, number of entrances as well as wasp species must be described.

After 24 hours, one week and two weeks post-treatment the activity or lack there of should be recorded by determination of the traffic rate at the treated and untreated nests. The check after one and two weeks is required since it is possible that, when pupae are not eliminated, wasps emerging from pupae can take over the duties of feeding the larvae.

15.2.3 Requirements per type of claim

Products intended for the control of the wasps' nest:

- field trial with at least 5 treated nests.

Products intended for the control of flying wasps:

- laboratory or simulated-use test.

Products intended for repelling wasps

- imulated-use or field trials.

15.3 Assessment of authorisation

15.3.1 Norms and criteria

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy". For wasps this is implemented in the following way.

Products intended for the control of the wasps' nest:

- required results in a field test:
  - in 80% of the treated nests mortality of the flying wasps should be 100% within 24 hours and all of the treated nests must have 100% mortality (i.e. no

visible signs of nest activity) after one and two weeks.

Products intended for the control of flying wasps:

- required results in a laboratory or simulated-use test:
  - ≥ 90% knockdown within a 5 -10 minutes after contact with the product (or according to the claim), direct after spray and at the end of the residual period;
  - mortality according to the label claim, preferably 90% in 1 hour.

Products intended for repelling wasps

- required results in a simulated-use or field test:
  - a simulated-use test showing repellence;
  - depending on the claim field test showing repellence.

Appendix 1. Additional information on label claims

ASSESSING THE EFFICACY OF BIOCIDAL PRODUCTS

The evaluation of the efficacy of biocidal products differs greatly from that of active substances.

Whilst the efficacy assessment of an active substance for Annex I inclusion requires only a minimal assessment, sufficient to show an innate level of activity for the active substance, the assessment needed for a biocidal product at the product authorisation stage is much more detailed.

Rather than looking at innate effects, the efficacy assessment of a biocidal product is based on substantiating the efficacy claims made for a product. The assessment is made on the product in its normal conditions of use.

This principle is set out in paragraph 51 of Annex VI of the Directive (Common Principles for the Evaluation of Dossiers for Biocidal Products), which states:

> *5.1 Data shall be submitted and evaluated to ascertain if the efficacy claims of the biocidal product can be substantiated. Data submitted by the Applicant or held by the Member State must be able to demonstrate the efficacy of the biocidal product against the target organism when used normally in accordance with the conditions of authorisation.*

The label claims for the product must be submitted as part of the common core data set, as set out in Annex IIB (Common Core Data Set for Biocidal Products), which requires:

> *V. INTENDED USES AND EFFICACY*
>
> *5.10. The proposed label claims for the product and efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate*

As the label claims are central to the efficacy evaluation for a biocidal product, it is important to understand exactly what is an efficacy claim, and be able to identify the individual components of a claim.

LABEL CLAIMS FOR BIOCIDAL PRODUCTS

As efficacy claims are assessed against the product 'when used normally in accordance with the conditions of authorisation', then it is important to define the 'normal use' of the product.

There are several pieces of information which will form part of the conditions of authorisation which relate to the efficacy assessment. These are:

1. The Formulation Type

This is determined by the product itself – e.g. a solvent based ready-for-use, a water based concentrate, a dusting powder, a gel bait, etc.

2. Application Method

This is the method by which the product is intended to be applied. e.g. coarse spray, ultra low volume (ULV) spray, bait station, skin lotion, etc.

The application method may also describe a specific pattern of treatment. This is particularly common for spray applications, but may also apply to other formulation types. General descriptions of some common treatment patterns are given below.

(i) Surface treatments

These are treatments where the product is applied over surfaces such as walls, floors and ceilings, or as a treatment to outdoor surfaces. These treatments may involve treating a large area of surface or may only involve application to a narrow band.

Surface treatments can also include application to temporary or permanent bodies of water (e.g. in mosquito control) and to solid and semi-solid manure.

(ii) Crack and crevice treatments

These are treatments where products are applied into cracks and crevices where insects hide and harbourage, 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.

(iii) Contact (direct) spray treatments

These involve application directly onto insects, and are normally only possible when the insects are visible and available to be sprayed.

In practice this often restricts direct application methods to controlling flying insects (such as adult moths and houseflies), although some limited control of minor infestations of crawling insects (such as ants or beetles) may be possible.

(iv) Space treatments

These are treatments where the product is applied into the air rather than onto a surface.

They are intended to disperse small droplets or particles into the atmosphere of a room or other open space, where they will normally stay for a period of time (very small particles may stay in the air for several hours under still conditions).

(v) Spot treatments

These are treatments where products are 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.

(vi) Baits

Bait treatments use products that are intended to be ingested by the target. This is normally through the insect feeding on the product directly, but may also include products which the target will come into contact with and later ingest during grooming/cleaning.

The attractiveness of these products is through the use of a palatable food base, however they may also incorporate an attractant (e.g. a pheromone) which is intended to attract the target pests over a greater distance.

3. Application Rate

This is the rate at which the product will be applied in use, e.g. apply 100 ml of product per square metre, apply at a rate of 1 bait station per 3 m^2, spray for 20 seconds, etc.

For efficacy assessment purposes, it is useful to consider the application rate as the amount of *active substance* applied to surface area or volume.

Unlike a human health or environmental risk assessment which look at the maximum amounts of product which are considered to be acceptable (i.e. if the amount of active or

application rate increase, the risks to man or the environment will be unacceptable), an efficacy evaluation looks at the *minimum* application/dose rate which will be effective (i.e. if the application rate decreases, the product may not work).

4. Frequency of treatment and any specific interval between applications

Some products will be used in a way that will require more than one treatment. These products will give information on the treatment schedule which should be followed (e.g. insecticide re-treatment intervals or rodenticide re-baiting periods).

Together, these pieces of information define the 'normal use' of the product (e.g. a solvent based ready-for-use product to be applied as a coarse spray at a rate of 100 ml product m^{-2}), and efficacy must be demonstrated for the product when it is used in this way.

Whilst information on the application method and rate etc. will normally be clearly defined, the claims made for the effects of the product are much more difficult to identify.

5. Other specific conditions to be taken into account

Occasionally, the "normal use" of a product will involve the use of the product in conjunction with other activities. This will include the cleaning of an area prior to treatment. The contributions made by other components of an Integrated Pest Management procedure may also have to be taken into account.

PRODUCT LABELS AND LABEL CLAIMS

The product label is the major source of information on a product. It will give the use pattern to help determine the 'normal use' of the product, but will also make claims about the effectiveness of the product.

These label claims form the core of any efficacy evaluation. Efficacy is assessed mainly in relation to the claims made for the product. The norms and criteria set per insect pest will further guide the evaluation.

Whilst the phrase 'label claims' is generally used, this phrase actually encompasses all claims made for the product, not just those made on the label itself. Claims may also be made for a product with any accompanying information (such as leaflets) or on advertising material.

For efficacy purposes, all of these claims also have to be justified before they can be allowed onto a label.

WHAT IS A LABEL CLAIM?

A label claim is anything on the product label that makes a claim about what the product does or the benefits that will result from its use. At this moment there is no standard format for making claims about the effects and benefits of using the product, and the type and style of label claims can vary widely between different Member States.

For example, a product which claims to be 'For the control of cockroaches' in one Member State may claim that it 'Kills cockroaches fast!!' in another.

To aid in the evaluation process, a standardised method for identifying the main components of a label claim is set out below.

LABEL CLAIMS – UNDERSTANDING THE COMPONENTS

A set of label claims will consist of 2 types of information which describe what the product will do when it is used (in accordance with its 'normal use'). These are:

1. The target species which the product will be effective against

   and

2. The effect (or effects) which the use of the product will have on the target species and the benefits which may result from this effect

TARGET SPECIES

The product label will give details about which species the product is to be used against. This information will often be quite specific (e.g. 'for the control of pharaohs ants' or 'kills ants, cockroaches, fleas and bed bugs or repels mosquitoes'). In these cases it is easy to identify what are the target species.

However there can also be instances where a more general claim is made, such as for use against 'crawling insects'. In these cases, it is difficult to require data on every crawling insect.

They will need to supply efficacy data on relevant representative species, which may be those used in standard test methods or those that the Applicant argues are representative of the use pattern of the biocide and the nature of the application (e.g. whether it is a space application or a surface application).

In some instances it is possible to allow a compromise on the label. For example, members of the general public may not know what species of fly is in their home, but the regulators will need to know what the product is effective against. In this particular instance it may be possible to allow a claim such as 'Effective against flying insects such as the housefly, mosquitoes and midges'.

THE EFFECTS OF USING THE PRODUCT

The remaining parts of the label claim will describe the effects on the target organisms and benefits of using the product.

The major effects which are generally claimed are that a product will:

- kill, knock down, repel, attract, reduce the numbers of or inhibit a target organism
- control, reduce or prevent the build-up of a population
- prevent or reduce an undesirable effect.

For insecticide products, the following claims are the ones that are frequently encountered:

'Kill' claims generally refer to the death of an individual or a number of individuals (the death of an entire population is more generally found under a 'control' claim) and generally refer to an existing infestation.

'Knockdown' claims are generally restricted to insecticides and acaricides. A knockdown effect is one where a target insect becomes unable to carry out coordinated movement, but has not been killed.

Knockdown effects are often included in an insecticide product to produce a rapid, visible effect on a target in order to satisfy user expectations. These effects can be reversible, with insects able to recover after a period of time. Recovery is often dependent upon dose administered.

Knockdown claims may be found in conjunction with a kill claim, and many 'dual action' insecticide products contain two active substances - with one active substance producing a quick knockdown effect (such as a flying insect falling out of the air) whilst a second, slower acting, active substance produces the killing effect. Combined claims may be along the lines of 'knockdown within 10 minutes and kill within 2 hours'.

When it comes to efficacy testing, some companies use the two terms interchangeably, so you will get products or test reports mentioning 'knockdown' where a killing effect is actually meant. For evaluation purposes, knockdown and kill are considered to be separate effects.

'Complete control', 'colony kill' or *'nest kill'* claims will generally refer to the elimination of an entire infestation or population - i.e. use of the product will essentially 'remove the problem'.

As stated above, the mortality of individuals (rather than populations) is considered to be a 'kill' effect.

To highlight the difference between 'kill' and 'control', we can take the example of an ant nest outside of a house, close to the back door. The queen (which does all of the reproduction) remains hidden away in the nest and produces new ants for the colony, and the only ants seen outside of the nest are the sterile female workers.

An aerosol product which is intended to be sprayed onto ants wandering around in your kitchen to kill them will only be having a 'kill' effect. Killing off individuals or numbers of workers will have little effect on the nest and the colony as a whole, as the queen and fertile males will remain unaffected in the nest.

In order to remove the problem, you actually have to kill off the colony. So a product claiming to 'control' an infestation of ants would have to eliminate the queen or disrupt the ability of the colony to reproduce.

'Reduce' claims will generally refer to reducing the numbers of (but not completely eliminating) a target population. Whilst not eliminating an infestation may seem to be an odd claim to make, there are situations where it would be practically impossible to totally control a target population and where the best result is to reduce the scale of the problem.

An example of this would be reducing the fly burden in a poultry house or intensive animal house. However, the issue of resistance must always be kept in mind when considering treatments which do not fully control a population.

MORE COMPLEX LABEL CLAIMS

Whilst a label claim is, at its most basic, a target and an effect, most claims are more complex, introducing further elements beyond the basic target/effect combination described above.

These additional parts of a label claim more fully describe the effects on the target organisms and benefits to be gained from using the product.

Claims for the effects and benefits of using the product can generally be broken down into 6 major components, which are described in Table 1.

The examples given in the table cannot be exhaustive, but are given to illustrate the type of information which appears in label claims.

Table 3: Components Making Up a Label Claim

A	Target organism(s)	Against what target organism(s) will the product be used? • Specific insect (e.g. ants) • Several insects (e.g. ants and wasps) • General claim (e.g. flying and crawling insects)
B	Type of effect	What effect will the use of the product have on the target? Examples include:

		• Kill • Knockdown • Control • Flushing • Attracting • Repelling
C	Time taken to produce the effect	How long will the product take to produce the effect? Examples include: • within 5 minutes • within 1 hour • within 3 months
D	Area of use	In what types of environment and on what type of surfaces will the product be used? For example: • indoors/outdoors • on hard porous and non-porous surfaces • on soft furnishings • in hospitals • in and around buildings
E	Duration of the effect	Will the product have a residual effect, and if so, how long for? For example: • for 6 weeks • for 3 months
F	User	Who can use the product? • Industrial use • Professionals • Consumers
G	Other specific claims	Does the product claim any other specific benefits? Examples include: • works against resistant species • helps prevent biting • protects fabric from damage

A label claim will not always contain all 7 components. For example, where no residual activity is being claimed, section E will not be represented, and where no specific other claims are being made, claims in section G will not be present.

The target organism (A), the type of effect (B) and area of use (D) and the user (F) should always be given.

On some labels, the time taken to product the effect (C) will not have been given (e.g. 'for the control of cockroaches') or is not a specific value (e.g. 'kills flies fast'). In these cases, the evaluator will use the norms and criteria given per insect for the evaluation of the data.

LINKING THE COMPONENTS OF THE LABEL CLAIM

When initially trying to understand how the components of the label claims fit together, it can help to place the assorted claims into a table in order to identify how the various elements interact. For example:

Table 4: Example of linking lable claims

B	C	D	E
Knocks down	within 5 minutes	- on hard porous and non-porous surfaces - on soft furnishings	for 6 weeks
Kills	within 1 hour		

The beneficial effect of the product (B) will be accompanied by the timescale in which the effect will happen (C). In these cases, it must be demonstrated that the product will be efficacious within the stated time.

In the above example, it must be demonstrated that the product is capable of both knocking down the target insects *within 5 minutes* AND killing them *within 1 hour*.

The area of use (D) gives information about the conditions in which the product will be used and the type of surfaces it will be used on. The efficacy data supplied should demonstrate that the product will be efficacious in the areas specified or on representative surfaces of the types described.

In the example, it would have to be demonstrated that the product would produce its knockdown and kill effects *within the times stated* AND *on both hard surfaces and soft furnishings*.

The duration of effect (E) specifies the length of residual activity which must be demonstrated.

In the example, it must be demonstrated that the product is still capable of producing the effects on the specified surfaces 6 weeks after treatment (although not necessarily to the same degree as a fresh treatment).

Other claims can be linked into this process in the same way. For example, if claims were being made that the product was to be used against resistant individuals, then all of the above elements would have to be proved using a resistant test population to generate the data.

Once the various elements making up the label claims have been identified then the evaluation of the efficacy data submitted can proceed.

General guidance on the assessment of label claims is included in the paper "Broad principles of assessing efficacy in relation to claims made on the label for biocidal products", which was agreed at the Technical Meeting TM III 05 in October 2005, and at the subsequent CA meeting.

Guidance on type of and amount of data which would normally be required to support many of the major label claims is given for the main pest species elsewhere in this guidance

Appendix 2. Species grid

Table 5: PT 18 Crawling Insects

	Action	SITE	APPLICATION METHOD	CLAIM	TEST SPECIES	RATIONALE	NOTES	INSECT STAGE
1A	Flushing	Indoor	Crack & Crevice	"Flushes cockroaches out of hidden places"	*Blattella germanica* or *Periplaneta*	Data show Periplaneta flush before Blattella N.B This is true with pyrethroids, the case may be different with other actives. Fast acting pyrethroids may knockdown Blattella faster than they can be flushed, use Periplaneta in this case.	Any additional species need specific data.	Nymphs Adults
1B	Knockdown	Indoor	Direct Spray	"Knocks down cockroaches"; "Knocks down cockroaches in x seconds"	*Blattella germanica* and either *Periplaneta* species **or** *Blatta orientalis*	These species are representative of all domestic cockroaches found in Europe and around the world. Behavioural differences between species do not come into play when testing aerosols for direct spray efficacy.	We see little or no value in producing nymph/immature data in aerosol direct spray tests. Testing with only adults provides a very clear picture of product activity for registration studies. More than one life stage is an unnecessary burden.	Adults
1C	Kills	Indoor	Direct Spray	"Kills cockroaches"; "Kills cockroaches in x seconds"	*Blattella germanica* and either *Periplaneta* species **or** *Blatta orientalis*	See B.	See B	Adults
1D	Kills	Indoor	Direct Spray	"Kills ants"; "Kills in x seconds"	Lasius sp.	*Monomorium* ants are much smaller and more sensitive so would be covered by data for		Adults

	Action	SITE	APPLICATION METHOD	CLAIM	TEST SPECIES	RATIONALE	NOTES	INSECT STAGE
						Lasius		
1E	Kills	Outdoor	Direct Spray	"Kills ants"; "Kills in x seconds"	*Lasius* sp.			Adults
1F	Knockdown	Indoor	Direct Spray	"Kills crawling insects and other arthropods"	C + D and a variety of other common species e.g. *Forficula auricularia, Acheta domesticus, Cimex lectularius, Attagenus, Dermestes* sp, fleas, silverfish, booklice, carpet beetles, woodlice, ticks, centipedes, spiders	Multiple species are common world-wide. Test species will depend upon seasonal and local availability. See also B.	See B	Adults
1G	Knockdown	Indoor	Space spray; aerosols, gases, fogs, smokes	Knocks down crawling insects	Wood borers, carpet beetles, stored product beetles, other small crawling insects. Data required for claims on cockroaches (C) and fleas as surrogates for others			Adults, immatures
1H	Kills	Indoor	Space spray; aerosols, gases, fogs, smokes	Kills crawling insects	Wood borers, carpet beetles, stored product beetles, other small crawling insects. Data required for claims on cockroaches (3) and fleas			Adults, immatures and if claimed eggs
1I	Residual Kill	Indoor	Surface or Crack & Crevice Spray, Powders	"Kills cockroaches"; "Kills cockroaches up to x weeks or	*Blattella germanica* and either		Consider substrate and ageing period in the method	Adults and or immature stages.

	Action	SITE	APPLICATION METHOD	CLAIM	TEST SPECIES	RATIONALE	NOTES	INSECT STAGE
				months"	*Periplaneta* species **or** *Blatta orientalis*			Specify realistic exposure period followed by reasonable "recovery" period.
1J	Residual	Indoor	Surface or Crack & Crevice Spray, Powder	Kills ants"; "Kills ants for x weeks or months"	*Lasius* sp. and/or *Monomorium pharaonis* as option (see 4)		Consider substrate and ageing period in the method	Adults Specify realistic exposure period followed by reasonable "recovery"
1K	Residual	Indoor	Surface or Crack & Crevice Spray, Powder	"Kills crawling insects and arthropods" ; "Kills for x weeks or months"	**K + L** and a variety of other common species e.g. *Forficula auricularia, Acheta domesticus, Cimex lectularius, Attagenus, Dermestes* sp, fleas, silverfish, booklice, carpet beetles, woodlice, ticks, centipedes, spiders		We propose only roaches be tested for full period.	Adults and immature stages. Consider substrate and ageing period in method. Specify realistic exposure period followed by "reasonable" recovery period.
1L	Residual	Indoor	Bait	"Kills cockroaches"; "Kills cockroaches for x weeks or months";	*Blattella germanica; Periplaneta americana* and		Either the claim is limited to a specific species or the three species are tested	Nymphs Adults. Consider

	Action	SITE	APPLICATION METHOD	CLAIM	TEST SPECIES	RATIONALE	NOTES	INSECT STAGE
					Blatta orientalis			ageing period in method. Provide harbourage and alternative food and water.
1M	Secondary kill	Indoor	Bait	"Kills cockroaches that do not visit the bait (secondary kill)"	*Blattella germanica; Periplaneta americana* and *Blatta orientalis*	Life stage to be tested depends upon a specific mode of action (necrophagy versus coprophagy). Either nymphs or adults could be used.	Either the claim is limited to a specific species or the three species are tested	Life stage to be tested depends upon a specific mode of action (necrophagy versus coprophagy). Either nymphs or adults could be used.
1N	Nest kill	Indoor	Bait	control of entire population of cockroaches	*Blattella germanica; Periplaneta americana* and *Blatta orientalis*		Either the claim is limited to a specific species or the three species are tested	Nymphs Adults
1O	Kill	Indoor	Bait	"Kills ants"; "Kills ants for x weeks or months";	*Monomorium pharaonis* and /or *Lasius niger*.		Either the claim is limited to a specific species or the two species are tested. Provide harbourage and alternative food and water.	Adults and all immature stages
1P	Colony kill	Indoor	Bait	"Kills the queen and the colony"	*Monomorium pharaonis* and /or *Lasius niger*.		Either the claim is limited to a specific species or the two species are tested.	Adults and all immature stages. Use entire

	Action	SITE	APPLICATION METHOD	CLAIM	TEST SPECIES	RATIONALE	NOTES	INSECT STAGE
							Provide harbourage and alternative food and water.	colonies including queens.
1Q	Kills	Indoor	Spray, powder	"Kills dust mites"	*Dermatophagoides* sp.			Adults and all immature stages, if claim include eggs.
1R	Residual Kill	Indoor	Spray, powder	"Kills dust mites for x weeks/months"	*Dermatophagoides* sp.		Consider substrate and ageing period in method. Specify realistic insect exposure period followed by reasonable "recovery" period.	Adults and all immature stages, if claim include eggs.
1S	Kill	Outdoor	Baits, Dusts, powders	Kills ants	*Lasius* sp			
1T	Kill	Outdoor	Baits, Dusts, powders	"Kills the queen and the colony"	*Lasius* sp and /or *Monomorium pharaonis*		Either the claim is limited to a specific species or the two species are tested. Provide harbourage and alternative food and water.	
1U	Kill	Outdoor	Sprays, liquid drenches	Kills ants	*Lasius* sp		Add colony kill	
1V	Kill	Outdoor	Sprays, liquid drenches	"Kills the queen and the colony"	*Monomorium pharaonis* and /or *Lasius niger*.		Either the claim is limited to a specific species or the two species are tested. Provide harbourage and alternative food and water.	Whole colony
1W	Kill or repellent	Outdoor	**Physico-chemical barrier.** Installation	**Preventive Pre- construction** treatment Prevent	All subterranean termites *Reticulitermes sp.* *Coptotermes sp.*			

	Action	SITE	APPLICATION METHOD	CLAIM	TEST SPECIES	RATIONALE	NOTES	INSECT STAGE
			between the soil and the future construction	construction attack	*Heterotermes* sp.			
1X	Kill or repellent	Outdoor	**Chemical barrier** Injection in wall and soil	**Preventive Pre-construction** treatment Prevent construction attack	All subterranean termites *Reticulitermes sp.* *Coptotermes sp.* *Heterotermes* sp.			
1Y	Kill or repellent	Outdoor	**Chemical barrier** Injection in wall and soil	**Curative Post-construction** treatment	All subterranean termites *Reticulitermes sp.* *Coptotermes sp.* *Heterotermes* sp.			
1Z	Kill	Outdoor	**Baits system**	**Curative Post-construction** treatment Colony elimination	*Reticulitermes sp.* *Coptotermes* sp.		Due to the specificity of baits, only species tested should be claimed on the product label	
1AA	Kill	Indoor	Curative (Prevention is PT 8)	Kills dry wood termites	**e.g.** *Cryptotermes sp.*			
1AB	Barrier treatment	Indoor / Outdoor	Sprays, Powders	Prevents entry of crawling insects for x weeks or months	*Blattella germanica* and either Periplaneta species **or** *B. orientalis*, *Lasius* sp. See list above ("F") for selection, but expect roaches and ants to be the main claim			

Table 6: PT 18 Flying Insects

	Action	SITE	APPLICATION METHOD	CLAIM	TEST SPECIES	RATIONALE	NOTES	INSECT STAGE
2A	Kills / Knocks down	Indoor	Direct spray or room treatment	"Knocks down and/or Kills flies, mosquitoes";	*Musca domestica; Culex sp. or Aedes sp.*	These two species are representative of most urban species.	Flies and mosquitoes would be proxy insects for gnats and midges	adults
2B	kills	Indoor/ Outdoor	Aerosol, Coils, mats or liquid electrics ; Plaquettes or similar devices	Kills mosquitoes for up to x hours	*Culex sp. or Aedes sp.*		All insects, for which claims are made, should be tested.	adults
2C		Outdoor	Nuisance flying insects (landfill area)	Kills "XYZ"	*Musca domestica* *Culex sp. or Aedes sp.*		All insects, for which claims are made, should be tested.	adults
2D		Outdoors	Direct and residual sprays	Kills "XYZ"	Claimed insects need to be tested			adult and larvae
2E		Indoor	Fumigants	Kills "XYZ"	Claimed insects need to be tested		All insects and insect stages for which claims are made, should be tested.	Adults , eggs, and larvae
2F	kills	Indoor	Direct spray or room treatment	"Kills flying moths"	*Plodia interpunctella* ***or*** *Tineola bisselliella*			adults
2G	kills	Indoor / Outdoor	Direct spray	"Kills wasps"	*Vespula sp.*			adults
2H	kills	Outdoor	Nest treatment (all methods)	"Kills wasp nests"; "Kills the queen"	*Vespula sp.* ***or*** *Dolichovespula* sp		Test on whole nests	adults, queen for specific claim
2I	kills	Indoor	Closet or confined space	"Kills clothes moths and	*Tineola bisselliella*		All insects, for which claims	adults, eggs and /

	Action	SITE	APPLICATION METHOD	CLAIM	TEST SPECIES	RATIONALE	NOTES	INSECT STAGE
			treatments	larvae"; "Kills for x weeks or months"			are made, should be tested.	or larvae depending upon claim
2J	kills	Indoor	Baits	Kills "XYZ"flies	*Specifc species claimed on the label*			adults
2K	kills	Outdoor	Mosquitoes	Kills mosquito larvae	*Culex sp. Or Aedes sp.*		for IGRs the larval stage needs to be selected according to the mode of action.	last instar larvae
2L	kills	Indoor / Outdoor	Fly larvicides	Kills "XYZ"flies	*Specifc species claimed on the label*		for IGRs the larval stage needs to be selected according to the mode of action. Specify substrate9s).	last instar larvae

Table 7: PT 19 – Repellents & Attractants

	Action	SITE	APPLICATION METHOD	CLAIM	TEST SPECIES	RATIONALE	NOTES	INSECT STAGE
3A	Personal repellent	Outdoor	Aerosol spray, pump spray, lotion , cream, towels etc.	"Protects for a minimum/average of x hours against mosquitoes"	*Aedes sp.and* *Culex sp. .* *Anopheles* sp. ,*Simuliidae sp.* *(if claimed)*	Aedes is widely used as it is an aggressive biting mosquito and it bites all day. Aedes is used for repellent testing in many places because it is easily reared and bites all day so tests can be done during work hours. Since Culex is the most common species in Europe and it has a different time of	Any additional pest claimed needs to be tested (Sandflies wasps) If biting flies are claimed they need to be tested;(*Stomoxys*) If malaria mosquitoes are claimed tests need to be carried out on *Anopheles* sp. If nuisance flies are claimed: *Musca domestica*	

	Action	SITE	APPLICATION METHOD	CLAIM	TEST SPECIES	RATIONALE	NOTES	INSECT STAGE
						biting (mainly night)it should be tested too..		
3B	Personal repellent	outdoor	Aerosol spray, pump spray, lotion , cream, towels etc.	Protects for a minimum/average of "x" hours against ticks	*Ixodes sp. or Dermacentor*			
3C	Area repellent	Indoor / Outdoor	Coils, mats or liquid electrics or other devices	"Protects for up to x hours against mosquitoes"	*Aedes sp. or* *Culex sp.*		If biting flies are claimed they need to be tested;(*Stomoxys*) If malaria mosquitoes are claimed tests need to be carried out on *Anopheles* sp. If nuisance flies are claimed: *Musca domestica* Clothes Moth: *Tineola bisselliella* Ants*: Lasius* sp. Bed bugs: *Cimex* Roaches*: B. germanica* & *B. orientalis or P. americana*	
3D	Insecticide for Fabric	Indoor/ outdoor Fabrics, Apparel, Bednets	Entire materials / sprays or liquids to impregnate these materials	Protects for up to x weeks against "XYZ"	*Mosquitoes (Aedes spec, Culex spec); ticks (Ixodes sp or Dermacentor spec.)*		The following claims need to be verified by appropriate test data: malaria mosquitoes – *Anopheles* spec; biting flies – *Stomoxys*; nuisance	
3E	Attracts	Indoor/ outdoor	Coils, mats or liquid electrics or other devices	"Protects for up to x hours against "XYZ"	*Aedes sp.and* *Culex sp. etc* *(Plodia sp* *Vespula sp.* *Musca domestica)*		Any pest claimed needs to be tested.	

	Action	SITE	APPLICATION METHOD	CLAIM	TEST SPECIES	RATIONALE	NOTES	INSECT STAGE
3F	Attracts and traps	Indoor/ outdoor	Sex pheromone	Attracts male insects and catches them in a (sticky) trap	Specific insects for which claims are made	Sex pheromones are species specific and should therefore be tested on the claimed target species.		
3G	Repels	Indoor	All	Protects against moths for up to x days/weeks.	*Plodia interpunctella* ***or*** *Tineola bisselliella*			adult males
3H	Repels flying insects on horses	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels flying insects, such as …. on horses'	Claim to be accompanied by a specification of the range of species; for all of these appropriate efficacy data should be provided			
3I	Repels mosquitoes on horses	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels mosquitoes on horses	against two species, namely *Culex spec* and *Aedes spec*			
3J	Repels mosquitoes on horses	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels tropical mosquitoes on horses	against *Culex spec*, *Aedes spec*, AND *Anopheles spec*.			
3K	Repels 'gnats & biting midges' on horses	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels gnats & biting midges on horses	*species prevalent in the region (Culicoides spec.)*			
3L	Repels flies on horses	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels horse flies (e.g. Tabanus bovines) on horses	against *Tabanid* species prevalent in the region, e.g. *Tabanus bovinus*			
3M	Repels flies on horses	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels deer flies on horses	*Chrysops caecutiens*			

	Action	SITE	APPLICATION METHOD	CLAIM	TEST SPECIES	RATIONALE	NOTES	INSECT STAGE
3N	Repels flies on horses	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels stable flies on horses	*Stomoxys calcitrans*			
3O	Repels flies on horses	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels black flies on horses'	*Simulium spec.,* e.g. *Simulium equinum*			
3P	Repels flies on horses	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels sand flies on horses	*Phlebotominae*			
3Q	Repels flies on horses	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels warble flies on horses'	*Hypoderma spec.* (e.g. *H. bovis* or *H. lineatum)".*			
3R	Repels flies on horses	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels horn flies on horses	*Haematobia irritans*			
3S	Repels flies on horses	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels Face flies, House flies on horses	appropriate *Musca spec* (e.g. *M. domestica, M. autumnalis*, et cetera).			
3T	Repels flies on horses	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels biting flies on horses	*at least 1 Tabanid* and *1 Culicoides species, prevalent to the region*			
3U	'Repels	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels Deer/sheep ticks on horses	*Ixodes scapularis/ricinus*			
3V	'Repels	Indoor/ outdoor	sprays, creams, gels, balms etc.	Repels ticks such as…. on horses	Two tick species prevalent in the region, e.g. *Ixodes scapularis* and *I. Ricinus.* Claim to be accompanied by a specification of the range of species; for all of which efficacy data need to be presented.			

Appendix 3. List of currently available standard test methods for product type 18 insecticides/acaricides and product type 19 repellents/attractants (as far as they concern insects and other arthropods)

Recognised standard methods for the efficacy testing of biocidal products intended for the control of insects, acarides and other arthropods. This list is derived from A-S Wernersson, 2008 (Efficacy testing of biocidal products. FB Engineering AB, Skärgårdsgatan 1, Göteborg, Sweden) with some changes and additions.

This is a list of available standard methods (as far as we know now of) without distinction on suitability, usefulness, repeatability, order of acceptability or robustness.

Table 8: Acronyms and Abbreviations

Acronym	Full name	Web page of organisation (if available)
AFPP	Association française de protection des plants	
AATCC	American Association of Textile Chemists and Colors	www.aatcc.org/
AFNOR	Association française de normalisation (NF standards)	www.afnor.fr/
AOAC	Association of Official Analytical Chemists	www.aoac.org/
ASTM	American Society of Testing and Materials	www.astm.org/)
ATCC	American Type Culture Collection	
BBA	Federal Biological Research Centre for Agriculture and Forestry (Biologische Bundesanstalt für Land - Und Forstwirtschaft Bundesrepublik Deutschland)	www.bba.de
BP	Biocidal Product	
BPD	Biocidal Product Directive (referring to 98/8/EG)	

BSI	British Standards Institute (BS standards)	www.bsi.org.uk/
CA	Competent Authority	
CEB	Commission Des Essais Biologiques	www.afpp.net/commande/commissions/CEB.htm
CEFIC	European Chemical Industry Council	www.cefic.org
CEN	European Committee for Standardisation	www.cenorm.be
CEPE	European council of paint, printing inks and artist's colours industry	www.cepe.org
CSMA	Chemical Specialties Manufactures Association	www.csma.org
CTBA	Centre Technique du Bois et de l'Ameublement, Bordeaux : old name of FCBA, CTBA-BIO-Exxx standards might now be available under FCBA-BIO-E with the same extension.	www.ctba.fr www.fcba.fr
EBPF	European Biocidal Product Forum	
EPA	United States Environmental Protection Agency	www.epa.gov
EPPO	European and Mediterranean Plant Protection Organization	www.eppo.org
FCBA	Forest, Building, Wood, Furniture (in French : Forêt, Construction, Bois, Ameublement)	www.fcba.fr
ISO	International Standards Organisation	www.iso.org/iso/home.htm
MAFF	Ministry of Agriculture Fisheries and Foods	
MS	Malaysian Standards	http://msonline.sirim.my/msonline
NF	NF standards, Association française de normalisation	www.afnor.fr/

OECD	Organisation for Economic Co-operation and Development	www.oecd.org
OCSPP	Office of Chemical Safety and Pollution Prevention (old name OPPTS)	www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series810.htm
OPPTS	Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency New name: Office of Chemical Safety and Pollution Prevention (OCSPP)	www.epa.gov/internet/oppts/
PT	Product Type	
SABS	South African Bureau of Standards	www.sabs.co.za
AFPP	Association française de protection des plants	
AATCC	American Association of Textile Chemists and Colors	www.aatcc.org/

REFERENCE LISTS

GENERAL
CRAWLING INSECTS
Cockroaches
Termites
Other crawling insects
FLYING INSECTS
INSECTICIDES AGAINST TEXTILE AND STORED PRODUCT PESTS
REPELLENTS & ATTRACTANTS

Table 9: General

GENERAL

Reference	Title	PT	Short test description (if test method available or information provided from elsewhere)	Type of Reference Source
OPPTS 810.3000 (1999)	General Considerations for Efficacy of Invertebrate Control Agents	18	General guide	Manufacturer; UK guidelines
CEB 196 (1997)	Trial method to evaluate the efficacy of insecticidal bait products against common species	18		TM II05 (Fr)
EPPO pp1/152 (3)	Design and analysis of efficacy evaluation trials		This standard provides detailed advice on the design and analysis of efficacy evaluation trials. Primarily intended for use in plant protection but also very useful for biocides.	EPPO web site
EPPO pp1/181 (3)	Conduct and reporting of efficacy evaluation trials, including good experimental practice		This standard provides guidance on how to organize trials, and how to plan, conduct and assess them, then record and interpret them, so as to obtain comparable and reliable results. It is also based on the principle that trials should be performed according to Good Experimental Practice (GEP).	EPPO website

Reference	Title	PT	Short test description (if test method available or information provided from elsewhere)	Type of Reference Source
EPPO Bulletin, 15 Pages 1-119, Paris (1983)	The EPPO Conference on Fumigation, Paris, 1983	18		TNsG on Prod Evaluation; UK guidelines
EPPO, Paris (1982)	EPPO Recommendations on fumigation standards (2nd Edition)	18		TNsG on Prod Evaluation;UK guidelines
OPPTS 810.3200	Livestock, poultry, fur- and wool-bearing animal treatments	18		Own searches
OPPTS 810.3300	Treatments to control pests of humans and pets	18		UK guidelines
OPPTS 810.3500	Premises treatments	18	General guideline	Manufacturer; UK guidelines
SABS 233 1st rev	Pesticides: Biological evaluation of mists and fogs - first revision	18		Manufacturer
SABS 576	Pesticides – Biological evaluation of insecticidal oil-based space spray in low-pressurized dispensers - first revision	18		Manufacturer
SABS 583	Pesticides – Biological evaluation of the contact efficacy of liquid residual insecticides - first revision	18		Manufacturer
SABS 6136 (2003)	Pesticides – Biological evaluation of materials that release an insecticide upon heating	18		Manufacturer

Reference	Title	PT	Short test description (if test method available or information provided from elsewhere)	Type of Reference Source
SABS 689 3rd ed (2002)	Pesticides – Biological evaluation of knock-down and killing proprieties of liquid and aerosol formulation (al posto di Standard methods SABS Method 8689-first revision)	18		Manufacturer
SABS 690 (DRAFT)	Pesticides: biological evaluation of the properties of solid fly baits - DRAFT	18		Manufacturer
SABS 807	Methods for testing insecticides against flying and crawling insects.	18		TNsG on Prod Evaluation; Manufacturer; UK guidelines
SABS 899 (1987)	Insecticidal space spray in pressurized dispensers	18		Manufacturer
Ref: CTD/WHOPES/IC/96.1	Protocols for laboratory and field evaluation of insecticides and repellents	18 &19	Report of the WHO Informal Consultation on the evaluation and testing of insecticides, WHO, Geneva, 7-11 October 1996,	WHO1996

Table 10: Crawling Insects: Cockroaches

CRAWLING INSECTS: Cockroaches				
Reference	**Title**	**PT**	**Short test description (if test method available or information provided from elsewhere)**	**Type of Reference Source**
AFPP	Methode d'essai d'efficacite, en laboratoire et en conditions pratiques d'utilisation, d'appats insecticides destines a la lutte contre les blattes dans les locaux Efficacy trials method, in laboratory or in practical conditions of use, for insecticide baits intended to control cockroaches in premises	18		French guideline
ASTM E654-96(2003)	Standard Test Method for Effectiveness of Aerosol and Pressurized Spray Insecticides Against Cockroaches	18	Test of insecticides against crawling insects: cockroaches Determines the relative efficiency of aerosol and pressurised spray formulations against cockroaches, but test data by this test method may also be adequate to support claims for use of the product to control the exposed or accessible stages of silverfish, ants, centipedes, spiders, and certain stored product pests. Applied as direct sprays for 30 s. on last instar nymphs. Observation period: 48h. The test is not designed to measure the residual action.Ten groups with 20 organisms in each. The test is run in conjunction with the Official Test Aerosol II (OTA II) (or Tentative Official Aqueous Pressurized Spray (TOAPS) as the standard basis of comparison. The mortality after 24h should be between 50 and 75% when testing with the OTA. The test specimens meet the standard if average % dead and moribund is equal to, above or within 10% points less than average % dead of the OTA series after 48h. Precision or bias is not specified,	UK guidelines; Test institute

Reference	Title	PT	Short test description (if test method available or information provided from elsewhere)	Type of Reference Source
			only states whether conforms to efficacy criteria.	
CEB 159 (1992)	Trial method to evaluate the efficacy of insecticidal products for the control of cockroaches in buildings under practical conditions	18		TM II05 (Fr)
OECD Guidance Document Series	Guidance Document on Assays for Testing the Efficacy of Baits against Cockroaches	18	Outlines methods available for testing efficacy and effectiveness of baits against cockroaches.	
SABS 458	Pesticides – Rearing and handling of the German cockroach (Blatella germanica (L.)) - second revision	18		Manufacturer
US CSMA Aerosol Guide 7 th Edition, pages 135-139 (1991)	Test method for pressurised spray products against cockroaches	18	Test of insecticides against crawling insects: cockroaches	TNsG on Prod Evaluation; UK guidelines
WHO/VBC/75.593 (1981)	Instructions for determining the susceptibility or resistance of cockroaches to insecticides	18		TNsG on Prod Evaluation; UK guidelines

Table 11: Crawling Insects: Termites

CRAWLING INSECTS: Termites				
Reference	**Title**	**PT**	**Short test description (if test method available or information provided from elsewhere)**	**Type of Reference Source**
CTBA-BIO-E-001	Epreuve de vieillissement naturel des murs traités.	18		Test institute
CTBA-BIO-E-002	Epreuve de vieillissement naturel des sols traités.	18		Test institute
CTBA-BIO-E-007	Evaluation de l'efficacité anti-termite d'une barrière placée en milieu alcalin.	18		Test institute
CTBA-BIO-E-008/2	Evaluation de l'efficacité anti-termite d'une barrière physico-chimique - Essai de terrain - Dispositif sans dalle de béton.	18		Test institute
CTBA-BIO-E-008/3	Evaluation de l'efficacité anti-termite d'une barrière - Essai de terrain - Dispositif avec dalle de béton.	18		Test institute
CTBA-BIO-E-016	Version 2 : Exposition de barrières physico-chimiques anti-termites aux rayonnements solaires.	18		Test institute
FCBA-BIO-E-038	Evaluation de l'efficacité d'un traitement insecticide des déchets de démolition infestés par les termites - Essai de laboratoire.	18		Test institute

Reference	Title	PT	Short test description (if test method available or information provided from elsewhere)	Type of Reference Source
FCBA-BIO-E-039	Evaluation de l'efficacité d'un traitement insecticide des déchets de démolition infestés par les termites - Essai de terrain.	18		Test institute
FCBA-BIO-E-041	Critères de performance des méthodes d'essais CTBA-BIO-E-xx et FCBA-BIO-E-xx	18		Test institute
ENV 1250-2	Wood preservatives - Methods for measuring losses of active ingredients and other preservative ingredients from treated timber - Part 2: Laboratory method for obtaining samples for analysis to measure losses by leaching into water or synthetic sea water	18		International guideline
NF X 41-542	Produits de préservation du bois - Produit de traitement antitermites des sols, murs, fondations et maçonneries - Epreuve de vieillissement accéléré des matériaux traités avant essais biologiques - Epreuve de percolation.	8+18	French guideline. Wood preservatives - Anti-termite treatment product for floors, walls, foundations, and masonry work - Accelerated ageing test of treated materials prior of biological testing - Percolation test.	French guideline
NF X 41-543-1, 2008	Produits de préservation du bois - Détermination de l'efficacité d'un système de pièges-appâts - Partie 1 : Efficacté de la formulation insecticide - Méthode de laboratoire"	8+18	Wood preservatives — Determination of the efficacy of a bait-trap system — Part 1: Efficacy of the insecticide formulation — Laboratory method	French guideline

Reference	Title	PT	Short test description (if test method available or information provided from elsewhere)	Type of Reference Source
NF X 41-543-2, 2008	Produits de préservation du bois - Détermination de l'efficacité d'un système de pièges-appâts - Partie 2 : Efficacté du système - Méthode de terrain	8+18	Wood preservatives — Determination of the efficacy of a bait-trap system — Part 2: Efficacy of the insecticide formulation — Field method. This test method is intended to evaluate the efficacy of the baits in an experimental site where termite activity is reported. Consumption of the tested bait must be registered at least in the first 6 months after the introduction of the baits. The elimination of termites in the experimental site should be registered maximum after 18 months (counted since the introduction of the first tested bait), excluding the winter period.	French guideline
NF X 41-543-3, 2009	Critères de performance des essais pièges-appâts	8+18		French guideline
NF X 41-550	Termites - Determination of the effectiveness against termites of products or materials used as barrier designed for ground and/or wall - Laboratory method	8+18		French guideline
NF X 41-551	Termites - Determination of the effectiveness against termites of products or material used as barrier designed for ground and/or wall- Performance criteria	8+18		French guideline
OPPTS 810.3800	Methods for efficacy testing of termite baits	8+18		Own searches

Table 12: Crawling Insects: Other Crawling Insects

CRAWLING INSECTS: Other crawling insects				
Reference	**Title**	**PT**	**Short test description (if test method available or information provided from elsewhere)**	**Type of Reference Source**
AATCC 194-2006	Assesment of the Anti-House Dust Mite Properties of Textiles under Long-Term Test Conditions	18	Applied to textiles	Manufacturer
OCSPP 810.3900	*Draft Product Performance Test Guidelines Laboratory Testing Methods for Bed Bug Pesticide Products.* US-EPA 712- Draft 2012	PT 18		
OPPTS 810.3100	Soil treatments for imported fire ants	18		Own searches
US AATCC Technical Manual Method 24 (1992)	Test method for textiles to determine resistance to insects (e.g. moths, carpet beetles)	18	Efficacy test against larvae	TNsG on Prod Evaluation; UK guidelines
WHO/VBC/81.809 (1981)	Instructions for determining the susceptibility or resistance of adult bed-bugs to insecticides	18		TNsG on Prod Evaluation;UK guidelines
WHO/VBC/81.814 (1981)	Instructions for determining the susceptibility or resistance of adult ticks to insecticides	18		TNsG on Prod Evaluation; UK guidelines
WHO/VBC/81.815 (1981)	Instructions for determining the susceptibility or resistance of fleas to insecticides	18		TNsG on Prod Evaluation; UK guidelines

Table 13: Flying Insects

FLYING INSECTS				
Reference	**Title**	**PT**	**Short test description (if test method available or information provided from elsewhere)**	**Type of Reference Source**
ASTM E652-91(2009)	Standard Test Method for Nonresidual Liquid Household Insecticides Against Flying Insects	18	Determines the relative efficiency of household and industrial-use, contact insecticides dissolved in base oils and applied in spray formulations. It is developed to test insecticides against house flies (*Musca domestica*, L), but test data may also be adequate to support label claims for the use of the products against mosquitoes, gnats, flying moths, wasps, and certain other small flying insects. Not designed to measure the residual action of the spray formulation. For Liquids, dose: 12 cm3, 100 flies, test chambers: Peet grady Chambers (6,02 m3), Test conditions:27ºC, 50%H.R. It has been superseded by ASTM	Own searches
ASTM E653-91 (2009)	Standard Test Method for Effectiveness of Aerosol and Pressurized Space Spray Insecticides Against Flying Insects	18	The test determines the relative efficacy of aerosol and pressurized space spray insecticide formulations against house flies (Musca domestica, L) strains and, with modifications in dosage, other flying insects. Test data obtained by this test method may also be adequate to support label claims for the use of the product against mosquitoes, gnats, flying moths, wasps, and certain other small flying insects. This test method is not designed to measure the residual activity. The test may be conducted using approximately 100 house flies per test (small group) or 500 flies per test (large group). Selected reference standards are the Official Test Aerosol II (OTA II) for oil based aerosol products and Tentative Official Aqueous Pressurized Spray (TOAPS) for water based aerosol products. Aerosol test knockdowns: % down of total flies at 5, 10, 15 minutes after application.	Test institute

Reference	Title	PT	Short test description (if test method available or information provided from elsewhere)	Type of Reference Source
			Aerosol test knock down mortality: dead knocked down x100/total flies. These numbers should on average be equal to, greater than or no more than 5% points below the corresponding numbers of the reference in order to meet the standard. No statement on precision or bias, only whether conformance to criteria for success specified in the procedure. For Sprays, dose: 3g/28m3, 100 flies, test chambers: Peet grady Chambers (6,02 m3), Test conditions:27ºC, 50%H.R. It has been superseded by ASTM	
BS 4172-1:1999	Hand-held pressurized aerosol dispensers against houseflies. Specification for insecticidal performance	18		TNsG on Prod Evaluation; TM II05 (Fr); UK guidelines
BS 4172-2:1 1999	Hand-held pressurized aerosol dispensers against houseflies	18	For Sprays, dose: 35,3g/50m3, 100 flies, test chambers: 25 - 60 m3, Test conditions: 26ºC, 45-75%H.R. The reference product is very well described, and easy to manufacture.	TNsG on Prod Evaluation; TM II05 (Fr); UK guidelines; Test institute
CEB 107 (1985)	Trial method to evaluate the efficacy of insecticidal products for the control of stable flies in premises for the rearing of domestic animals under practical conditions	18		
MS 1398 part 2 (1996)	Specification for mosquito electric liquid vapourizer: part 2: method for evaluation of biological efficacy - glass chamber method	18		Manufacturer

Reference	Title	PT	Short test description (if test method available or information provided from elsewhere)	Type of Reference Source
MS 1398 part 3 (1996)	Specification for mosquito electric liquid vapourizer: part 3: method for evaluation of biological efficacy - glass cylinder method	18		Manufacturer
MS 1497 (2000)	Methods of biological evaluation of the efficacy of repellent - bioassay method for mosquito repellent on human skin	18		Manufacturer
MS 23 part 1 (1998)	Specification for mosquito coils: Part 1: physical and chemical requirements (third revision)	18		Manufacturer
MS 23 part 2 (1996)	Specification for mosquito coils: Part 1: method for evaluation of biological efficacy - glass chamber method (first revision)	18		Manufacturer
MS 23 part 3 (1998)	Specification for mosquito coils: Part 1: method for evaluation of biological efficacy - Peet Grady method	18		Manufacturer
NF T72-320 March 1977	Insecticides for flying insects. Insecticide distributed under pressure ("aerosol" type). Determination of the efficiency rating.	18	For Aerosols, dose: 1seg/10m3, 100 flies, test chambers 25-50 cubic meters, Test conditions:25ºC, 60%H.R.	TNsG on Prod Evaluation; TM II05 (Fr); UK guidelines; Test institute
NF T72-321 March 1977	Insecticides for flying insects. Permanent insecticide distributor. Determination of the efficiency	18	For Vaporizers, 100 flies, test chambers 25-50 cubic meters, Test conditions:25ºC, 60%H.R.	TM II05 (Fr); Test institute

Reference	Title	PT	Short test description (if test method available or information provided from elsewhere)	Type of Reference Source
	rating and the regularity rating.			
OPPTS 810.3400	Mosquito, black fly, and biting midge (sand fly) treatments	18	Test of insecticides against flying insects: Mosquito, Black Fly and Biting Midge (Sand Fly)	UK guidelines
US CSMA Aerosol Guide, 7 th Edition, pages 129-134 (1981)	Test method for aerosol space sprays against flying insects	18	Test of insecticides against flying insects:	TNsG on Prod Evaluation; UK guidelines; Manufacturer
Verwey & Sosa, 2007	Liquid Electric test method	18	For testing pyrethroids (draft method) and natural actives (Pyrethrum extract) on mosquitoes (knockdown). Efficacy criteria: "effective against mosquitoes for X hours". Knockdown is measured repeatedly for 2h and mortality after 24h. Control (no treatment) knockdown: maximum 10%. 2-4 chamber replicates, 50 organisms in each. Mean and Standard Deviations for each time calculated as well as KT50 and KT80 (Mean time to 50% and 80% knockdown respectively).	Manufacturer
WHO/VBC/81.212 (1981)	Instructions for determining the susceptibility or resistance of mosquito larvae to insect development inhibitors	18		TNsG on Prod Evaluation
WHO/VBC/81.806	Instructions for determining the susceptibility or resistance of adult mosquitoes to organochlorine, organophosphate and carbamate insecticides - diagnostic test	18		TNsG on Prod Evaluation; UK guidelines
WHO/VBC/81.807	Instructions for determining the	18		TNsG on Prod

Reference	Title	PT	Short test description (if test method available or information provided from elsewhere)	Type of Reference Source
(1981)	susceptibility or resistance of mosquito larvae to insecticides			Evaluation; UK guidelines
WHO/VBC/81.811 (1981)	Instructions for determining the susceptibility or resistance of blackfly larvae to insecticides	18		TNsG on Prod Evaluation; UK guidelines
WHO/VBC/81.812 (1981)	Instructions for determining the susceptibility or resistance of mosquito larvae to insect development inhibitors	18		UK guidelines
WHO/VBC/81.813 (1981)	Instructions for determining the susceptibility or resistance of houseflies, tsetse flies, stable flies, blowflies etc. to insecticides	18		TNsG on Prod Evaluation; UK guidelines
WHO/CVB/81.5	Instruction for the bio-assay of insecticidal deposits on wall surfaces	18	For Vaporizers, 100 flies, test chambers 25-50 cubic meters, Test conditions:25ºC, 60%H.R.	Test institute
WHO 1998	Insecticide resistance monitoring	18	Test procedures for insecticide resistance monitoring in malaria vectors, bio-efficacy and persistence of insecticide on treated surfaces, Geneva, World Health Organization, 1998.	Ref: WHO/CDS/CPC/MAL/98.12
WHO/CDS/WHOPES/GCDPP/2003.5	Space spray application of insecticides for vector and public health pest control – a practitioner's guide	18	Brief description of the main types of space spray equipment as well as the operational guidelines for space spray application of insecticides.	TM II05 (Fr)
WHO/CDS/WHOPE	Guidelines for laboratory and field	18	This document provides specific and standardized procedures and guidelines for testing larvicides,	WHO 2005

Reference	Title	PT	Short test description (if test method available or information provided from elsewhere)	Type of Reference Source
S/GCDPP/2005.13	testing of mosquito larvicides		including bacterial larvicides and insect growth regulators against mosquitoes.	
WHO/CDS/NTD/WHOPES/GCDPP/2006.3	Guidelines for testing mosquito adulticides for indoor residual spraying and treatment of mosquito nets	18	This document provides specific and standardized procedures and guidelines for testing mosquito adulticides for indoor residual spraying and for treatment of mosquito nets.	WHO 2006
WHO/HTM/NTD/WHOPES/2009.2	Guidelines for efficacy testing of insecticides for indoor and outdoor ground-applied space spray applications	18	The document provides guidance and stepwise procedures on laboratory studies, field testing and evaluation leading to the determination of efficacy, and application rates of insecticides for operational use in indoor and outdoor ground-applied space spray applications. While most examples provided pertain to mosquitoes, with some modifications the guidelines can be used to determine efficacy against other flying vectors and pests.	WHO 2009

Table 14: Insecticides Against Textile and Stored Product Pests

INSECTICIDES AGAINST TEXTILE AND STORED PRODUCT PESTS				
Reference	**Title**	**PT**	**Short test description (if test method available or information provided from elsewhere)**	**Type of Reference Source**
CEB 135bis (1996)	Laboratory test method to evaluate the efficacy of insecticidal products in premises for the storage, industrial processing and sale of products from animals or plants	18	Space treatments	TM II05 (Fr)

Reference	Title	PT	Short test description (if test method available or information provided from elsewhere)	Type of Reference Source
CEB 213 (1999)	Trial method to evaluate the efficacy of a fumigant for insect control in premises for the storage, processing and production of food	18		TM II05 (Fr)
CEB 224 (2001)	Trial method to evaluate the efficacy of fumigants for insect control in stored products	18		TM II05 (Fr)
EPPO Bulletin, 15 Pages 1-119, Paris (1983)	The EPPO Conference on Fumigation, Paris, 1983	18		TNsG on Prod Evaluation; UK guidelines
EPPO, Paris (1982)	EPPO Recommendations on fumigation standards (2nd Edition)	18		TNsG on Prod Evaluation;UK guidelines
EPPO PP 1/201(1)	Fumigants to control insect and mite pests of stored plant products	18 + 20		TM II05 (Fr); UK guidelines
EPPO PP 1/202(1)	Space and structural treatments of store rooms	18		TM II05 (Fr); UK guidelines
EPPO PP 1/203(1)	Admixture of plant protection products to stored plant products to control insects and mites	18 + 20		TM II05 (Fr)
EPPO PP 1/204(1)	Laboratory testing of plant protection products against insect and mite pests of stored plant products	18		UK guidelines

Reference	Title	PT	Short test description (if test method available or information provided from elsewhere)	Type of Reference Source
NF G39-011 April 2001	Properties of textiles - Textiles and polymeric materials having antiacarien properties - Characterisation and measurement of antiacarien activity	18		Manufacturer; TM II05 (Fr)
NF X41-516 January 1980	Protection of textiles. Protection against certain insect pests. Methods of testing.	18		TM II05 (Fr)
SABS 332	Pesticides – Rearing and handling of the common clothes moth (Tineola bisselliella Hummel) - second revision	18		Manufacturer
ISO 3998	Determination of resistance to certain insect pests	18	For treated materials. Comparing the resistant material against a non-resistant material.	Test institute
US AATCC Technical Manual Method 24 (1992)	Test method for textiles to determine resistance to insects (e.g. moths, carpet beetles)	18	Efficacy test against larvae	TNsG on Prod Evaluation; UK guidelines

Table 15: Repellents & Attractants

REPELLENTS & ATTRACTANTS				
Reference	**Title**	**PT**	**Short test description (if test method available or information provided from elsewhere)**	**Type of Reference Source**
ASTM E939-94(2012)	Standard Test Method of Field Testing Topical Applications of Compounds as Repellents for Medically Important and Pest Arthropods (Including Insects, Ticks, and Mites): Mosquitoes	19	Evaluates the repellency of promising compounds that have undergone primary laboratory studies and approved for skin application for secondary testing. The method is designed for the study of mosquito repellents, but can be modified to determine the repellency of candidate compounds for other flying insects that attack humans.	Own search
ASTM E951-94(2006)	Standard Test Methods for Laboratory Testing of Non-Commercial Mosquito Repellent Formulations On the Skin	19	Can be used to test the efficacy of repellent compounds that can be diluted with ethanol, acetone etc. Both biological effectiveness and persistence of the repellent can be assessed. ED50 and ED95 are determined for comparative and practical purposes respectively. Precision of the test can be evaluated (confid intervals).	Own search
Dautel H, Kahl O, Siems K, Oppenrieder M, Müller-Kuhrt L, Hilker M. *Ent Exp Appl.* 1999;**91**:431–441	A novel test system for detection of tick repellents	19	The so-called Moving Object Bioassay is described, a tool for testing the strength of potential tick repellents quantitatively. Endpoint measured is the attachment rate of Ixodes ticks.	Dossier
Fradin & Day, July 2002, N Engl J Med vol 347 vol 13-18	Comparative efficacy of insect repellents against mosquito bites	19	Human subjects: Arm in cage studies (15 volunteers, 10 mosquitoes (Aedes aegypti) in each cage. Endpoint: elapsed time to first bite. Category of protection A-H (significantly different mean complete protection time; ANOVA & Tukey's). No need to recalculate the results to "real condition" (simulate real condition)	Dossier

Reference	Title	PT	Short test description (if test method available or information provided from elsewhere)	Type of Reference Source
Hummel, E., Kleeberg, H. 1997. in: Practice orientated results on use and production of Neem-Ingredients and Pheromones V. Proceedings of the 5th workshop, Wetzlar, Germany, January 22-25, 1996	Effect of the neem extract formulation neemazal-t/s on the green pea aphid acyrthosiphon pisum in the laboratory (1995), in: Practice orientated results on use and production of Neem-Ingredients and Pheromones V	19		Dossier
SABS 695	Pesticides – Biological evaluation of the efficacy of mosquito repellents - first revision	19		Manufacturer
US EPA Guideline, OPPTS 810.3700 (2010); EPA 712-C-10-001)	Insect repellents to be applied to human skin	19		UK guidelines
WHO/HTM/NTD/WHOPES/2009.4	Guidelines for efficacy testing of mosquito repellents for human skin	19	The purpose of these guidelines is to provide specific and standardized procedures and criteria for efficacy testing and evaluation of mosquito repellents for human skin. Their aim is to harmonize the testing procedures carried out in different laboratories and institutions in order to generate comparable data for registering and labelling such products by the national regulatory authorities.	WHO

Appendix 4. Efficacy guideline with Cockroach; field trial

This guidance describes an example of a field trial to determine efficacy of a product against the German cockroach (*Blattella germanica.*).

Global design

In a pre-test it is established whether the population of cockroaches in an object is large enough for a field trial. An indication of the population size is obtained in the pre-test by using a spray with expelling action or by setting glue traps.

If the population size is large enough, a pest control operation is performed. The efficacy of the product is determined by measuring the population size again 8 weeks later and comparing it to the initial value.

During these 8 weeks the effect of the control operation should be checked at least 4 times at regular intervals (possibly using glue traps). The investigator himself should perform these checks during the trial.

Requirements for the practical use situation in order to be suitable as test object.

The field trial is performed in three separate objects.

Recommendations for the practical use situation to produce a good field trial for control of the German cockroach are as follows:

1. History of insecticide use should be described with as much detail as possible (which product, active ingredient, when …). Object with recent insecticide use should not be included in the test.
2. The test object should preferably and where possible be hermetically sealed off from the surrounding buildings. If there are adjacent buildings, all cracks and crevices on the outside of the test object should be treated with an authorised biocidal product with residual action.
3. The test object should preferably contain at least a kitchen or kitchen unit, with one or more refrigerators or freezers.
4. Cockroaches should be present in the test object, both in the kitchen or kitchen unit as elsewhere.
5. In the preceding 8 weeks no other chemical control of cockroaches should have taken place in the test object.

Field trial

The pre-test

Aim: To determine whether the population is large enough for a field trial.
Execution: Within 1 week before the control operation.
The pre-test can be conducted in two different ways.

1. By using a spray liquid with an expelling action (e.g. pyrethrins):
   Spray under the refrigerator and one other place in the kitchen where there are probably many cockroaches.
   Spray for 3 seconds and count the cockroaches that emerge during 1 minute.

2. By using glue traps
   Place glue traps at places where many cockroaches are expected.
   Number per unit area: 5 glue traps per 100 m^2
   Describe clearly where the glue traps are placed, and record the number of trapped cockroaches after an appropriate period, usually either overnight, or after up to 3 days (e.g. weekend), depending upon the scale of the infestation (shorter trap periods for heavier infestations to avoid traps becoming saturated and failing to catch cockroaches later during the monitoring period; longer periods when infestation level is low and few cockroaches are trapped each night).

Criteria for a suitable test object

- When a trap is placed for 48 hours in the kitchen or in the kitchen unit behind the refrigerator, it should contain at least 10 adult cockroaches at the end of this time, as well as several nymphs.
- Several cockroaches should be caught on at least one glue trap, which is placed at another place in the kitchen or kitchen unit and on one trap, which is placed outside the kitchen or kitchen unit, within 48 hours.

Or:

- When using a spray with expelling action, at least 5-10 cockroaches per sprayed site should be counted.

The test

Duration of the control period until measurement of efficacy is about 8 weeks.
The pest control is performed according to the directions for use of the product.
During these 8 weeks the investigator will check the progress of the control at least 4 times.

Directions for use of an insecticide in the form of a spray liquid:

- It should be clear how much product is used, on average 1 L/20 m^2 is sprayed;
- Treatment of cracks and crevices should be done where necessary;
- If stated on the label, a second treatment can be performed.

Directions for use of an insecticide in the form of a powder:

- It should be clear how much product is used.

Directions for use of an insecticide in the form of bait:

- Number of baits placed per unit area should be according to directions for use;
- Precise descriptions of where the baits are placed should be given;
- The baits that are placed remain *in situ* for 8 weeks continuously, unless stated differently on the label.

Required results

At least 4 times during the test and at the end of the test (about 8 weeks after the start), an estimate of the population size is obtained in the same manner as during the pre-test. The difference in population size before and 8 weeks after the control operation provides the degree of efficacy of the product.

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