Last updated: 23 February 2005

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

RODENTICIDES

CONTENTS

DEFINITION OF TERMS

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

FOREWORD

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

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

i) establish that a product is efficacious in relation to its conditions of approved use and that label claims are justified, and;

ii) satisfy the requirements of Ministers who give approval on the basis of recommendations from the ACP and IDS.

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

2. This document gives ***guidance*** on the nature and extent of the efficacy data required to gain a commercial approval for the sale, supply, use, storage and advertisement of a pesticide containing an active ingredient(s) intended for use as a rodenticide.

3. Under COPR, HSE's registration responsibilities for rodenticides covers all products not solely used for plant protection. Those products clearly intended for plant protection use (i.e., repellents used in the field to protect crops and warfarin to control grey squirrels) will continue to be regulated by DEFRA's Pesticides Safety Directorate (PSD).

4. This document, which will be included in HSE's non-agricultural pesticides Registration Handbook, is a revision of a previous document issued in December 1990 'Guidelines on Efficacy Testing for Rodenticides' which was part of the former PSD/HSE Registration Handbook for Pesticides, Biocides and Plant Protection Products (Part Three/A3/Appendix 3, formerly working document 10/2).

5. This document and the information within it has been drafted in a similar presentation style to other HSE efficacy guidance documents and aims to add clarity with respect to data requirements for different types of product application. N.B., it is not HSE's intention to dilute the data requirements presented in the previous rodenticide efficacy guidelines issued in support of approvals under COPR.

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

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

1

INTRODUCTION

This document gives guidance on the nature and extent of the efficacy data required to gain commercial approval of a pesticide containing active ingredient(s) for use as a rodenticide against rats and/or mice and also for continuing approval of current products containing existing active ingredients following review. The HSE is the Registration Authority to which such applications should be submitted. When a rodenticide product is to be used solely for plant protection, the application should be submitted to PSD.

(For further information contact PSD at Mallard House, Kings Pool, York, YO1 7PX, or by phone on 01904 455775 or email at: p.s.d.information@psd.maff.gsi.gov.uk).

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

EACH STUDY PRESENTED WILL BE EVALUATED ON ITS OWN MERITS.

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

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

2

WHEN EFFICACY DATA ARE REQUIRED

To support the approval of rodenticide products, BPU will generally require efficacy data to support the majority of product applications. However, the nature and extent of the data required will vary according to the type of application sought. BPU will ordinarily require data at a number of key stages as outlined below:

i) To support applications for most formulation changes to an approved rodenticide product.

ii) To support applications for new rodenticide products based on existing active substances and existing formulation types.

iii) To support application for products containing an existing active ingredient but claiming efficacy against novel* target pests.

iv) To support applications for products containing an existing active ingredient but which incorporate either a novel* formulation type or a novel* application/delivery method.

v) To support existing active ingredients (and their products) at review**.

vi) To support, as appropriate, any post approval or post review data requirements set for an active ingredient or product.

vii) To support applications for products containing a new active ingredient yet to be assessed prior to first approval in the UK.

Section 5 of this document addresses the nature and extent of data required for different product applications.

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

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

3 FRAMEWORK OF THE ASSESSMENT PROCESS FOR COMMERCIAL APPROVAL

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

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

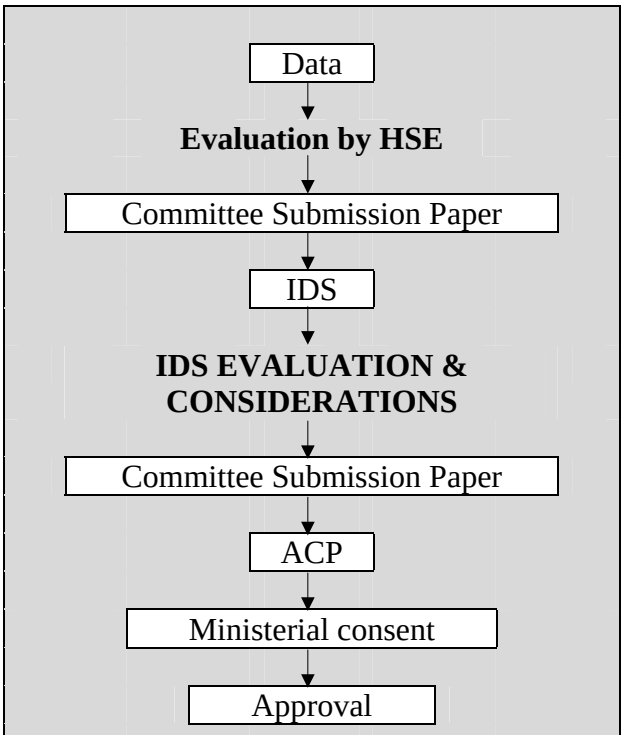

Figure 1 – Application progression

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

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

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

It is worth noting that the majority of rodenticide applications will be processed internally by BPU as most of these will be based on existing precedents. However, should any rodenticide application be significantly different from that already approved it will likely follow the Committee route.

4

DRAFT LABEL INFORMATION/LABEL CLAIMS

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

Hence, for an evaluation to be undertaken, BPU will require a draft label or statements concerning any claims that will be made on the product label. Such information will need to be sufficiently detailed to enable an assessment to be made, and will need to include:

i. The target pest(s) that the product is to be used against.

ii. The application methods, rates and/or baiting densities, as appropriate, for the product.

iii. Any specific directions for use (or relevant supplementary label information) for the product against the claimed target pest(s).

iv. Details of any specific claims e.g., for the control of resistant strains.

v. The expected effect on pest activity (e.g., degree of control, reduction of population) arising from application of the product.

Users of this guidance are again referred to Appendix 1 for further information on the examples of typical claims that may be made for a product and the activity that may need to be shown through efficacy testing.

5

DATA REQUIREMENTS

5.1 INTRODUCTION

This section provides information on the types of efficacy data that might be generated, what will generally be required for specific applications, and how the information should be presented to HSE.

The characteristics of rodents as pests and the toxicological properties of the chemicals used in their control are such that the techniques familiar in other areas of pest control (such as broadcast spray or fabric treatments) are not applicable. Instead, 'spot' applications of rodenticide are made in a manner calculated to maximise the chance of rodents approaching and voluntarily consuming a lethal dose, whilst minimising the risks to users, to non-target vertebrates or of environmental contamination.

Similarly, since rodent infestations are normally highly localised in the vicinity of suitable food sources and harbourage, the unit of infestation or treatment is usually an individual structure or property.

Such factors mean that efficacy tests for rodenticides are of a rather specialised nature and the approach to testing dissimilar in some respects from that adopted for other pesticides.

The advice given in these guidelines can only present the basic requirements for trials. For further information, reference should be made to EPPO Guidelines (EPPO, 1982, a, b – see Appendix 6). COPR does not require rodenticide test houses to be 'Officially Recognised'. However, HSE will require all efficacy laboratory and field trials conducted in the UK to adhere to the provisions of the Animals (Scientific Procedures) Act 1986, under which a Project Licence issued by the Home Office may be required.

N.B. Before beginning a programme of efficacy testing and assessment for rodenticide products, it is recommended that the applicant considers the guidance outlined in the document "Guidelines on Humaneness Requirements: Vertebrate Pesticides, Repellents and Chemosterilants" (Formerly Appendix 5 of PSD/HSE Registration Handbook) and if necessary consult HSE.

5.2 METHODS OF DATA GENERATION

Three methods of generating efficacy data within the development programme of a product containing the active ingredient(s) in question may be considered when evaluating an efficacy data package. These are laboratory studies, tests under semi-natural conditions and field trials.

The different approaches generate data on specific aspects of a rodenticide's performance, as follows:

Laboratory Studies

1. To demonstrate the potency of both the active ingredient and the formulation and hence estimate the amount of product the target rodent should consume in order to be controlled.

2. To demonstrate the palatability of the proposed product to rats and mice and thus the likelihood that the target animals will eat it when other food is available.

Semi-Natural Conditions

These are often used to measure the effectiveness of a product on social groups of rats or mice (usually wild strains) under conditions not likely to be affected by non-product related factors, such as adverse weather or predator activity. Social groups of rats or mice are established and are introduced into an enclosed area (semi-natural). Such enclosures are an intermediate step between laboratory and field trials, but in general are not a substitute for the latter (especially in the case of rats). In general, small-scale indoor systems provide the best compromise between the ability to operate and control the study, and relevance to the natural situation.

Field Trials

These are used to demonstrate the efficacy of the rodenticide in 'real-life' situations in which the proposed product is used in the manner described on the product label.

When conducting any efficacy tests it is recognised that there may be considerable variation in response because rats and mice have individual preferences for textures, flavours and odours. This is particularly true with wild animals, for which little of their past history will be known. For these reasons, all efficacy tests conducted under laboratory, semi-natural or natural conditions should normally be conducted using the product for which approval is being sought.

5.3 ACCEPTABLE SOURCES OF DATA

Data from any source will be considered provided they are valid and relevant to the application. These data could represent studies conducted to national/international test standards, if these are available and relevant. A list of current test standards available for efficacy testing of rodenticides is presented in Appendix 6. Sources of data may include:

i) Well conducted studies, carried out or commissioned by the applicant, which are either laboratory, semi-natural or field studies. Unpublished work from persons or organisations other than the applicant will only be accepted if accompanied by the appropriate authorisation e.g. statements that the work was conducted on behalf of the applicant or the right to access these data has been granted to the applicant.

ii) Evidence relevant to the product from published work in reputable journals. Scientific/technical papers in refereed journals are usually acceptable. It is recognised that published data in support of an application may often lack important detail. The applicant should explain whether the formulation(s) referred to in a published paper is equivalent to

that for which approval is sought. If the test formulation is not identical, BPU will examine the data and decide whether or not they are adequate in support of the proposed product.

iii) Data from outside the UK are also acceptable provided it can be shown that the methods used, climatic conditions (for non-laboratory work) and pest(s) studied are relevant to the application.

iv) Lack of complaints, customer testimonials and anecdotal evidence will not be acceptable as a demonstration of efficacy.

5.4 OVERVIEW OF TYPES OF EFFICACY TEST AVAILABLE

5.4.1 INTRODUCTION

The main attributes of a rodenticide product that contribute to its efficacy are the potency of the active ingredient and the palatability of the formulation. While these attributes can be evaluated by suitable laboratory tests, the ultimate test of efficacy is how well the product performs in the field. In the field, additional factors come into play, notably the quantity, distribution and frequency with which the rodenticide is applied, as well as those unrelated to the product, e.g., adverse weather.

Although laboratory testing with wild rodents is preferable, BPU recognises the difficulty and constraints associated with obtaining and maintaining them for testing purposes. Therefore, for tests conducted within the laboratory, animals sourced from a recognised commercially available strain (e.g., Wistar, Sprague-Dawley, etc.) are generally acceptable, provided a reasoned case is made for laboratory strains representing a good model of the wild type biology.

Where wild animals are used in laboratory or semi-natural studies, these may be live trapped from the wild, reared in either outdoor colonies or under laboratory conditions such that it permits the animals to retain much of their natural physiological and behavioural characteristics. Breeding stock used for rearing wild rodents shall not be selected for docile qualities or other characteristics that significantly alter their wild tendencies.

5.4.2 READY-TO-USE BAITS

5.4.2.1 Laboratory Studies

5.4.2.1.1 Estimate of oral potency of active ingredient

An estimate of the potency of a new active ingredient must be provided for rodents of both sexes of the target species. This is derived from the dose-mortality relationship and is normally expressed as an LD_{50} (lethal dose required to kill 50 % of the target population) with 95 % Confidence Limits. Such estimates should be obtained by oral administration to rodents of a solution, or if necessary a suspension, of the active ingredient to be used in the bait.

5.4.2.1.2

Potency of the formulation – No-choice feeding test

Information on the potency of all formulations is required to demonstrate free feeding toxicity. The duration of the test should be appropriate to the proposed method of use of the rodenticide, normally one day for single dose rodenticides (fast and slow acting) and four or more days for multiple dose rodenticides. Data must be presented to show the daily intake of laboratory diet prior to the test and test bait during the treatment period, body weight of test animals, symptoms of poisoning and days to death, with appropriate statistical analysis.

A specimen protocol on how to conduct a No-choice feeing test can be found in Appendix 2. Please note that this protocol is only to be used as a guide and does not represent the only protocol that BPU will accept to fulfil this data requirement.

It should be noted that, evidence of oral potency of the formulation may be provided by palatability data (Choice test) providing the active ingredient is both stable and the content does not vary over the test period. To accurately demonstrate retention of potency BPU would require palatability data to be presented on both fresh and aged bait, ideally with several doses presented to the rodents. Therefore, levels of mortality and time to death in Choice tests are likely to give an indication of the potency of the formulation (pers.comm.).

5.4.2.1.3 Palatability of the formulation – Choice test

However potent the rodenticide, its acceptability in a bait in the presence of competing alternative food is of critical importance. Information on the palatability of bait formulations must be provided from studies in which the rodents are given a choice between the rodenticide formulation and an untreated diet. The untreated diet should preferably consist of the standard laboratory chow, EPA meal or one that the rodents are used to eating prior to the study commencing.

Full details of the methods should be provided and data should be presented to show the daily intake of both untreated diet and test bait, the palatability ratio (amount of test bait: amount of untreated diet) or bait acceptance (amount of test bait eaten expressed as a percentage of total (treated + untreated) bait consumption) for different sexes of rodent, any signs of poisoning and days to death, with appropriate statistical analysis.

A specimen protocol on how to conduct a Choice feeing test can be found in Appendix 3. Please note that this protocol is only to be used as a guide and does not represent the only protocol BPU will accept to fulfil this data requirement.

5.4.2.1.4 Humaneness

For anticoagulants, no new humaneness data are required as there are sufficient data in the public domain to support approval of these products. Applications for new products must include a reference to the humaneness data. For future submissions of other rodenticide products, applicants must refer to an existing humaneness submission to which they have access, or provide information relevant to the assessment of humaneness for efficacy.

5.4.2.1.5

Storage stability

The standard requirement for approval with regard to storage stability is 'Evidence (i.e., actual test results) of retention of the active ingredient content and appearance before and after two* years storage of the product at ambient temperatures in the sales pack'.

For rodenticide baits, including lards and pastes, active ingredient content after storage may be demonstrated either by an appropriate chemical method or by bioassay. Evidence of retention of palatability must also be provided. An appropriate format for the presentation of this data requirement is shown below:

Either

i. Evidence of retention of active ingredient content (results of chemical analysis) and a report of visual appearance before and after two years storage of the product at ambient temperatures in the sales pack.

Plus

ii. Data demonstrating retention of palatability before and after two years storage of the product (Choice tests).

Or

i. Efficacy data (bioassay data demonstrating retention of the active ingredient content (No-choice tests) and palatability (Choice tests)) generated before and after two years storage of the product at ambient temperature in the sales pack. Applicants should note that if there is adequate mortality in the palatability study, the requirement for a No-choice feeding test may be waived (see 5.4.2.1.2).

Applicants are encouraged to seek advice from BPU when they are unsure as to what data are required to be generated, before initiating studies in this area.

**A provisional approval may be granted for formulations that have retained stability after storage for at least 6 months.*

5.4.2.2 Semi-Natural Studies

Additional evidence of efficacy of a rodenticide product may be obtained from trials against colonies of wild rodents housed within a semi-natural environment. Such colonies are likely to be family groups, as unrelated animals, particularly males, can be very aggressive towards each other. Studies of this kind may provide useful supporting information, in case incomplete control occurs in field trials due to factors that could not be controlled by the applicant.

5.4.2.3 Field Trials

Ideally, sites chosen for 'field' trials should be representative of locations where the rodenticide is to be used, and should be infested with sufficient numbers of target rodents so that the effectiveness of the product can be clearly demonstrated. The sites should also be distributed throughout the UK and the studies carried out in both winter and summer months

to ensure that the product is tested under diverse ecological and environmental conditions. The rodent infestations on the sites chosen should, as far as possible, be discrete infestations of one target species with little chance of re-invasion, and be large enough to provide accurate estimates of activity which should be determined before and after treatments using at least two standard techniques. Sketch maps of the sites, approximately to an indicated scale, showing all the important features including signs of infestation and location of rodenticide application should be provided. Data should be presented to indicate levels of rodent activity both before and after treatment, amounts of bait consumed and all relevant information regarding treatment details.

Further guidance on field trials can be found in Appendix 4. Please note that the information supplied does not represent the only way a field trial can be conducted or the only information BPU will accept to fulfil this data requirement.

5.4.3 SPECIAL CONSIDERATIONS FOR FORMULATIONS OTHER THAN READY-TO-USE BAITS

5.4.3.1 CONCENTRATE RODENTICIDES

Some rodenticides are supplied as concentrates, which are subsequently made up into baits by diluting with a variety of ingredients, such as wheat, oatmeal, and with a range of additives such as ground nut oil. The choice of bait base is, therefore, large and will depend on:

i. The alternative food available to the rodent infestation.

ii. The moisture conditions at the infestation site.

iii. The target species.

iv. The operator's experience and preference.

Both laboratory studies and field trials will be required to support the claims made on the concentrate label. When a concentrate is being tested, the range of possible bait bases available is large and full efficacy data will not be required to support all bait mixes that are specified on the label or may be used in practice. As a minimum, applicants for approval should submit full efficacy data for at least one of the bait mixes on the label. While the choice of mix used to meet the full efficacy data requirement is at the discretion of the applicant, it is suggested that data are provided for the least palatable of the recommended mixes for the trial situation, and with justification that this is the case.

Furthermore, when drawing up the label with suggested bait mixes for an anticoagulant rodenticide, the applicant should give due consideration to the vitamin K status of the suggested additives, and whether the additives will affect absorption of vitamin K present in other components of the diet or synthesis by the bacterial contents of the gastro-intestinal tract. The application should also consider the effect of any other constituents on the efficacy of the bait. The conclusions from such considerations, including appropriate evidence and references, should be presented in support of the application.

N.B. The sale of any 'ready-to-use' bait prepared from an already approved concentrate rodenticide must be under its own label and therefore requires its own approval. Consequently, efficacy data will be required to support an application for such a product.

5.4.3.2 Contact Formulations and Burrow Fumigants

A number of these formulations exist and are generally recognised as being effective and, sometimes, indispensable for use in certain restricted circumstances. In practice, they are used on an occasional basis and on a small scale, usually by professional operators and usually in combination with or supplementary to the use of bait-based rodenticides.

Three particular difficulties can be foreseen in developing standard tests for such formulations. First, the market in these supplementary products may be too small to justify, economically, a special programme of testing, if it is at all extensive; but this ought not to be allowed to dictate the disappearance of useful products from the market. Second, though various laboratory tests can be conceived, the difficulty of confirming the results in the field is substantial. Third, since many contact formulations are supplementary products, problems of compounding arise when testing them in combination with primary products.

Although BPU will not stipulate specific protocols for contact formulations and burrow fumigants, the type of information that should be presented in order to demonstrate efficacy will include:

For contact rodenticides

i. Estimates of the oral potency of the active ingredient (see Section 5.4.2.1.1)

ii. Estimates of time to death from individually caged rodents to the formulation for stated periods of time. Reference to EPPO Guidelines (EPPO, 1986) should be made.

iii. Evidence from laboratory and field trials that the target rodents will pick up the required dose from the application method recommended. For field trials, the use of contact dusts alone for the control of an infestation is more likely to provide the necessary data than use in combination with baits.

For burrow fumigants

i. Estimates of the potency of the active ingredient and formulation by inhalation (see Sections 5.4.2.1.1 and 5.4.2.1.2).

ii. Evidence of the efficacy from field trials where assessments have been made to estimate population size and activity, both before and after treatment. Such assessments may include bait census, tracking activity measurement or other observations including visual, where appropriate.

iii. Any other information deemed relevant. This may include weather conditions, temperature data, soil moisture, soil porosity, burrow numbers and size, or other supplementary information.

5.4.4 REASONED CASE OR READ-ACROSS OF EFFICACY DATA BETWEEN THE SAME FORMULATION TYPES AND APPLICATION METHODS

Given that the key factors that contribute to a product's efficacy are the potency of the active ingredient and the palatability of the formulation, it will be necessary to provide supporting data for the majority of product formulations. However, there may be occasions when it is technically justified to read-across from one data set to another. Justification may be submitted to BPU through either the provision of a reasoned case based on data or, alternatively, through bridging arguments. In such instances, BPU will consider these applications on a case-by-case basis.

An example of read-across may be a situation in which one bait is found to be effective in both the laboratory and in the field and a slightly modified version is found to be as effective in the laboratory. In this situation, the new product may be allowed to 'ride on the back' of the first product's field data.

A further example is evidence of the oral potency of a new formulation containing an existing active ingredient, this may be provided by palatability data (providing the active ingredient is both stable and the content does not vary over the test period).

An example where read-across or the preparation of a reasoned case is not acceptable would be the extrapolation of data between two very different formulation types, e.g., from a grain-based bait to a gel or from a loose-grain bait to a wax block.

Further advice on the preparation of reasoned cases was presented in the Pesticides Newsletter No. 38, March 1998. Copies of this information may be obtained from BPU.

5.5 DATA REQUIREMENTS FOR SPECIFIC APPLICATIONS

5.5.1 INTRODUCTION

Please see below for the data required for specific rodenticide applications. The list is not exhaustive and therefore does not cover every specific application scenario. The data requirements outlined in this section are the minimum BPU will accept for each type of application. If you have other data that are deemed relevant and are of an equal scientific standard then these should be submitted to BPU with a statement explaining why the information is relevant.

A list of currently approved rodenticide formulation types can be found in Appendix 5.

5.5.2 NEW PRESENTATION OF AN EXISTING FORMULATION

When an existing rodenticide product is presented in a new way (e.g., a ready-to-use whole grain bait now supplied in a purpose built bait box), comparative (Choice) tests should be designed to demonstrate that the product is as effective at controlling the target species as the original product.

5.5.3 ADDITIONAL SPECIFIC LABEL CLAIMS

Whenever additional specific claims are made on the product label, these need to be justified and BPU will require evidence that these claims are valid. For example, if the following types of claims are made then the indicated data will be required.

5.5.3.1 '….controls warfarin resistant populations' or '…..controls rats and mice resistant to first generation anticoagulants'

Tests should be conducted on known resistant laboratory or wild-caught strains (the location from where wild rodents were obtained should be stated). Resistance of rodent strains can be determined by blood clotting response (BCR) (EPPO, 1995) tests or by feeding studies developed by the World Health Organisation (WHO). The following information should be submitted to the Registration Authority:

i. Oral potency of the formulation – No-choice tests (outlined in Section 5.4.2.1.2)

ii. Results of BCR or WHO feeding tests.

5.5.3.2 '….suitable for use in damp conditions'

Applicants who wish to claim that their product is suitable for use in damp conditions should submit the following efficacy data to BPU:

i. Prevention of mould growth of the test formulation in damp conditions.

ii. Prevention of germination of the test formulation in damp conditions (relevant for whole grain baits only).

5.5.4 APPLICATION FOR CHANGES TO AN EXISTING APPROVED FORMULATION

When making changes to an approved formulation, data will normally be required. However, the amount of data required by BPU will be dependent on the change the applicant wishes to effect. For example, if the changes are so minor they are unlikely to alter the efficacy of the product then a statement should be submitted to BPU explaining why this is the case, e.g., decreasing the amount of dye in the approved product from 0.28 to 0.27 % w/w may be deemed insignificant. Adding or removing attractants, flavourings and bittering agents will be treated on a case-by-case basis.

When any changes are to be considered that may affect the efficacy of the product, e.g., changing the lard (or fat) base, BPU will require the following data:

i. Oral potency of the formulation to demonstrate no change in bioavailability – No-choice test.

ii. Palatability of the formulation – Choice test (outlined in Section 5.4.2.1.3).

iii. Storage stability (outlined in Section 5.4.2.1.5).

5.5.5 APPLICATION FOR AN APPROVAL BASED ON AN EXISTING FORMULATION TYPE AND AN EXISTING ACTIVE INGREDIENT

When submitting an application for an existing formulation type, based on an existing active ingredient, BPU will require the following information:

i. Oral potency of the formulation – No-choice test*.

ii. Palatability of the formulation – Choice test.

iii. Storage stability.

**N.B. When both the formulation and the active ingredient level do not change, evidence of oral potency of the formulation may be obtained from the palatability test, since the test formulation will be offered to rats and/or mice at one concentration.*

5.5.6 APPLICATION FOR APPROVAL OF A NOVEL FORMULATION TYPE BASED ON AN EXISTING ACTIVE INGREDIENT

When submitting an application for a novel formulation type, based on an existing active ingredient, (e.g., where an active ingredient has previously only been used in approved wax block formulations, and the applicant wishes to use it in a liquid bait), BPU will require the following information:

i. Oral potency of the formulation – No-choice test.

ii. Palatability of the formulation – Choice test.

iii. Storage stability.

iv. A minimum of 2-3 field trials (outlined in Section 5.4.2.3)

5.5.7 NEW ACTIVE INGREDIENT

When submitting an application for a new active ingredient, within a rodenticide product, BPU will require the following data:

i. Oral potency of the active ingredient (outlined in Section 5.4.2.1.1)

ii. Oral potency of the formulation – No-choice test.

iii. Palatability of the formulation – Choice test.

iv. Data on humaneness.

v. Storage stability.

vi. Semi-natural tests (if applicable to support field information – outlined in Section 5.4.2.2)

vii. A minimum of 6 field trials.

If the proposed application falls outside of any of these categories, please contact BPU for further clarification.

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

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

The data submitted should include all information necessary to enable a complete evaluation to be made. BPU will evaluate the data with respect to its completeness and adequacy (i.e., covering the reliability of the data and also its relevance to the proposed use of the product).

5.6.1 GENERAL INFORMATION WHICH SHOULD BE SUBMITTED ON NEW ACTIVE INGREDIENTS

For the activity of the product containing a new active ingredient a number of basic details are required to aid the initial stages of the efficacy evaluation. These are as follows:

i) the chemical group of which the active ingredient/biocide is a member, e.g., coumarin anticoagulant.

ii) the mode of action of the active on the target pests. This need only be a brief statement, but should give details such as the route and nature of the action, e.g., contact poison, and the nature of the effect.

5.6.2 THE INFORMATION WHICH SHOULD BE SUBMITTED ON EACH STUDY

For a critical scientific assessment of the efficacy data package to be undertaken, each study must be reported in sufficient detail to facilitate such an assessment. Each study must include details of the test protocol, which will include different elements depending on the nature of the study, i.e., whether it is conducted in the laboratory, under semi-natural conditions or in the field.

The following list is a detailed description of the type of information that it may be necessary to supply for each study:

Test reference

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

Pests used in the study

This is the scientific name and age of the rodent, collection and rearing conditions (for wild caught individuals) and numbers and sexes used in the study. In all cases, the test species must be appropriate to the product's draft label claims. When using rodent pests, particular reference should be made to the strain (wild or laboratory) used and, where relevant, the resistance status (susceptible or anticoagulant resistant). Basic information should also include the weight of each rodent before testing commences.

Active ingredient and formulation type

The active ingredient in the formulation used in the study should be relevant to the product application submitted, i.e., the same specification as that stated for the proposed product. In addition, both the type of formulation and the complete formulation details should be stated (a list of typical rodenticide formulation types is presented in Appendix 5).

Application method(s)

Where relevant, the method(s) used to apply the product during all laboratory, semi-natural and field tests should be the same as that proposed on the label.

Application rate

This should be reported in the test and should be able to support the proposed product application rate. Most rodenticide products are applied in such a way that bait is always available, regardless of the number of rodents feeding on it. This is often referred to as 'saturation' or 'surplus' baiting. If the bait runs out before the next inspection, efficacy may be impaired. However, some rodenticides may be regarded as sufficiently toxic that under surplus baiting conditions, rodents will eat far more than is needed to control them. Under these circumstances, bait points that run out of bait may be left empty for several days before replenishment with no loss of control efficiency. This type of baiting is referred to as 'pulse' baiting. For palatability studies, the amount of toxic bait and challenge diet consumed by each animal should be included.

Study environment

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

Pesticide exposure details

All periods of exposure and method of introducing the pests into the exposure scenario should be detailed in the test report. In addition, methods of recording/scoring the effect of exposure on the target pest should be given. In field trials, details of the monitoring regime

adopted and any procedures to reduce human bias, e.g., reducing sampling bias from different operators during monitoring work, should be given.

Applicants should also include the following:

- Details of death and body weight (at autopsy) for each animal. Bodyweight should also be recorded for any animals that survive both the exposure period and observation period.

- Unusual or unnatural behaviour patterns.

- Variations or special conditions, such as length of the test period, temperature, food, etc., that deviate from a standard protocol, if a standard protocol was used in the testing.

- Amount of toxic bait and challenge diet consumed by each animal.

5.7 PRESENTATION OF RESULTS FROM EFFICACY STUDIES

The results for each study may be presented in the form of tables, figures or graphs, as appropriate, but where either of the latter two is presented, the data used to construct the figure or graph should also be provided. Ideally, the results should be presented before correction for the control results and the corresponding control data should also be given. If detailed statistical analyses (e.g., analysis of variance, etc) are to be presented, it will not be accepted without the raw data on which these statistical analyses were performed

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

Where applicable, the potential for the target pest to develop resistance to the active ingredient in the product should be considered through a qualitative commentary. When resistance is known to exist in specific areas of use for the product, statements should be made with regard to the effectiveness of the formulation under these conditions and when specific claims are made for use against a resistant pest strain they must be supported by efficacy data.

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

6

CONCLUDING COMMENTS

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

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

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

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

APPENDIX 1

PESTS ON LABELS

The methods described in this guidance document are primarily based on experience gained in testing rodenticide formulations to control the commensal rodents *Rattus norvegicus* (brown, common, Norway, wharf or sewer rat), *Rattus rattus* (black, ship or roof rat) and *Mus domesticus* (house mouse), but they may also be applicable to some other species of rodents having behavioural patterns, physiology and feeding preferences similar to those mentioned.

The pests selected for efficacy testing should be those found in the UK and named on the product label. Either common or generic names may be used in the label. For examples of specific or broad label claims, please see below:

Data requirements

FOR USE AGAINST MICE – this will require testing against *M. domesticus**.

FOR USE AGAINST RATS – this will require testing against *R. norvegicus* or *R. rattus***.

FOR USE AGAINST RATS AND MICE – this will require testing against both *M. domesticus* and *R. norvegicus*.

**Laboratory strains derived from Mus musculus (house mouse) must not be used for testing purposes.*

***There is no potential for 'read-across' from data on the efficacy of products against R. norvegicus and R. rattus and vice versa. In the past, data on R. norvegicus have been used as a starting point for investigations into the potential efficacy against R. rattus, simply because no laboratory strains of R. rattus exist and wild R. rattus are difficult to work with.*

APPENDIX 2

SPECIMEN PROTOCOL' FOR A NO-CHOICE TEST

To determine that the product, containing a known concentration of active ingredient, is fully effective against the target species, a No-choice feeding study is conducted against laboratory rodents. The study consists of an acclimatisation period, followed by a pre-test diet take assessment, then a 1 d (single dose rodenticide) or 4 d (multiple dose rodenticide) test period and at least 14 d of post-treatment observation.

Two groups (test and a control) of 10 (5 males and 5 females) healthy, adult rodents of known strain are used in the study. Females should not be pregnant. All animals are weighed (for Norway rats and house mice minimum body weights should be 200 g and 15 g respectively, at the start of the test) and individually caged. Ambient conditions should conform to those prescribed under current legislation controlling animal experiments. Tap water is freely available throughout the study period.

The animals are acclimatised to the test conditions for a minimum of 3 d prior to the No-choice feeding period. A feeding dish is placed centrally at the front in each cage and is filled with ground laboratory diet at the desired rate. All other food is removed. On the third day, a weighed amount of fresh diet is placed in the pot, the quantity to be in excess of the normal daily requirement. After 24 h, the diet remaining is weighed and the amount eaten by each rat/mouse calculated. Inspection of the figures should confirm that all animals are eating normally from the food pots.

For the no-choice test, 1 group of 10 rodents is offered weighed amounts of the product and the second group of 10 is offered the test rodenticide minus the active ingredient. The quantity of product in each pot should be in excess of the rodent's normal daily requirements. Every 24 h throughout the test period, any product spillage is collected and any extraneous matter such as faeces removed. Unconsumed product is then weighed, and the total amount eaten calculated by subtraction. If the test period is 1 d, the product is then removed and replaced with the normal laboratory diet for the duration of the observation period. If the test period is 4 d, used product is discarded and replaced with a fresh supply each day. On the last day, uneaten product is replaced with the normal laboratory diet for the following observation period. Throughout the feeding period, the rodents are observed at least twice daily. Daily takes are added up and the amount of active ingredient ingested is calculated. These results are subject to statistical analysis.

During the observation period, the rodents are observed at least twice daily and any toxic symptoms and mortality recorded. Any rodents exhibiting severe symptoms of poisoning from which they are unlikely to recover are culled and recorded as dead on the day or on the following day, depending upon the severity of the symptoms.

For liquid bait formulations

The test shall be carried out as above except that:

i. A suitable compounded laboratory diet shall be freely available.

ii. Tap water shall be withdrawn during exposure to the rodenticide.

iii. All procedures relating to the laboratory diet and solid bait shall instead be applied to the tap water and liquid bait, as appropriate.

iv. Liquid baits shall be provided in containers with non-drip nozzles or suitable open pots. A filled container shall be placed out of reach of the animals in order to check for weight loss due to evaporation.

APPENDIX 3

'SPECIMEN PROTOCOL' FOR A CHOICE TEST

A feeding test is conducted to determine the extent to which rodents will eat the product when they are given a free choice between that and their normal food. This type of palatability test is most suited to slow-acting toxicants. The test consists of an acclimatisation period, followed by a pre-test diet take assessment, then a 4 d test period and at least 14 d of post-treatment observation.

For the test, 20 wild or laboratory strain rodents (10 males and 10 females) are required. Laboratory rodents should be healthy, non-pregnant adults of known strain. Where wild adult rodents are used, they should be healthy and obtained from free-living populations. On arrival at the laboratory, the wild strains should be treated with an appropriate insecticide to kill ectoparasites and then caged individually. With wild rats especially, it is advisable to place all items (i.e. food pots) required for the test in the cage before each animal is released into it. Wild rodents should be acclimatised to laboratory conditions for at least 3 weeks to ensure that no females are pregnant when the test begins. During this time, they should be offered a laboratory animal diet and water should be freely available. To encourage variation in response, animals with body weights throughout the range normally expected for the species should be used as far as possible.

Before the test period begins, it is necessary to ensure that the animals are feeding normally. Following acclimatisation, 2 food pots placed either side at the front of the cage are filled with ground laboratory diet. All other food is removed, but water remains freely available. The quantity of food placed in each pot should be sufficient to meet each animal's daily needs. After 24 h, the diet remaining in each pot is weighed and the total amount of food eaten by each rodent calculated. All used diet should be discarded and the pot refilled with a fresh supply. This procedure should be repeated for a further 3 d and on the last day the animals should be weighed. Any rodent not eating normally by the last day should be discarded. The palatability test commences with 2 clean pots, one filled with a quantity of the test product and the other with a suitable challenge diet (e.g. EPA meal or standard laboratory chow). Again, the quantity in each pot should exceed the normal daily requirement for each animal. After 24 h, the diet remaining in each pot is weighed and the total amount of food eaten by each rodent calculated. All used test and challenge diet is discarded and fresh quantities of each diet are placed in clean pots. In placing the pots back in the cage, the positions of the rodenticide and the challenge diet should be interchanged to avoid place preference. This procedure should be repeated for a further 3 d. After day 4, the animals should be returned to the standard laboratory diet.

During the observation period, the rodents are observed at least twice daily and any toxic symptoms and mortality recorded. Any rodents exhibiting severe symptoms of poisoning from which they are unlikely to recover are culled and recorded as dead on the day or on the following day, depending upon the severity of the symptoms. All rodents dying during the test and observation periods should be autopsied to confirm cause of death.

Liquid bait formulations

The test shall be carried out as above except that:

i. A suitable compounded laboratory diet shall be freely available.

ii. Tap water shall be used as the control bait.

iii. All procedures relating to the solid control and test baits shall be applied instead and as appropriate to the liquid control and test baits.

iv. When the positions of the test and control baits are interchanged the positions of the drinking tubes, if used, should not be interchanged.

v. Liquid baits shall be provided in containers with non-drip nozzles or suitable open pots. A filled container shall be placed out of reach of the animals in order to monitor weight loss due to evaporation.

APPENDIX 4

GUIDANCE ON FACTORS TO BE TAKEN INTO ACCOUNT AND CONTROLLED WHEN CONDUCTING FIELD TRIALS

Ideally, field trials should:

i. Be conducted with separate rat and mice populations (as appropriate to label claims).
ii. Be carried out at sites that are representative of label claims (industrial, commercial, domestic).
iii. Use sites distributed throughout the United Kingdom.
iv. Include sites where anticoagulant resistant populations are known to be established. The resistance status of a population should be determined by an appropriate method (BCR test or WHO feeding tests).
v. Have no rodenticide treatments currently in progress
vi. Incorporate lag phases before and after the treatment phase.
vii. For testing concentrates, cover a range of bait bases, including the least palatable one stated on the label.
viii. Use the bait container in which the product is sold (if one is present).

The following suggested method for bait formulations details the extent of the data required, but the methods may be replaced or supplemented by new techniques as appropriate.

Suggested procedure for bait formulations:

Trial sites

Each trial site should, as far as possible, comprise a discrete infestation of one target species, with little chance of reinvasion from adjoining areas.

Before the trial begins, draw a sketch map showing all significant features of the site including signs of infestation.

Data on field efficacy is likely to be more reliable if infestations of Norway rats are selected on the basis that a stable level of activity, as determined by or census baiting and/or tracking techniques, is obtained during the pre-treatment assessment.

Data on field efficacy is likely to be more reliable if infestations of house mice are selected on the basis that a stable level of activity, as determined by census baiting and/or census trapping, is obtained during the pre-treatment assessment.

Pre-treatment activity measurement/estimation of numbers

Indices of the target species population should be obtained both before and after the test treatment normally by at least 2 of the following:

i) Pre-treatment bait census - the position of the census bait points should be indicated on the site sketch plan. Census bait should be laid for at least 4 days to cover the whole infestation in quantities at each bait point which as far as possible exceed the maximum daily

take by rodents. The number of census baits should be approximately the same as the planned number of test bait points. Census points should not be located at the same place chosen to lay poison points but should be at different (intermediate) positions. Census bait should be different to the bait base used in the test product.

The number of points where take has occurred and the take of the census bait should be recorded daily and an indication of the change in weight of the bait due to moisture loss or uptake should be included.

At the end of the bait census all baits and containers should be removed from the trial site. The total amount of census bait consumed will give an index of population size.

ii) Tracking activity measurement (recommended for rats only) - should be measured over at least 3 days, simultaneously with the bait census, using tracking patches/boards laid around the site in numbers similar to the census bait points but as far as possible, not in the same locations. The locations of the patches/boards should be indicated on the plan.

The patches/boards should be inspected for signs of activity and resurfaced daily. A simple scoring system can be devised to assess the number of rodent footprints per patch/board: summing the individual scores gives a daily activity index. When the pre-treatment assessment is complete, the tracking patches/boards may be removed from the site or maintained to provide supplementary information on rodent activity.

iii) Census by trapping (recommended for mice only) - should be carried out for a period of at least 3 days using a rodenticide-free bait in the traps. Traps should be laid around the site in numbers appropriate to the situation and likely population size.

Animals caught should be marked by fur clipping and subsequently released. The numbers caught should be recorded and used to estimate the size of the population.

The traps should then be removed from the test site during the rodenticide treatment.

Lag period

Once the pre-treatment population measurement has been conducted, there should be a lag period, normally 3-14 days (or longer for acute poisons where no pre-baiting is recommended) with no experimental interference (other than tracking) on the site.

Test treatment

The test formulation must be applied in accordance with the label or proposed label, for an appropriate period. The locations of test bait points should, as far as possible, be different from those of the census bait points, traps, and tracking patches/boards.

Where applicable the following items should be recorded:

i) The locations of the bait points on the plan.

ii) The amount of bait deposited at each point at each visit and the amount retrieved, including details of the type of container used.

iii) The number and species of rodents and other animals found dead, and the dates on which they were found.

iv) The dates of all observations, treatments and censuses.

v) Any other information deemed relevant. This may include, for example weather conditions, temperature data, site changes instituted by the occupier (including improvements in hygiene and proofing), or supplementary information on rodent tracking activity.

On termination of the treatment, all poisoned baits and bait containers should be removed from the trial sites.

Post-treatment lag period

On completion of the treatment, there should be a lag period sufficient to allow poisoned animals to die or survivors to recover from the sub-lethal effects of the rodenticide. This period may be 3-14 days, depending on previous observations of time to death or full recovery. During this period, there should be no experimental interference with the site other than tracking.

Post-treatment activity measurement/estimation of numbers

Once the post-treatment lag period is completed, the methods employed to measure pre-treatment activity should be conducted in exactly the same way. Traps, baits and tracking patches should be laid in exactly the same places as in the pre-treatment census.

After each field trial, a comparison of population indices before and after treatment determines how successful the product has been in controlling the target population. The degree of control is expressed as a percentage reduction in the pre-treatment index.

REFERENCE DATA

Regardless of the methods used to monitor population changes during field trials, there can still be doubts as to whether a detectable drop in numbers is attributable to the rodenticide treatment or to other confounding factors, such as bad weather, habitat disturbance or natural population fluctuations. Simultaneous treatments using plain bait may serve as ‘controls’ for population changes, but the potentially large number of differences that can occur naturally between rodent populations makes such controls of dubious value. The solution to the problem lies in carrying out field trials across a range of habitats where rodents live and where the product is likely to be used. With sufficient replication, a reduction in rodent numbers can be confidently ascribed to a rodenticidal effect.

APPENDIX 5

POSSIBLE RODENTICIDE FORMULATION TYPES

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

Groups of formulations	**Individual types**
Ready-to-use bait:	Solid Loose Pastes Gels Pellet Liquid
Concentrates	
Contact oisons:	Dusts Gels Specialist ready-to-use product/device
Fumigants	

APPENDIX 6

AVAILABLE TEST STANDARDS

Standard	Title	Target Organism(s)	Mode of Application
EPA/OPP Protocol Number 1.201	Standard Norway Rat and Roof Rat Anticoagulant Liquid Bait Laboratory Test Method	Norway Rat/Roof Rat	Liquid bait
EPA/OPP Protocol Number 1.202	Standard House Mouse Anticoagulant Liquid Bait Laboratory Test Method	House Mouse	Liquid bait
EPA/OPP Protocol Number 1.203	Standard Norway Rat and Roof Rat Anticoagulant Dry Bait Laboratory Test Method	Norway Rat/Roof Rat	Dry Bait
EPA/OPP Protocol Number 1.204	Standard House Mouse Anticoagulant Dry Bait Laboratory Test Method	House Mouse	Dry Bait
EPA/OPP Protocol Number 1.205	Standard Norway Rat/Roof Rat Anticoagulant Tracking Powder Efficacy Laboratory Test Method	Norway Rat/Roof Rat	Tracking Powder
EPA/OPP Protocol Number 1.212	Standard House Mouse Anticoagulant Tracking Powder Efficacy Laboratory Test Method	House Mouse	Tracking Powder
EPA/OPP Protocol Number 1.213	Standard Norway Rat/Roof Rat Anticoagulant Wax Block and Wax Pellet Laboratory Test Method	Norway Rat/Roof Rat	Wax Block and Wax Pellet
EPA/OPP Protocol Number 1.214	Standard House Mouse Anticoagulant Wax Block and Wax Pellet Laboratory Test Method	House Mouse	Wax Block and Wax Pellet
EPA/OPP Protocol Number 1.217	Standard Norway Rat and Rood Rat Anticoagulant Placepack Laboratory Test Method	Norway Rat/Roof Rat	Placepack dry bait
EPA/OPP Protocol Number 1.218	Standard House Mouse Anticoagulant Placepack Penetration Laboratory Test Method	House Mouse	Placepack Penetration
EPA/OPP Protocol Number 1.221	Proposed Norway Rat Anticoagulant Technical and Concentrated Dry Bait Laboratory Test Method	Norway Rat	Technical and Concentrated Dry Bait
EPA/OPP Protocol Number 1.225	Proposed House Mouse Anticoagulant Technical and Concentrated Dry Bait Laboratory Test Method	House Mouse	Technical and Concentrated Dry Bait
EPA/OPP Protocol Number: 1.207	Standard Norway Rat/Roof Rat Acute Liquid Bait Laboratory test method	Norway Rat/Roof Rat	Liquid Bait
EPA/OPP Protocol Number: 1.208	Standard House Mouse Acute Liquid Bait Laboratory Method	House Mouse	Liquid Bait
EPA/OPP Protocol Number: 1.209	Standard Norway Rat/Roof Rat Acute Dry Bait Laboratory Test Method	Norway rat/Roof rat	Dry Bait

Standard	Title	Target Organism(s)	Mode of Application
EPA/OPP Protocol Number: 1.210	Standard House Mouse Acute Dry Bait Laboratory Test Method	House Mouse	Dry Bait
EPA/OPP Protocol Number: 1.211	Standard Norway Rat/Roof Rat Acute Tracking Powder Efficacy Laboratory Test Method	Norway rat/Roof rat	Tracking Powder
EPA/OPP Protocol Number: 1.219	Standard Norway rat/Roof rat Acute Placepack Penetration Laboratory Test Method	Norway rat/Roof rat	Placepack penetration
EPA/OPP Protocol Number: 1.220	Standard House Mouse Acute Placepack Dry Bait Laboratory Test Method	House Mouse	Placepack dry Bait
EPA/OPP Protocol Number: 1.222	Proposed Norway Rat Acute Technical and Concentrated Dry Bait Laboratory Test Method	Norway rat	Technical and concentrated dry bait
EPA/OPP Protocol Number: 1.226	Proposed House Mouse Acute Technical and Concentrated Dry Bait Laboratory Method	House Mouse	Technical and concentrated dry bait
EPA/OPP Protocol Number: 1.227	Proposed House Mouse Acute tracking Powder Efficacy Laboratory Method	House Mouse	Tracking Powder
BBA 9 - 3.1	Richtlinie fur die prufung von Nagetierbekampfungsmitteln gegen Hausmause		
BBA 9- 3.2	Richtlinie fur die prufung von Nagetierbekampfungsmitteln gegen Wanderratten		
EPPO 1982	Guidelines for the Biological Evaluation of Rodenticides No1. Laboratory Tests for Evaluation of the Toxicity and Acceptability of Rodenticides and Rodenticide Preparations		
EPPO 1982	Guidelines For the Biological Evaluation of Rodenticides. Field Tests Against Syanthropic Rodents (*Mus musculus, Rattus norvegicus, Rattus rattus*)		
EPPO 1986	Guidelines for the Biological Evaluation of Rodenticides. Laboratory and Field Tests for the Evaluation of Rodenticidal Dusts		
ASTM E 565-95	Standard Test Method for Efficacy of a Single-Dose Acute Rodenticide Under Laboratory Conditions for Commensal Rodents	Norway rat/Roof rat/ House mouse	Dry Bait
ASTM E 593-95	Standard Test Method for Efficacy of a Single-Dose Acute Rodenticide Under Laboratory Conditions	Norway rat/Roof rat/ House mouse	Dry Bait

APPENDIX 7

REFERENCE LIST

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