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

**ANTIFOULING
PRODUCTS**

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DEFINITION OF TERMS

Active ingredient	The component of a product which fits it for use as a pesticide.
Application	An application seeking approval to sell, supply, store, use or advertise a pesticide product in Great Britain.
Approval	An approval given jointly by Ministers under Regulation 5 of The Control of Pesticides Regulations 1986 (As Amended) (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 of Transport, Local Government and the Regions (DTLR), 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 Assessment Unit (BPAU).

FOREWORD

1. As part of the commitment to 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 the 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 active ingredient/biocides(s) intended for use as an antifouling product, or to support continuing approval of current products containing existing active ingredient/biocide(s) at review.

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

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

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

1 INTRODUCTION

This document gives guidance on the nature and extent of the efficacy data required to gain a commercial approval of a pesticide containing active ingredient/biocide(s) for use as an antifouling product against fouling organisms on vessels, floating/submerged structures and apparatus or equipment used in the cultivation and harvesting of fish and shellfish (aquaculture), and also for continuing approval of current products containing existing active ingredients following review. The HSE is the Registration Authority to which such applications should be submitted.

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

EACH STUDY PRESENTED WILL BE EVALUATED ON ITS OWN MERITS.

The assessment will be made solely in relation to the recommended use as outlined in the relevant commercial/technical literature for the antifouling product being evaluated. These may include reference to the suitability of the use of the product on, for example, nets or other aquaculture equipment/apparatus, or suitability for deep sea ships or yachts.

The data submitted should demonstrate the innate activity of the active ingredient/biocide as a potential antifouling biocide. In addition, data should be provided to demonstrate that the formulation of the biocide into representative coating(s) will result in a product that demonstrates effective antifouling capability. *The effective service life of a coating will not be considered in an assessment nor will any information be used as the basis for a product guarantee scheme.*

2 WHEN EFFICACY DATA ARE REQUIRED

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

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

i) e.g. to support applications for products containing an active ingredient yet to be assessed prior to first approval in the UK.

ii) e.g. to support applications for products containing an active ingredient previously used in agricultural pesticides (e.g. an agricultural herbicide active ingredient now intended for use in non-agricultural pesticides as an antifouling product).

iii) e.g. to support applications for products containing an active ingredient previously used in another sphere of non-agricultural pesticide use (e.g. an active ingredient currently used in wood preservative products now intended for use in antifouling products).

iv) e.g. to support applications for products containing an existing active ingredient but incorporating novel formulation types and/or novel* application/delivery methods.

v) e.g. to support applications for products containing an existing active ingredient targeted against novel* organisms.

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

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

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

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

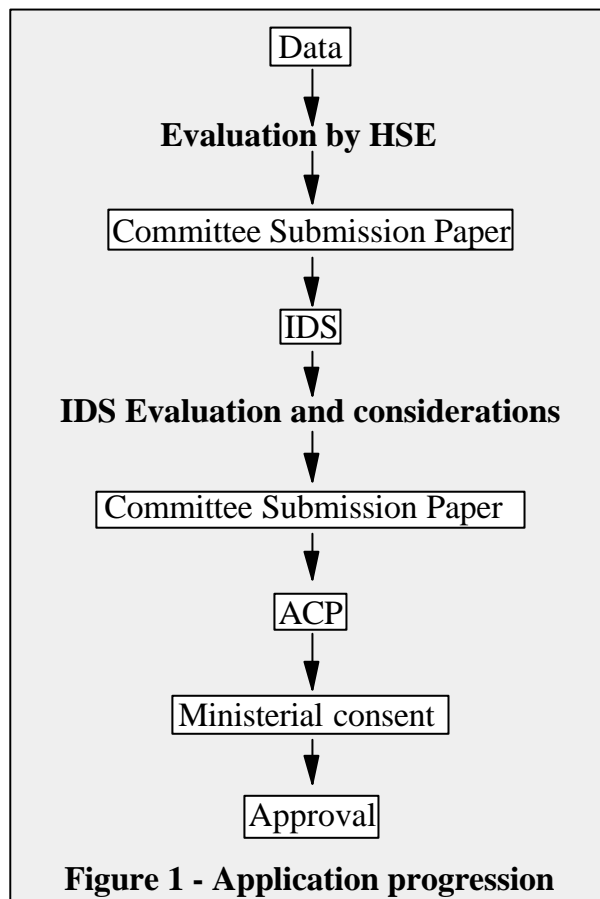
3 FRAMEWORK OF THE ASSESSMENT PROCESS FOR COMMERCIAL APPROVAL

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

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

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

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



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

4 PRODUCT PERFORMANCE CLAIMS

The efficacy data submitted in support of an application will be assessed to establish if the product containing the active ingredient/biocide(s) has a reasonable level of performance with respect to its coating type and any product literature claims.

Hence for an evaluation to be undertaken, statements will be required concerning the claims, including recommended dry-docking intervals (i.e. the service period between dry-docking for the purpose of removal of old coating and application of a new one) which are claimed for the product. It is appreciated that the maximum period of service life of an antifouling product is dependent on several factors, such as trading pattern, and thickness and type of antifouling coating applied. A statement on the anticipated or recommended use(s) for a product will also be required. The uses may include marine, freshwater, deep sea, low activity, use on yachts, aquaculture and so on.

It is recognised that the individual specifications of an antifouling product for a vessel's particular operating conditions will vary considerably, but the general effectiveness of a product under typical fouling conditions will need to be demonstrated.

4.1 CURRENT GROUPS OF ANTIFOULING COATINGS

The current range of antifouling coatings can be broadly divided into 4 major groups outlined below:-

- i) Soluble matrix antifouling**
- ii) Insoluble matrix antifouling**
- iii) TBT self polishing co-polymer antifouling**
- iv) TBT-free self polishing antifouling**

The categorisation of coating types outlined above is very generalised. It should be noted that apart from the TBT self polishing co-polymer products, the majority of other antifouling products do not necessarily rely on one single coating technology and a composite of different technologies may have been developed by antifouling formulators to suit customer specifications and environmental requirements.

Further descriptions and properties of the major coating types are detailed in Appendix 1 of this document.

Table 1 presents the CEPE (European Council of Paint, Printing Ink and Artists' Colours Industry) agreed maximum protection period that can be expected for each type of antifouling coating type.

It should be noted that the maximum protection periods presented in Table 1 are a generalisation of maximum protection periods that may be achieved within these very broad groupings and these agreed intervals reflect a compromise position reached between CEPE members. In addition the

table does not provide an indication of the level of performance that can be obtained by a product specified within those time periods or the level of performance required by a particular specification. Performance ratings are heavily dependent upon the particular coating being applied to specification (surface preparation, primers undercoatings, dry film thickness etc.), trading and sailing pattern of the vessel and a wide variety of environmental factors.

Table 1. Maximum periods of service expected for the different types of antifouling coating type (CEPE)

Type of coating	Soluble matrix	Insoluble matrix	TBT self polishing co-polymer	TBT-free self polishing
Maximum period of service	18 months	24 months	5 years	5 years

5 DATA REQUIREMENTS

5.1 DATA SOURCES

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

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

5.2 TYPES OF DATA GENERATED

A number of methods of generating efficacy data, within the development programme of a product containing the active ingredient/biocide(s) in question, may be considered when producing an efficacy data package. These include laboratory tests, simulated use tests and field tests. More details of these tests are shown in Example Box 1.

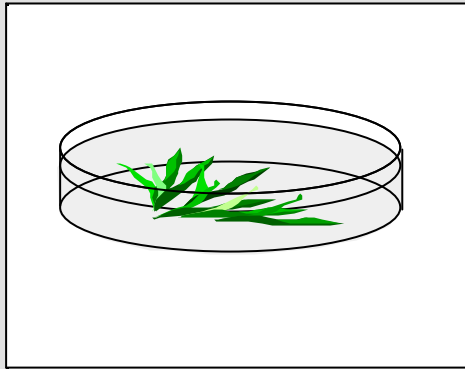
A useful definition of the types of studies which may be carried out are given below.

5.2.1 Laboratory tests (including *in vitro* screening tests)

To support applications for products, the applicant should provide evidence of the innate efficacy of the candidate active ingredient/biocide(s). Such evidence may be produced using 'screening' type laboratory tests which can be used to assess the toxicity of the biocide. More details may be found in Appendix 2. It is acknowledged that surrogate or substitute species may be used in these tests. In cases where they are used, a reasoned case/argument supporting their use should be given. Consideration should be given to use of species known to be tolerant/resistant to existing antifouling biocides, in addition to those regarded as sensitive.

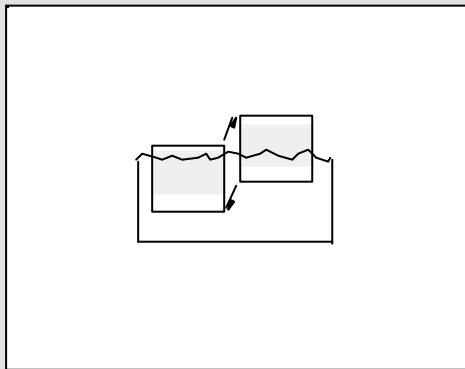
Example Box 1 - Examples of possible studies that may be used to assess antifouling

Laboratory studies e.g.. *In vitro* toxicity screening tests



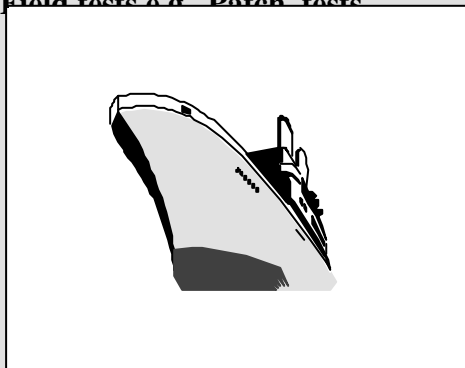
To demonstrate the inherent biological properties of an active ingredient as an anti-weed, anti-animal etc. agent.

Simulated field tests e.g.. Raft tests



Panels coated with the test formulation and immersed in water for a period of time. Demonstrates antifouling capability under static conditions.

Field tests e.g.. Patch tests



Strips or patches of a test product applied to the hull of a vessel. Demonstrates the antifouling capability under in-use service conditions.

5.2.2 Simulated field tests

These may be studies which are conducted with the active ingredient/biocide incorporated into a model coating type. Such tests would include static raft testing with panels coated with a test coating and immersed for a period of months in a river, estuary or sea.

There is currently only one internationally recognised method of evaluating antifouling products and that is raft testing. Two examples of standard test protocols for conducting such tests are referenced below. However, it should be noted that it is not mandatory to conduct efficacy tests to these protocols, and that the Regulatory Authority will consider alternative testing strategies and non-standard test data provided they are relevant.

Antifouling coatings - Method of the generation of efficacy data. CEPE Antifouling working Group, 1993.

American Society of Testing methods (ASTM) standard method for testing antifouling panels in shallow submergence, D3623 - 78a, (R. 1998).

5.2.3 Field tests/in-service monitoring

These may be studies which are conducted with the coating that is intended to be marketed, the one for which approval is sought. Field tests permit antifouling products to be tested under similar operating conditions and stresses encountered as when the antifouling product is in service. Possible examples of these tests include panel tests where coated panels are attached to a vessel for a short period of time, and patch tests where vessels are painted with the test coating as a strip or patch on the side of the hull. Monitoring reports of the performance of an antifouling product on a fully treated vessel, where available, may also be submitted.

Since field tests involve long term exposure to practical conditions, they can be regarded as service tests and as such any field data generated in support of an application should be conducted on products or representative products that resemble closely the fully formulated commercial product. It should be pointed out that evidence of performance based on service or field trial testing will be more convincing, owing to the difficulties of representing the conditions of service through laboratory or simulated use testing.

It is recognised that data generation from field trials requires many years to carry out and is more likely to be available for products incorporating established biocides in coatings of well known technology, rather than for products containing newer biocidal active ingredients and for coating types, based on new technology.

Where field data are not available the applicant has the option to provide bridging studies, based on data, to support their applications as appropriate. Such studies could be compiled on the basis of:

Composition of 'old' (and well documented) and 'new' antifouling product;
simulated field tests of 'old' and 'new' antifouling;

field data on 'old' antifouling formulation;
 further justification why bridging is justified (e.g. in-service monitoring).

Additionally it is understood that where established biocides have been introduced into products based on new technology, neither extensive field test data nor bridging data will always be available.

There are no current national or international standards which cover field evaluation of antifouling products. This should not deter applicants submitting data generated from company protocols of panel tests etc. or in-service data.

5.2.3.1 Formulation/coating type to be used in the generation of data

The formulations used in screening studies in the laboratory may be simple solutions of the active ingredient/biocide, whereas those used in simulated use studies should mirror the type of coating/formulation for which approval is sought or may be the actual product that is intended to be marketed. It is recognised that field studies are more likely to be conducted on a product that resembles the commercial product for which approval is sought.

Table 2. shows a summary of the kinds of test that can be conducted on the different stages of the development of a new antifouling product.

Table 2. Examples of types of efficacy study conducted with the different development stages of a new antifouling product

Type of study	Biocide (active ingredient) in simple solution	Model or 'frame' coating(s)	Coating/product for which approval is sought
laboratory test	✓	✗	✓/✗
simulated field test	✗	✓	✓
field tests	✗	✗	✓
In-service reports	✗	✗	✓



same as in the proposed product application



not always necessary to resemble or mirror that proposed in the product application

The table illustrates the principle that efficacy studies generated before the final product coating has been developed have a part to play in the evaluation of an active ingredient/biocide in an antifouling product.

5.3 THE IMPORTANCE OF 'CONTROLS' IN EFFICACY STUDIES

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

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

It is recognised that generation of such control data can be relatively straight forward in well defined test situations such as laboratory tests. With simulated use studies, for example raft tests, a blank (i.e. uncoated panel) can serve as a control. However, it is recognised that this can present a problem in field trials where a patch of the test product is painted on to the side of a vessel. In certain situations, it may be considered necessary to use positive controls i.e. test alongside appropriate existing coatings.

5.4 SUMMARY OF DATA REQUIREMENTS

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

In many situations laboratory data alone are unlikely to be enough to support the commercial approval of a product whereas the provision of other types of studies (e.g. static raft test data and/or other relevant information) or combinations of such studies are more likely to lead to a successful application.

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

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

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

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

6.1 GENERAL INFORMATION WHICH SHOULD BE SUBMITTED ON THE ACTIVE INGREDIENT/BIOCIDE

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

- i) The chemical group of which the active ingredient/biocide is a member e.g. organotin, methylurea, ethylene bis (dithiocarbamate), dimethyl dithiocarbamate;
- ii) the mode of action of the active ingredient/biocide on the target fouling organisms. (this need only be a brief statement).

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 a laboratory, simulated use or field trial study.

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

Test reference	The submitted test should be provided with a full reference including the following (where appropriate): author(s), title, test house, year and a statement on whether these results have been published (if so a full journal reference should also be included whenever possible).
Fouling organisms used in the study	This is the scientific name, life cycle stage, rearing conditions, numbers and sexes used in the study (where appropriate).

Active ingredient and coating type	The active ingredient/biocide(s) in the test formulation used in the study should be relevant to the product application submitted i.e. the same specification as that stated for the proposed product. Therefore the source should be presented in the study. In addition, the coating type (see Appendix 1 for description of types) should be presented in the study, and where possible the complete formulation details of the product should be stated i.e. biocide(s) present in test formulation, principal solvents and matrix.
Biocide release rate	Expressed in $\mu\text{g cm}^2 \text{ day}^{-1}$ - if appropriate to coating type under test.
Study environment	Full details of the study environment should be provided with any test results. These should include such details as temperature, humidity and lighting conditions for laboratory tests. For simulated field and field tests, such information as, vessel's trips and trading pattern, and where appropriate details of salinity, pH, tides and currents should be included. The method of assessment/scoring of the degree of fouling that has occurred during the test period should be given.
Exposure details	All periods of exposure of fouling organisms to the test antifouling biocide/product should be detailed in the test report. In addition, methods of recording/scoring the effect of exposure on the target organisms should be given. In field studies, details of the monitoring regime adopted and any procedures to reduce human bias, e.g. reducing sampling bias from different operators during monitoring work, should be given.
Scoring/Assessment methods	Full details of the method of assessing/scoring the degree of fouling in simulated field and field tests be included. Any indices or other manipulation of the data should be explained.

Example Box 2 - A BASIC CHECKLIST FOR DETAILS TO BE INCLUDED IN A SUBMITTED STUDY

Test reference		yes Z
Test Species in screening studies	Scientific name	Z
	Stage of the life cycle	Z
	Collection and rearing conditions/source of test organisms	Z
	Numbers/sex used in the test	Z
Active ingredient and coating type	Source	Z
	Coating type	Z
	Complete formulation (where available)	Z
Study details	Name and number of any standard protocol used (if applicable)	Z
	Any deviation from standard protocols (if standard protocols used)	Z
	Method of application (brush, spray, roller)	Z
	Wet or dry film thickness, weight of film/number of coats	Z
(laboratory tests)	Temperature and lighting	Z
	Number of replicates	Z
	Controls	Z
	How toxicity is assessed	Z
(simulated use/field tests)	Location of test site(s)	Z
	Type of test panel (e.g.. steel, aluminium, formica, wood, other)	Z
	Size and number of panels	Z
	Period(s) of immersion	Z
	Study environment	Z
	Assessment method/scoring	Z
Results	Results/data (including photographs and/or diagrams where appropriate)	Z
	Interpretation	Z

NB. This checklist is not exhaustive and the items required on this list will vary between the test types that are reported in the efficacy data submission for a product. For

6.3 PRESENTATION OF RESULTS FROM EFFICACY STUDIES

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

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

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

7 CONCLUDING COMMENTS

These guidelines are designed to be flexible and are intended to provide *advice* regarding the nature and type of efficacy data required to support the approval of non-agricultural pesticide products containing active ingredient/biocide(s) intended for use as antifouling products. They do not set out a protocol to be followed exactly nor do they specify rigid protocols to which tests must be conducted in the process of generating efficacy data. They cannot give details on every possible evaluation situation, but outline the nature of the data required and the policy framework within which the 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 ingredient/biocide(s) at review or addressing post approval data requirements, or interested parties requiring any further guidance on efficacy requirements are encouraged to contact Biocides and Pesticides Assessment Unit (BPAU) at their earliest convenience.

Biocides and Pesticides Assessment Unit
Health & 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

CURRENT ANTIFOULING COATINGS

The major types of antifouling coatings together with a brief description of their properties are outlined below. These coating types will be used when considering efficacy evaluations for antifouling products. This list is not an exhaustive one into which all product applications must be categorised. Applicants may submit novel coating 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 a product cannot be readily categorised into one of these groups.

Coating Type	Description , mode of action and properties
Soluble matrix	In coatings of this type the biocide(s) have been physically mixed (freely associated') into a rosin matrix. Upon exposure to sea water the slightly acidic matrix slowly dissolves releasing the biocide(s) into the water (sea water is slightly alkaline (pH8) and the acidic matrix readily dissolves). Continuous dissolution of the coating surface occurs resulting in fresh biocide(s) being released until eventually the film is exhausted. Soluble matrix antifouling products typically show a biocide release rate curve which decays exponentially. The soluble matrix coatings have poor mechanical properties which limit film thickness, the paint film thickness of these coatings depletes over time in an imprecise manner and the film does not show smoothing characteristics on ships in service. As the matrix rosin is a natural product, batches differ and therefore coating lifetime is unpredictable. Such coatings are normally specified for lifetimes approximating 12-18 months. Typically coatings are applied in two coats by airless spray giving a total dry film thickness of 100 - 150 microns.
Insoluble matrix	Within this type of coating the binder or matrix is insoluble, and the biocide(s) is physically mixed into the matrix (often at higher concentrations than is the case with the soluble matrix coatings). As sea water enters the paint film the biocides are released by dissolution and diffusion from within the insoluble matrix. After biocide is released from the film the binder remains intact and an empty 'honeycomb' structure (the leached layer) remains at the paint surface. This type of coating has a high initial release rate, which decreases exponentially with time as the biocide(s) has further to travel through the paint film. Rate of diffusion of biocide from within the film then becomes a limiting factor in maintaining an effective biocide release rate and hence preventing fouling. Insoluble matrix antifouling coatings do not show film-depletion or polishing as the resin is insoluble. This release process continues until exhaustion of the coating. The higher mechanical strength obtained with these coatings allow applications of thicker systems and coating lifetimes of approximately 24 months are attainable. Application of these coatings is typically by airless spray; two coats resulting in a dry film thickness of 150 microns.

TBT self polishing co-polymer

In this type of coating the TBT biocide is chemically bound to the binder of the paint, a methacrylic acid/methylmethacrylate co-polymer matrix into which other biocides can be incorporated. The co-polymer hydrolyses at a predictable rate in sea water (depending on temperature, pH and rate of movement of a vessel through water) releasing the biocide(s) into the surrounding water, creating a localised concentration at the paint surface discouraging the growth of settling organisms. This hydrolysis results in a softening of the surface layer of the co-polymer and together with the physical wearing away of the binder by the action of passing sea water, 'polishing', exposes fresh surface layers. With this mode of action the biocide relapse and polishing rates are both dependent on the same (chemical) process. The paint film thus smooths, reduces drag and turbulence until eventually, through these processes, the whole of the coating is exhausted. After initial rapid release, a steady biocide release is achieved; the life of the coating is proportional to its thickness and is accurately predictable. The co-polymer has a high mechanical strength, allowing build up of very thick systems and hence correspondingly long coating lifetimes. For deep sea vessels a maximum of 5 years in-service period can be specified with these products. Typically a 3 year specification for a TBT self polishing co-polymer product (at new building stage) requires two coats applied by airless spray giving a total dry film thickness of up to 300 microns, for 5 years three or four coats are needed resulting in dry film thickness of up to 600 microns.

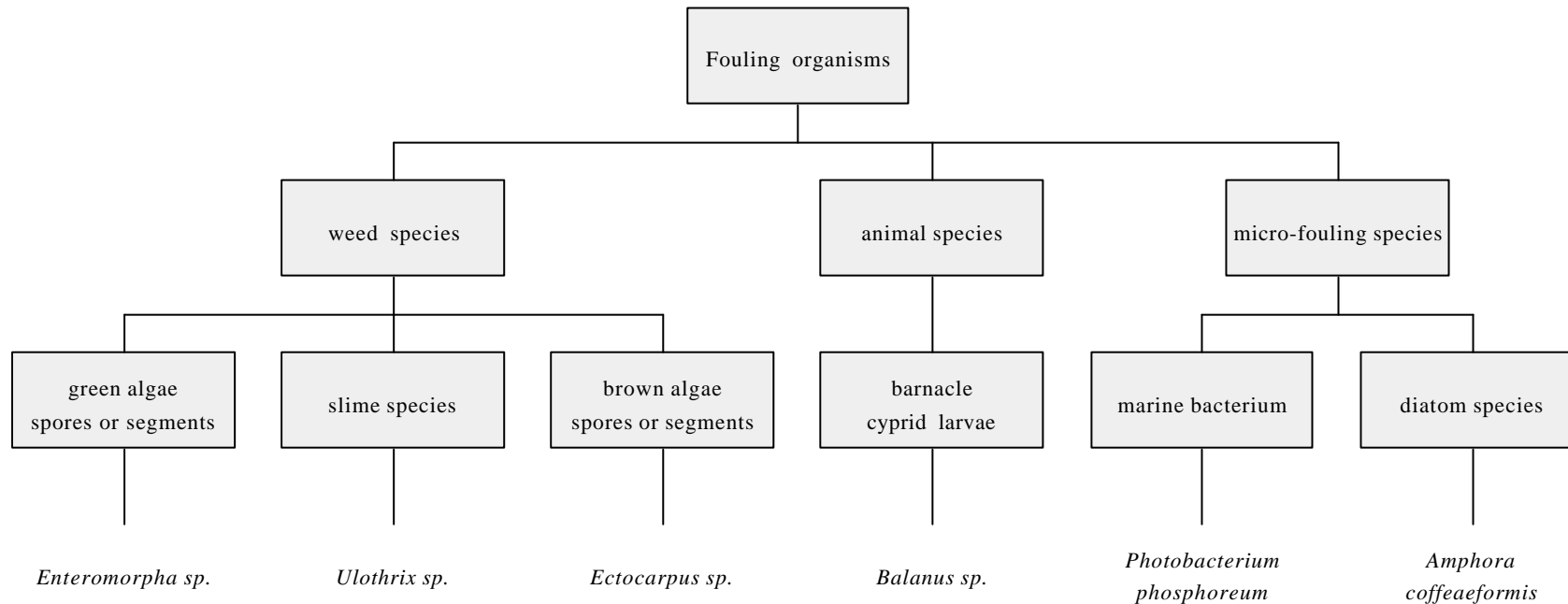
TBT-free self polishing

Coatings of this type rely on polymers selected from hydrolysable, soluble and insoluble resins. When in service these coatings polish, smooth and exhibit consistent biocide leaching rate and leach layer thickness. The lifetime of these coatings is directly dependent upon film thickness, and is accurately predictable. Extended in-service periods of up to 5 years can be specified. Since these new technologies are highly product specific it is not possible to provide generalised specifications such as recommended number of coats and final dry film thickness.

APPENDIX - 2

FOULING ORGANISMS THAT MAY BE USED IN LABORATORY TOXICITY SCREENING TESTS

The different groups of fouling organisms and an example of a species within each group are given in the chart below:



Notes: The green alga *Chlamydomonas* sp. can be used as a substitute or surrogate species for *Enteromorpha* sp.

The nauplia of the brine shrimp *Artemia salina* can be used as a substitute or surrogate species for species of barnacle.

The examples above are representatives of the fouling community, and not intended to be an exhaustive or prescriptive list of organisms that may be tested.