

Transitional Guidance on the Biocidal Products Regulation

Transitional Guidance on Efficacy Assessment for Product Type 21 Antifouling Products

May 2014

LEGAL NOTE

This document contains Transitional Guidance on Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Biocidal Products Regulation, the BPR).

Users are reminded that the text of the BPR is the only authentic legal reference and that the information in this document does not constitute legal advice. Only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

The European Chemicals Agency does not accept any liability with regard to the contents of this document.

Transitional Guidance on Efficacy Assessment for Product Type 21 Antifouling Products

Publ.date: May 2014

Language: EN

© European Chemicals Agency, 2014

Cover page © European Chemicals Agency

Reproduction is authorised provided the source is fully acknowledged in the form "Source: European Chemicals Agency, <http://echa.europa.eu/>", and provided written notification is given to the ECHA Communication Unit (publications@echa.europa.eu).

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at: http://echa.europa.eu/about/contact_en.asp

European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland

Visiting address: Annankatu 18, Helsinki, Finland

PREFACE

This Transitional Guidance is to be applied to applications for active substance approval and product authorisation submitted under the Biocidal Product Regulation (the BPR). This document describes the BPR obligations and how to fulfil them

This Guidance replaces the Technical Notes for Guidance (TNSG) on Data Requirements (EU, 2008a) in support of Directive 98/8/EC (Biocidal Product Directive - BPD).

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

This Transitional guidance document has been discussed and supported by the Efficacy WG of the Biocidal Products Committee (BPC). The document has undergone a "transitional" consultation with the Biocidal Competent Authorities and Accredited Stakeholder Organisations and is waiting for inclusion into Volume II Part B of the new BPR guidance structure.



NOTE to the reader:

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

Table of Contents

LEGAL NOTE	1
PREFACE	3
1. GENERAL INTRODUCTION.....	6
1.1 INRODUCTION.....	6
1.2 TYPES OF COATING.....	6
1.3 MODE OF ACTION	6
1.4 CATEGORISATION OF ANTIFOULING PRODUCTS.....	7
1.5 SPECTRUM OF ACTIVITY	7
1.6 DOSSIER REQUIREMENTS.....	7
1.7 LABEL CLAIMS	7
1.7.1 Areas Of Use.....	8
1.7.2 Application method/dose rate	8
1.8 EFFICACY TESTS.....	9
1.8.1 Laboratory tests (including in-vitro screening tests).....	9
1.8.2 Simulated field tests (static raft testing).....	9
1.8.3 Field tests/In-service monitoring	10
1.8.4 Replication of efficacy tests.....	11
1.9 STANDARD TEST METHODS.....	11
1.9.1 Simulated use test methods.....	11
1.9.2 Field/In-service tests	12
1.10 RESISTANCE.....	12
1.11 REPORTS OF DEVELOPMENT OF RESISTANCE SHOULD ALWAYS BE MENTIONED.SERVICE LIFE	12
2. PRODUCTS INTENDED FOR MARINE USE	13
2.1 INTRODUCTION	13
2.2 DOSSIER REQUIREMENTS	13
2.2.1 Heading level 3	14
2.3 ASSESSMENT OF AUTHORISATION.....	14
2.3.1 Norms and criteria.....	14
3. PRODUCTS FOR FRESHWATER USE.....	15
3.1 INTRODUCTION	15
3.2 DOSSIER REQUIREMENTS	15
3.2.1 Testing and field trials.....	15
3.3 ASSESSMENT OF AUTHORISATION.....	15
3.3.1 Norms and criteria.....	16
4. PRODUCTS FOR USE IN AQUACULTURE	16
4.1 INTRODUCTION	16
4.2 DOSSIER REQUIREMENTS.....	16
4.2.1 Testing and field trials.....	16
4.3 ASSESSMENT OF AUTHORISATION.....	16
4.3.1 Norms and criteria.....	17
5. APPENDICES	17

APPENDIX 1. CURRENT ANTIFOULING COATINGS 17

APPENDIX 2. PUBLISHED PAPER (CEPE ANTIFOULING WORKING GROUP) 19

APPENDIX 3. EXAMPLE OF HOW AN OVERALL FOULING ASSESSMENT MAY BE CARRIED OUT
FOR PANEL TESTING IN MARINE WATERS 24

This document deals with the methodology for the evaluation of efficacy tests for antifouling products that is applicable for the authorisation of products under the EU Biocidal Products Regulation (BPR, Regulation (EU) 528/2012).

1. General Introduction

1.1 Introduction

This chapter describes the nature and extent of data which should be available to support the label claims for biocidal products within Product Type 21 - Antifouling Products. These are defined in the BPR as "Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment, or other structures used in water".

1.2 Types of Coating

The antifouling products currently available can be categorised into the following broad coating types:

- Soluble matrix
- Insoluble matrix
- Self polishing

The categorisation of coating types outlined above is general. It should be noted that some antifouling products do not necessarily rely on one single coating technology and combinations of different technologies have been developed by antifouling formulators to suit customer specifications and environmental requirements. A description of the main coating types can be found in Appendix 1.

It should be noted that the protection periods described in the appendix for each coating type are typical life times that may be achieved by using products within these very broad groups. The efficacy of an antifouling coating will heavily depend upon use, for instance a vessel's operational pattern (such as dry-docking interval, sailing speed, and idle times as well as the temperature, fouling intensity, and other environmental characteristics where the vessel is trading). It also depends on the extent to which the antifouling paint specification has been tailored to meet these specific conditions. Surface preparation, primers, quality of work, dry film thickness, etc. may also affect the quality and/or duration of the protection.

1.3 Mode of Action

Antifouling products form paint films that act as release vehicles for the active substance(s) contained in the paints. The active substance(s) will be released over the specified lifetime of the products, creating a microlayer of biocide rich water at the paint surface. Here, in this water microlayer, the concentration should be sufficient to deter the settlement and/or growth of fouling organisms. A more detailed description of the respective modes of action and physical characteristics of the various coating types are outlined in Appendix 1 of this document.

1.4 Categorisation of antifouling products

Antifouling paints are made available for different use types. Typically they are prescribed for yachts, commercial vessels (such as bulk carriers, tankers, container ships, car carriers, passenger ships, etc.), and aquaculture.

The three broad categories of products (in Appendix 1) can be defined by the way in which the products control the release the active substance(s). Given the fact that a single active substance may not have a sufficiently broad spectrum activity to control the wide range of fouling organisms, antifouling products often contain more than one active substance.

1.5 Spectrum of activity

Target organisms belong to very different taxonomic groups. There are many organisms that can live within a fouling community, but only a few cause severe fouling problems. Which organisms will present a problem depends on the local conditions and the operation of the individual vessel. For example, typical target organisms in European waters may include, but are not limited to, various species of the following genus: *Pseudomonas* (light slime), *Amphora* (dense slime), *Ulva* (macro-algae), and *Semibalanus* (animals).

Fouling organisms and growth rates differ between tropical and temperate regions. The fouling intensity and the species that dominate a fouling community may vary locally and seasonally. While it is not normally feasible to claim efficacy against specific target organisms, applicants may choose to supplement their label claim that the product is an 'antifouling product' with an indication as to whether the product will be effective against one or more of the following fouling groups:

- Slime
- Weed (macro-algae)
- Animals

1.6 Dossier requirements

The following aspects are required for the efficacy evaluation of antifouling products:

1. The label claims and instructions for use including the technical data sheet
2. Efficacy data on the product

1.7 Label claims

For each product a set of label claims should be provided as part of the dossier submitted. Claims for the activity of the product include those made on a technical data sheet or other associated documentation, as well as those on the label itself. To simplify the text, only the term 'label claim' will be used below.

In general the claim for antifouling products can be rather unspecific, for instance 'antifouling product for professional application'. The label should also indicate to which fouling groups (see 1.5) the product is effective and whether it can be used in marine or fresh water.

The label claim for products used in areas other than on vessels, such as products used for aquaculture, in the inlet and outflow pipes of cooling systems, or for other "non-vessel" uses should be more precise, and clearly describe purposes for which the product can be used.

According to Article 69(2)(f) of the BPR the label must clearly and indelibly show the uses for which a biocidal product is authorised.

1.7.1 Areas Of Use

The product label, technical data sheet or other associated documentation should contain information on the main use categories for the product, for example use on vessels and larger boats, yachts, stationary installations, or aquaculture equipment, etc. This will normally also include information on whether the product is intended (primarily or exclusively) for use in either marine or fresh water.

As the fouling challenge is more severe under static conditions, installations and recreational boats (which are normally tied up in marinas) will foul more quickly than commercial vessels that spend most of their time in motion. Therefore, if a product is intended specifically for static or recreational use, this should be specified in the label claims.

(For human risk assessment purposes, it is important that a label claim specifies if a product is intended for amateur use or if is for application by professionals only.)

1.7.2 Application method/dose rate

Antifouling coatings may be applied using methods such as airless and conventional spray, brush and roller, or dipping and immersion (aquaculture). The specified total dry film thickness will vary depending on the intended dry-docking interval, activity of the vessel (such as sailing speed and idle times), and on the temperature, fouling intensity, and other environmental characteristics where the vessel is operating. Furthermore, larger vessels will normally have different antifouling products and different paint film thicknesses specified for different parts of the underwater hull depending on, for instance, water flow and light conditions. Some areas, such as those with less frequent maintenance intervals than those for the rest of the underwater hull, and those with strong water throughput (e.g. inside thrusters) may require higher film thicknesses to minimize the risk of transmigration of non-indigenous species in these areas.

It is important to note that the paint thickness does not affect the efficacy of a product, which will control fouling regardless of the thickness of the paint applied. Instead, the film thickness will define the in-service life of the product.

For antifouling paints there is no direct relationship between the applied dose (paint film thickness applied) and the efficacy of the product (unlike agrochemicals, for example, where applying more pesticide increases the concentration of the pesticide and therefore the magnitude of the controlling effect on the pest).

Recommended dry film thicknesses are given to ensure that enough paint is applied to the vessel to avoid the coating being 'polished through' during service, exposing the underlying anticorrosive paint which will be susceptible to fouling. When paint is applied by spray, more than one coat of paint is normally applied to protect against possible application defects, such as 'pin holing', where small areas of the anticorrosive are left exposed.

As the three major types of antifouling coatings (Appendix 1) vary in their ability to maintain a sufficient release of active(s), this is reflected in their different typical lifetimes.

1.8 Efficacy tests

1.8.1 Laboratory tests (including in-vitro screening tests)

Laboratory tests are typically conducted on a single active substance and with a limited number of test organisms, and may provide information about the specific action of a substance against a known fouling species. It is acknowledged that model target organisms may be used in these tests as well as those that may successfully be cultivated in a laboratory (e.g. juvenile barnacles). Consideration should be given to the use of species known to be critical fouling species.

Laboratory tests are routinely used to demonstrate efficacy of an individual active substance, often at a very early stage during research in order to screen new active substances.

Laboratory testing of individual paints is not undertaken as it is not considered to be a realistic evaluation of the product. Field testing is routinely undertaken instead (described below).

1.8.2 Simulated field tests (static raft testing)

These may be studies that are conducted with the candidate product or with the active substance(s) incorporated into a model coating type. Such tests involve the immersion of panels treated with the test coating on static rafts for a period of months or years at an appropriate location. For aquaculture products this could be nets or (sections of) cages treated with the test product and immersed at an appropriate site.

Efficacy data on antifouling coatings should normally be generated by testing over at least six months of peak fouling activity. As far as is practical the test location(s) should be representative of the intended uses of the product. When testing in locations with seasonal variation in fouling challenge, the test period should cover the full fouling season. The length of a season will vary depending on the location of the test site. When choosing the test location(s), factors such as shelter (from strong waves and ship traffic) and access have to be balanced against water exchange conditions and other characteristics determining whether the water at a site is representative for the end use conditions.

Since raft testing is carried out in natural environments, the same product may perform differently at the same site in different years. This variability in fouling intensity, and thus the test results, is due to weather conditions, availability of nutrients, and other uncontrollable factors that may affect the type and extent of fouling and its rate of settlement and growth. Therefore, a negative control (a surface which has no antifouling effect) should be included in all tests, which will indicate the degree of fouling that would be present under static conditions if the tested coatings were totally ineffective. A reference coating of proven or known efficacy (a positive control) may also be used. The absolute amount of fouling present on a test coating may not be reproducible at the same site from year to year.

Efficacy studies include regular assessments of fouling throughout the period. These assessments usually describe the major types of fouling (e.g. slime, algae and other weeds, and barnacles or other fouling organisms), but describing these as to genus and species is unnecessary. As sharp edges on test panels may be difficult to protect, fouling that is not growing on the front of panels (i.e. attached along the edges) should be disregarded.

The presentation of data should include the assessment method (the rating/scoring for the test panels and how these are interpreted), together with photographs and/or diagrams of the test panels.

1.8.3 Field tests/In-service monitoring

Since field tests involve long-term exposure to practical conditions, they can be regarded as in-service tests. Field tests permit antifouling products to be tested under similar operating conditions and stresses as those encountered when the antifouling product are in service. Possible examples of these tests include:

- Panel tests where coated panels have been attached to a vessel during parts of or during a complete dry-docking interval
- Patch tests where vessels have been painted with the test coating as a strip or patch on the hull
- In-service monitoring of aquaculture nets, cages, etc.

Any field data generated in support of an application should be conducted on the candidate product or representative products that closely resemble the fully formulated commercial product. A robust justification should be provided to support bridging of data from a similar (but not identical) product.

It is recognised that it may not be possible to run concurrent untreated panels or patches during field trials. Therefore information on the performance of the main antifouling coating over the test period should be provided instead. Monitoring reports of the performance of an antifouling product on a fully treated vessel may also be submitted, where these are available. It is also recognised that data generation from field trials may require many years to carry out and are more likely to be available for well-known technologies than for products containing new active substances (or new combinations or concentrations of active substances) or for coating types based on new technologies.

Where field data are not available, the applicant has the option to provide data on other existing formulation(s) where appropriate, and read across to the current application through scientific reasoned cases and arguments. Such arguments may include:

- The composition of the 'old' (and well documented) and the 'new' antifouling product
- Simulated field tests of the 'old' and the 'new' antifouling product
- Possible field data on the 'old' antifouling formulations
- Further justification, such as why bridging is appropriate (e.g. in-service monitoring)

It is understood that extensive field data or bridging data may not be available when established biocides have been introduced into products based on new technology or new active substances are being developed. Field tests from different ships have limited value for the purpose of comparing efficacy due to the diversity of operational patterns and trading routes and the likeliness for unforeseen circumstances or incidents not recorded. This, together with the complexity with respect to application and monitoring and the long exposure times required, explain why in-service tests are normally not available for new antifouling products. However, when data on in-service/field tests are available, these should be submitted as additional information.

However, field data are required at renewal of a product authorisation, as the product will have been on the market for several years by this point. Further guidance on how to perform and assess these data will be developed in the future and incorporated into this guidance.

1.8.4 Replication of efficacy tests

Antifouling paints are normally tested in series during product development, where panels treated with a range of formulations, with only small variations between them, are tested to assess the effects of exposure on other paint properties, as well looking at the efficacy of the formulations.

Since the testing takes place in a natural environment, the variation in fouling propagation and intensity between different years at the same test site will vary. A variable natural environment, the differences in fouling activity between years, and the criteria for establishing efficacy (the general nature of a label claim) make very detailed evaluations unnecessary.

However, to increase the scientific rigour of the evaluation, the results of three replicate plates should be submitted.

It is acknowledged that it is not common practice to test multiple replicates of individual formulations, however panels treated with similar formulations containing the same combination and concentration of active substances may be considered replicates when these are supported by a suitably robust reasoned case explaining the relevance of these formulations to the candidate product. The results from such panels should be submitted, along with details of the formulations used, as well as the reasoned case.

1.9 Standard test methods

1.9.1 Simulated use test methods

The standard test methods available for the generation of simulated field data through raft testing of antifouling coatings are:

1. Efficacy evaluation of antifouling products. Conduct and reporting of antifouling efficacy evaluation trials. CEPE Antifouling Working Group, June 2012. This methodology has also been adopted by the International Paint and Printing Ink Council – IPPIC and presented at Technical Meeting I 2013 PT 21 efficacy workshop (Appendix 2).
2. American Society of Testing Methods (ASTM) - ASTM D3623 - 78a (2004) Standard Test Method for Testing Antifouling Panels in Shallow Submergence which is linked to ASTM D6990-5(2011) Standard Practice for Evaluating Biofouling Resistance and Physical Performance of Marine Coating Systems.

Reports based on both the above methods should be accepted.

However, it should be noted that the ASTM methods were primarily developed to satisfy the detailed requirements of the US Navy and are not commonly used by the general antifouling industry. The main reasons for this are that they are resource intensive (in terms of the level of detail required in both the materials used as well as the analysis and reporting of the fouling species [including the number and diameter of individual organisms), thereby exceeding the requirements for substantiating a general product label claim (since normally specify only the general types of fouling and their extent are reported for regulatory purposes)] and that they specify relatively dated materials (paints), for which better and more applicable alternatives are available. Notwithstanding, the methods may provide a good basis for biological research.

1.9.2 Field/In-service tests

There are currently no national or international standards that cover field evaluation of antifouling products. Field tests (application on ships) are rarely used to screen formulations and establish the basis for an efficacy claim since they are time consuming and costly and since the results are heavily dependent upon the operations of individual vessels. To the extent field trials are used, their purpose is normally to determine relative differences in efficacy between already commercial formulations during different use conditions (such as vessel speed, idle times, etc.).

Typically a new antifouling paint represents an incremental improvement or an adaptation to a specific user requirement. Normally, therefore, the experience from similar commercial products will contribute to the confidence the manufacturer has with respect to the efficacy of a new product.

However, at the point of renewal of a product authorisation, a product will have been on the market for several years and field data should be generated to demonstrate the actual performance of the product in use.

1.10 Resistance

Resistance is discussed in the general part of the TNsG on Product Evaluation in Chapter 6. A review of resistance is part of the evaluation at product authorisation. If new information is available which was not reviewed during the approval of active substance, this information should be provided at the time of product authorisation.

In general development of resistance is not to be expected for marine use, as ships are treated with several antifouling paint products containing different active substances. However, this may not be the case for use in fresh water and aquaculture.

1.11 Reports of development of resistance should always be mentioned. Service life

Amateur antifouling products for recreational crafts are normally claimed to last for one yachting season, and are recommended to be retreated annually. Commercial vessels will have extensive tailor made paint specifications depending on their dry-docking interval and operational pattern. Different products and film thicknesses are frequently used at different parts of the vessel due to different light conditions and hydrodynamic forces. In the case where a label claim includes different types of use (e.g. both vessels and static installations), the corresponding protection times may differ.

With respect to the ability of fouling organisms to settle and attach, static conditions are much more favourable than the conditions on vessels that are only idle for relatively short periods at the time. This together with the greatest levels of marine growth occurring in near shore conditions (as described in 2.1), explain why static raft testing is a worst case test. For recreational craft, however, the use conditions may be very different. Therefore, tests are frequently carried out for the same number of fouling seasons as the recommended use.

It is not obligatory to state on the label what the service life of a product will be.

2. Products intended for marine use

2.1 Introduction

Raft tests represent worst case conditions with respect to fouling intensity due to their static nature and because the tests are carried out in near shore environments. As the release of active substances from antifouling paints is assisted by hydrodynamic forces (i.e. through polishing), fouling will be more severe on static surfaces compared with moving boats and ships.

Coastal waters are known to have the highest fouling intensity. The littoral zone along coasts constitutes a tiny part of the world's oceans, but contributes markedly to the total marine production. The reason is that benthic production (per unit surface area) exceeds pelagic production by a factor of ten. Coastal macrophytes account for two-thirds of the total biomass of marine photo-synthetic organisms although they can only inhabit less than 0.5 % of the surface area of the oceans¹. Therefore, when efficacy is demonstrated in coastal waters (the worst case situation), a product is also assumed to be effective in open sea and brackish conditions, and the data can be used to support these uses.

2.2 Dossier requirements

A report of the results from efficacy testing may also include the following about the test site, the test procedures, and the data reported:

- Method of application and information on the panel type and panel preparation
- Location, geography, and water exchange conditions
- Water temperature and salinity, including seasonal variations
- Orientation, dimensions, and exposure depth of the test surface
- Dimensions and type of material of test panels
- Identity of the tested product and the control(s)
- Details on the panel preparation (application technique, possible primer paint, paint film thickness, number of coats)
- Date and duration of test
- Date and raw data from each individual assessment of a test panel
- Photos of test panel and control(s)
- The overall fouling assessment rating at each inspection during the exposure period
- A description of the reporting company's weighting system used to provide the overall fouling assessment rating. This should include how fouling coverage has been weighted in order to provide an overall efficacy assessment. The description should be transparent and explicitly explain the calculations carried out. (See example in Appendix 3)
- An interpretation of the data including a conclusion and a discussion of the validity of the results relative to the unprotected reference and the label claim for the product tested

¹ R.S.K. Barnes and R.N. Hughes. An introduction to Marine Ecology. Blackwell Scientific Publications, 1986. Page 37-39

2.2.1 Heading level 3

The recommended method for demonstrating efficacy of marine antifouling products is static raft testing. Raft testing allows a high number of formulations to be tested at worst case conditions.

At least one raft test in European coastal waters should be provided. Test in Atlantic or Northern European Seas are preferred; however, other European waters are acceptable too. It is preferable to also provide the reports from additional tests, although these additional tests can be performed in other locations (e.g. in Europe or elsewhere in the world). At least three replicate panels should be provided per product (see section 1.8.4 for more information on replication of tests). Tests should be performed for at least one fouling season, which is at least six months covering the period of peak fouling activity.

2.3 Assessment of authorisation

The ability a product has to produce an antifouling effect is determined by a combination of the activity of the active substance(s) and the mechanical/physico-chemical properties of the paint. Parameters that will define the efficacy of an antifouling product include:

- The potency and release rate of the active substance(s)
- Operational patterns (e.g. speed, idle times, dry-docking interval, etc.)
- Physico-chemical conditions of the water and other climatic, seasonal, or local factors affecting fouling intensity (e.g. concentration of nutrients, hours of daylight, salinity, temperature, presence of ice, turbidity, etc.)

The efficacy data submitted in support of an application represent part of the information assessed to establish if the product has the claimed level of efficacy. It is recognised that the actual in-service performance of an antifouling product will be dependent on a range of factors, which may include how and where a boat or vessel is operated, seasonal and annual variations, as well as the specifics of the antifouling coating itself. Commercial vessels receive tailor-made product specifications in order to meet various planned (and unforeseen) operational conditions. Thus, the general efficacy of a product under typical fouling conditions according to criteria in paragraph 2.3.1 should be demonstrated.

2.3.1 Norms and criteria

The purpose of an efficacy test is to support the label claim. Efficacy is evaluated by comparing the extent of fouling on the test substrate with the fouling on a similar, but unprotected substrate which has been exposed simultaneously and at the same site.

Fouling coverage is frequently evaluated based on the coverage of the typical marine fouling species such as slimes, algae and animals (barnacles, mussels, etc.).

The three types of fouling species (slime, macro-algae and animals) may be rated differently when merged to an overall fouling assessment for the tested product since slime fouling is less significant compared to macro-fouling (for instance for the fuel consumption and manoeuvrability of a ship). An overall fouling assessment may describe the efficacy of a panel in categories such as for instance: 'Excellent', 'Good', 'Fair', and 'Poor'. An example to illustrate how the coverage of the main categories of fouling may be combined to provide an overall fouling assessment is given in Appendix 3.

Since different companies may use different overall fouling assessment systems and interpretation of the result may vary with the type of product (what is 'poor' efficacy for marine water vessels might be 'good' for fresh water yachts), these ratings are not used as

the pass/fail criterion for authorisation. Instead, the percentage fouling on the control and test panels is used.

Normally, when tested in marine waters, the negative control will have at least 75 % fouling coverage at the end of the test. In this case, the result from a product under test should be acceptable if the coverage of macro-fouling on the panels is below 25 %. Macro-fouling is defined as large, distinct multicellular organisms visible to the human eye such as barnacles, tubeworms, or fronds of algae². Algae shorter than 5 mm should be regarded as micro-fouling, together with slimes.

If the 25 % criterion is not met, a justification should be provided for why the product may still be regarded as sufficiently efficacious for the intended use.

3. Products for freshwater use

3.1 Introduction

Fresh and brackish waters are known to represent a less severe fouling challenge compared to marine waters. Effective antifouling protection may be environmentally important even where the general fouling challenge is low. For example, to reduce the risk of translocating invasive species (such as zebra mussels) into or between inland waterways, lakes, or brackish seas.

3.2 Dossier requirements

See 2.2 for the requirements on reporting the test procedure and data.

3.2.1 Testing and field trials

For products intended for use in both fresh water and marine waters, a raft test in marine coastal water is sufficient and a separate efficacy test under fresh water conditions is not normally carried out for. Since fresh and brackish waters are known to represent a less severe fouling challenge compared to marine waters, it is common practice to use the bridging principle and refer to tests conducted in marine waters.

For products only intended to be used in fresh water, at least one raft test in fresh water should be provided. When raft tests are carried out in fresh water, the test site should be one known to have relatively high fouling levels, preferably in an area where zebra mussels are present. However, it is preferable to also provide the reports from additional tests. At least three replicate panels should be provided per product (see section 1.8.4 for more information on replication of tests). Tests should be performed for at least one fouling season, which is at least six months covering the period of peak fouling activity.

3.3 Assessment of authorisation

See section 2.3.

² IMO's 2011 Guidelines for the Control and Management of Ship's Biofouling to Minimize the Transfer of Invasive Aquatic Species, Section 2.1. Definitions.

3.3.1 Norms and criteria

The purpose of an efficacy test is to support the label claim. Efficacy is evaluated by comparing the extent of fouling on the test substrate with the fouling on a similar, but unprotected substrate which has been exposed simultaneously and at the same site.

In the case that an efficacy test is carried out in fresh water, it should be noted that as the fouling challenge is low, a 75 % or more coverage of fouling organisms on a negative control test panel cannot be expected. Therefore, if a test is carried out where micro-fouling is predominant and the coverage of macro-fouling is less than 75 %, the test may still be valid. In the case where less than 75 % of the surface of the negative control is covered with fouling, an explanation should be provided for why the test should be considered valid.

It is also possible that in freshwater, macro-fouling (such as freshwater hydrozoans or zebra mussels) may completely cover a negative control.

For tests in fresh water where the control panel has 75 % or more coverage of fouling organisms, the result from a product under test should be considered acceptable if the coverage of macro-fouling on the panels is below 25 %.

For tests in marine water see Section 2.3.1 for criteria.

4. Products for use in aquaculture

4.1 Introduction

In aquaculture use, antifouling products are used to treat infrastructure, including immersed structures such as cages, nets, ropes, buoys and pontoons, as well as equipment such as pipelines, pumps, filters, and holding tanks.

4.2 Dossier requirements

See 2.2 for the requirements on reporting the test procedure and data.

4.2.1 Testing and field trials

Relevant field or simulated use trials should be provided to demonstrate the efficacy under in-use conditions. Static testing closely resembles real life conditions for aquaculture use. Test surfaces may include panels and net/cage samples suspended securely from the raft.

At least one field test should be provided. However, it is preferable to also provide the reports from additional tests. At least three replicates should be provided per product (see section 1.8.4 for more information of replication of tests). Tests should be performed for at least one fouling season, which is at least six months covering the period of peak fouling activity.

4.3 Assessment of authorisation

The ability a product has to produce an antifouling effect is governed by mechanical and physico-chemical properties of the paint. Relevant parameters to be taken into account when assessing the efficacy of an antifouling product include:

- The potency and release rate of the active substance(s) in the paint

- Physico-chemical conditions of the water and other climatic, seasonal or local factors affecting fouling intensity (e.g. concentration of nutrients, hours of daylight, salinity, temperature, presence of ice, turbidity, etc.)

A report of results from efficacy testing should include the following information about the test site, the test procedures, and the data reported:

- Method of application (e.g. dipping of nets) and type of test substrate
- Location, geography, and water exchange conditions
- Water temperature and salinity
- Orientation, dimensions, exposure depth of test surface, and date and duration of the test
- The extent and main categories of fouling and an interpretation of this relative to an unprotected surface and the label claim for the product tested

4.3.1 Norms and criteria

The purpose of an efficacy test is to defend the label claim. Efficacy is evaluated by comparing the extent of fouling on the test substrate (panel, cage, net, etc.) with the fouling on a similar, but unprotected substrate which has been exposed simultaneously and at the same site. Efficacy is demonstrated if fouling on the treated surface is considerably reduced compared to the fouling on the unprotected surface.

Fouling coverage is frequently evaluated based on the coverage of typical fouling species. These ratings are then merged to provide a consolidated figure for the three major types of fouling species: slime, macro-algae and animals (Appendix 3, Table 2). The three types may be rated differently when combined to an overall fouling assessment for the tested product. For example, slime fouling is less significant compared to macro-algae and large hard animals for the water exchange through nets and cages.

If a product for aquaculture use is tested on panels, the pass/fail criteria for the test may be the same as in paragraph 2.3.1.

5. Appendices

Appendix 1. Current Antifouling Coatings

The current major types of antifouling coatings are outlined below, together with a brief description of their properties. This list is not exhaustive, and product applications may not fall within these categories. Applicants may submit novel coating types not covered by this list.

Coating Type	Description, mode of action and properties
Soluble matrix	<p>In coatings of this type the active substance(s) has (have) been physically mixed ('freely associated') into a resin matrix. Upon exposure to seawater the slightly acidic matrix slowly dissolves releasing the active substance(s) into the water. (Seawater is slightly alkaline (pH 8) and the acidic matrix dissolves). Continuous dissolution of the coating surface will occur resulting in fresh actives being released until eventually the film is exhausted. Soluble matrix antifouling products typically show a biocide release rate curve which decays exponentially.</p> <p>The soluble matrix coatings have reduced mechanical properties that limit their</p>

	<p>film thickness. The paint film thickness of these coatings depletes over time in a fairly imprecise manner and the film does not show smoothing characteristics on ships in service. Such coatings are normally specified for lifetimes of typically 12-36 months.</p>
Insoluble matrix	<p>This type of coating contains a mixture of resins that together form an insoluble binder phase. One or more active substances are physically mixed into this matrix. As seawater enters the paint film, the biocides are released by dissolution and diffusion from within the insoluble matrix. After active substance have been 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 active substance(s) have further distance to travel through the paint film. The 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.</p> <p>Insoluble matrix antifouling coatings do not show film-depletion or polishing as the resin is insoluble. The biocide release process continues until exhaustion of the coating. The higher mechanical strength obtained with these coatings allows for applications of thicker systems and coating lifetimes of typically 12-36 months are attainable.</p>
Self polishing	<p>This group is currently the most common and covers a range of different technologies that deliver the active substance through a gradual depletion/ablation of the paint film throughout the lifetime of the coating.</p> <p>These coatings use binder systems which control polishing behaviour by different mechanisms. A broad range of binder technologies are found in this group and these have replaced TBT copolymer based paints which have been withdrawn from use. Binder systems range from those based on the dissolution of metal carboxylates and polymers relying on ion-exchange to polymers relying on hydrolysis to control the rate of polishing.</p> <p>Modification of the binder systems and pigment phases of products within this group can be used to tailor the products towards different end uses. The requirements for protection of a fast moving and very active vessel can be very different from that of a slow moving less active one. Such modifications can also be used to tailor performance to accommodate the potential intensity of fouling.</p> <p>The different binder technologies can be used alone or in combination and result in products with varying levels of antifouling protection. Other binder components may also be added in order to modify the overall properties of the paint film. Typical dry-docking intervals for vessels coated with self polishing antifouling paints range from 24 to 60 months, however these systems may also be specified for lifetimes beyond this period.</p>

Appendix 2. Published paper (CEPE Antifouling Working Group)

NOTE: In the following CEPE methodology there are several issues that contradict with the requirements in the guidance document (e.g. number of trial panels, period of testing). The CEPE methodology can be used as long as the agreements of the guidance are respected.

TMI2013-PT21_efficacy_workshop-CEPE Efficacy Methodology for BPR - Revised 19 June 2012.doc

The European Council of producers and importers of paints, printing inks and artists' colours
- CEPE

Guidance developed by the CEPE Antifouling Working Group

Efficacy evaluation of antifouling products

Conduct and reporting of static raft tests for antifouling efficacy

Specific scope

This document provides a baseline methodology for evaluating and reporting the efficacy of antifouling coatings. Efficacy is assessed by static raft testing relative to a negative control and, if used, a positive control coating. Efficacy may be indicative of, but has no direct one-to-one relationship with the actual performance of a product under real life conditions.

Document version

First approved in 2011-04.

Revised in 2012-06

1. Scope

Overview: The purpose of this document is to provide a methodology for determining efficacy of antifouling coatings by panel testing on static floating rafts. The document provides guidance on how to conduct, assess, record, and report results from efficacy evaluations.

Efficacy is evaluated relative to a suitable inert, negative control. A positive control of proven antifouling performance may also be included. This static exposure methodology for natural environments is not suitable for establishing absolute performance characteristics of antifouling coatings in service.

Objective: This methodology may be used by industry to obtain efficacy data during the development of new antifouling coatings. This methodology may also be used to provide national registration authorities with the information required to support the label claim of antifouling products. Efficacy is demonstrated

when the extent of fouling is visibly less than on a blank panel.

The methodology is especially useful for:

- the persons responsible for writing the protocols for antifouling efficacy trials
- the persons responsible for conducting trials including the evaluation and recording of results
- the persons responsible for assembling and submitting dossiers for the registration of antifouling paints
- the national authorities which are responsible for the assessment of registration dossiers.

Reproducibility and accuracy: In static raft testing the fouling intensity will vary significantly between different geographical locations, between positions on the same rafts, and from season to season. More importantly, fouling will vary from one year to the next even for identical panels where exposure starts around the same date in different years. This variability in fouling intensity, and thus the test results, is

due to weather conditions, availability of nutrients, and other uncontrollable factors that may affect the type and extent of fouling and its rate of settlement and growth. Therefore, the absolute amount of fouling present on the test coating and controls may not be reproducible at the same site from year to year.

Interpretation of results: The results obtained by this methodology demonstrate the ability of antifouling coatings to prevent settlement of fouling organisms under static conditions relative to a suitable negative control and, if used, a positive control tested simultaneously at the same site. An evaluation of the relative antifouling effect of an antifouling coating compared to the negative control and, if used, the positive control is used as a tool to indicate the potential of a tested coating to protect underwater structures. The results can be used to support appropriate label claims of the antifouling coating tested and to screen for new candidate products.

Efficacy testing on raft panels represents a worst case scenario compared to real life conditions. The main reason is that the exposure is static with limited opportunity for organisms to be removed by hydrodynamic forces. Ships' and boats' movement through water also aid the release of active ingredients from their antifouling. Furthermore, fouling intensity is generally recognised as being greater near the coast relative to the open seas.

2. Definitions

Antifouling coating: A material which, when applied as a surface coating, is used to control the settlement and/or growth of fouling organisms on submerged surfaces including ships, boats, aquaculture equipment, offshore oil installations, and other man made structures.

Negative control: An inert reference surface that does not control fouling, e.g. an anti-corrosive coating.

Positive control: A reference surface coated with an antifouling coating of appropriate efficacy relevant to the intended end use of the test coating.

Fouling season: The months of the year during which significant settlement and growth

of fouling organisms typically occur on a negative control at the test site.

3. Apparatus

The following equipment will be required to undertake efficacy testing according to this methodology.

Panels: Panels are typically made of plastic (e.g. PVC), reinforced polyester, steel, aluminium, marine grade plywood, or other material suitable for extended immersion in natural waters. (Metal panels must be adequately protected with an anticorrosive paint system.)

Panels should be designed to allow them to be securely fixed to the test raft, for example via a suitable panel rack. Where the design requires fixing holes through panels, these holes should be drilled prior to the application of the coating to prevent damage.

The panels may be designed to allow one or more coatings and/or controls to be tested on each individual panel. The total immersed area of each coating or control should be no less than 100 cm².

Raft: A free floating platform which has been designed to allow test panels to be affixed and immersed at a constant depth in natural waters. The design of the raft should enable panels to be readily removed for inspection.

The minimum depth of water below the raft at low tide should generally be 2.5 m.

The floating raft should be of sufficiently rigid construction to withstand prolonged exposure to weather and wave action and prevent excessive flexing or movement of test panels. It should be designed to ensure the occupational safety of users.

The raft should be designed to ensure that all test coatings and controls of the same test series are exposed to similar levels of sunlight and water flow to minimise variation. To increase the testing capacity, panels may be affixed to the raft in rows at the same depth. Where relevant the spacing between parallel rows at the same depth should generally be at least 20 cm to allow sufficient water circulation and illumination.

Generally, the raft design should ensure that panels are fully and permanently immersed. Panels should normally be exposed vertically and at a fixed depth from 0-3 m below the water surface. The lower edge of the panel should always be at least 0.5 m above the sea bed.

The raft may also be designed to allow coatings that are intended for use in darker or lighter areas to be tested under relevant conditions where the coating receives less or more sunlight. In such cases panels may be mounted on the raft facing partly down or up. Shade may also be provided by covering parts of the raft.

4. Safety

This test methodology does not address possible safety, health and environmental concerns associated with its use. All operations should be performed in accordance with all relevant local and national regulations.

Personal protection: Antifouling coatings may contain hazardous materials that could cause skin and eye irritation on contact and adverse physiological effects if inhaled. Thus, application and drying should take place in a well ventilated area and appropriate personal protective equipment should be worn during application. Product safety data sheets should be consulted when available.

Environmental protection: Unused paint and other contaminated material as well as panels after exposure should be disposed of as hazardous waste.

5. Procedure

All controls and test antifouling coatings should be tested under equivalent conditions. The exposure (immersion) of controls and test antifouling should start simultaneously (around the same date) and the exposure should be at the same location at the same depth and orientation.

Panel preparation: The test coating and positive control should be applied to panels according to the manufacturer's guidelines to ensure adhesion during the period of the study. Appropriate drying and recoating intervals and temperature and ventilation requirements for application of the coatings should be followed.

An appropriate means of application should be used. Typical methods include spray, roller, brush, or specialised application equipment like a bar type applicator. Sufficient film thickness, taking the expected polishing and leaching rate characteristics of the product into account, should be applied to last for the planned duration of the test. Unless both sides of a panel are used as test substrates, the back of the panel may be coated with an antifouling of proven efficacy to prevent fouling on the back. Edges may be painted with the coating under test or with a different coating of proven efficacy. All panels should be marked indelibly with a suitable reference code to aid identification.

Replicates: In cases where the purpose of the test is simply to demonstrate the efficacy of a test coating relative to a negative control, the use of single panels may provide data of sufficient quality. When replication is used, the number of replicates should be appropriate for the specific purpose of the test and should have the same orientation as the test panels and controls. Read-across to efficacy data from other test panels in a test series of similar formulations with the same content of active ingredients may also be used when justified and reasonable to support the results obtained for the test coating.

Exposure time: To verify efficacy, the minimum immersion time for testing is six months. In locations where the fouling season is shorter than six months this period may be reduced. The efficacy test should cover at least one continuous and complete fouling season where appropriate. Since raft panel exposure is static, fouling intensity is high, and the tests may be regarded as an accelerated test for products for vessels.

6. Evaluation

Frequency: Antifouling coatings under test and controls should be regularly inspected and evaluated for surface fouling, typically about every two months during the fouling season. Evaluations are not necessary during periods where there is minimal settlement and growth of fouling organisms (e.g. in cold and temperate regions where winter conditions do not support fouling settlement). Generally, the panels will be removed from the water for evaluation and,

except at the end of the test period, returned to the water immediately after evaluation.

Rinsing: Optionally, panels may be rinsed gently with water from the site in order to reduce the influence of non-sessile organisms (that would be removed by low shear forces). Rinsing may also be carried out to remove possible sedimentary material (clay or silt). If utilised, rinsing must be performed on all panels equally and at each inspection. The method chosen, or if panels are not rinsed, must be specified in the final report.

Evaluation procedure: The type and severity of fouling that is present on the test coating and controls shall be assessed at each inspection. Evaluation may be made by visual assessment on site or any other appropriate method e.g. image analysis. The three major types of fouling observed on the test coating or controls; Slime, algae, and animals, should be separately assessed since the same percentage of coverage may have very different economical penalties during actual in-service use (e.g. effect on the friction of a vessel through water). Also fouling organisms that are known not to attach on moving vessels, but may be frequent on static surfaces, should be assessed separately (e.g. amphipods).

Further classification of the fouling organisms present may, in addition to slime (biological film of microfouling including bacteria, diatoms, micro-algae, and extracellular biopolymers), generally be restricted to main categories such as green, red, and brown macro-algae, bryozoa, hydrozoa, barnacles, tube worms, ascidians, and mussels. A more detailed determination is generally not necessary since products shall prevent attachment of fouling irrespective of species (or other taxonomic ranking).

As the assessment is based on a visual inspection, it is advised that this is done by a trained operator. This will help to improve consistency and data quality.

Assessment for the severity of fouling for each type of organism should be semi-quantitative, for example using a scale from 0-4, where 0 indicates the absence, and 4 indicates complete coverage of the class of organism in

question. Optionally an estimation of the percentage coverage can be used.

The assessment of the coverage of algae and other soft fouling (e.g. arborescent bryozoans, and hydroids), should be based on the area covered by the "hold fast" (the attached base of the organisms) and not by the area covered by the "fronds" (leaves of macro-algae) or offshoot colonies.

Overall fouling assessment: The individual assessments of the fouling coverage of each type of organism may be combined to provide an overall fouling assessment. To generate this, a weighting of the coverage of the different types of fouling may be applied to rate and characterise the severity of the fouling present.

When the coating under test is intended for use on ships, fouling never seen on active vessels (e.g. amphipods) may be disregarded during the weighting. Biofouling attached to other fouling organisms (secondary fouling) should also be excluded from the overall fouling assessment.

Only the fully immersed surface area (if parts of the panel are subject to splash only) should be included in the determination of the fouling rating. Fouling attached within 1 cm from all edges of the test panel and fouling around the cable ties/studs/etc. may be disregarded in cases where an edge effect is seen. (Fouling around edges is normally attributed to insufficient antifouling paint film thickness around sharp panel edges.)

Fouling caused by physical defects or damages in the substrate or accidental damages of the antifouling should be disregarded. Fouling on exposed anticorrosive paints or other substrates (except where these are used as negative controls) or on other antifouling paints that may be used to coat panel edges, should be excluded from the assessment.

Physical defects (detachment, blistering, cracking, etc.) attributed to the inherent properties of the antifouling paint itself should be recorded and reported.

Photos: Inspection reports should include panel photos from each inspection.

7. Reporting

The report should contain all relevant information obtained from the efficacy trial for a given product. This may include:

- The name of the reporting company (and client if the test is carried out on assignment)
- The geographical location of the test raft(s) (including longitude and latitude)
- The geography (e.g. open sea, bay, estuary, etc.), depth of water, and water exchange conditions (tide, currents) at the raft site
- Typical local conditions. E.g. water temperature, salinity, and pH at the raft site
- Relevant information on the typical fouling community at the test site and seasonal influences where applicable.
- A discussion of any special conditions or variables that may have arisen particular to the specific test
- Orientation and exposure depth of test panels
- Dimensions and type (material) of test panels
- Identification of the tested product and control(s)
- Details on the panel preparation for the product under test and the control(s) (No. of coats, film thickness, application technique, etc.)
- Number of replicates if used
- Initial date of immersion and the cumulative exposure time (in months) for subsequent inspections
- Raw data from each individual assessment of a test panel
- The overall fouling assessment rating at each inspection during the exposure period
- Photos of test and control panels
- A systematic appraisal of the efficacy of the test product in relation to the negative control and, if used, any positive controls and the method by which that appraisal has been conducted
- A description of the reporting company's weighting system used to provide the overall fouling assessment rating
- A discussion on the validity and acceptability of the test result relative to the intended label claim for the product tested when commercialised [e.g. recommended use area (recreational yachts, ships' niche areas, ships' flat bottoms, ships' water line,

etc.) protection time/dry-docking interval, fouling conditions in targeted markets, etc.].

- An interpretation of the test data generated and a conclusion on the efficacy of the coating under test.

Appendix 3. Example Of How An Overall Fouling Assessment May Be Carried Out For Panel Testing In Marine Waters

In order to assess panels out in the field, an effective and simple system is needed. Very detailed assessments of fouling coverage do not increase the quality of the test, as field conditions are highly variable and static raft tests can only provide an indication of products' real life performance.

Individual companies have different ways of assessing the coverage of the main categories of fouling into an overall description of the efficacy of test panels. However, the principles of the example should apply to most assessment systems. Transparency of how the overall assessment is carried out is important in order to evaluate an efficacy report.

The fouling coverage on raft panels will be assessed based on coverage intervals. Each interval will be recorded by a different 'rating'.

Table 1: Example of categorisation of fouling coverage into ratings from 0 to 4

Fouling Coverage (examples of company specific intervals for coverage of fouling)		Rating
Company 1	Company 2	
0-10%	0%	0
10-30%	>0-25%	1
30-50%	25-50%	2
50-80%	50-75%	3
80-100%	75-100%	4

As different fouling species can contribute to different impacts on a vessel (e.g. fuel consumption of a ship), the coverage ratings may be weighted in several ways to take this into account. The applicant may provide references to literature that provide more detail on the assessment and weighting factors³.

Table 2: Example of weighting of ratings

Type of fouling	Weighting (of ratings from 1-4)			
	Trace (1)	Slight (2)	Medium (3)	Heavy (4)
Light slime	0	1	3	5
Dense slime	3	5	10	20
Macro-algae	5	10	30	50
Animals	5	10	30	50

³ e.g. IMO MEPC/60/4/21, 2010 from IPPIC

A score may be calculated by adding up the weightings. In this example, that value is then subtracted from 100. Zero growth (apart from traces of light slime) gives the fouling resistance rating 100 (100-0) and heavy fouling of both algae and animals gives the rating 0 [100-(50+50)]. The rating is then allocated to descriptions of the overall efficacy.

Table 3: Example of categorisation of overall efficacy

Fouling resistance rating	Efficacy
Company specific score intervals, each with a corresponding characterisation of the efficacy	Excellent
	Good
	Fair
	Poor

Description of types of fouling:

Slime: Bacteria, micro-algae, and protozoa.

Light slime is easily removed from the surface.

Dense slime is not easily removed from the surface.

Algae (weed): Green algae, red algae, and brown algae.

Animals: Barnacles, tubeworms, mussels, hydroids, and bryozoans.

RELATING COMPANY FOULING ASSESSMENTS TO THE NORMS AND CRITERIA FOR PRODUCT AUTHORISATION.

When applying for authorisation of an antifouling product, the applicant should provide their overall fouling assessment of the product, together with the raw data and photographs/diagrams of the panel tests.

This guidance document only takes into account the percentage of macro-fouling on the raft panels as pass/fail criterion, not the classification in the applicant's assessment system.

As the percentage coverage per rating may differ between different company's assessment systems (see Table 1), some systems might not record 25 % coverage (the pass/fail criterion) in their rating system (e.g. in Table 1 Company 1 has a borderline at 30 % not at 25 %). Therefore, not only the ratings and end category of the product should be provided but also the raw data of the panel tests. The percentage coverage with macro-fouling per panel can then be identified from the raw data. This percentage is used to see if the product is sufficiently effective (i.e. <25 % macro-fouling)

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU