Assessment of efficacy and excess toxicity of antifouling paints for leisure boats

A guide for copper-based antifouling paints intended for use in the Baltic Sea region

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February 2021

This report was initiated and funded by the Swedish Chemicals Agency

Summary

The regulation of antifouling paints in the European Union falls under the Biocide Products regulation (BPR, Regulation (EU) 528/2012) and consists of two assessments: an environmental risk assessment (ERA) and an efficacy assessment. The efficacy assessment is key for the placement of an antifouling paint on the market as a biocidal product must be shown to be effective to gain approval. At the same time, the BPR states clearly that biocidal products should not be excessively toxic, i.e. release active substances to the environment in excess of the minimum necessary to achieve the desired effect. According to the BPR guidance document, an acceptable efficacy for antifouling paints is obtained if a static panel test is able to demonstrate a **surface coverage of macrofouling below 25% on the treated surface when the control has at least 75% coverage**. Guidance on how to determine whether a paint is excessively toxic is however lacking from the document.

Objective and method

The overall objective of this report was to **compile the current knowledge on the efficacy of antifouling products and the minimum dose of copper**. Regional pleasure craft marina scenarios for emission estimation were recently introduced for the harmonised environmental risk assessment of antifouling paint, whereby marine EU waters have been divided into four regions (Baltic, Baltic Transition, Atlantic and Mediterranean). This report focuses solely on the Baltic, Baltic Transition and Atlantic regions and all results were related to these three regions. A review was conducted where both peer-reviewed scientific articles and previously unpublished data relating to fouling pressure and efficacy assessments of copper and biocide-free antifouling paints in these regions were compiled. Even though the Atlantic region is included in the assessment it must be emphasised that the data for this region is exclusively collected from the northern Swedish west coast (Skagerrak). Most of the data were obtained from the EU BONUS-project CHANGE (Changing antifouling practices for leisure boats in the Baltic Sea) which contained both fouling and efficacy assessment of copper coatings in marinas during up to four consecutive years (2013–2016). Additional studies from 2018 and 2020 were also included in the compilation. The efficacy of a total of 10 copper coatings (cuprous oxide or copper powder) available on the Swedish market could thus be assessed at as many as 18 locations across 6 different years.

Fouling pressure

The minimum necessary dose will depend on the fouling pressure (i.e. the intensity and type of fouling organisms) of the region where the paint is intended for use. The fouling pressure, measured as the surface coverage of macrofouling on static control panels in the Baltic Sea region, was found to exceed 25% at all studied marinas (17 locations) and years (4 years). However, in 20% of the cases, the macrofouling coverage was below 75%, indicating that **the brackish Baltic Sea does not confine well to the current requirements for efficacy testing**. The fouling pressure was highest at the Atlantic site but varied considerably between sites in the Baltic and Baltic Transition regions. Also, high interannual variation in macrofouling cover was observed for several of the marinas in these two regions. The two most northern sites of the Baltic region were dominated by mainly soft fouling indicating a lower need for biocidal coatings. **No general patterns of fouling pressure could however be concluded for the three regions**.

Efficacy of copper paints

The **efficacy assessments of 10 commercial copper-based coatings showed acceptable results at 82 – 100% of evaluated locations**. Products currently on the Swedish market are thus highly efficient, with macrofouling coverages on static panels well below the 25% macrofouling criteria. A combination of high fouling pressure and low surface seawater temperatures were often found to coincide at the few instances where some copper paints failed to meet the set efficacy criteria. The lower temperatures may have acted to slow the release of copper, resulting in some paints failing to withstand the presiding high fouling pressure. Hence, **both biotic (fouling pressure) and abiotic factors (temperature) may influence the results of an efficacy assessment in the Baltic Sea region**, in particular for low-leaching copper paints.

Efficacy of biocide-free paints

The efficacy of a fouling release coating (i.e. silicone coating) was assessed during a 5-months long field experiment in 2020 at one test site in the Baltic and two test sites in the Atlantic region. The result showed the control panels deployed in the Atlantic region to be heavily fouled with macrofouling (100% coverage) but the fouling release coating had no macrofouling and was as effective as two copper-based coatings for professional use. Thus, **silicone paints present an effective biocide-free antifouling strategy already available to boat owners**.

Excessive toxicity

Efficacy test results offer limited support for the evaluation of excessive toxicity, especially if the test is carried out in a region other than that of intended use. An **evaluation of excessive toxicity is therefore proposed based on field release rates**. Copper release rates of 2 and 7 µg/cm^2/day were found to be sufficient to prevent all macrofouling settlement in the Baltic and Baltic Transition regions, respectively. Copper paints with field release rates in excess of these values can thus be considered excessively toxic. In absence of field release rates, a model is proposed for their estimation. The use of the model is however limited to hard and polishing paint only, due to lack of data for self-polishing paints. Gradient panels with paint stripes of increasingly diluted paint (i.e. decreasing amounts of biocide(s)) could also be used for the assessment of excess toxicity. Ideally, this assessment should be coupled with environmental release rate data to justify the need for the dose delivered by a given product.

Considerations specific to the Baltic Sea region

The combined findings of this report show that the conditions of the Baltic Sea region require specific consideration. The release rate of copper needed to deter macrofouling is lower in the Baltic than the Baltic Transition and Atlantic regions. The **evaluation of efficacy and excessive toxicity should therefore be carried out in the marine region of intended use**. Variability in fouling pressure and environmental parameters both between locations and years, even within the same marine region suggest however that care should be taken when choosing the test location. Additionally, **the duration of the efficacy test should reflect product use**. A period of 5 – 7 months of exposure is therefore suggested.

SAMMANFATTNING

Inom Europeisk Unionen regleras tillhandahållningen och användningen av antifoulingfärger genom biocidförordningen (förordning (EU) 528/2012). Förordningen bygger på två bedömningar: en miljöriskbedömning och en effektivitetsbedömning. Effektivitetsbedömningen är avgörande för att en antifoulingfärg ska tillhandahållas på marknaden eftersom en biocidprodukt måste visas vara effektiv för att få godkännande. Samtidigt anger biocidförordningen tydligt att biocidprodukter inte bör vara överdrivet giftiga, dvs. frigöra aktiva ämnen till miljön som överstiger det lägsta som krävs för att uppnå önskad effekt. Enligt biocidförordningens vägledningsdokument erhålls en godtagbar effekt för antifoulingfärger om ett statiskt paneltest kan visa på en yttäckning av makroskopisk påväxt under 25% för den behandlade ytan, givet att kontrollen har minst 75% yttäckning. Vägledning om hur man avgör om en bottenfärg är överdrivet toxisk saknas dock i dokumentet.

Syfte och metod

Det övergripande syftet med denna rapport var att sammanställa det nuvarande kunskapsläget om hur effektiva antifoulingfärger är på att motverka påväxt samt den lägsta nödvändiga dosen av koppar som krävs för att effektivt motverka påväxt. För en harmoniserad miljöriskbedömning av antifoulingfärg, introducerades nyligen ett antal regionala fritidsbåtshamnscenarier där EU: s marina vatten delats in i fyra regioner (Baltic, Baltic Transition, Atlantic och Mediterranean). Denna rapport fokuserar enbart på regionerna Baltic, Baltic Transition och Atlantic och alla resultat refererar till dessa tre regioner. En sammanställning gjordes där både granskade vetenskapliga artiklar och tidigare opublicerade data ingick. I sammanställningen inkluderades data kopplade till påväxttryck och effektivitetsbedömningar av kopparbaserade och biocidfria antifoulingfärger. Även om region Atlantic ingår i bedömningen är resultaten för denna region uteslutande från norra västkusten (Skagerrak). Merparten av datan erhölls från EU-BONUS-projektet CHANGE (Changing antifouling practices for leisure boats in the Baltic Sea) som inkluderar både påväxt- och effektivitetsbedömningar av kopparfärger i småbåtshamnar för upp till fyra år i rad (2013–2016). Ytterligare studier från 2018 och 2020 ingick också i sammanställningen. I underlaget ingick totalt 10 kopparfärger som finns registrerade på den svenska marknaden där effektivitetsbedömningar utförts på sammanlagt 18 olika lokaler under totalt 6 år.

Påväxttryck

Den lägsta nödvändiga dosen av en eller flera biocider beror på påväxttrycket (dvs. intensiteten och typen av påväxtorganismer) i färgens tilltänkte användningsområde. Påväxttrycket, mätt som yttäckning av makroskopisk påväxt på statiska kontrollpaneler i Östersjöregionen, översteg 25% i alla studerade småbåtshamnar (17 platser) och år (4 år). I 20% av fallen var dock yttäckning av makroskopisk påväxt lägre än 75%, vilket tyder på att de nuvarande kraven för effektivitetstestning inte är väl anpassade för det bräckta Östersjön. Påväxttrycket var högst i Atlantic-regionen men varierade avsevärt mellan de undersökta testlokalerna inom Baltic och Baltic Transition. Dessutom observerades höga årliga variationer i makroskopisk påväxt för flera av testlokalerna inom dessa två regioner. De två nordligaste lokalerna i Östersjön dominerades av främst mjuk påväxt, vilket tyder på ett lägre behov av biocidfärger. Inga generella slutsatser om påväxtmönster kunde dock dras för de tre regionerna.

Kopparfärgers effektivitet

Effektivitetsbedömningen av 10 kommersiella kopparbaserade antifoulingfärger visade att de uppfyllde en acceptabel effektivitet (<25% makroskopisk påväxt) på 82 - 100% av de undersökta testlokalerna. Produkter som för närvarande finns på den svenska marknaden är därför mycket effektiva, med täckningsgrad av makroskopisk påväxt långt under kriteriet på 25% makroskopisk påväxt. En kombination av högt påväxttryck och låga ytvattentemperaturer visade sig ofta sammanfalla i de enstaka fall där vissa kopparfärger inte klarar av att uppfylla effektivitetskriteriet. De lägre temperaturerna kan ha lett till ett minskat läckage av koppar, vilket resulterat i att vissa färger då inte klarade det höga påväxttrycket. Således kan både biotiska (påväxttryck) och abiotiska faktorer (temperatur) påverka resultaten vid en effektivitetsbedömning, särskilt för kopparfärger med lågt läckage.

Biocidfria färgers effektivitet

Effektiviteten av en silikonfärg bedömdes efter ett fem månader långt fältexperiment 2020 på en testlokal i Baltic-regionen och två testlokaler i Atlantic-regionen. Resultatet visade att kontrollpanelerna i Atlantic-regionen hade kraftig makroskopisk påväxt (100% täckningsgrad) medan silikonfärgen inte hade någon makroskopisk påväxt och var lika effektiv som två kopparbaserade fartygsfärger. Således utgör silikonfärger en effektiv och biocidfri antifoulingstrategi för båtägare.

Överdriven toxicitet

Effektivitetsresultat ger begränsad information för utvärdering av överdriven toxicitet, särskilt om testet utförts i en annan marin region än den som är tilltänkt för produktens användning. En utvärdering av överdriven toxicitet föreslås därför utifrån läckagehastigheter uppmätta i fält. Läckagehastigheter av koppar på 2 och 7 $\mu g/cm^2$/dag är tillräckligt för att förhindra all makroskopisk påväxt i regionerna Baltic och Baltic Transition. Kopparfärger med fältläckage som överstiger dessa värden kan således betraktas som överdrivet toxiska. Vid avsaknad av fältläckage föreslås en modell för att uppskatta fältläckaget. Modellens användning är dock begränsad till hårda och polerande färger då tillräckliga data saknas för självpolerande färger. Gradientpaneler med utmålade band av gradvis utspädd färg (dvs. med minskande mängd biocid) kan också användas för bedömning av övertoxicitet. Helst bör denna bedömning kopplas till uppmätta läckagehastigheter för att motivera behovet av den dos (läckagehastighet) som produkten har.

Specifika överväganden för Östersjöregionen

De sammanlagda resultaten i denna rapport visar att förhållandena i Östersjöregionen kräver särskilda överväganden. Läckagehastigheten av koppar som behövs för att helt motverka makroskopisk påväxt är lägre i regionen Baltic än i Baltic Transition och Atlantic. Utvärdering av effektivitet och överdriven toxicitet bör därför utföras i den region produkten är tänkt att användas i. Variation i påväxttryck och vattenförhållanden både mellan lokaler och år, även inom samma region, visar dock på att val av testlokal är långt ifrån oviktigt. Dessutom bör effektivitetstestets tid återspegla produktens användning. En exponering på 5–7 månader föreslås därför då det motsvarar en typisk båtsäsong i Östersjöregionen.

CONTENTS

1. INTRODUCTION

1.1. BALANCING THE BIOCIDAL RELEASE FROM ANTIFOULING PAINTS

The colonization of submerged surfaces in seawater by fouling organisms is a continuous problem for leisure boating since fouling translates to increased maintenance work, drag, fuel consumption and atmospheric emissions (Almeida et al., 2007). The most common method to prevent fouling is to coat the boat hull with an antifouling paint that contains and leaches biocides into the surrounding water (Yebra et al., 2004). Antifouling biocides are biologically active substances intentionally released to repel, poison or kill fouling organisms to prevent them from settling on a boat hull. As such, they may also pose a hazard to non-target organisms (Dafforn et al., 2011).

The balancing act of releasing enough biocides to prevent fouling but not so much as to cause adverse environmental effects is challenging but also necessary to reduce the risk of environmental impact of antifouling paints. The current authorisation scheme of PT21 products such as antifouling paints in the European Union reflects this dual aspect (**Figure 1**). The regulation falls under the BPR (Regulation (EU) 528/2012) and comprises of both an efficacy (i.e. antifouling performance) and an environmental risk assessment which should have acceptable outcomes for a product to gain approval.

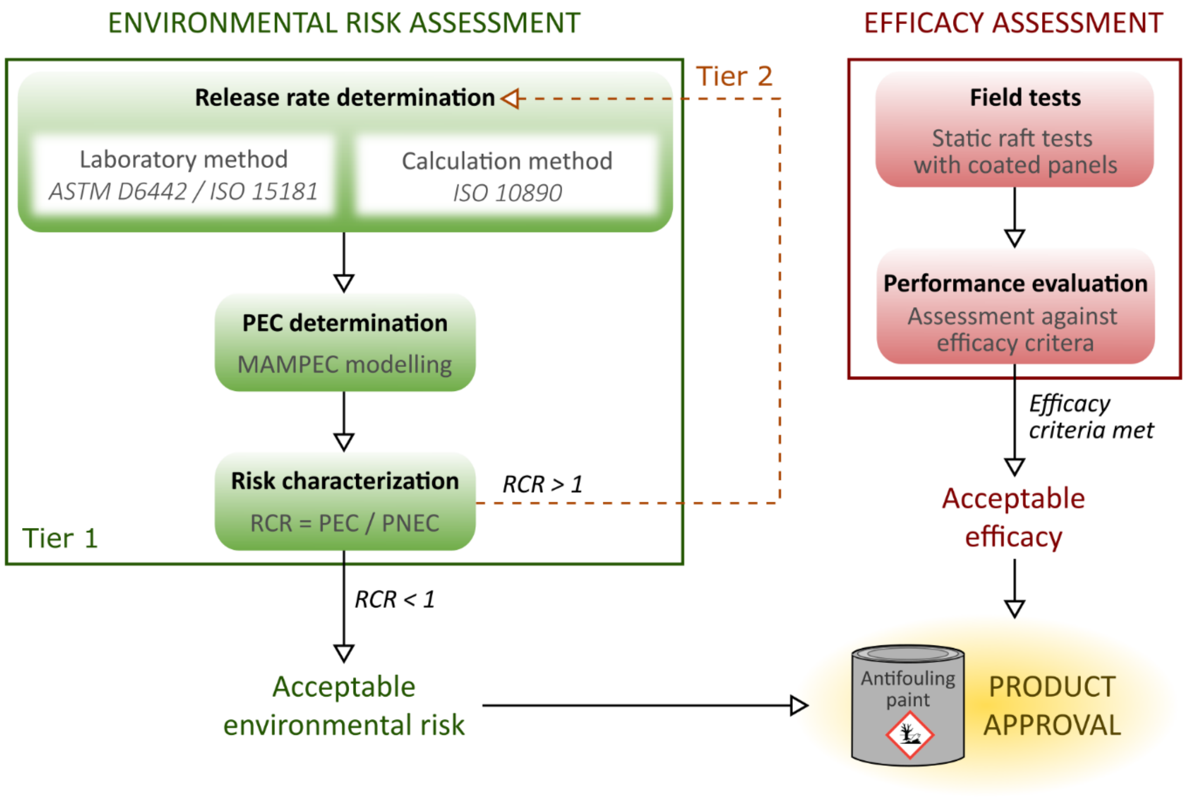

Figure 1. Product authorisation process for antifouling paints under the European Union Biocidal Products Regulation (BPR, Regulation (EU) 528/2012).

A new, harmonised procedure for the ERA has recently been proposed by which EU waters have been divided in two categories: freshwater and marine. Marine waters have further been sub-divided into four marine regions: Baltic, Baltic Transition, Atlantic and Mediterranean (**Figure 2**).This report focuses on copper-based antifouling paints and their use in the Baltic, Baltic Transition and Atlantic regions. During the last decade, the global antifouling market has been dominated by rosin-based paints that contain copper compounds, e.g. cuprous oxide, as the main biocide and, as a result, leisure boating is one of the largest anthropogenic sources of copper to coastal marine ecosystems. For example, the load of copper from the leisure boat fleet in the Baltic and Baltic Transition regions has been reported to be 57 tons annually (Johansson et al., 2020), which can be compared to the total natural and anthropogenic waterborne inputs to the Baltic Sea which is 886 tons annually (HELCOM, 2011).

It should also be noted that the emissions from leisure boats are concentrated to coastal environments and occur primarily during the 5-months long summer season when marine ecosystems are particularly sensitive to pollution. Due to the extensive use of copper-based antifouling products, dissolved copper concentrations exceeding environmental quality standards have been reported from recreational boat marinas in several EU countries such as Sweden (Kylin and Haglund, 2010; Lagerström et al., 2020a), Finland (Brooks, 2006; Lagerström et al., 2020a), Germany (Daehne et al., 2017) and UK (Jones and Bolam, 2007). These findings suggest that a successful balancing act between efficacy and environmental sustainability has yet to be achieved for copper-based antifouling paints.

1.2. AIMS AND REPORT STRUCTURE

The overall objective of this report was to compile the current knowledge on efficacy of antifouling products and the minimum dose required when the products are used in the Baltic, and Baltic Transition and Atlantic regions. This was achieved through the compilation of results in scientific, peer-reviewed articles as well as unpublished data from studies carried out within the EU BONUS CHANGE-project (2013-2016). Additionally, a field study conducted in 2020 to assess the efficacy of, amongst other, biocide-free foul-release coatings was carried out for the specific purpose of this report.

Before presenting the findings of the compiled studies, the principles of the assessments required for product authorisation of antifouling products under the BPR to which the results of all the considered scientific studies are related, are firstly outlined (Section 2). All studies and their design are outlined in section 3.1. The subsequent sections present the findings of the studies with respect to the specific aims of this report which were to:

- Evaluate the **fouling pressure** with respect to macrofouling in marinas in the considered marine regions (section 3.2)
- Assess the **efficacy of copper-based antifouling paints** and their potential variation in performance between locations and years (section 3.3)
- Assess the **efficacy of biocide-free paints** (section 3.3)

- Compile assessments of the **release rate of copper needed to prevent macrofouling** in the Baltic Sea region (section 3.4)
- Provide a guide for the evaluation of excess toxicity with respect to copper (section 4).

Finally, some reflections and recommendations regarding efficacy assessment of antifouling paints for leisure boats related to its particular application in the considered marine regions based on the compiled findings are outlined in section 5.

2. Product authorisation under the BPR – assessments & concepts

Outlined in this section is a description of the efficacy and environmental risk assessments required for approval of antifouling paints under the BPR. Although also conditional for granting authorisation of a biocidal product (Article 19), assessments for human health risks are not discussed as the focus of this report is on the efficacy assessment and the environmental risk assessment (ERA) of antifouling paints.

To aid in the harmonization of the product authorisation procedure of antifouling paints across members states, common guidelines for the efficacy assessment under the BPR have been established and a new tool has also been developed for the ERA of paints for leisure boats within four defined marine regions (Baltic, Baltic Transition, Mediterranean and Atlantic). Although the efficacy guidelines and the new ERA tool have yet to be used in conjunction in Sweden, they are intended to be applied in future product approvals of antifouling paints for the Swedish market. Their principles are presented over the next two sections.

2.1. Efficacy assessment

Guidelines for the assessment of the antifouling performance of a paint have been established by the European Chemicals Agency (ECHA) for products intended for both marine and freshwater use (ECHA, 2018). As the use of biocidal antifouling products in freshwater is not permitted in Sweden, only the guidelines for products intended for marine use are considered here. For efficacy testing, static raft tests should primarily be used whereby treated (coated) panels are exposed statically for a certain period after which the surface coverage of fouling is evaluated. Static raft testing in coastal waters is recommended by ECHA as it represent a worst-case scenario given that the static conditions combined with the high fouling intensity of near-shore coastal waters act to strongly favour the settlement of fouling organisms. By this reasoning, a product with demonstrated efficacy in marine coastal waters can also be assumed to also be effective in open sea and brackish waters. Preferably, results from additional tests, even if performed in other parts of the world or under other conditions, should also be provided by the applicant.

Two standard raft test methods are mentioned in the guidelines: Efficacy evaluation of antifouling products from 2012 by the CEPE Antifouling Working Group, and ASTM D3623 - 78a(2004)/D6990-5(2011). Reports according to these are acceptable but as they exceed the requirements for substantiating a general product label claim applying these standard methods is by no means a requirement. Criteria for an acceptable static raft test of a product are therefore also given as follows:

- Location: although it is mentioned that the test location(s) should be, as far as is practical, representative of the intended uses of the product, it is also stated that any location within EU coastal waters is acceptable. Tests in Atlantic or Northern European Seas are however preferred. This last statement is not appended by any justification.

- Duration: at least one fouling season (i.e. at least 6 months covering the period of peak fouling activity)
- Number of tests: at least one test
- Number of replicates: at least three per product
- Control: a negative control (defined as “a surface which has no antifouling effect”) should be included to indicate the degree of fouling that would be present under static conditions if the tested coating was totally ineffective.

The criteria outline in the guidance document are thus rather broad and currently hold no requirements with regards to, for example, panel type, dimensions, orientation or exposure depth, nor the inspection frequency. These must nonetheless be reported as they are part of the dossier requirements, along with other information about the test procedure (method of application, date and duration of test, etc) and test site (temperature and salinity, including seasonal variations, water exchange conditions, etc).

At the end of the trial, the percentage fouling on control and test panels is evaluated with respect to macrofouling coverage. An acceptable result is obtained if test panels have a surface coverage of macrofouling below 25% when the control has at least 75% fouling coverage. Fouling organisms are typically divided into three categories: slime, weed/macro-algae and animals (e.g. barnacles, mussels, etc). Macrofouling is here defined as “large, distinct multicellular organisms visible to the human eye such as barnacles, tubeworms, or fronds of algae”. Algae shorter than 5 mm as well as slime should be regarded as microfouling. The guidance document does not specify how to treat the test results if the macrofouling coverage on the control is below 75%.

Any origin or justification for the 25% macrofouling criterion is not specified. The raft test conditions and the 25% macrofouling criterion applies to antifouling paints for both recreational and commercial vessels, even though they have very different operational patterns. For a commercial ship with little idle time, the static raft tests may indeed represent a worst-case scenario. On the other hand, for a Swedish recreational boat which is idle for on average 90% of the boating season (The Swedish Transport Agency, 2015), the static raft tests may rather reflect the actual conditions of use.

2.2. ENVIRONMENTAL RISK ASSESSMENT (ERA)

In addition to efficacy testing, a product must also undergo an ERA to gain approval for its placement on the market (**Figure 1**). In the ERA, predicted environmental concentrations (PEC) in leisure boat marinas are modelled based on the estimated release rate of the biocides and Substances of Concern (SoC, e.g. Zn) from the paint surface to the water. The PEC values are subsequently divided with pre-defined predicted no effect concentrations (PNEC) to produce risk characterisation ratios (RCRs) of the individual biocides/SoCs as well as a cumulative RCR if more than one biocide/SOC is included in the product. If the RCR is less than unity (< 1), the concentration in the environment is likely to be lower than the critical threshold value; the risk of adverse effects is considered low. If the ratio is higher than unity (> 1), risk for adverse effects exists and actions to reduce the risk are recommended. This includes higher tier refinements where correction factors can be applied to the biocidal release rate (ECHA, 2017).

A new ERA tool is currently proposed by ECHA to be used for antifouling paints for recreational vessels. The modelling is performed in a newly developed Excel calculation tool which automatically generates PECs of the biocides and SoCs in pleasure craft marinas within four defined European marine regions (Baltic, Baltic Transition, Atlantic and Mediterranean). The PECs are derived for all marinas, but it is the 90th percentile PEC that should be used to calculate the RCR and is intended to represent a realistic worst case.

According to the new tool, the Swedish coastline would border three different marine regions (**Figure 2**). The division between Baltic and Baltic Transition is nearly the same as the current regions of east coast and west coast (**Figure 13**). According to the report which outlined the geographical borders of the marine regions, Skagerrak is assigned to the Atlantic marine region (Shan-I et al., 2013). The Swedish west coast therefore borders two marine regions (Baltic Transition and Atlantic).

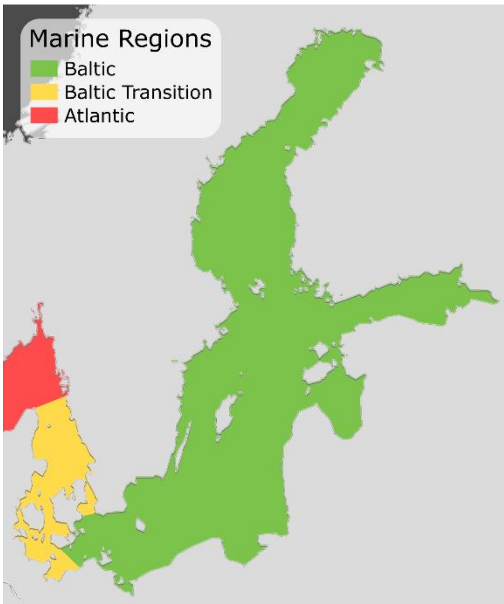

Figure 2. Marine regions bordering the Swedish coastline according to the new ERA tool.

It is the estimated release rates or leaching rates of active substances and SOCs in µg/cm^2/day that form the very basis of the ERA and thus dictates its outcome. The accuracy of the methods used to determine such release rates is consequently critical for the validity of the ERA. Release rates generated from either a laboratory method (ASTM D6442, 2020; ISO 15181, 2007) or a mass balance calculation method (ISO 10890, 2010) are currently accepted within the EU. The derived release rates are used as estimates of the release occurring in the field when the product is applied to a hull, even though neither method was developed for this purpose. In several studies at locations along the Swedish coastline, comparison of copper and zinc release rates for several antifouling paints on the Swedish market generated with the two methods and those of a method able to determine release rate occurring in-situ have shown the former to not accurately reflect the release occurring in the field (Lagerström et al., 2018, 2020a; Ytreberg et al., 2020). These studies conclude that the use of non-representative release rates (generated with the two currently accepted methods) and, in particular, the permitted use of correction factors which reduce the estimated release rate(s) in case of a Tier 2 assessment, has resulted in improper authorisation of several products. Consequently, paints which in fact pose an unacceptable risk to the environment are currently approved and used along the Swedish coast.

2.3. DOSE RATE, APPLICATION AMOUNT AND APPLICATION RATE

The BPR guidance document states that the *dose rate* used in the efficacy assessment and risk assessment should be consistent (ECHA, 2018). The dose rate thus refers to that which is typically denominated as the release rate or leaching rate of an active substance(s) for antifouling paints. The dose rate will determine the efficacy of an antifouling paint. However, antifouling paints are different compared to other biocidal products (e.g. agricultural pesticides) given the following two points:

1. there is no relationship between the amount applied on a hull (paint thickness) and its dose rate or efficacy, i.e. applying more paint does not increase the level of fouling protection

2. there is not necessarily a relationship between the contained amount of active substances and its dose rate or efficacy, i.e. a product with a higher copper content will not necessarily leach more copper or provide better protection than one with a lower copper content

The first point stems from the fact that the release of active substances only occurs from the top of the coating that is exposed to seawater. The release from the paint surface to the water phase will be the same regardless of how much paint is present underneath it, at least until the coating is nearly eroded. The paint film thickness, referred to as dry film thickness or DFT, will instead define the in-service life of the product as, depending on paint type, the coating will either be continuously eroded and/or exhausted of active substances. Thus, in order to assure a sufficient release of the active substance(s) during the specified lifetime of a product, an adequate thickness of paint must be applied.

The second point is a result of differences between paint formulations. Paint types are defined based on the properties of their paint matrix/binder which are typically divided into three categories: insoluble, soluble or self-polishing (Pei and Ye, 2015) (**Figure 3**). In the case of insoluble matrix paints, the release of active substance(s) is solely dependent on its own solubility as well as the length of the diffusion path through the intact binder (which will increase with time and act to slow the release). For soluble and self-polishing coatings, the surface of the paint film is continuously renewed through dissolution or chemical reactions such as hydrolysis or ion-exchange. For self-polishing paints, it is not unusual for different binder technologies to be used in combination within the same product. The polishing rate/erosion rate of soluble and self-polishing coatings will therefore depend on the properties of the specific binder in the given paint. To complicate matters more, environmental parameters such as salinity, temperature and pH can also affect the release and their effect on the active substance and the binder may not always act in accordance. Increased salinity may for example act to increase both the dissolution rate of cuprous oxide and rosin, a commonly used binder in soluble paints (also called colophony or colophonium). Increased pH will however yield opposite effects: a decrease in cuprous oxide solubility and an increase in rosin solubility (Rascio et al., 1988). As a result of these facts, the copper content is thus by no means necessarily directly proportional to the copper release that will occur from the paint surface. Also, two antifouling coatings with the same copper content can perform differently.

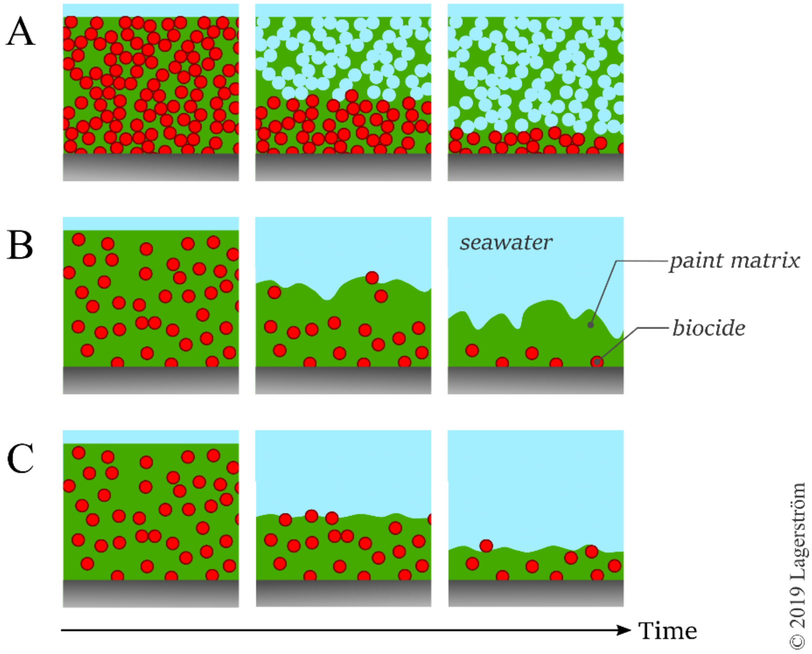

Figure 3. Schematic of the three different paint types, insoluble matrix (A), soluble matrix (B) and self-polishing (C), and their release of biocide(s) over time.

In summary, when it comes to both the environmental and the efficacy assessments, the dose rate (i.e. release rate) of an active substance rather than its concentrations in the paint or the amount applied to the hull is what will ultimately matter. However, the *application amount* (DFT) and *application rate* (re-coating interval) are not irrelevant. From an efficacy point of view, these need to be properly specified to ensure adequate fouling protection over time. This is especially important if the lifetime was part of a product's (optional) label claims. From an environmental point of view, it is important that the lifetime of the paint is not underestimated as this will lead to unnecessary and premature re-application of paint on the hull. This would in turn results in build-up of paint layers on the hull which can be shed during hull maintenance activities and pollute the soil of recreational boatyards (Eklund et al., 2014; Eklund and Eklund, 2014; Lagerström et al., 2016; Eklund and Watermann, 2018).

2.4. Minimum necessary dose

2.4.1. Concept of minimum dose under the BPR

The point of view on the dose rate in the efficacy and environmental risk assessments differ: whereas the ERA evaluates the maximum release rate of active substance acceptable to the environment, the efficacy assessment focuses instead on the minimum application or dose rate required for the product to be effective (**Figure 4**). For authorisation, a paint's biocidal release should be high enough to be effective whilst low enough to pass the ERA (scenario D in **Figure 4**). It is thus imperative that the minimum necessary release rate is below or at that of the maximum allowable permitted by the ERA. A product with a higher release rate may nonetheless be granted authorisation (scenario C in **Figure 4**) where not authorising the biocidal product would result in "*disproportionate negative impacts for society*" (BPR, article 19.5).

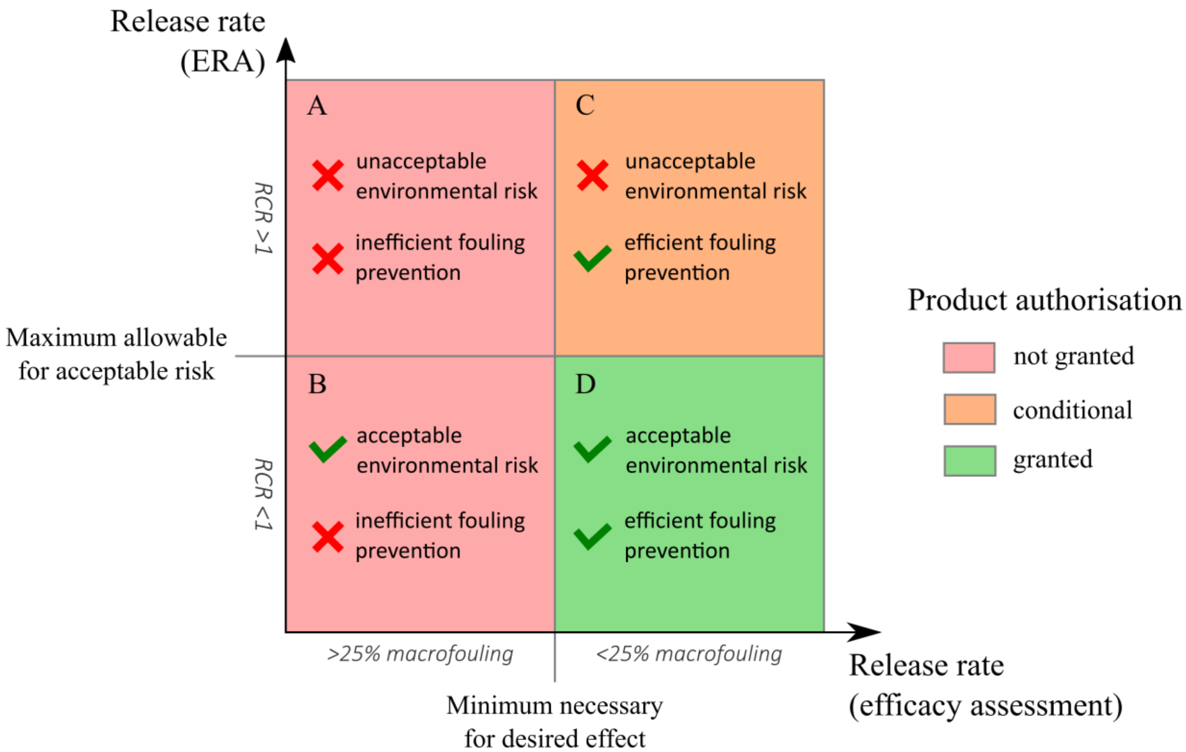

Figure 4. Relationship between the environmental risk assessment and the efficacy assessment for an antifouling paint with respect to the biocidal release rate.

Even though a product is shown to be effective and able to pass the ERA, it should still not be excessively toxic, i.e. release unnecessary amounts of active substances. The BPR (Annex VI art. 77) states that, "[…] *the recommended dose is the minimum necessary to achieve the desired effect*". In accordance with the efficacy criteria in the guidance document, the statement in Article 77 of the BPR would translate as follows for antifouling paints: the recommended release rate is the minimum necessary to obtain <25% macrofouling coverage on treated panels in a static raft test after at least 6 months exposure.

In order to assess whether a product's recommended dose is indeed the minimum necessary, Annex VI art. 77 of the BPR states that "T*he evaluating body shall evaluate dose-response data generated in appropriate trials (which must include an untreated control) involving dose rates lower than the recommended rate, […]".* This applies to both products seeking to be approved on their own as well as product families, (i.e. a group of products with the same active substance(s) and similar use, but small differences in the formulation). For the latter, the guidance document states that a comparison of active substance concentrations between family products should be made. Furthermore, the efficacy tests should be performed on the product with the lowest concentration of active substance, under the worst-case circumstances. If effective, the applicant should request authorisation for the products with the lowest concentration of active substance or justify the need for having different formulations. When seeking approval for product families, comparison of active substance concentrations should also be made to existing products on the market. Such comparisons are however not currently required for products authorised on their own which should be "*evaluated on their merits and not in comparison to other products*" (section 5.2.6. of the guidance document).

2.4.2. Minimum versus critical release rate

Determining the release rate of copper yielding exactly 25% macrofouling coverage on a treated panel is practically difficult. More easily determined is instead the critical release rate (RR_{crit}) which is defined as the leaching rate of an active substance needed to completely prevent the attachment of a given fouling organism (WHOI, 1952). If macrofouling organisms are considered as a whole, the critical release rate is the lowest release rate resulting in 0% surface coverage of macrofouling. A paint with a release rate below the critical release rate can thus still be deemed efficient according to the EU efficacy guidelines (**Figure 5**). Knowledge of the critical release rate can nonetheless give an indication of the minimum release rate and can thus be used to assess if a specific product is leaching biocides in excess to the marine environment.

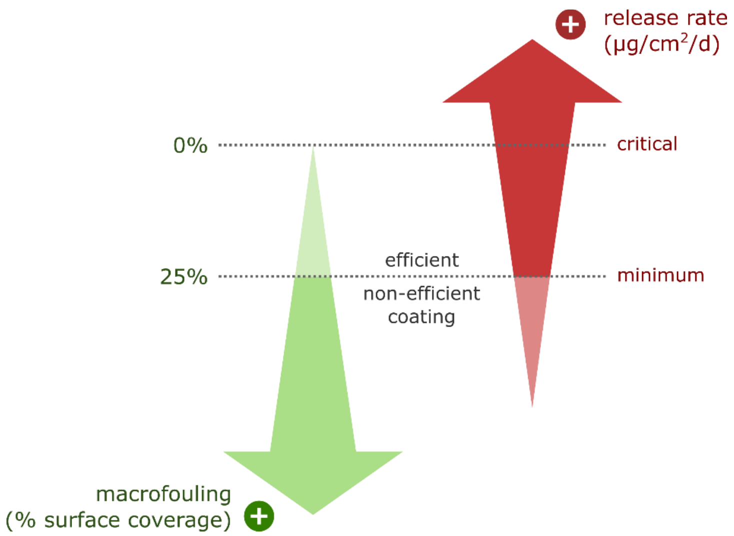

Figure 5. Relationship between macrofouling coverage and critical and minimum release rates.

The magnitude of both the minimum and critical release rates (in µg/cm^2/day) is determined by two key factors: the toxic properties of the active substance itself and the intensity and composition of fouling organisms (i.e. the fouling pressure). The latter will depend on both location and season. In the temperate climate zone, the fouling pressure is typically higher in the summer as compared to the winter season due to increased light conditions and temperatures. In addition, other abiotic factors such as salinity and nutrient supply will affect the intensity and composition of fouling organisms. In the next section, the prevailing fouling pressure with respect to macrofouling for various location in the Baltic and Baltic Transition will be outlined.

3. Review of scientific field studies in the Baltic Sea region

3.1. Considered studies and their design

Several projects have been performed in the Baltic Sea region to assess the efficacy of antifouling paints, environmental release rates of copper and fouling pressure at different test sites. However, a comprehensive review on how the data and knowledge could be used in policy has not previously been conducted. This section summarises the available knowledge regarding fouling pressure and efficacy assessments of antifouling paints exposed in the Baltic Sea (Baltic region), Kattegat (Baltic Transition region) and Skagerrak (Atlantic region). Most of the data were derived from the CHANGE project during the time interval 2013-2016, but data from Lagerström et al (2020) and field data derived from the current study was also used in this review (**Table 1**).

Table 1. Assessment year of antifouling and fouling research conducted in the Baltic Sea from 2013 to 2020 which are used in the current review.

	CHANGE project	Lagerström et al. (2020)	This study
Commercial coatings	2013-2016	2018	2020
Experimental copper coatings	2015-2016	n/a	2020
Hard biocide free coating	2013-2016	2018	2020
Fouling release coating	n/a	n/a	2020

The experimental design in the CHANGE project and in Lagerström et al., 2020b with respect to fouling pressure studies (section 3.2) and efficacy of commercial and experimental copper-based antifouling paints (section 3.3) are the same. Briefly, four replicate panels were deployed vertically along weighted polypropylene lines (**Figure 6**) and hung from jetties in leisure boating marinas, at a water depth of approximately 1 m and exposed for 5 months (mid-May to mid-October). The depth was chosen to simulate the position of a boat hull in the water, which is also in line with the CEPE, (2012) recommendations stating that test panels should be placed at a depth between 0-3 m. The time frame (5 months) was selected to simulate one full boating season in the Baltic Sea, which at least in the Nordic countries is in general from mid-May to mid-October. This differs slightly from the recommended 6 months field testing required in the guidance document for efficacy evaluation (ECHA, 2018). However, the CHANGE studies were not designed based on the ECHA recommendations, but instead designed to cover the fouling pressure during a typical boating season in the Baltic Sea. In addition, the fouling season in the Baltic Sea mainly occurs during the summer months (June-August) when water temperatures are relatively high.

Since the CHANGE project primarily focused on commercial copper-based coatings, an additional aim of the current study was to investigate how efficient experimental low-leaching copper-based coatings and biocide-free fouling release coatings are in preventing fouling. Thus, an additional experiment was conducted in 2020 where fouling release coatings, experimental low-leaching copper-based coatings, biocide free hard coatings and high leaching copper coatings where assessed in the Baltic region and Atlantic region. A similar set-up was used as described above, with the exception that the 5-month field exposure was conducted from July to November. Ideally this latter experiment should have been performed between May to October but since the project started in July this was not an option.

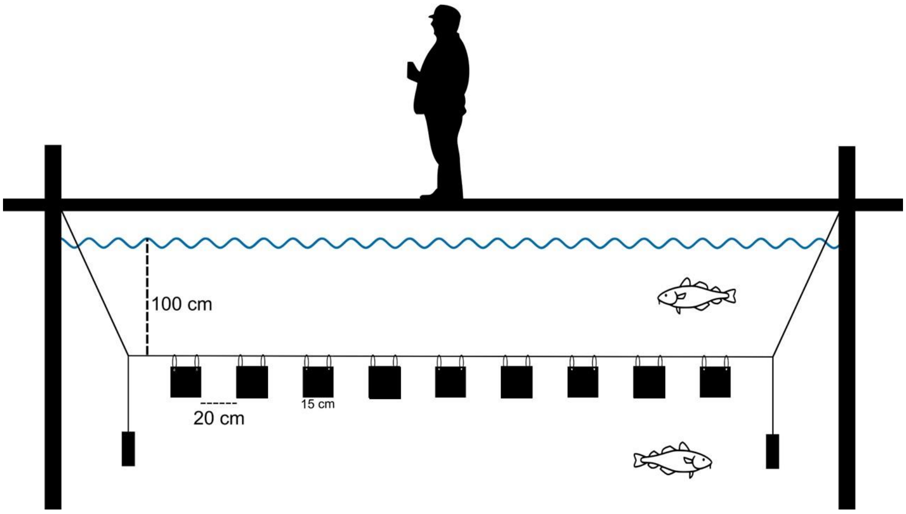

Figure 6. Panels were attached to lines and hung at 1m depth from jetties in leisure boat marinas during the field study 2013-2016 in the Baltic Sea region. (From: adapted from Wrange et al 2020)

3.2. Fouling Pressure

3.2.1. Large-scale and long-term monitoring of macrofouling

In general, biocidal products such as antifouling paints, should only be used when necessary to prevent problematic fouling on boat hulls. If the fouling pressure (i.e. the intensity and type of fouling that attaches to a non-biocidal surface) is low, paints may not be necessary and other methods could be suitable to avoid fouling. However, until now, there have been no large-scale field studies focused on how biofouling relevant to boat hulls, varies in time and space in the Baltic sea region. To better understand how fouling varies in time and space, a large-scale panel study was conducted during four consecutive boating seasons (2013-2016) in the Baltic Sea region. Panels made of polymethyl methacrylate (PMMA) were coated with a biocide-free black antifouling paint (International Lago racing) and deployed at 17 sites around the Baltic Sea including sites in Sweden (12), Denmark (1), Germany (1) and Finland (3) (**Figure 7**). Out of these sites, one was located in the "Atlantic" region according to the new ERA tool (**Figure 2**), whereas five were located in the "Baltic Transition" and 11 in the "Baltic". In 2013, only 10 Swedish locations were included in the study, whereas all 17 sites throughout the Baltic were included in 2014-2016. The results from the latter three years are described in Wrange et al. (2020).

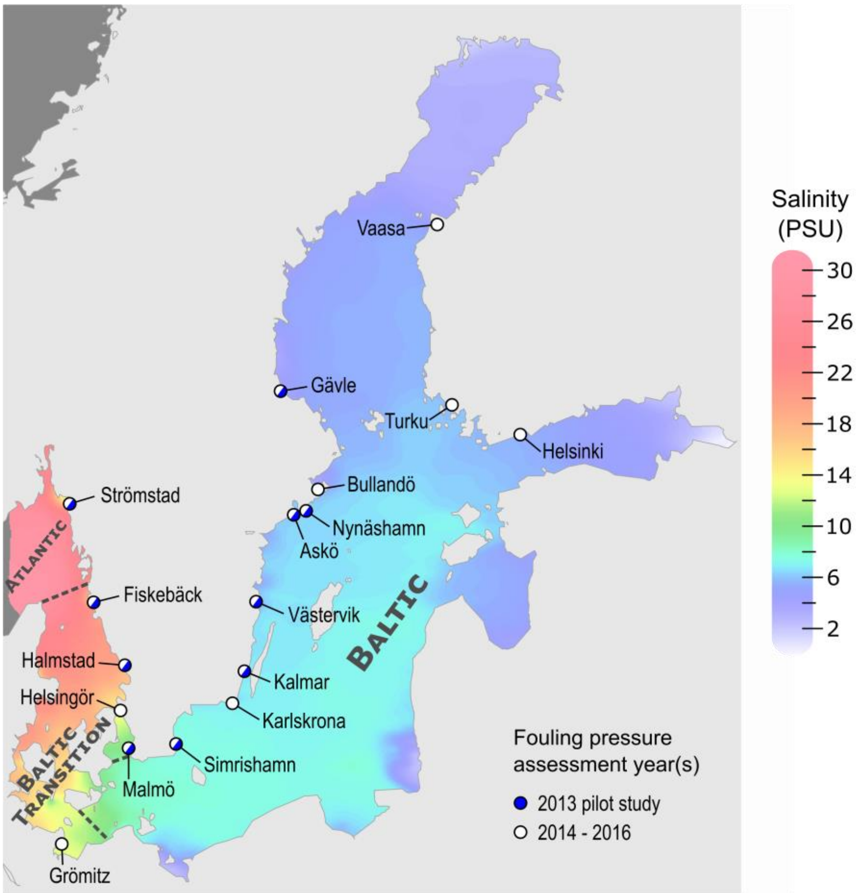

Figure 7. Study sites where panels were placed during 2013-2016 to study fouling pressure. In 2013, only 10 sites in Sweden were included as a pilot study. All sites were included in the field exposure in 2014-2016.

The PMMA panels were hung from jetties in leisure boating marinas, at a water depth of approximately 1m (**Figure 6**) and exposed for 5 months (mid-May to mid-October). At the end of each of the four boating seasons (2013-2016), the panels were retrieved and transported to a lab where the panels were photographed from above. The photos were analysed by counting the percentage cover of the total panel surface (excluding the edges) for each of the macroscopic species groups according to the standardized method of the American Society for Testing and Materials (ASTM D 6990, 2011). Following the ASTM method, panels with multiple layers of macrofouling were carefully analysed under a stereomicroscope and secondary layers were removed, keeping the layer of organisms attached to the actual surface of the panels for the estimation of coverage. Biofilm was not included in the final analysis due to difficulties to distinguish between biofilm and inorganic silt layers from sedimentation in the marina (hence not attached to the panel). Therefore, the focus of this study was on total percentage cover of macroscopic fouling organisms. As part of the analysis of temporal and spatial variation in fouling pressure (Wrange et al., 2020), the different types of fouling organisms were also classified into three groups based on attachment strength where; Hard Fouling Strongly attached (HFS) including e g barnacles and tubeworms with calcareous shells; Hard Fouling Weakly attached (HFW) including mussels and bryozoans; and Soft Fouling Weakly attached (SFW) including filamentous algae, tunicates, sponges and hydroids (**Figure 8**).

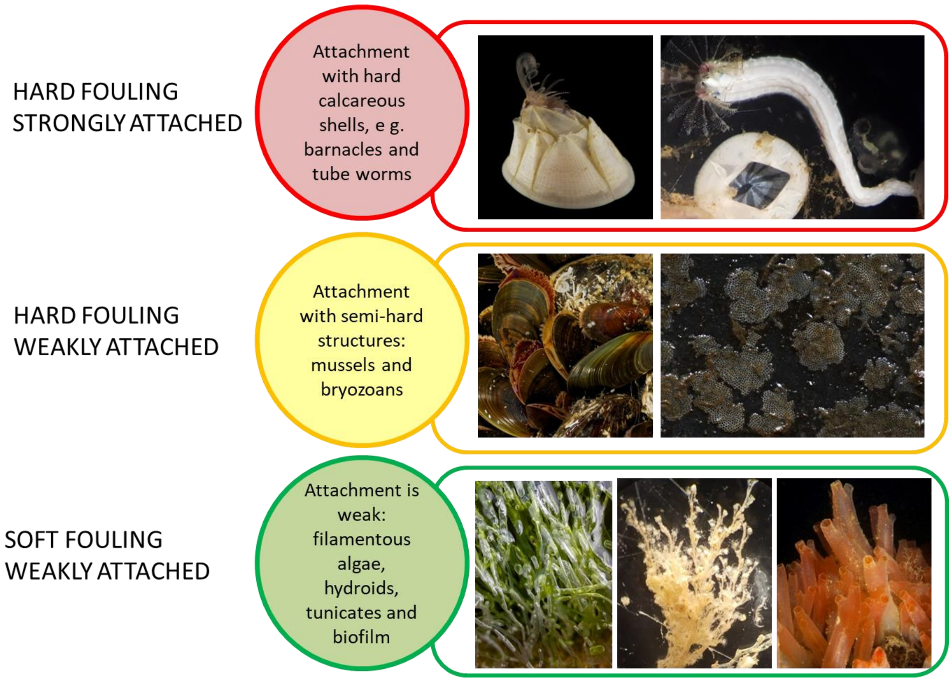

Figure 8. Macrofouling was categorised into three types, based on the difficulty for boat owners to remove them from the boat hull. Hard Fouling Strongly (HFS) attached (red category) includes calcareous species that are the most problematic for boat owners to remove, whereas Hard fouling weakly (HFW) attached includes e g mussels and bryozoans that required moderate cleaning efforts and Soft Fouling Weakly attached (SFW, green category) includes filamentous algae and tunicates that are more easily removed.

3.2.2. Variations in fouling pressure in time and space

The coverage and structure of macrofouling communities showed a high inter-annual variation in most of the monitored sites (**Figure 9Error! Reference source not found.**). Only four sites showed similar macrofouling pressure (amount and type) through-out the study. These included the Swedish sites Fiskebäck (dominated by barnacles), Karlskrona (dominated by bryozoans and barnacles) and Gävle (dominated by hydroids), as well as Turku in Finland (dominated by barnacles).

The fouling pressure (including all layers of macrofouling) was generally higher along the Swedish west coast compared to most of the Baltic Sea, although this difference is not clearly visualised when only analysing the percentage cover of panels (according to the ASTM standard 2011). To show this difference more clearly, a quantification of total weight of macrofouling would have been useful. The macrofouling in the marina located in the Atlantic region showed a consistent high fouling cover over time (99±1%). In the Baltic Transition and Baltic regions there was more variation between marinas within the same region as well as high inter-annual variation at many locations. The fouling coverage in the Baltic marinas varied between 39 and 100% during the study period and a similar range was observed in the Baltic Transition marinas (37 to 100% coverage) (**Figure 9**).

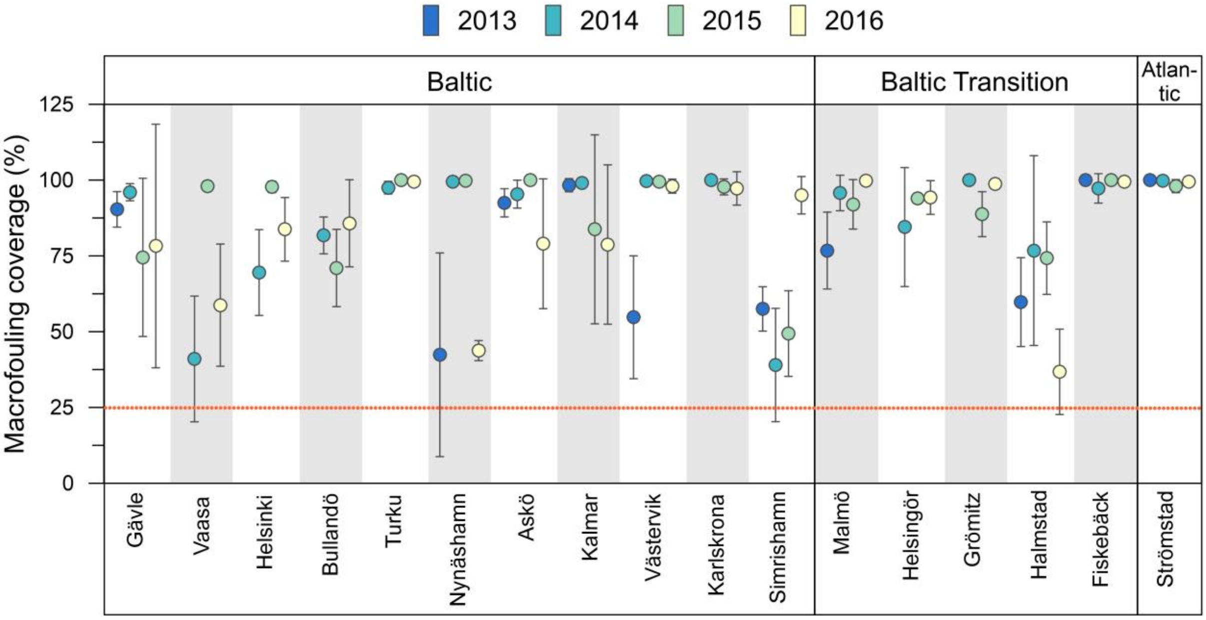

Figure 9. Average of macrofouling cover (%) on biocide-free panels at the different study sites in the Baltic, Baltic transition and Atlantic regions during the four years of fouling pressure study. In 2013, only Swedish sites were included in the study.

The marinas in the Atlantic and Baltic Transition region was mostly dominated by hard fouling strongly attached (HFS) but also hard fouling weakly attached (HFW) was present in many locations (**Figure 10**). In the Baltic region, there was more variation between locations in what species were present on the panels. The marinas located in the southern part of the Baltic region displayed a mixture of HFS and HFW, whereas the two locations in the most northern part of the Baltic region were dominated by soft fouling (SFW) (**Figure 10**). One Baltic marina that different considerably from the rest was Turku in Finland which displayed consistently high cover of barnacles (HFS) throughout the study.

Figure 10. Average of macrofouling cover (%) at the different study sites in the Baltic, Baltic transition and Atlantic regions used in the ERA tool. The macrofouling is divided into three categories based on the difficulty for boat owners to remove them. HFS = Hard fouling strongly attached (includes barnacles and tubeworms); HFW = Hard fouling weakly attached (including bryozoans and mussels); SFW = Soft fouling weakly attached (including hydroids, filamentous algae, tunicates and sponges). Modified from: Wrange et al 2020.

Classification of marinas according to the Fouling Index

By combining the intensity (% cover of macrofouling) with the type of fouling, a Fouling Index (FI) was developed making it possible to identify potential "hotspots" for problematic fouling for leisure boat owners. The index is calculated as a weighted sum of the recorded coverage (%) of different types of fouling organisms (HFS, HFW, SFW, see **Figure 8**) where each of the three groups is assigned a categorical value that is related to the attachment strength of the fouling, hence how problematic the fouling is to remove; HFS = 2 (high cleaning effort needed to remove fouling from the hull), HFW = 1 (intermediate cleaning effort required) and SFW = 0.5 (low cleaning effort required to remove fouling). The exact formula and details about the FI are described further in Wrange et al (2020). The highest FI values were observed in Turku (Fin) (0.94), Fiskebäck (Swe) (0.91), Karlskrona (Swe) (0.75), Strömstad (Swe) (0.74) and Grömitz (Germ) (0.72). These are marinas located in both the Baltic, Baltic Transition and Atlantic regions (**Figure 11**). The lowest FI values (below 0.40) were observed in marinas in the inner Baltic Sea (Gävle and Vaasa, except Helsinki), sites mainly dominated by soft fouling.

By combining these two aspects it is possible to obtain more detailed information about how macrofouling varies in the Baltic region. As an example, if two sites both have a high % cover of macrofouling, but one has mainly calcareous species such as barnacles (high FI) and the other is covered by filamentous algae (low FI), the first site will be more problematic for boat owners and may motivate the use of antifouling paints more compared to the second site.

As shown from the study of fouling pressure in the Baltic Sea region, a hard biocide-free paint does not provide enough protection against macrofouling but requires some type of complementary mechanical cleaning or other suitable antifouling practice to avoid fouling. However, some locations displayed mainly soft fouling over time (e g Gävle and Vaasa) which could indicate that the fouling pressure is less problematic and mechanical methods would be easy to apply.

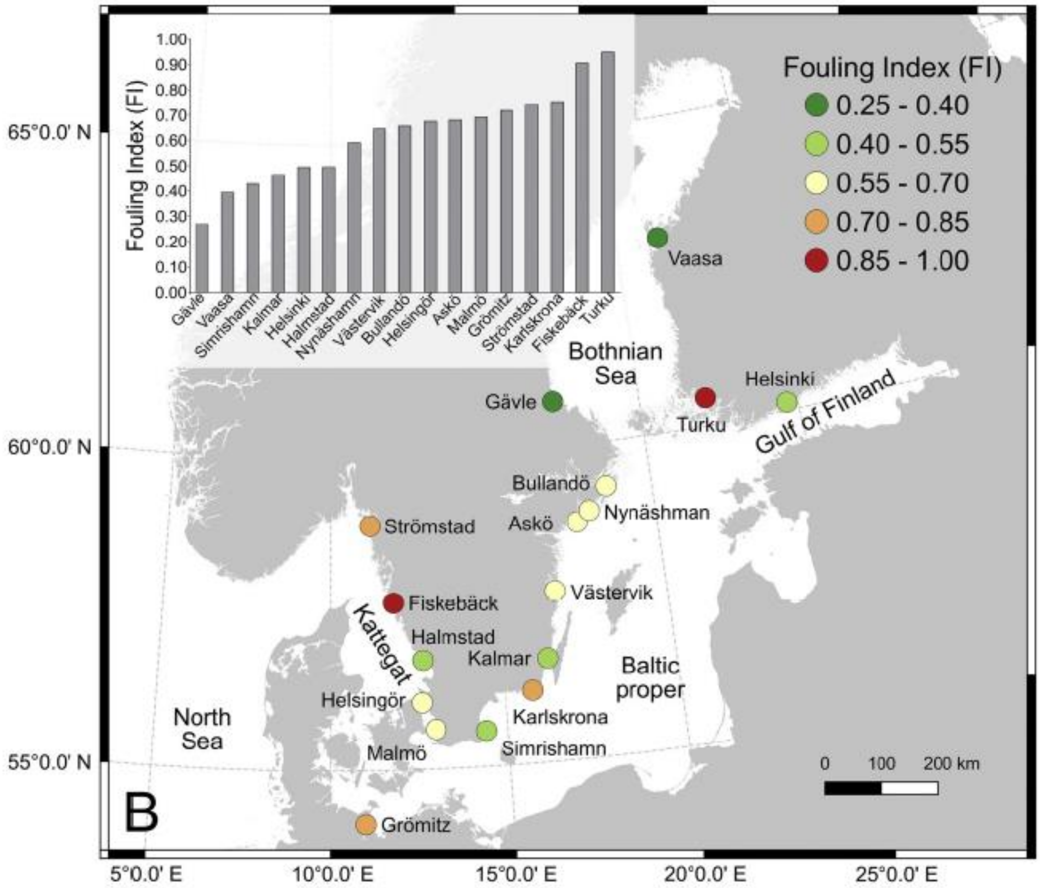

Figure 11. The marinas were classified using the Fouling Index, which combines the intensity (% fouling cover) and type of fouling. A high FI value indicates a location with high macrofouling coverage on panels after 5 months exposure and fouling dominated by hard fouling strongly attached (HFS), whereas a low FI value indicates a location with low fouling cover and/or dominance of soft fouling weakly attached (SFW).

Influence of environmental parameters on fouling variability

To understand which factors that influence the variability in fouling pressure in time and space, the patterns in macrofouling cover on panels was compared to several environmental factors (mean seasonal salinity and temperature, size of marina (number of boats and water volume inside the marina). The models showed that salinity could explain 10% of the variability, whereas most of the variability was connected to other marina-specific factors that were not included in this study (Wrange et al., 2020). Temperature did not explain a significant part of the variation in macrofouling between years (**Figure 12**). These could potentially include water exchange rate in relation to size of marina and water depth (resulting in e g a local increase in temperature at times), freshwater run-off, eutrophication, pH, shading from jetties, re-suspension of sediments and pollution from boating activities (and other sources) as well as local biodiversity (as a source of larvae of fouling species) and bottom substrate type inside and nearby the marina.

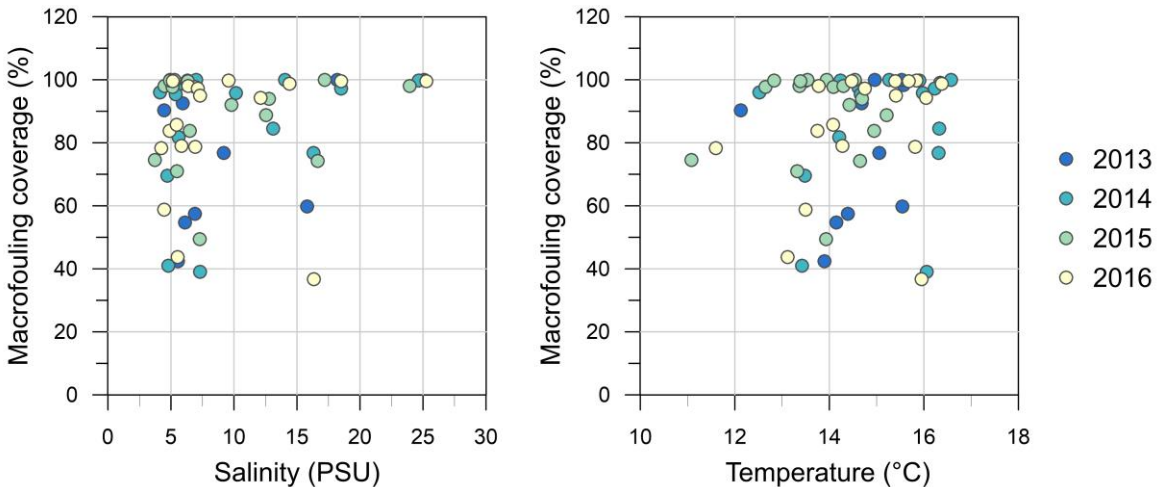

Figure 12. Macrofouling coverage (%) on biocide-free panels versus mean seasonal (May-Oct) sea surface salinity (left) and mean sea surface temperature (right).

Panel testing can support use of biocide-free alternatives

Panels are not only useful for efficacy testing of antifouling paints, but can also provide a tool to monitor biofouling pressure in different parts of the Baltic Sea to provide indications of marinas with high (or low) fouling problems, which may influence the boat owners' willingness to change their antifouling practices and provide support for decision-making concerning authorisation of antifouling products. Short-term active monitoring (e g. weekly or bi-weekly checking the panels) can be a useful tool to facilitate the use of mechanical cleaning during the summer season. This type of "early warning system" provided through a web-based interface (e g. "Havstulpanvarningen", http://batmiljo.se) has already been available in Sweden for over 20 years with generally good results for the boat owners that have use it in the Stockholm region in Sweden.

3.2.3. Fouling pressure with respect to efficacy assessment criteria

All sites in the fouling pressure study (biocide-free panels) obtained a macrofouling coverage above 25% (**Figure 9**). However, not all sites within year reached above 75% coverage which is the lowest level of macrofouling required on control panels when performing efficacy testing of paints in marine conditions. This was observed in 17% of the cases. The ECHA guidance document (2018, p.245) states that: "*In the case that an efficacy test is carried out in fresh water […] a 75 % or more coverage of* *fouling organisms on a negative control test panel cannot be expected*". The document further states that an efficacy test with below 75% on control panels can still be valid, however an explanation should be provided for why the test should be considered valid. However, it also mentions that "*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.*" However, it is still unclear how these interpretations should be done in a consistent way.

3.3. EFFICACY OF ANTIFOULING PAINTS

3.3.1. Efficacy of commercial copper-based antifouling paints

Paint performance with respect to macrofouling was assessed from two existing studies (the CHANGE project, unpublished data and Lagerström et al., (2020b)) for a total of 10 commercial paints approved for the Swedish market. Sweden has regional restrictions for the use of biocidal antifouling paints and the market is thus divided into two types of products: east coast paints and west coast paints (**Figure 13**). The Swedish regional restrictions entail a higher level of environmental protection on the east coast compared to the west coast (Swedish Chemicals Agency, 2017). East coast paints therefore contain, and leach lower amounts of copper compared to west coast paints (Lagerström et al., 2018, 2020b). Consequently, east coast paints may be used on all boats between Örskär and the Norwegian Border whereas the use of west coast paints is restricted to boats with home mooring between Trelleborg and the Norwegian border.

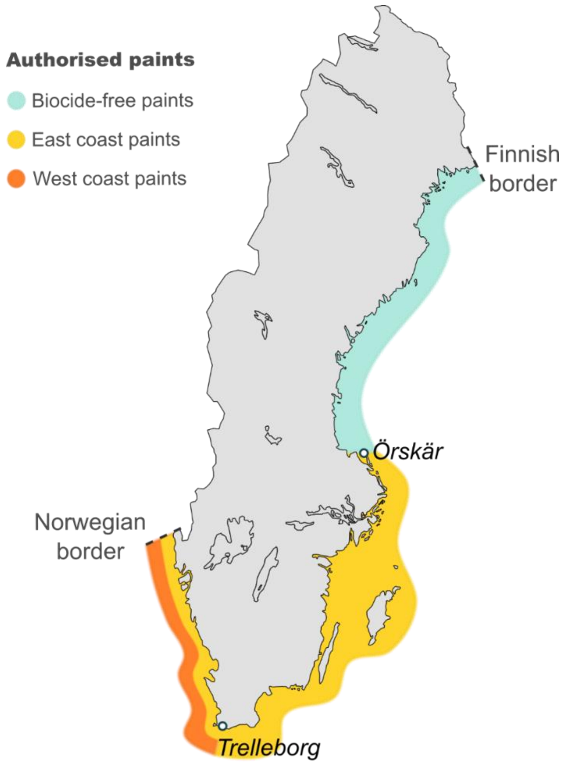

Figure 13. The division of the Swedish coast into regions where different antifouling paints are authorised.

In the referred studies, four of the investigated paints were so-called east coast paints whereas the other six were west coast paints (**Table 2**). As there were roughly 25-30 approved antifouling paints for amateur use at any given time over the course of the referenced studies, the sample size of 10 paints covers a large portion of paints on the Swedish market. Furthermore, paints of the main three types (hard, polishing/ablative and self-polishing) are all represented, albeit only one of the studied paints is of self-polishing type. The concentrations of copper in the paints cover a wide range of concentrations (6.9 to 34.6% Cu_2O).

In both studies, the paints were applied to four replicate panels and exposed statically in leisure boat marinas for 5 months during the summer boating season (May-October). The performance of the paints was carried out through comparison of the macrofouling coverage to the 25% macrofouling criteria. However, since many boat owners (and paint manufacturer) would not consider a 25% fouling coverage as an efficient product, a second efficacy criteria of 0-5% fouling coverage was used in the assessment. The exposure locations from the two studies are shown in **Figure 14**.

Table 2. Antifouling paints available for the Swedish market that have been evaluated for efficacy. The paint type, as marketed by the manufacturer was either polishing (P), self-polishing (SP) or hard (H). Cell colours for the authorised use correspond to those in Figure 13.

Paint	Product name registration number (*authorization year*)	Active substance (wt%, ww)	ZnO (wt%, ww)	Authorised use	Study years	Studied colour	Marine study sites
P-1	Mille Light Copper 5039 (*2011*)	Cu_2O 6.9%	10 – 25%	East coast	2014-2016 2018	Black Red	17 3
P-2	Biltema Antifouling BS 5149 (*2013*)	Cu_2O 7.5%	10 – 25%	East coast	2014-2016	Black	17
P-3	Cruiser One 5001 (2011)	Cu_2O 8.5%	2.5 – 25%	East coast	2013-2016 2018	Black Red	17 3
P-4	Biltema AF 4943 (*2010*)	Cu_2O 13%	20 – 25%	West coast	2013-2016 2018	Black Red	17 3
P-5	Micron Superior 5146 (*2013*)	Cu_2O 31.93%	2.5 – 25%	West coast	2018	Red	3
SP-1	Mille Xtra 4595 (*2009*)	Cu_2O 34.6%	10 – 25%	West coast	2013-2016	Black	17
H-1	Lefant Nautica 4881 (*2009*)	Cu_2O 7.0%	20 – 100%	East coast	2018	Red	3
H-2	VC17m 5008 (*2011*)	Cu powder 17.96%	0%	West coast	2018	Graphite	3
H-3	Racing VK 4197 (*2010*)	Cu_2O 22.02%	10 – 25%	West coast	2018	Red	3
H-4	Hard Racing Xtra 4596 (*2009*)	Cu_2O 33.1%	10 – 25%	West coast	2018	Red	3

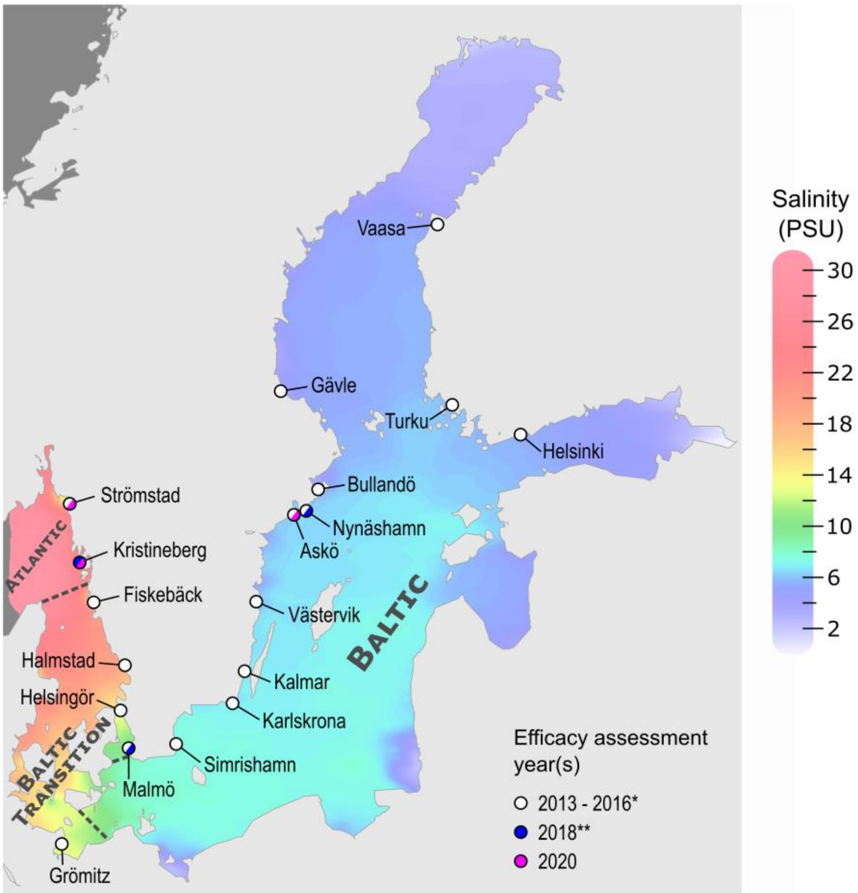

Figure 14. Map of exposure locations for the various assessment years (*CHANGE, **(Lagerström et al., 2020b), and the field testing 2020).

Large-scale panel testing in the Baltic Sea (2013-2016)

In this comprehensive study, the efficacy of five commercial antifouling paints was assessed. PMMA panels coated with different black commercial antifouling paints were exposed at 17 sites around the Baltic Sea during four consecutive boating seasons (2013-2016) (**Figure 14**). In 2013, only 10 of the Swedish sites and 3 of the 5 commercial paints were included as a pilot study (**Table 2**). The assessed paints were chosen to obtain a range of different copper content and included paints P-1 (6.9% Cu_2O), P-2 (7.5% Cu_2O), P-3 (8.5% Cu_2O), P-4 (13% Cu_2O) and SP-1 (34.6% Cu_2O) (**Table 2**). As a control, a black biocide-free hard paint was used (International Lago racing). The control panels were the same as the ones described in the fouling pressure study in section 3.2.

The panels were coated with one layer of primer followed by two layers of antifouling paint (with sufficient drying time in between) using a high-end roller system with nylon and super wool resulting in dry film thicknesses of roughly 65 ± 5 µm. The coated panels where thereafter attached to thin lines and hung vertically along jetties inside leisure boat marinas around the Baltic Sea. The panels were retrieved at the end of each boating season (after 5 months exposure) and transported to the laboratory for analysis. Each panel was photographed and the percentage coverage of macrofouling was analysed based on the photos.

High performance of paints in most parts of the Baltic sea region

The results, presented in **Table 3**, show that most paints were highly efficient in preventing fouling throughout the Baltic Sea region. The paint P-4 was extremely effective (<5% macroscopic fouling cover) for all years and all locations throughout the whole Baltic Sea region (including the Baltic Transition and Atlantic sites). Two paints produced for Baltic Sea conditions (P-1 and P-2) were consistently very effective against macrofouling at all Baltic Sea sites but also at most sites along the Swedish west coast (Baltic Transition/Atlantic) except in one year (2015) where coverage of macrofouling reached above 25% at the Atlantic site (Strömstad).

Two of the paints (P-3 and SP-1) did show some inconsistency in performance between years and sites. P-3 obtained fouling above 20% cover during six occasions, where most occurred in 2015. P-3 was not effective (>25% cover) in the Atlantic (Strömstad) in any of the boating seasons that were tested and displayed fouling cover just below 25% (mainly barnacles) in Turku (Finland) both 2015 and 2016. Similar to P-3, the paint with the highest copper oxide content (34.6%) of the five commercial paints tested (SP-1), showed surprisingly low performance in the Baltic site Turku in both 2015 and 2016, with a macrofouling cover above 60%. Similar to P-3, SP-1 did not perform well (>25% cover) in Karlskrona (Baltic) and Strömstad (Atlantic) in 2015.

Environmental factors impact paint performance

The observation of poor performance of P-3 and SP-1 at certain sites within some years leads to the question if environmental conditions could explain the results. Therefore, data on mean seasonal (May-October) salinity and temperature for surface water (0-3m depth) was obtained from the biogeochemical NEMO-SCOBI model (Liu et al., 2013) provided by the Swedish Meteorological and Hydrological Institute (SMHI) for all locations where panels were exposed during 2013-2016. Data on means and variability were retrieved both from the four years where the paints were exposed in the field, as well as an extended time period (2008-2018) to investigate if the selected years for the panel tests were representative for the locations or not.

The environmental parameters showed that 2015 was a colder year compared to the other years, both in comparison to the four panel years (**Figure 15**), as well as compared to the 11-year time series provided by the NEMO-SCOBI model (**Table 4**). Salinity also varied slightly between years within location, but the pattern was not consistent for all locations and did not correlate to the variation in paint performance between sites (**Figure 15**).

% macrofouling coverage	Efficacy assessment
< 5	Effective
5-25	Effective
≥ 25	Not effective

Table 3. Average macrofouling coverage (%) on panels in static raft testing after 5 months exposure at 17 locations for the five commercial paints studied in the CHANGE project during 2013-2016. In 2013 only 10 Swedish sites and three of the paints were included in a pilot study, which was then extented during the following three years. The salinity corresponds to average yearly salinity as modelled between 0-3 m depth by the NEMO-SCOBI biogeochemical model for 2013-2016.

			Control (0% Cu_2O)				P-1 (6.9% Cu_2O)				P-2 (7.5% Cu_2O)				P-3 (8.5% Cu_2O)				P-4 (13% Cu_2O)				SP-1 (34.6% Cu_2O)			
Marine region	Location	Salinity	2013	2014	2015	2016	2013	2014	2015	2016	2013	2014	2015	2016	2013	2014	2015	2016	2013	2014	2015	2016	2013	2014	2015	2016
Baltic	Gävle	4.1	90	96	75	78		0	0			0	1		7	0	0		0	0	0		0	0	0	
	Vaasa	4.7		41	98	59		0	0	0		0	0	0		0	0	0		0	0	0		0	3	0
	Helsinki	5.1		70	98	84		0	0	0		0	0	0		1	0	0		0	0	0		0	0	0
	Bullandö	5.3		82	71	86		0	0	0		0	0	0		0	0	0		0	0	0		0	0	0
	Turku	5.3		98	100	100		0	0	1		0	0	1		1	22	24		0	0	0		0	61	74
	Nynäshamn	6	42	100	100	44		1	0	0		1	0	1	0	1	0	0	0	1	0	0	0	0	0	0
	Askö	6.2	93	95	100	79		0	1			0	2		0	0	9		0	0	0		0	0	3	
	Västervik	6.7	55	100	100	98		1	0			1	0		1	2	0		1	2	0		2	1	0	
	Kalmar	6.7	98	99	84	79		0	0			0	0		0	0	0		0	0	0		2	0	0	
	Karlskrona	7		100	98	97		0	0	3		0	4	1		5	20	7		0	3	1		0	36	7
	Simrishamn	7.3	58	39	49	95		0	0			0	0		0	0	0		0	0	0		0	0	0	
Baltic Transition	Malmö	10.1	77	96	94	100		2	0			1	0		0	2	1		0	0	0		0	0	1	
	Helsingör	13.1		85	94	94		1	13			0	6			3	13			0	2			0	3	
	Grömitz	13.9		100	89	99		5	0	4		8	0	0		3	0	0		2	0	0		1	0	0
	Halmstad	16.8	60	77	74	37		1	0			1	0		0	3	1		0	1	0		0	0	0	
	Fiskebäck	17.8	100	97	100	100		0	1	1		0	0	0	0	0	2	2	1	0	0	0	0	0	0	0
Atlantic	Strömstad	25.1	100	100	98	100		8	40			4	38		29	54	92		0	4	2		0	0	72	
% of tested locations where paint was deemed effective			0	0	0	0		100	94	100		100	94	100	90	94	94	88	100	100	100	100	100	100	82	88

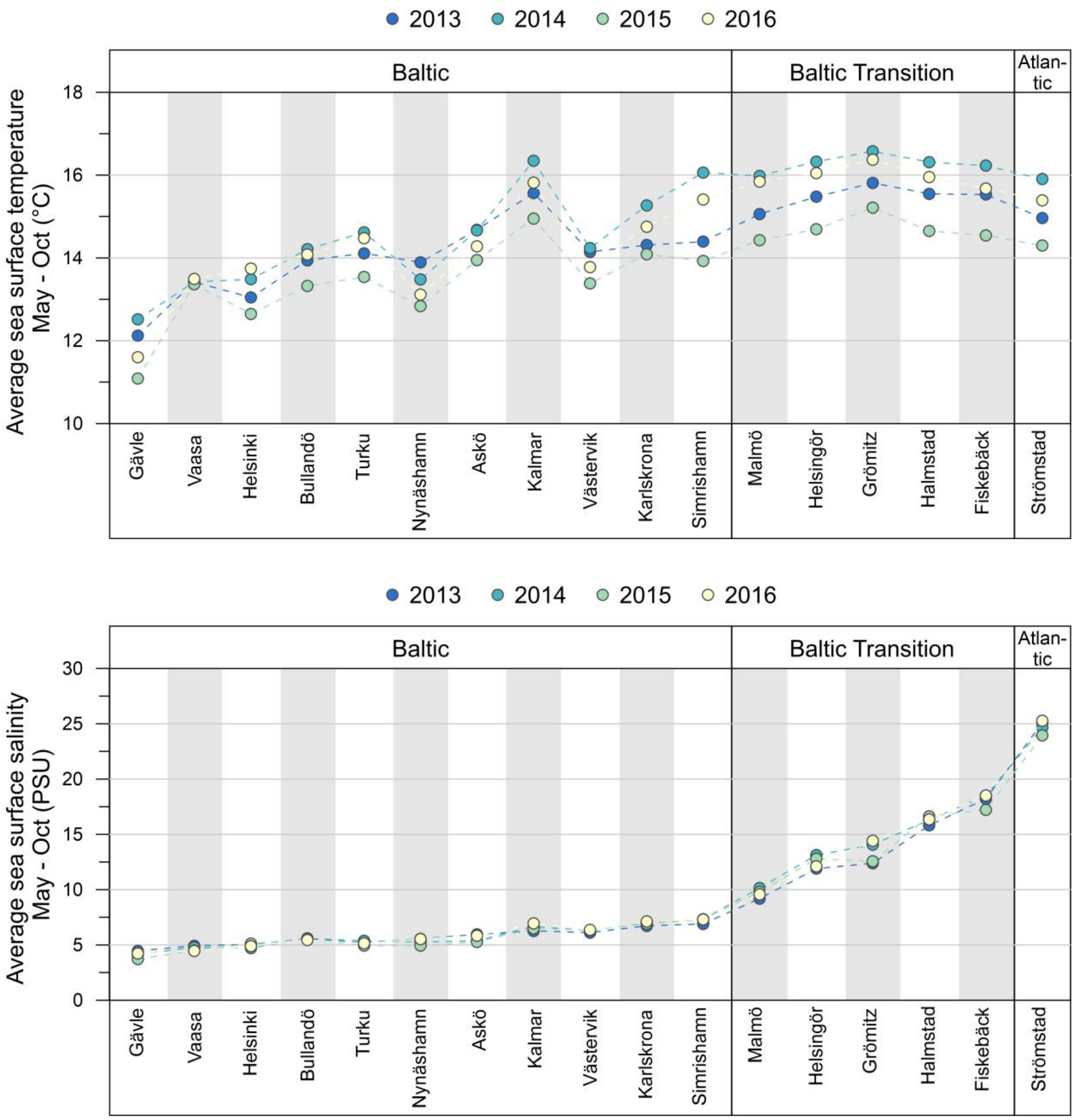

Figure 15. Mean seasonal (May-October) temperature (top graph) and salinity (bottom graph) between 0-3 m depth based on the NEMO-SCOBI biogeochemical model for the four years of large-scale panel testing in the Baltic Sea. Sites are sorted based on long-term mean yearly salinity (average of a modelled 11 years' time series 2008-2018) for each site (stated in parenthesis).

Temperature and salinity are known to affect the release rate of copper from antifouling paints (Ferry and Carritt, 1946; Rascio et al., 1988; Lagerström et al., 2018, 2020b). Low temperature and low salinity have been shown to reduce the release of copper which could lower the performance of the paints. This could potentially explain the reduced performance of both P-3 and SP-1 in 2015, despite performing well during the other years. In addition, the three sites where these two paints showed reduced performance are also among the four sites with highest fouling pressure (Strömstad (100% macrofouling cover), Turku (99%) and Karlskrona (98%)). Hence, the variation in seasonal temperature between the years (**Figure 15**), supports the hypothesis that a combination of high fouling pressure and low seasonal water temperature resulted in reduced performance of some paints in 2015. It also indicates that higher water temperatures in 2014 may have provided favourable conditions for paints to perform especially well (**Table 3**). The four years of large-scale field testing (2013-2016) represent a wide range of seasonal temperatures, which covers part of the expected variation over time as observed in the long-term modelling data (**Table 4**).

As previously mentioned, the performance of antifouling paints is affected by a combination of several environmental factors including e g. fouling pressure, temperature and salinity, but possibly also other factors that are not accounted for in this study. This highlights the importance of taking environmental factors into account when determining the paint performance as well as the need for relevant field testing in areas where the paints are to be used.

Table 4. Modelled average sea surface temperatures (°C) in May – Oct for 2008 – 2018 at the efficacy assessment locations, based on the NEMO-SCOBI model. For each location, the colour of the cells highlights the years where the temperature was ≥ 5% below (blue) or above (red) the 2008 – 2018 average temperature.

Location	Salinity	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Gävle	4.1	12.2	10.6	11.0	12.3	11.4	12.1	12.5	11.1	11.6	11.7	11.7
Vaasa	4.7	11.7	11.8	12.2	13.7	12.6	13.4	13.4	13.4	13.5	12.6	14.3
Helsinki	5.1	12.9	12.7	13.5	13.8	12.6	13.0	13.5	12.6	13.7	12.3	14.1
Bullandö	5.3	13.6	12.8	13.1	13.8	12.8	13.9	14.2	13.3	14.1	14.1	14.5
Turku	5.3	14.7	14.3	15.4	15.9	13.6	14.1	14.6	13.5	14.5	14.1	15.7
Nynäshamn	6	12.6	11.4	12.6	12.9	11.9	13.9	13.5	12.8	13.1	12.6	13.7
Askö	6.2	13.4	12.5	13.7	14.2	13.1	14.7	14.7	13.9	14.3	13.8	15.1
Kalmar	6.7	16.2	15.9	15.2	15.8	14.9	15.6	16.3	15.0	15.8	15.7	16.9
Västervik	6.7	13.6	12.3	12.6	13.2	12.3	14.1	14.2	13.4	13.8	13.3	13.8
Karlskrona	7	13.6	12.7	12.7	13.1	12.3	14.3	15.3	14.1	14.8	13.5	14.8
Simrishamn	7.3	14.0	13.2	13.2	13.2	12.6	14.4	16.1	13.9	15.4	13.9	16.1
Malmö	10.1	15.1	14.5	13.9	14.9	14.2	15.1	16.0	14.4	15.8	14.5	16.3
Helsingör	13.1	15.5	14.9	14.7	15.4	14.7	15.5	16.3	14.7	16.0	15.1	16.8
Grömitz	13.9	15.6	15.2	15.2	15.1	14.9	15.8	16.6	15.2	16.4	15.7	17.2
Halmstad	16.8	15.4	15.0	14.9	15.7	14.8	15.5	16.3	14.7	16.0	15.3	17.1
Fiskebäck	17.8	15.2	15.0	14.2	15.2	14.9	15.5	16.2	14.5	15.7	15.3	17.0
Strömstad	25.1	15.3	14.8	14.2	14.7	14.5	15.0	15.9	14.3	15.4	14.9	16.5

Efficacy of paints during two boating seasons

To investigate if the commercial paints were effective during more than one field season, the panels from 2015 were gently cleaned from biofilm and silt using water and a soft sponge and stored in a cool and dry place during winter. They were deployed again in May 2016 and exposed for yet another boating season following the same exposure method and efficacy assessment as described previously.

The results show that all commercial paints were highly effective against fouling (<5% macrofouling cover) at the two brackish sites located in the Baltic Sea (Bullandö (Swe) and Helsinki (Fin)). Furthermore, two out of five commercial paints (P-2 and P-4) showed excellent performance during at least two full boating seasons in Fiskebäck (Swe) – a marina with a high fouling pressure in the Baltic Transition area. One of these two paints (P-2) is designed specifically for use in the Baltic Sea. The results show that several commercial antifouling paints are highly effective during two full boating seasons in the Baltic region (2x5 months) without re-painting, despite having a paint thickness of about 65 µm which corresponds to approximately 1.5 boating seasons (since the recommended paint layer is around 45um for most of the tested paints). This is provided that the coating is cleaned carefully using a sponge instead of high-pressure hosing (which boat owners often use) to avoid damaging the paint layers and also provided that the paint surface does not erode due to friction from boating activities (**Figure 16**). By encouraging boat owners not to re-paint each year, pollution from maintenance work (scraping and painting) can be reduced. In addition, this could also save both time and money for the boat owners without compromising fouling prevention.

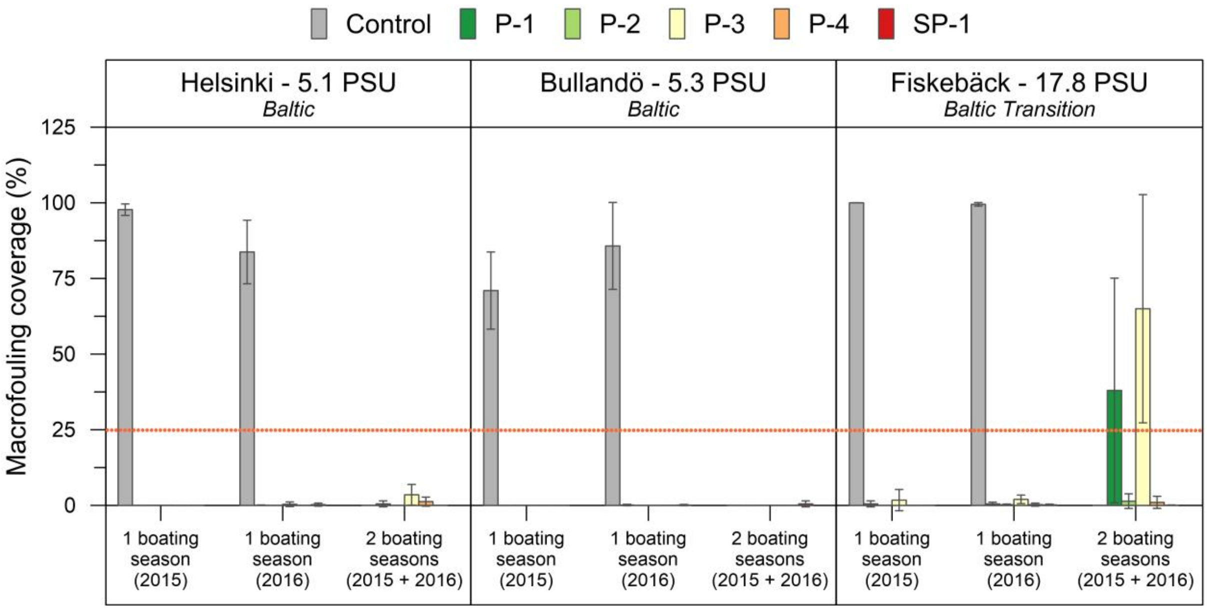

Figure 16. Macrofouling cover (%) on painted panels exposed during one or two boating seasons (one season = 5 months) at three sites in the Baltic and Baltic transition region in 2015-2016. Performance of commercial Cu2O-based paints was compared to a newly painted biocide-free control panel (Lago racing) (grey bars). The painted panels from 2015 were saved and exposed during 2016, which is shown to the right within each location.

Results from Lagerström et al. 2020b (exposure in 2018)

In 2018, eight copper paints and a control paint were assessed for efficacy at three coastal location, each in one of the three marine regions: Nynäshamn (Baltic), Malmö (Baltic Transition) and Kristineberg (Atlantic) (**Figure 14**). The average macrofouling coverage is shown in **Table 5**. The coverage on the control shows the fouling pressure at the three locations to be within the range of that observed during both previous (**Table 3**) and subsequent years (**Figure 18.** Antifouling performance of the fouling release coating (Silic One, Hempel), Cu Paint A (Sigmarine 530, PPG), Cu Paint B (Sea Force 60, Jotun) and the Cu-gradient panel based on VC 17m (International).). All paints were found to be highly efficient, with an average macrofouling coverage of 2.5% at the most (paint H-1). In nearly all instances, no macrofouling at all was present on the panels after 5 months. As seen in **Table 4**, the seawater temperatures in 2018 were elevated in many locations, which may have caused higher leaching rates of copper from the studied paints. This could perhaps explain the extremely high efficacy observed for all the eight paints this year.

Table 5. Average macrofouling coverage (%) on panels in static raft testing after 5 months exposure at 3 locations for 8 copper-based paints and a control during 2018. Colour coding matches that of Table 3.

Paint	Baltic	Baltic Transition	Atlantic
	Nynäshamn (6.4 PSU)	Malmö (7.5 PSU)	Kristineberg (26.9 PSU)
Control	37.5	97.25	100
H-1	2.5	0	0.25
H-2	0	0	0
H-3	0	0	0
H-4	0	0	0
P-1	0	0	0
P-3	0	0	0.5
P-4	0	0	0
P-5	0	0	0

3.3.2. Alternatives to high leaching copper-based antifouling paints

As shown in section 3.3.1, most commercial antifouling paints were efficient in preventing fouling irrespectively of Cu_2O concentration in the paint. This indicates that at least some of the commercial coatings leached copper in excess and one possible solution to reduce excessive use of copper in antifouling paints could be to adjust the amount of copper in the coatings and investigate the maximum concentration of copper required to prevent fouling in different marine regions. Another more sustainable solution to reduce emissions of biocides would be to use biocide free antifouling strategies, e.g. epoxy coatings, fouling release coatings, hull covers, brush washing stations and different hand-held cleaning devices. The current knowledge on the level of efficacy of these strategies to prevent biofouling is limited, particularly in comparison to commercial copper-based antifouling paints.

Efficacy of fouling release coatings, high-leaching copper coatings and experimental low-leaching copper coatings during 2020

The efficacy of fouling release coatings, commercial professional antifouling coatings (to be used on ships) and experimental low-leaching copper coatings was compared in field trials during 2020. The copper coatings for professional use; Sigmarine 530 (PPG), from now on referred to as Paint A and Sea Force 60 (Jotun), from now on referred to as Paint B, are not intended to be used on recreational vessels but were included in the study to represent products with excessive toxicity. The fouling release coating Silic One (Hempel) was included as it represents a biocide-free alternative to copper-based coatings. The low-leaching experimental copper coatings was included to investigate the lowest dose required to prevent macrofouling in different sea regions. The experiment was conducted for a 5-month period (beginning of July to end of November) with coated 10*10 cm panels exposed statically at 1 m depth (±0.3 m) at Askö research station (Baltic region), Kristineberg (Atlantic region) and Tjärnö (Atlantic region) (exposure locations are shown in blue in **Figure 14**).The set-up in the field is shown in **Figure 17**. Since the panels had to be deployed as early as possible during the summer to cover the fouling season (project started officially in July), no field release rates of copper were determined due to time constraints. In future projects, it is however recommended to include field release rate measurements in efficacy assessments of antifouling paints.

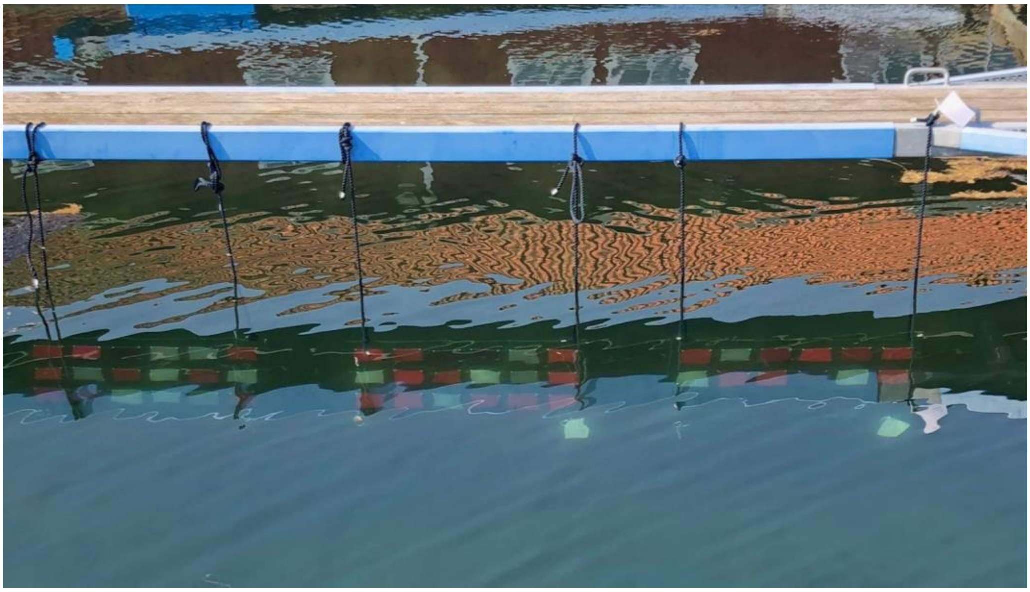

Figure 17. Arrangement of static panels in the field trials. Picture shows the experiment at Kristineberg marine research & innovation center (Atlantic region according to new ERA tool).

All paints except the experimental coatings were applied in two layers on 10*10 cm PVC (Poly Vinyl Chloride) panels using a 10 cm wide roller (with sufficient time to allow for drying of the paint). For comparison and to assess the fouling pressure, panels with primer paint (Hempel's Underwater primer) were used as controls. The panels used for the fouling release paint and the two copper coatings were precoated with the primer prior to the painting with fouling release and copper paints, respectively. The thin-film copper-based antifouling paint VC 17m (International) (see **Table 2** for further details about the paint) was used to develop five different experimental copper paints and a control. VC17 m consist of a can of paint (which consists mainly of solvents) and a bag containing copper powder that shall be mixed thoroughly prior to application. The copper powder was used and mixed in different amounts with the paint to obtain a series of paints holding copper concentrations of 0%, 2.5%, 4.8%, 9%, 17.1% and 32.6% Cu (in wet weight %). The second highest Cu concentration (17.1%) is close to the actual copper concentration obtained if the copper powder is mixed with the paint matrix (17.96 %). The six paints were applied on a 30*10 cm PVC panel to obtain a copper-gradient; starting with the control and increasing copper concentrations. Two layers of paints were applied using a 5 cm wide roller to obtain 5 cm wide stripes of each coating. The results after 5 months exposure is shown in **Figure 18**.

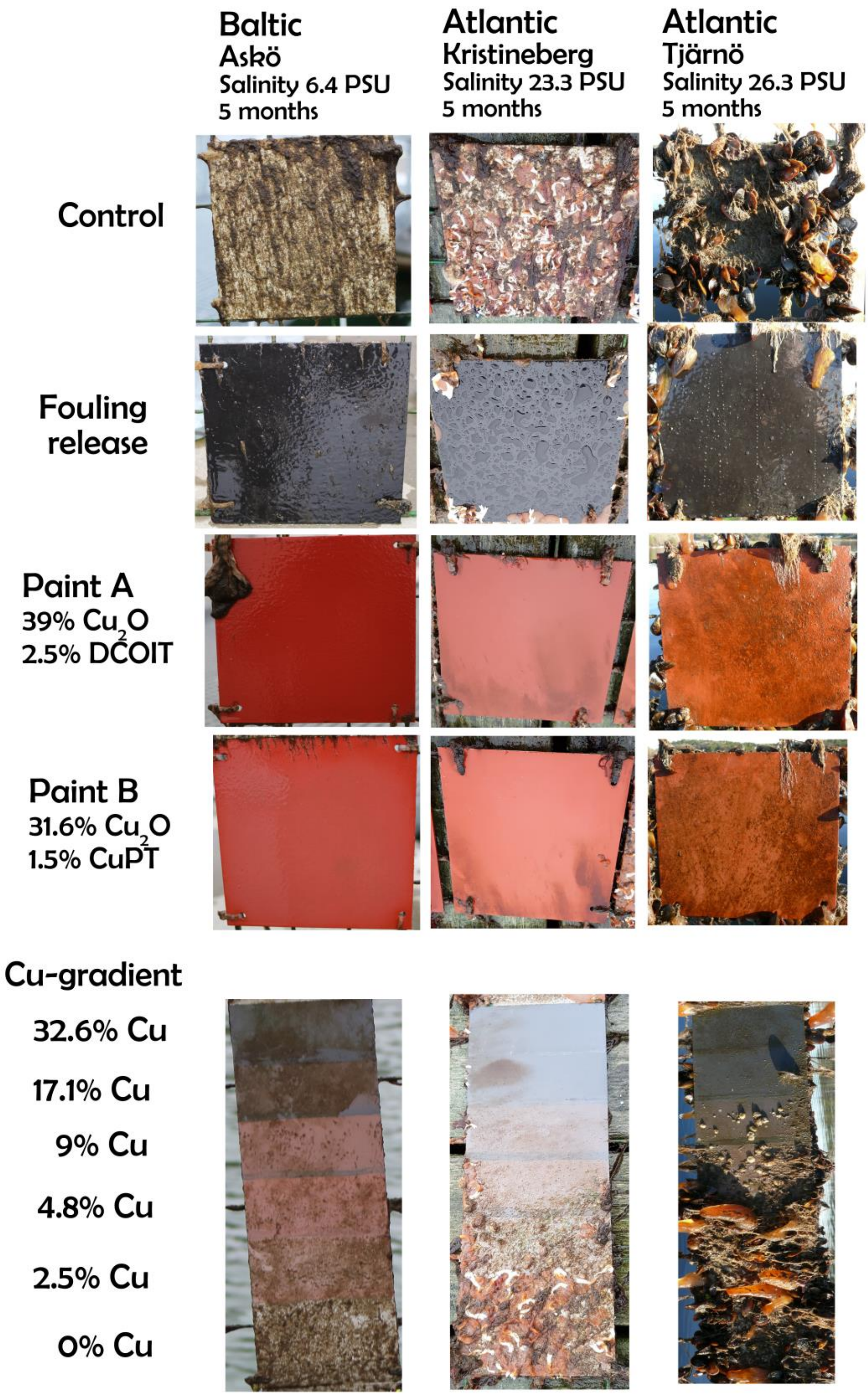
Baltic
Askö
Salinity 6.4 PSU
5 months
Atlantic
Kristineberg
Salinity 23.3 PSU
5 months
Atlantic
Tjärnö
Salinity 26.3 PSU
5 months
Control
Fouling release
Paint A
39% Cu_2O
2.5% DCOIT
Paint B
31.6% Cu_2O
1.5% CuPT
Cu-gradient
32.6% Cu
17.1% Cu
9% Cu
4.8% Cu
2.5% Cu
0% Cu

Figure 18. Antifouling performance of the fouling release coating (Silic One, Hempel), Cu Paint A (Sigmarine 530, PPG), Cu Paint B (Sea Force 60, Jotun) and the Cu-gradient panel based on VC 17m (International).

The fouling was lowest on the controls exposed in the Baltic Sea and consisted primarily of soft fouling (algae). The fouling pressure was higher at the more saline study site Kristineberg where the control panels were completely covered with macrofouling comprised of mainly calcareous tubeworms, barnacles and encrusting bryozoans. The fouling pressure was even higher at Tjärnö with multiple layers of blue mussels, barnacles and tunicates on the control panels. The fouling release coating demonstrated nonetheless an excellent performance in preventing hard fouling. No hard fouling was observed on any of the panels (other than on the edges, but this is due to fouling growing on the back of the panel). In addition, no soft fouling was observed on the fouling release paints exposed at Askö or Kristineberg and only a thin layer of microalgae was observed at Tjärnö. This antifouling performance is comparable to what was observed for the commercial "ship paints" Paint A and Paint B, both holding high Cu_2O concentration and booster biocides (DCOIT or copper pyrithione). This is in line with results from Oliveira and Granhag (2020) who investigated the performance of a fouling release coating and a copper-based ship coating during a one-year field study in Gothenburg harbour. The result showed both coatings to efficiently prevent macrofouling, but the fouling release coating had significantly lower coverage of slime. These results go against what older studies have suggested, i.e. that fouling release coatings is not efficient in static conditions and require a speed higher than 8 knots to remove fouling (Lejars et al., 2012).

The copper gradient panel exposed in the Baltic Sea (Askö) did not show any macrofouling at any copper concentration, including the control. Hence, no settling of barnacles, which are the main macrofouling species in the Baltic Sea, did occur during the 5-month exposure at Askö. Slime was however found to completely cover the control (0% Cu) after 5 months. The slime was reduced substantially in the lowest copper concentration (2.5% Cu) and only a minor reduction in slime coverage was then observed with increasing copper concentrations. For Kristineberg, macrofouling was present on 100% of the gradient containing 0 or 2.5% Cu. However, on the 4.8% Cu treatment no macrofouling was present, except on the edges on the panel which is excluded in the analyses. For Tjärnö, 17.1% Cu was required to completely prevent macrofouling, but also the 9% Cu treatment fulfil the efficacy requirements of <25% surface cover of macrofouling.

This gradient-methodology could be used to site-specifically assess how much copper that is required to prevent macrofouling in other EU marine regions. The method could also be used by paint manufacturer to demonstrate that their product fulfils the requirements of minimum necessary dose. It is however recommended that future efficacy studies are complemented with field measurements of biocidal release rates from the coatings.

Efficacy of experimental low copper AF paint in the Baltic region during 2015 and 2016

Experimental antifouling paints were also developed in the CHANGE-project to evaluate the minimum concentration of copper oxide required in paints to efficiently prevent macrofouling. The paints were developed together with a paint manufacturer (Boero Group) where cuprous oxide and zinc oxide were added in different concentrations (see Table 6). Zinc oxide was included in the experimental set up to investigate if and to what extent it increased the antifouling property of the paints. PMMA panels (15x15 cm) were coated with paint using the same method as in the CHANGE studies explained previously in section 4.1., i.e., one coat of primer followed by two coats of antifouling paint. The panels were subsequently deployed along thin ropes at approx. 1m depth from jetties in leisure boat marinas. The panels were exposed for 5 months during the boating season (mid-May to mid-Oct) in six marinas in 2015 and three marinas in 2016 around the Baltic Sea. The panels were retrieved and analysed by photographing and estimating macrofouling percentage cover as described in section 3.3.1.

Table 6. Cu_2O and ZnO concentration added to a generic rosin-based paint.

Marine Region	Location	Year	Cu_2O %	ZnO 0%	ZnO 10%	ZnO 20%
Atlantic	Strömstad	2015	0	x	x	x
Baltic Transition	Fiskebäck	2015-2016	4.3	x	x	x
Baltic	Simrishamn	2015	6.1	x	x	x
	Bullandö	2015-2016	8.5	x	x	x
	Vaasa	2015	11.7	x	x	x
	Helsinki	2015-2016	16.3	x	x	x

The results from 2015 showed a large variation in fouling pressure between the stations (**Figure 19**). In Strömstad (Skagerrak) and Fiskebäck (Kattegat), the control paint (0% Cu_2O and 0% ZnO) had almost 100% cover of macrofouling after 5 months exposure. A similar fouling pressure was observed in Helsinki (87% cover). In contrast, only 6% of the control panels were covered with macrofouling in Bullandö (Baltic Proper) while Vaasa (64% cover) and Simrishamn (42% cover) showed moderate fouling pressure. The results showed that the addition of Cu_2O to increase the antifouling efficacy at all stations, but the minimum concentration required to prevent macrofouling differed substantially between the test sites. In Fiskebäck and Vaasa, less than 2% macrofouling coverage was observed on the coatings with the highest (16.3%) Cu_2O concentration (when no ZnO was included). For Helsinki, Simrishamn and Bullandö, 11.7% Cu_2O was required to prevent macrofouling (<1% coverage) and in Strömstad even the highest Cu_2O treatment showed >30% coverage of macrofouling. The antifouling efficacy increased when 10% ZnO was included in the copper coatings. Only 4.3% of Cu_2O was required to prevent macrofouling in Fiskebäck, Simrishamn, Bullandö, Vaasa and Helsinki when 10% ZnO was included in the paint formulation. In Strömstad, none of the paint formulation did however completely prevent macrofouling, but the best protection was observed when 20% ZnO and 16.3% Cu_2O was added (<2% coverage of macrofouling).

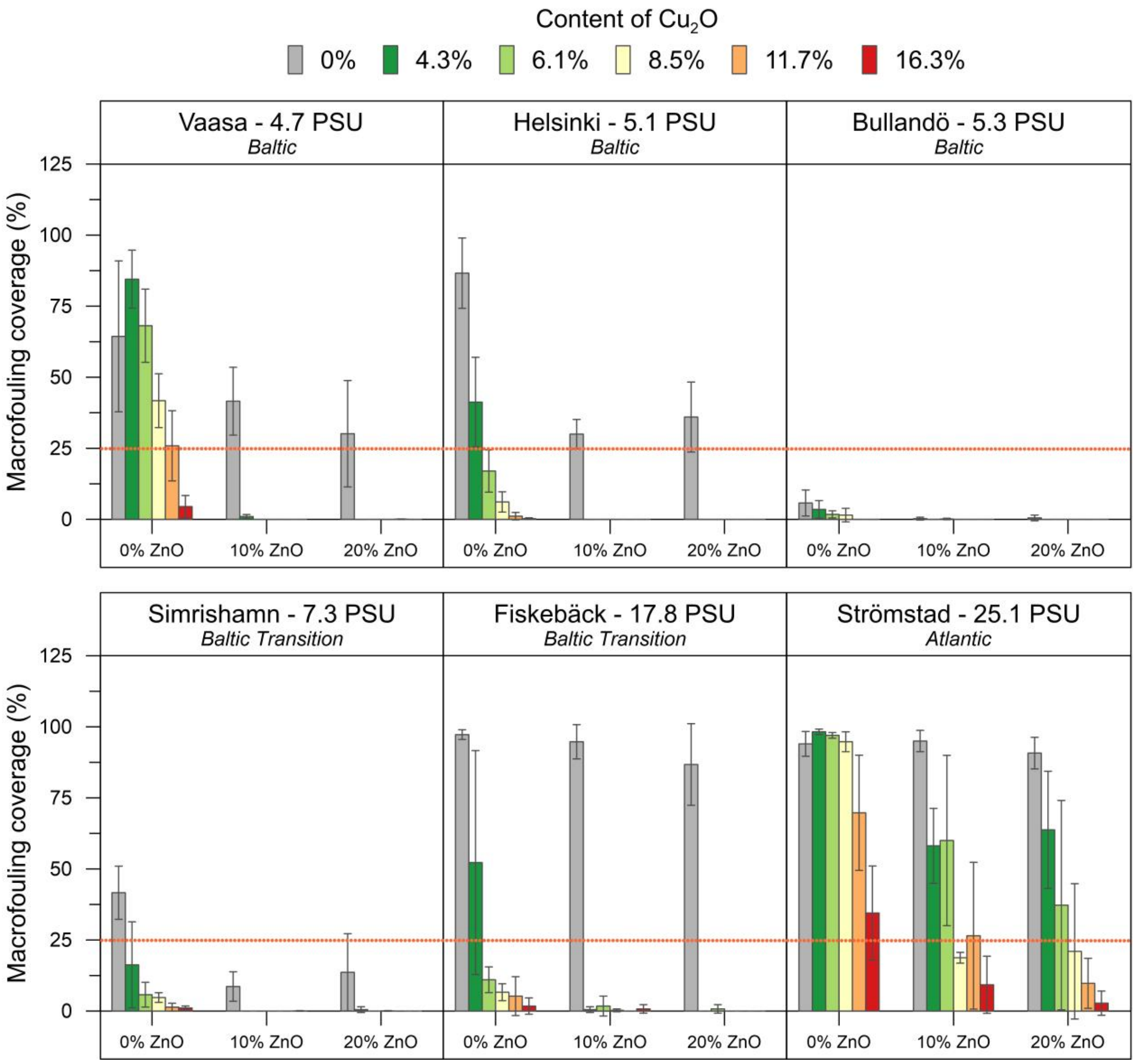

Figure 19. Antifouling performance of experimental coatings holding different Cu_2O and ZnO concentrations. The coatings were exposed under static conditions in 2015 for 5 months in marinas located in the Baltic Sea (Vaasa, Helsinki, Simrishamn, Bullandö), Baltic Transition (Fiskebäck) and Atlantic (Strömstad). The bars show averages (+/- standard deviation).

In 2016, a similar experiment was conducted in Fiskebäck, Bullandö and Helsinki with the same experimental paint formulations. Although the fouling cover of control panels was equally high or higher (>75%), the results of the Cu_2O paints were quite different with almost no macrofouling present (<5%) even on the lowest Cu_2O paint (when no ZnO was included) at all three test sites (**Figure 20**). As discussed in section 3.3.1, the increased antifouling protection in 2016 could be explained by the higher water temperature which has shown to have a major impact on both the dissolution rate of Cu_2O and of rosin (i.e. the paint formulation) but also a potential increase of fouling pressure during warmer years.

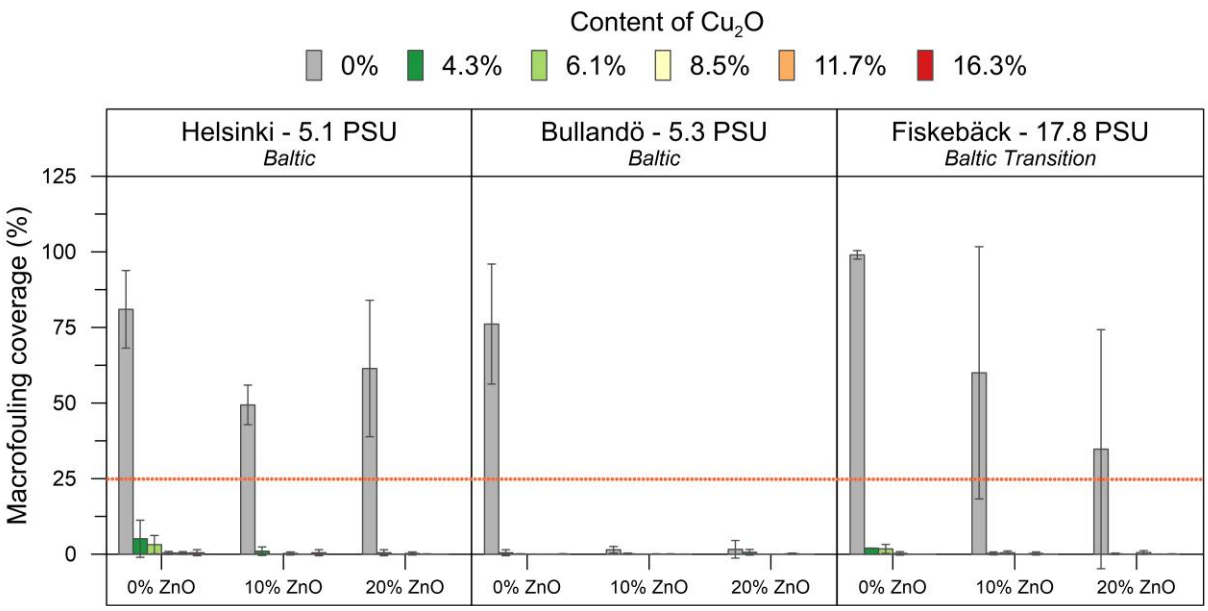

Figure 20. Antifouling performance of experimental coatings holding different Cu_2O and ZnO concentrations. The coatings were exposed static 2016 in marinas located in the Baltic Sea (Helsinki and Bullandö) and Kattegat (Fiskebäck).

3.4. CRITICAL & MINIMUM RELEASE RATE OF COPPER

3.4.1. Critical release rate

To estimate the critical release rate of copper (RR_{crit}) in different areas of the Baltic, Baltic Transition and Atlantic regions, data from three studies were compiled (**Table 7**). In all the studies, static panel tests with copper paints were performed over the summer boating season at a total of 5 different locations along the Swedish coast within the period 2015 - 2018. For all studies but Lindgren et al., 2018 in which panels were exposed for a maximum of only 84 days (~ 3 months), the assessment of macrofouling was performed after 5 months static exposure. The assessment of the efficacy of the paints in combination with the field release rates of copper determined between day 14 and day 56 by X-Ray Fluorescence analysis was used to estimate the release rate necessary to completely deter the settlement of macrofouling at each location. More information about the X-Ray Fluorescence method can be found in Ytreberg et al. (2017) and Lagerström and Ytreberg (2020).

For each site, the lowest release of copper which resulted in no settlement of macrofouling was determined. In most cases, all the evaluated paints at a given study site were found to deter macrofouling completely. No exact determination of the critical release rate was then possible, and the only conclusion was that RR_{crit} was at or below (≤) that of the lowest measured copper release rate. At the sites where not all paints were found to be able to completely deter macrofouling, RR_{crit} was estimated to be above (>) that of the highest leaching “ineffective” paint, and at or below (≤) that of the lowest leaching “effective” paint.

Table 7. Studies with static panel tests used to assess the critical copper release rate in different parts of the Baltic Sea, Öresund and Skagerrak.

Study	Year	Locations	Marine region	Salinity (PSU)	Studied paints
Lindgren et al., 2018	2015	Fiskebäck	Baltic Transition	13.8	Experimental paints with varying concentrations of Cu_2O and ZnO
Lagerström et al., 2018	2015	Värmdö Fiskebäck	Baltic Baltic Transition	5.1 13.8	5 commercial paints
Lagerström et al., 2020	2018	Nynäshamn Malmö Kristineberg	Baltic Baltic Transition Atlantic	6.4 7.5 27	8 commercial paints

In addition to releasing copper, all the evaluated commercial coatings released zinc which is also toxic to marine organisms. Thus, to carry out this assessment, the effect of the release of Zn on the efficacy of the paints must be assumed to be limited. Poor antifouling performance of zinc oxide by itself in Baltic Transition and Altantic was indeed demonstrated by the efficacy results with the experimental coatings (Figure 19). The results from the locations in the Baltic region (e.g. Helsinki and Simrishamn) suggest however that zinc may enhance the efficacy of antifouling paints.

In Lagerström et al., 2020, the results of the assessment described here were compiled in the form of a map (Figure 21). The compilation shows that for the Baltic region, a release rate of 2 µg/cm^2/d, as measured by XRF during day 14-56 of exposure, is likely sufficient to deter all macrofouling on a painted panel during static conditions for 5 months. For the Baltic Transition, the critical release rate seems to increase with increasing salinity. Farthest to the south (Malmö), a release rate of 2 µg/cm^2/d is enough while a release rate of 4-5 µg/cm^2/d is required further north (by the city of Gothenburg). Even further north, just past the border of the Atlantic marine region (Kristineberg), a copper release rate closer to 6 or even 7 µg/cm^2/d is needed, likely due to the higher prevailing fouling pressure there.

Previous estimates of the critical release rate of copper in the scientific literature have been determined only for Atlantic waters and are quite dated (Table 8). For seawater, a critical release rate of 10 µg Cu/cm^2/day has generally been assumed to be enough to prevent the attachment of most animal forms, although some algae may still attach at even higher leaching rates (Barnes, 1948; WHOI, 1952). As demonstrated here, however, the critical release rates of copper (and perhaps biocides in general) are lower in the Baltic Sea, as compared to full marine waters. Species living in the brackish waters of the Baltic Sea are subject to constant osmotic stress, making them more sensitive to hazardous compounds (Magnusson and Norén, 2012), which could explain why lower release rates of copper are required.

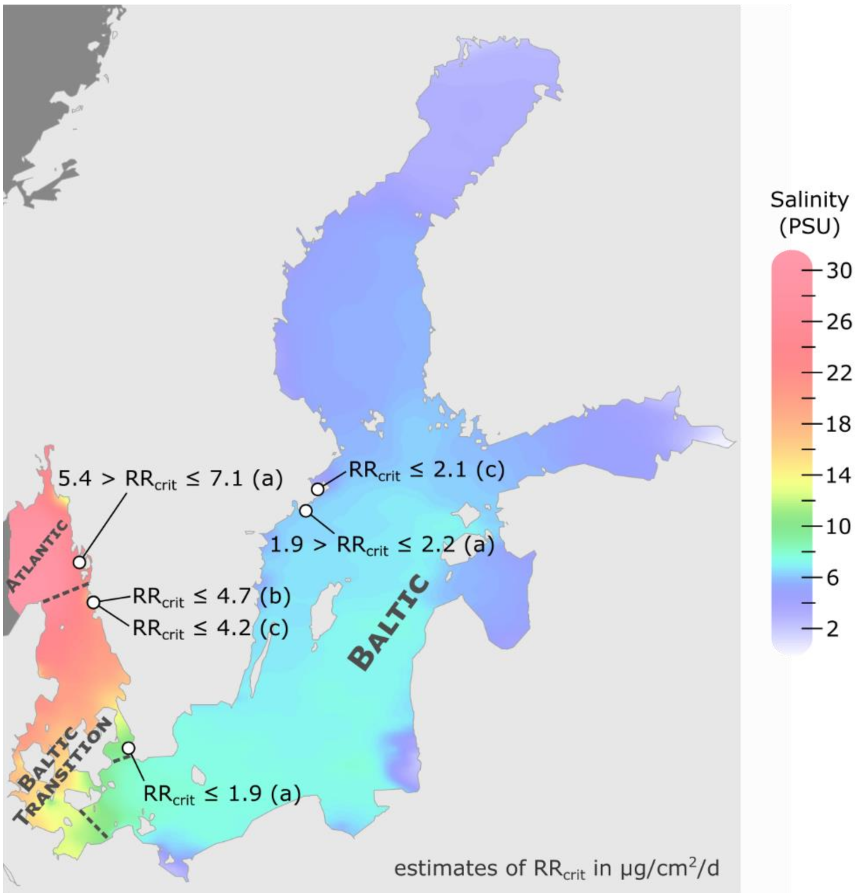

Figure 21. Salinity map of the Baltic Sea showing estimates of the critical copper release rates (RR_{crit}) at five locations along the Swedish coast from Lagerström et al. 2020 (a), Lindgren et al., 2018 (b) and Lagerström et al., 2018 (c).

Table 8. Critical release rates of Cu for some marine organisms determined for Atlantic waters (* Scotland, UK or **Netherlands).

Organism	Critical Cu release rate (µg/cm²/d)	Reference
Algae		
"Brown Mats" (algal growth)	20*	Barnes, 1948
Unspecified	22**	de la Court, 1988
Ectocarpus, filamentous brown algae	10*	Barnes, 1948
Tube worms (*Tubularia*)	10*	Barnes, 1948
Barnacles (*Balanus*)	9*	Barnes, 1948
	16**	de la Court, 1988
Hydrozoans (*Obelia*)	4*	Barnes, 1948
Calcareous worms (*Pomotoceros*)	3*	Barnes, 1948

3.4.2. Minimum versus critical release rates

As outlined in section 2, it is the minimum necessary release rate, i.e. the release rate resulting in 25% surface coverage of macrofouling, and not the critical release rate that should be used to assess for excessive toxicity. However, all of the copper paints in the studies where release rate measurements have been paired with efficacy assessments (**Table 7**) performed well in preventing macrofouling and where not anywhere near to 25% macrofouling coverage.

The nature of the relationship between copper release rate and macrofouling coverage for release rates ≤ RR_{crit} is currently unknown. This is illustrated in **Figure 22** where the release rates of copper and macrofouling coverage at three locations and for eight paints (and control) studied in 2018 are plotted. If a mathematical function could be assigned with some certainty to the data below RR_{crit}, the relationship could be used to predict the release rate corresponding to a 25% macrofouling coverage, i.e. the minimum release rate. As a hypothetical theory, if a linear decrease is assumed (as illustrated in **Figure 22**), the factor of difference between minimum and critical release rates would be 1.4 – 3.0, depending on location. Whether the macrofouling coverage is in fact decreasing linearly or following an e.g. polynomial, s-shaped or exponential curve as the copper releases increases cannot currently be surmised from the data. To fill this knowledge gap, further studies would be required.

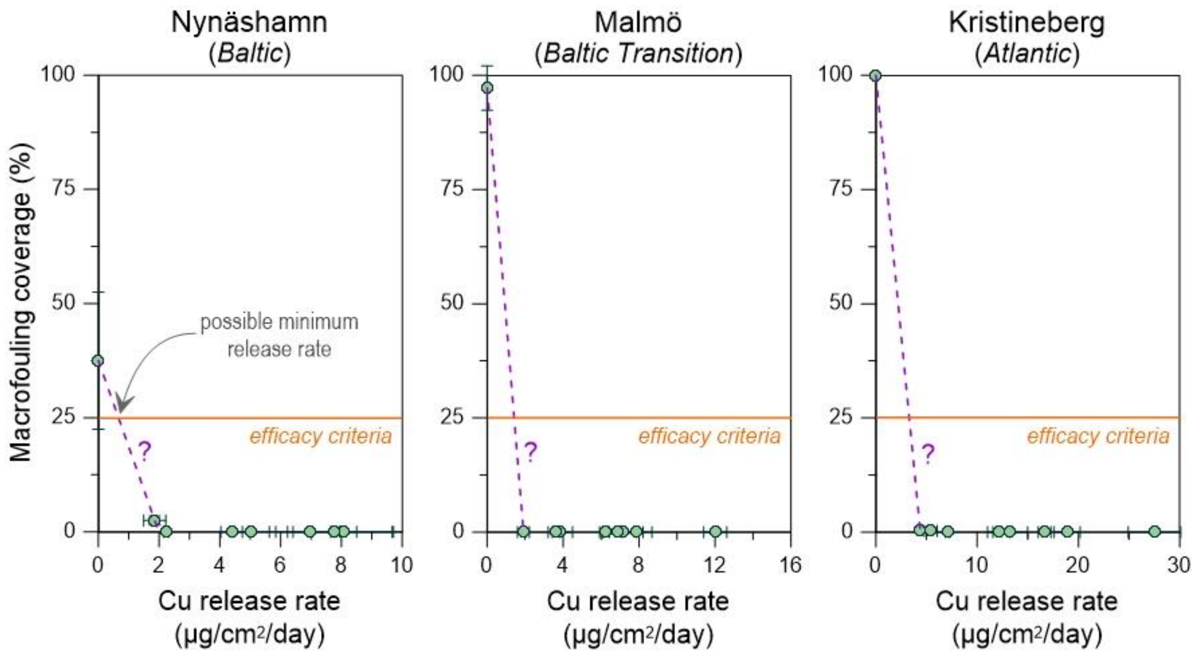

Figure 22. Macrofouling coverage and copper release rates for eight copper paints and the control paint from the 2018 study (Lagerström et al., 2020b). The nature of the relationship between macrofouling coverage and copper release rates below that of the critical release rate is unknown. Illustrated here, as an example, is a hypothetical linear relationship (dashed purple line). An estimate of the minimum release rate would be obtained by using the established relationship and calculating the release rate yielding 25% surface coverage of macrofouling.

4. How to assess for excessive toxicity?

For product authorisation, applicants must submit both efficacy data and biocidal release rate data. Investigated here is their possible use to assess for excess toxicity in the Baltic and Baltic Transition regions. The Atlantic region is not included here due to lack of data

4.1. From raft test results

Given the efficacy results presented for 10 copper paints in section 4, this report has investigated whether there was any information in the paint's original efficacy assessment that could give an indication of excess toxicity. Information from the product application reports was therefore gathered. These only contain the main conclusions of the fouling assessment and detailed information of test specifics was not always specified (e.g. coating thickness). A summary of the efficacy test specifics and their result for each paint as derived from the product authorisation applications is given in **Table 9** and show large variability in exposure location, exposure time and efficacy assessment method.

When it comes to test location there were only two paints that were tested for efficacy in the intended region of use (P-2 and P-3, in the Baltic). The remaining 8 paints were tested in the Mediterranean (4 paints) or the Atlantic (4 paints). None were tested in the Baltic Transition although a few paints were tested in estuaries which could hold similar salinities (P-5, H-2, H-3). For three of the products (P-1, P-5 and H-1), the tests were not carried out with the actual product but instead with a similar coating. As for exposure times, these were either shorter (2 paints), comparable (2 paints) or in excess (6 paints) of the typical length of the Scandinavian boating season (5 months). A majority of products were thus exposed for longer time periods.

The large variability in test locations and exposure times makes the efficacy test of the paints difficult to compare to each other and to assess for excessive toxicity. However, a few conclusions can still be drawn with respect to the latter for the Baltic, and perhaps also the Baltic Transition. The fouling intensity is generally higher in fully marine waters (Atlantic and Mediterranean) than brackish waters (Baltic Transition and Baltic) (Canning-Clode, 2008). If a static raft test is thus performed in e.g. the Mediterranean for a paint intended for use in the Baltic or Baltic Transition and it is shown to be effective for longer periods of time than the length of the Scandinavian boating season, this may indicate potential excessive toxicity. Such examples can be seen in **Table 9**:

- Paint P-4 was found to be effective during 9 months of exposure in the Mediterranean where the control was heavily fouled after only 2 months.
- Paint H-4 was found to only have 2% surface coverage of fouling animals (compared to 100% coverage for the control) when exposed during 1 full year in the Mediterranean

Results from an efficacy test can thus offer some, albeit limited, assistance with regards to the evaluation of potential excessive toxicity. Of greater importance is however the release rate.

Table 9. Specifications of efficacy tests performed for the 10 studied copper paints and excerpts of text from the efficacy evaluation in the product's authorisation applications to the SCA.

Paint	Exposure region	Exposure time	Number of coats	Efficacy assessment
P-1 2011	Mediterranean Spain	65 weeks (1.25 yrs)	1 (80-100 µm)	Test on similar product Fouling assessment every 4-8 weeks Treated panels notably less fouled compared to control
P-2 2013	Mediterranean Italy	6 months	1 or 2 coats (up to 120 µm DFT)	Fouling assessed after 1.5, 3, 4 and 6 months Treated panels not heavily fouled until after 6 months, tubeworms but no barnacles present on treated panels. More tubeworms on the panels with 1 coat
	Baltic Sweden (Värmdö)	5 months	1 (40 µm DFT) or 2 coats	Fouling assessment every month No difference between treated panels and the control No difference between 1 or 2 coats
P-3 2011	Baltic Sweden (Oskarshamn)	6 months		Significantly better performance for product compared to the control Panels were fouled only by light weed after 6 months (no barnacles)
P-4 2010	Mediterranean Italy	9 months	2 coats (100-120 µm DFT)	Control (primer) heavily fouled after 2 months Good antifouling effect shown over the whole test period
P-5 2013	Atlantic UK (estuary)	78 weeks (1.5 yrs)		Test on similar product Efficacy for up to 78 weeks proven
SP-1 2009	Mediterranean Spain	54 weeks (1 yr)		Significantly less fouled compared to control after 26 weeks (6 months), but no difference compared to control at weeks 41 and 54 according to applicants own fouling assessment scale. However, assessment of fouling animals shows only 2% coverage for the treated panels compared to 100% coverage of the control.
H-1 2009	Atlantic Germany	3.5 months	2 coats (15-30 µm DFT)	Test results are for a similar experimental paint and for a partially dynamic test, assessment every 4 weeks after towing Control shows fouling by animals which the treated panels do not
H-2 2011	Atlantic UK (estuary)	8 months	2 coats	Moderate weed after 8 months Control had barnacles, hydroids and sea squirts
H-3 2010	Atlantic Norway (estuary)	4 months	2 coats (100 µm DFT)	Control (primer) heavily fouled after 1 month but satisfactory performance for AF paint after 4 months Fouling pressure comparable to Swedish west coast
H-4 2009	Mediterranean Spain	54 weeks (1 yr)		Significantly less fouled compared to control after 26 weeks (6 months), but no difference compared to control at weeks 41 and 54 according to applicants own fouling assessment scale. However, assessment of fouling animals shows only 2% coverage for the treated panels compared to 100% coverage of the control.

4.2. FROM COPPER RELEASE RATES

4.2.1. Assessment concept

To effectively assess for excessive toxicity, applicant release rates should in fact be compared to the minimum necessary release rates but, as outlined in 3.4.2, these cannot currently be estimated without further studies. Comparisons can therefore only be made to estimates of the critical release rate, RR_{crit}. On the other hand, as stated in the guidance document, efficacy for the lowest concentration of active substance should be proven under worst case circumstances for the approval of product families. As shown in 3.3, the performance of a paint can vary between years due to changes in environmental parameters such as temperature which can cause variations in the copper release rate. To take height for this type of effects on the release rate of products, and thus not risk the authorisation of products which may be ineffective due to yearly variations in temperature, it could in fact be more appropriate to perform the evaluation against the critical release rate rather than the minimum release rate. As the critical release rate corresponds to a more stringent efficacy criteria (0% macrofouling coverage) than the minimum release rate (25% macrofouling coverage), a paint whose release rate exceeds that of RR_{crit} is, by definition, excessively toxic. Should its release rate be lower than RR_{crit}, it may still be excessively toxic if it's above the minimum release rate. However, as the latter is not known, a paint with a release rate $\leq RR_{crit}$ will here be regarded as not excessively toxic.

As mentioned in section 2.2, there are two standardised methods used by applicants for the release rate determination which consist of a laboratory method and a calculation method. Release rates derived with these two methods have however been shown to correlate poorly with field release rates measured in marinas. This is problematic given that field release rates form the basis of the critical release rate estimates in section 3.4.1. The release rate of copper from a paint will depend on environmental parameters such as salinity, temperature and pH (section 3.3.1). The impact of salinity has been found to be especially important: the release rate from a given paint may double or even triple when increasing the salinity from 5 to 14 PSU (Lagerström et al., 2018). As the standardised methods do not account for variations of such environmental parameters, they cannot and should not be used for comparison to the critical release rates established in this report. Accurate and direct comparison can thus only be performed using release rates obtained with a suitable field method. As the critical release rate is region-specific, the release rate should need also be measured at a location in the marine region of intended product use. However, given that no standardised field methods are currently available, an option by which to estimate field release rates from calculation method release rates using a model is also given. Two approaches will therefore be presented subsequently in this section: one based on *measured* field release rates and another based on *approximated* field release rates (Figure 23). The estimation of approximated release rates will be associated with uncertainties (the model's inherent prediction error) that need to be taken into account during the comparison stage if this option is chosen (step 2), before a final assessment with respect to excessive toxicity is rendered (step 3). Due to lack of data, the model for approximated field release rates is limited to polishing/soluble matrix and hard/insoluble matrix paints only and cannot be applied to self-polishing paints. The evaluation is also limited to the marine region Baltic and Baltic Transition as RR_{crit} estimated for the Mediterranean and Atlantic regions are lacking.

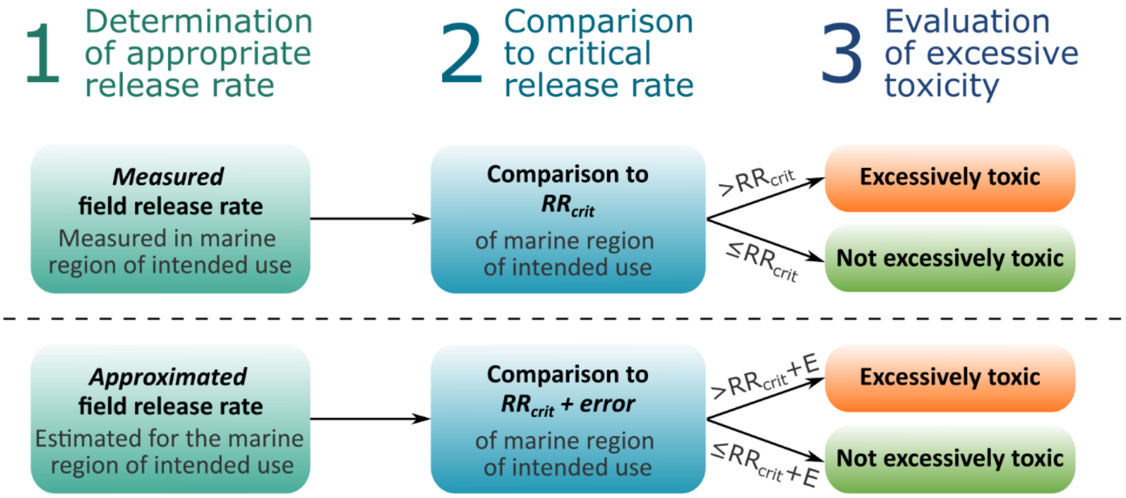

Figure 23. Suggested step-wise procedure for the evaluation of excessive toxicity from either measure (top) or approximated (bottom) field release rates. For the latter, the model error used to derive the release rate needs to be taken into account during step 2.

Table 10. Critical release rates to use for comparison to measured or approximated field release rates

Marine region	Critical Cu release rate ($\mu g/cm^2/d$) for comparison to *measured* field release rate	Critical Cu release rate ($\mu g/cm^2/d$) for comparison to *approximated* field release rate
Baltic	2	5 (RR_{crit} + model error = 2 + 3)
Baltic Transition	7	10 (RR_{crit} + model error = 7 + 3)

4.2.2. Evaluation based on measured field release rates of copper

The findings presented in **Figure 21** show that it is reasonable to assume that the critical release rate of copper for the Swedish coast in the Baltic marine region is 2 $\mu g/cm^2/day$. Even though a release rate of 4 – 5 $\mu g/cm^2/day$ may be sufficient in the Baltic Transition in the area of Gothenburg, a release rate between 5.4 and 7.1 $\mu g/cm^2/day$ is required in Kristineberg, located just north of the region border. This suggests that a higher release rate may be required in the most northern part of the Baltic Transition region as compared to the Gothenburg area. To account for the worst case conditions found north of Gothenburg in the Baltic Transition, a release rate of 7 $\mu g/cm^2/day$ is therefore assumed necessary in the Baltic Transition region (**Table 10**).

An evaluation of excessive toxicity of 10 different paints based on field release rates of copper between day 14 and 56 is exemplified in **Table 11**. Even though field release rate measurement were also performed in Malmö for 8 of the paints in 2018, only the release rates from Kristineberg are presented as conditions there are more representative of the worst-case scenario for the Baltic Transition. In the instances where two field release rate measurements had been made during different years, the average was used for assessment against RR_{crit}. The results show that 9 of 10 paints were deemed excessively toxic in either one (4 paint) or both (5 paints) regions.

Table 11. Evaluation of excessive toxicity for the 10 copper paints based on measured field release rates. Release rates from Kristineberg were included in the assessment for the Baltic Transition as it is located in very near proximity to this region.

Paint	Marine region	Measured field release rate (µg Cu/cm²/d)	RR_{crit} (µg Cu/cm²/d)	Evaluation
P-1	Baltic	3.5 (Bullandö 2015, 5.1 PSU) 2.2 (Nynäshamn 2018, 6.4 PSU)	2	Excessively toxic
	Baltic Transition	6.7 (Fiskebäck 2015, 13.8 PSU) 7.1 (Kristineberg 2018, 26.9 PSU)	7	Not excessively toxic
P-2	Baltic	3.3 (Bullandö 2015, 5.1 PSU)	2	Excessively toxic
	Baltic Transition	6.8 (Fiskebäck 2015, 13.8 PSU)	7	Not excessively toxic
P-3	Baltic	2.3 (Bullandö 2015, 5.1 PSU) 4.4 (Nynäshamn 2018, 6.4 PSU)	2	Excessively toxic
	Baltic Transition	4.9 (Fiskebäck 2015, 13.8 PSU) 4.4 (Kristineberg 2018, 26.9 PSU)	7	Not excessively toxic
P-4	Baltic	5.0 (Bullandö 2015, 5.1 PSU) 5.0 (Nynäshamn 2018, 6.4 PSU)	2	Excessively toxic
	Baltic Transition	10.8 (Fiskebäck 2015, 13.8 PSU) 12.1 (Kristineberg 2018, 26.9 PSU)	7	Excessively toxic
P-5	Baltic	7.8 (Nynäshamn 2018, 6.4 PSU)	2	Excessively toxic
	Baltic Transition	27.5 (Kristineberg 2018, 26.9 PSU)	7	Excessively toxic
SP-1	Baltic	0.7 (Bullandö 2015, 5.1 PSU)	2	Not excessively toxic
	Baltic Transition	8.7 (Fiskebäck 2015, , 13.8 PSU)	7	Excessively toxic
H-1	Baltic	1.9 (Nynäshamn 2018, 6.4 PSU)	2	Not excessively toxic
	Baltic Transition	5.4 (Kristineberg 2018, 26.9 PSU)	7	Not excessively toxic
H-2	Baltic	8.0 (Nynäshamn 2018, 6.4 PSU)	2	Excessively toxic
	Baltic Transition	13.3 (Kristineberg 2018, 26.9 PSU)	7	Excessively toxic
H-3	Baltic	7.0 (Nynäshamn 2018, 6.4 PSU)	2	Excessively toxic
	Baltic Transition	18.9 (Kristineberg 2018, 26.9 PSU)	7	Excessively toxic
H-4	Baltic	8.1 (Nynäshamn 2018, 6.4 PSU)	2	Excessively toxic
	Baltic Transition	16.7 (Kristineberg 2018, 26.9 PSU)	7	Excessively toxic

4.2.3. Evaluation based on approximated field release rates of copper

If field release rates are not available for a product, a prediction model was developed for its estimation from calculated release rates using the ISO:10890 standard (ISO 10890, 2010). However, the prediction model is based on release rate data from polishing/soluble matrix and hard/insoluble matrix paints, use of the model to predict release rates from self-polishing paints is therefore not recommended.

The prediction model requires two input parameters: the calculated release rate and salinity. Next follows a description on how the calculated release rates should be derived, and which salinities would be considered appropriate for the Baltic and Baltic Transition regions.

Input 1: release rate using the calculation method (IS0:10890)

Given that the release rate submitted by an applicant can be derived using either of two methods and that the estimation of product lifetime is subjective in the case of release rates generated with the calculation method, a standardised way to derive calculated release rates was determined. The below stipulated criteria for the calculation of the release rate are a pre-requisite for the correct utilization of the model.

According to ISO:10890, the following equation is used to solve for the steady-state release rate Y:

$$X + \left(Y \times \left(\frac{365 \times t}{12} - 14\right)\right) = La \times a \times Wa \times \frac{100}{vs} \rho \times DFT$$

- X: amount of biocide released during the first 14 days (µg cm^{-2})
- t: specified lifetime of the paint (months)
- La: fraction of the active ingredient in the dry film released during the lifetime t (equal to 0.9 according to European regulatory authorities),
- a: mass fraction of active ingredient in the biocide
- Wa: concentration of biocide in the wet paint (weight %)
- vs: volume solids (%)
- ρ: paint density (g cm^{-3})
- DFT: dry film thickness specified for the time t (µm)

For the correct calculation of the release rate to be used as input into the prediction model, the following is required:

- La = 0.9
- t = 7 months
- DFT is equal to the thickness of 1 layer of paint, typically assumed to be the corresponding dry film thickness of a 100µm wet film thickness (i.e. 100 x vs)
- no correction factor should be applied

Input 2: salinity

The release rate of copper is highly dependent on salinity which is taken into account by the prediction model. An appropriate salinity must therefore be provided for the calculation. Locations of leisure boat moorings along the stretch of Swedish coastline where the use of biocidal antifouling paints is allowed were recently mapped in a project for the Swedish Agency for Marine and Water Management (**Figure 24**).

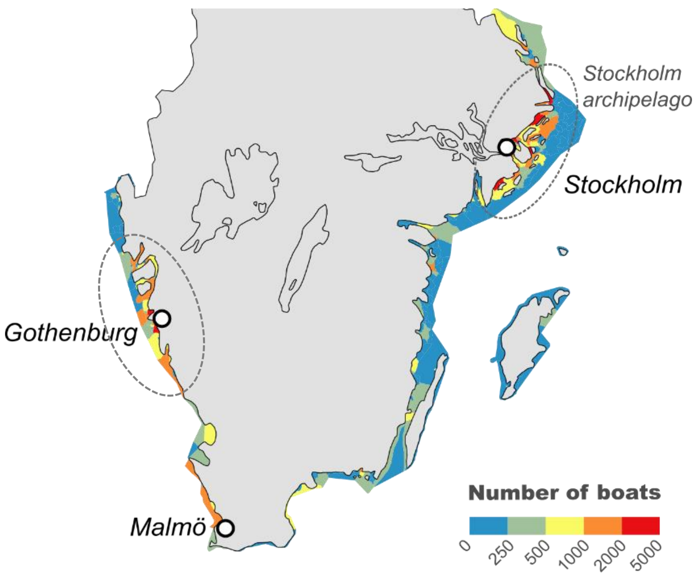

Figure 24. Number of leisure boat moorings per coastal water body along the Swedish coast where the use of biocidal antifouling paints is currently allowed.

The mapping shows that a majority, 64%, of leisure boat moorings on the Swedish east coast are found in the Stockholm archipelago. A similar sized area around Gothenburg was found to hold 74% of Swedish west coast boats. The mean salinity of coastal water bodies in these delimited areas were derived as 5.1 ± 1.5 and 22.0 ± 3.3 PSU, respectively. It is therefore proposed that a salinity of 5 (Baltic) and 22 (Baltic Transition) PSU is used.

Prediction model

The prediction model was derived based on a total of 40 measured field release rates from 9 polishing or hard copper paints, each with data from 2 to 6 different salinities. Multiple linear regression analysis was performed which identified two significant parameters for the prediction of field release rates: the calculated release rate (input 1) and salinity (input 2). **Figure 25** shows the actual release rates plotted against those predicted by the model. The overall agreement is generally good (r^2 = 0.758), but rather large errors where the model can both overestimate and underestimate the actual release rate can occur. The current model's inability to accurately predict all release rate stems from the fact that some key factors controlling the release, likely related to the paints' specific properties, are currently not accounted for. This is reflected in the model's coefficient of determination r^2 which reveals that the model is not able to account for roughly 24% of the variation.

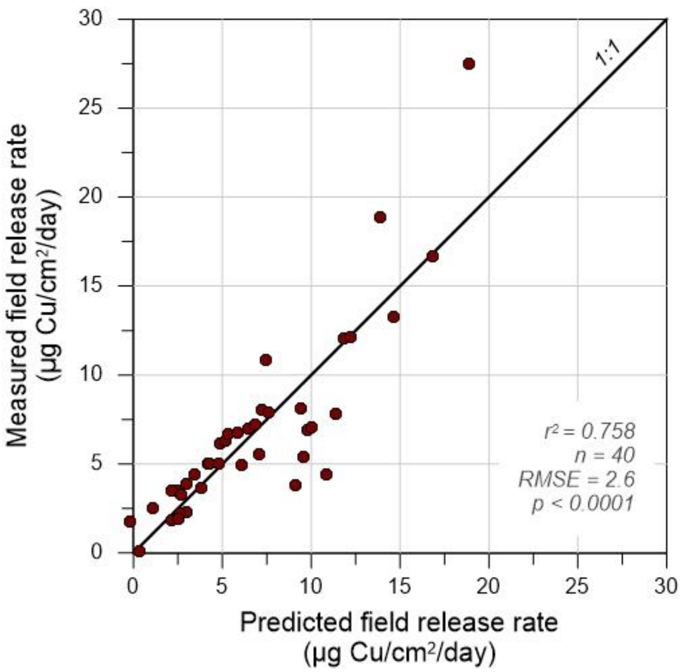

Figure 25. Predicted versus actual field release rates. The line shows the 1:1 agreement.

The equation for the prediction of release rate (µg Cu/cm^2/day) is as follows:

$$\text{Approximated field release rate} = 0.363 \times \text{ salinity} + 0.512 \times \text{calculated release rate} - 1.026$$

, where the salinity should be in PSU and the calculated release rate in µg Cu/cm^2/day.

The root mean square error of the model was calculated to 2.6 µg Cu/cm^2/day. Given that the predicted release rate will be inherently associated with uncertainties, the error of the model has been added to RR_{crit} prior to evaluation. For simplification, the error was rounded to 3 µg Cu/cm^2/day, yielding the critical release rates in **Table 10** that are to be used for comparison.

Outcome comparison

Following the previously outlined approach, the field release rates were estimated for the 10 paints and these were yet again evaluated for excessive toxicity (**Table 12**). The outcome was then compared to that obtained using the field release rates to check for type I and type II errors. Note that no estimated field release rate was derived for paint SP-1 as it is of self-polishing type.

Table 12. Evaluation of excessive toxicity for the 10 copper paints based on estimated field release rates.

Paint	Marine region	Estimated field release rate (µg Cu/cm^2/d)	RR_{crit} + error (µg Cu/cm^2/d)	Evaluation
P-1	Baltic	2.1 (5 PSU)	5	Not excessively toxic
	Baltic Transition	8.3 (22 PSU)	10	Not excessively toxic
P-2	Baltic	2.7 (5 PSU)	5	Not excessively toxic
	Baltic Transition	8.8 (22 PSU)	10	Not excessively toxic
P-3	Baltic	2.9 (5 PSU)	5	Not excessively toxic
	Baltic Transition	9.1 (22 PSU)	10	Not excessively toxic
P-4	Baltic	4.3 (5 PSU)	5	Not excessively toxic
	Baltic Transition	10.4 (22 PSU)	10	Excessively toxic
P-5	Baltic	10.9 (5 PSU)	5	Excessively toxic
	Baltic Transition	17.1 (22 PSU)	10	Excessively toxic
H-1	Baltic	1.6 (5 PSU)	5	Not excessively toxic
	Baltic Transition	7.8 (22 PSU)	10	Not excessively toxic
H-2	Baltic	6.7 (5 PSU)	5	Excessively toxic
	Baltic Transition	12.9 (22 PSU)	10	Excessively toxic
H-3	Baltic	6.0 (5 PSU)	5	Excessively toxic
	Baltic Transition	12.1 (22 PSU)	10	Excessively toxic
H-4	Baltic	8.9 (5 PSU)	5	Excessively toxic
	Baltic Transition	15.1 (22 PSU)	10	Excessively toxic

The estimated release rates in **Table 12** show the need for the addition of the error to RR_{crit} for the evaluation as all but one paint in one region (H-1, Baltic) would have been considered excessively toxic if the comparison had been made directly to RR_{crit}. Compared to the outcome based on the measured field release rates, which is to be considered the more reliable of the two, the evaluation based on the estimated field release rates would then falsely identify some paints as excessively toxic. When the evaluation is instead performed against RR_{crit} + error, no such type II errors (false positives) were detected (**Table 13**). On the other hand, type I errors (false negatives) were detected on 4 occasions, i.e. paints were not deemed excessively toxic even though field measurements suggest the opposite. However, given the uncertainties associated with this approach, type I rather than type II errors are preferable. To refine this approach and reduce its uncertainties, more studies are needed.

Table 13. Outcome comparison between the two approaches.

Paint	Marine region	Evaluation based on *measured* field release rate	Evaluation based on *estimated* field release rate	Error associated with outcome based on *estimated* field release rate
P-1	Baltic	Excessively toxic	Not excessively toxic	Type I
	Baltic Transition	Not excessively toxic	Not excessively toxic	
P-2	Baltic	Excessively toxic	Not excessively toxic	Type I
	Baltic Transition	Not excessively toxic	Not excessively toxic	
P-3	Baltic	Excessively toxic	Not excessively toxic	Type I
	Baltic Transition	Not excessively toxic	Not excessively toxic	
P-4	Baltic	Excessively toxic	Not excessively toxic	Type I
	Baltic Transition	Excessively toxic	Excessively toxic	
P-5	Baltic	Excessively toxic	Excessively toxic	
	Baltic Transition	Excessively toxic	Excessively toxic	
SP-1	Baltic	Not excessively toxic		
	Baltic Transition	Excessively toxic		
H-1	Baltic	Not excessively toxic	Not excessively toxic	
	Baltic Transition	Not excessively toxic	Not excessively toxic	
H-2	Baltic	Excessively toxic	Excessively toxic	
	Baltic Transition	Excessively toxic	Excessively toxic	
H-3	Baltic	Excessively toxic	Excessively toxic	
	Baltic Transition	Excessively toxic	Excessively toxic	
H-4	Baltic	Excessively toxic	Excessively toxic	
	Baltic Transition	Excessively toxic	Excessively toxic	

5. REFLECTIONS & RECOMMENDATIONS ON EFFICACY TESTING

5.1. EFFICACY TEST DESIGN

5.1.1. Test location

As outlined in the conditions for granting an authorisation of a biocidal product, the evaluation of the fulfilment of the criteria with respect to efficacy, human health risk and environmental risk should take into account "*realistic worst case conditions under which the biocidal product may be used*" (BPR, Article 19.2). As described in 2.1, worst case conditions for antifouling paints are currently accounted for in the efficacy evaluation through the static raft testing. Lacking from the efficacy test criteria are however any specific requirements with regards to exposure location. Exposure in any EU waters is currently acceptable, regardless of intended marine region of use. Most sensible would of course be to assess the efficacy of antifouling paints in the waters in which they are intended to be used. However, as shown in 3.2, the fouling pressure in the Baltic Sea region can vary on a local scale. Consequently, the choice of exposure location, even within a given region could in fact impact the results of the efficacy assessment. According to the BPR, a realistic worst case should be considered. This is however not meant to cover all extremes. In the ERA, realistic worst case conditions are represented by the 90th percentile PEC of the biocide(s) leached from the paint (ECHA, 2017). Locations of extreme fouling pressure such as Turku (Baltic) and Fiskebäck (Baltic Transition) should perhaps not primarily be used for efficacy demonstration.

As shown in 3.4.1, paints in the Baltic and Baltic Transition do not need to leach as much copper as paints in e.g. the Atlantic in order to be efficient. A large portion of tested coatings currently on the Swedish market are thus leaching more copper than what is required even for full prevention of macrofouling (**Figure 22**). There is thus potential to substantially reduce the environmental impact of copper paints in the Baltic and Baltic Transition without any loss in efficacy. For such (future) products, raft tests should be performed in the intended region of use as the paints would likely not be as effective in other, higher fouling intensity regions such as the Mediterranean or the Atlantic.

5.1.2. Exposure year

The evaluation of paint performance carried out for up to 4 consecutive years in the CHANGE study (see 3.3.1) shows that yearly variations in abiotic factors such as temperature can affect the performance of antifouling paints. The pairing of intense macrofouling pressure and low water temperatures may have caused some of the studied paints' performance to not meet the 25% macrofouling criteria at a few locations. Firstly, as mentioned in the previous section, such locations with high fouling pressure could perhaps be avoided when performing efficacy tests in the Baltic and Baltic Transition regions. Secondly, should nonetheless such extraordinary conditions occur during efficacy testing of a product resulting in its failure to meet the efficacy criteria, arguments based on reported e.g. temperature, salinity, etc, as part of the dossier requirements, could be put forward by the applicant to nevertheless allow for authorisation due to mitigating circumstances.

Figure 26 shows the variation in temperature and salinity at the 17 study locations of the CHANGE project along with the average macrofouling coverage observed on control panels in 2013 – 2016. Ideally, a suitable test location should have low variation in temperature, salinity and fouling pressure to avoid large differences in performance between years. The magnitude of the fouling pressure should also be at a representative level for the given region. Hence, in the Baltic and Baltic Transition regions, locations with comparatively higher variations in temperature (e.g. Karlskrona and Simrishamn), salinity (e.g. Fiskebäck) and macrofouling coverage (e.g. Vaasa, Nynäshamn, Västervik, Simrishamn and Halmstad) should primarily be avoided. Additionally, locations with low (e.g. Simrishamn and Halmstad) or, oppositely, very intense (e.g. Turku, Karlskrona and Fiskebäck) macrofouling pressure compared to other locations within the same region should also be omitted. For the Baltic, locations such as Gävle, Helsinki, Bullandö, Askö and Kalmar would thus be more suitable. Similarly, Malmö and Helsingör could be appropriate test locations for the Baltic Transition. More studies including different test sites are required in the Atlantic region in order to determine suitable test locations there.

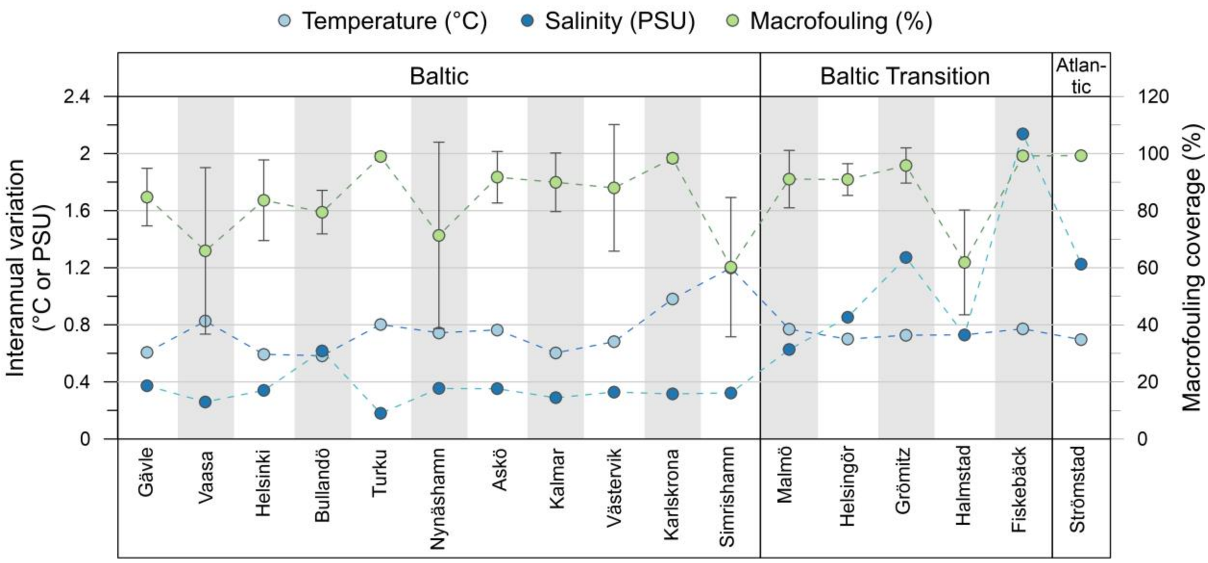

Figure 26. Interannual variation (calculated as the standard deviation) in temperature (°C) and salinity (PSU) in the years 2008 – 2018, as well as average macrofouling coverage (in % surface coverage) on static control panels in 2013 – 2016.

Although 2015 was an unusually cold year, climate change will likely cause seawater temperatures to rise. Other effects of climate change on the environmental conditions in high latitude waters include decreases in pH and salinity (IPCC, 2019). The potential impact of climate change on antifouling performance are summarised in **Table 14**. Climate change will also affect the composition of biofouling communities (Dobretsov, 2009). The critical biocidal release rate required for protection against macrofouling could thus be subject to change and may evolve as the climate changes.

Table 14. The impact of factors associated with global climate change on performance of antifouling coatings (from Dobretsov, 2009).

Factors associated with climate change	Potential consequences on paint performance
Seawater temperature rise	• Increased polishing and biocide leaching rates • Earlier paint exhaustion • Paint efficiency and the leached layer thickness
Seawater pH decrease	• Decreased hydrolysis reaction rate for both acrylate- and rosin-based binders with decrease of polishing rates • Potentially lower dissolution rates for hydrolysing particulate organic biocides • Increased Cu_2O dissolution rates • Increased biocide-leached layer thickness, with negative effects on paint performance
Seawater salinity decrease	• Lower Cu_2O dissolution rates • Potential changes on the hydrolysis rate of specific binders

5.1.3. Exposure duration

The current criteria in the guidance document state that raft testing should be performed for at least 6 months and cover the peak fouling season. They do however not specify the evaluation frequency. Given the length of the Scandinavian boating season, efficacy proven for at least 5 months but for no longer than 7 months would be of main relevance and should thus be presented by the applicant.

5.2. Efficacy criteria and the minimum dose

The current efficacy criteria (25% macrofouling coverage) applies to antifouling paints for both commercial and recreational vessels, even though their operational pattern differs extensively. Given that the static raft test closely resembles the conditions of use of a leisure boat on the Swedish coast, they do not necessarily constitute a worst case scenario. As demonstrated in this report, current products on the market are highly efficient in deterring the settlement of macrofouling. The current efficacy criteria would however permit the approval of lower-leaching copper paints that allow for macrofouling coverages of up to 24 % during static conditions. Such high surface coverage of macrofouling on boat hulls could have the undesired effect of increased fuel consumption (and increased emissions to the atmosphere of e.g. CO_2, NO_X, PM) and that boat owners would resort to apply mechanical cleaning methods to their painted hulls to remove the fouling. The latter could result in the spread of antifouling paint particles to the marine environment (Turner, 2010).

According to the provisions under the BPR, dose-response data for the target organisms should be evaluated in order to assess the minimum necessary dose for a given product. As demonstrated in 3.3.2, gradient panels with stripes of paint containing lower amounts of biocide(s) coupled with release rate measurements (to indeed demonstrate that the release rate also decreases) would be ideal to justify the need for a certain concentration of active substance in a given product.

What is currently lacking in the guidance document is some recommendation as to how to judge an efficacy test result where the control has less than 75% macrofouling coverage. As seen in **Table 3**, a macrofouling coverage >75% on the control was not obtained in 20% of the cases. In **Figure 18**, the control paint (0% Cu_2O) on the gradient panel at Askö exposed in 2020 was found to have no macrofouling at all. Similarly, the efficacy results for coating P-2 in **Table 9** showed no difference in efficacy between the treated panels and the control. In these cases, the minimum dose for the prevention of macrofouling would not be possible to determine as the results ultimately show that copper paints are not required for macrofouling protection.

5.3. NECESSARY APPLICATION AMOUNT AND RATE

A product should be efficient over the specified lifetime of the product. However, the lifetime of a product will vary as a function of salinity when it comes to copper-based paints given that the release rate of copper increases with increased salinity. To ensure that a product is not re-applied in vain, the recommended application amount and rate (time interval for coating re-application) should ideally be tailored to the intended water of use. To better estimate a paint's lifetime and recommend both realistic application amounts and re-application intervals, efficacy tests could be performed on different numbers of layers. This is exemplified for coating P-2 in **Table 9** where both 1 and 2 coats were tested during a 5 months period. No difference in performance was observed between the two, suggesting that 1 coat was sufficient. It is however important to take note that when leisure boats are in active use, the polishing rate of an antifouling paint may increase, requiring higher application amounts compared to fully static conditions.

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