BACKGROUND INFORMATION

Reassessment of antifouling paints
September 2011
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Introduction

The following document provides background to the “Application to determine whether there are grounds for the reassessment of antifouling paints”.

It includes the most important up-to-date information regarding overseas regulatory actions on biocides used in antifouling paints currently approved in New Zealand and an evaluation summary of the NIWA report ‘Relevance to New Zealand of the OECD Emission Scenario Document (ESD) for antifouling products’.

An overall view of the regulatory status of the biocides at the international level is provided. The jurisdictions were selected based on their activity in this field, and their overall profile and reliability as regulators.

Subsequently, a more detailed description of regulatory decisions on each biocide is given. This section includes the rationale behind the grouping of the biocides in ‘green’, ‘red’ and ‘orange’ categories.

“Green” substances – low expected risk:
- Substances that are registered in most of the jurisdictions checked, or that have been already reviewed by these jurisdictions such that in most cases the continuation of their use as active ingredients in antifouling formulations was granted.

“Red” substances – high expected risk:
- These substances have been reviewed and their approvals were revoked or severely restricted by most of the overseas jurisdictions.

“Orange” substances – moderate/uncertain level of risk:
- There is a lack of consistent information on this group of substances, regulatory actions taken so far have been variable and for some substances there is lack of reviews or decisions which means that a full review of the products that contain these active ingredients is required.

The last section of this document summarises the most important conclusions of the report ‘Relevance to New Zealand of the OECD Emission Scenario Document (ESD) for antifouling products’ that NIWA was commissioned to prepare for the EPA. These conclusions will allow for appropriate New Zealand-specific environmental exposure modelling. In addition, the need for a more comprehensive feedback from the industry to develop maintenance (application and removal of the antifouling paint) scenarios based on statistically robust average values or practices was identified and specific information required from industry for that purpose is summarised at the end of this document.
### Overall regulatory status of chemicals used as active ingredients in antifouling paints in New Zealand

<table>
<thead>
<tr>
<th>Sea-Nine</th>
<th>Copper</th>
<th>Chlorothalonil</th>
<th>Copper pyrithione</th>
<th>Dichlofluanid</th>
<th>Diuron</th>
<th>Irgarol 1051</th>
<th>Mancozeb</th>
<th>Octhilinone</th>
<th>Thiram</th>
<th>Tolyfluaniid</th>
<th>Ziram</th>
<th>Zinc pyrithione</th>
<th>Zineb</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Australia</strong></td>
<td>Registered</td>
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<td>Registered</td>
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<tr>
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<td>Registered</td>
<td>Registered</td>
<td>Not registered</td>
<td>Under registration</td>
<td>Under reregistration</td>
<td>Not registered</td>
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<td>Not registered</td>
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<tr>
<td><strong>State of California</strong></td>
<td>Registered</td>
<td>To be phased out</td>
<td>Not registered</td>
<td>Registered</td>
<td>Not registered</td>
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<td></td>
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<td><strong>State of Washington</strong></td>
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<tr>
<td><strong>Denmark</strong></td>
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<td>Not registered</td>
<td>Restricted use</td>
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</tr>
<tr>
<td><strong>Sweden</strong></td>
<td>Restricted use</td>
<td>Restricted use</td>
<td>Not registered</td>
<td>Restricted use</td>
<td>Not registered</td>
<td>Being phased out</td>
<td>Not allowed</td>
<td>Not registered</td>
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<td>Not registered</td>
<td>Not registered</td>
<td>Restricted use</td>
<td>Not registered</td>
</tr>
<tr>
<td><strong>Finland</strong></td>
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</tr>
<tr>
<td><strong>UK</strong></td>
<td>Registered</td>
<td>Revoked</td>
<td>Restricted use</td>
<td>Provisional approval</td>
<td>Revoked</td>
<td>Restricted use</td>
<td></td>
<td>Not registered</td>
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<td>Not supported</td>
<td>Not registered</td>
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<td>Provisional approval</td>
</tr>
<tr>
<td><strong>Netherlands</strong></td>
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<td>Not registered</td>
<td>Registration expired</td>
<td>Registered</td>
<td>Registered</td>
</tr>
<tr>
<td><strong>European Union</strong></td>
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<td>Being reviewed</td>
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<td>Being reviewed</td>
<td>Not supported</td>
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<td>Not supported</td>
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<td>Not supported</td>
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<td>Being reviewed</td>
</tr>
</tbody>
</table>

1. Diuron’s review in Australia was completed recently. For more details on this review, see next section.
Ochilinone was re-evaluated and in the reregistration eligibility decision (RED) document its use in antifouling formulations is approved.

Very stringent regulatory actions taken by Denmark regarding all biocidal antifouling paints, some of them being:

- No biocidal antifouling paints are allowed to be applied in pleasure vessels that are primarily used in the freshwater environment.

- Import, sale and use of biocidal antifouling paints on recreational boats less than 200 kg that are used primarily in salty waters is prohibited (does not apply to wooden boats, or recreational boats that have permanent water space in ports, as in the insurance industry’s port list are classified as A or B ports).

- Import, sale and use of biocidal antifouling paints that release substances that meet the requirements for classification for environmental effects with the risk phrase “May cause long term adverse effects in the aquatic environment (R53)” alone or in combination with other phrases related to risk for the aquatic environment for recreational boats is prohibited from 1 January 2012.

For biocide specific restrictions see next section.

Most of the regulatory decisions on biocides used in antifouling paints mentioned in Table 1 were made after the UK (ACP) reviewed them. For biocide specific restrictions see next section.

The European Union is reviewing some of the biocides mentioned in Table 1. For those where “not supported” is indicated, the industry did not support their review at the EU level. Each of the supported biocides has been or is being reviewed by a rapporteur member state on the behalf of the European Union.
Overseas regulation of active ingredients and the rationale behind flagging

Green-flagged chemicals

Copper

*Main regulatory actions taken by overseas jurisdictions on copper*

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Regulatory actions/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK (June 1999)</td>
<td>Approvals for copper antifouling products were allowed to continue together with those for amateur use</td>
</tr>
<tr>
<td>EU</td>
<td>Supported for inclusion in Annex I to Directive 98/8/EC as an active substance for use in product type 21 (Antifouling products). Currently being reviewed by the EU</td>
</tr>
</tbody>
</table>
| Sweden             | Antifouling use on vessels operating solely in the Baltic and North Sea areas must have a copper release rate of less than 55 μg copper/cm²/day  
Very recently (August 2012) the Swedish Chemicals Agency decided to approve an anti-fouling paint designed for pleasure boats on the east coast, from Örskär to the Norwegian border.  
This decision was made because the company in its environmental assessment of the product showed that the use is acceptable even in view of the particular sensitivity of the Baltic. The product is a relatively low-leaching colour with 8.5 per cent copper (I) oxide as an active substance |
| California EPA     | No paint containing copper will be allowed to be manufactured, sold and distributed from 2015 onwards                                                                                                                       |
| Washington         | The use of copper in antifouling formulations has been recently restricted by Washington State, only for recreational vessels smaller than 65 ft (25 m) effective from 2020 for Washington max 0.5% copper concentrations allowed                                 |
| Denmark (December 2008) | Import, sale and use of biocidal antifouling paints where the release of copper exceeds 200 μg/cm² after the first 14 days and 350 μg/cm² after the first 30 days from the time of the infliction by pleasure boats of 200 kg or more used primarily in salty waters, is prohibited |

The EPA acknowledges that:

- Preliminary results for New Zealand scenarios in the NIWA report show that exceedances of EELs for copper are predicted for New Zealand’s marinas and ports.
- There is an increased international concern regarding copper uses in antifouling paints and biocide-free paints with more frequent and appropriate hull cleaning are strongly recommended by some jurisdictions at the moment (Sweden, US EPA, Denmark). The main conclusion of the final report published in 2011 by
the US EPA on Safer Alternatives to Copper Antifouling Paints for Marine Vessels was that viable alternatives to copper are available for use today but there is a need of engagement by the users who should familiarise with the selection of the appropriate paints, education and training of the hull cleaning industry and more involvement in general which may lead to successful use of alternatives.

- An attempt by the Dutch authorities in 1999 to propose a ban of copper in antifouling paints on pleasure crafts on the basis of environmental risks was not accepted by an EU scientific committee due to uncertainties regarding bioavailability and the real risks coming solely from copper leached by ship hulls in the environment. Currently, the EU is reviewing copper and its uses as an antifouling agent.
- Except for California and Washington State authorities, there is a reluctance of overseas regulators to take immediate actions against the use of copper, as copper is used as the primary biocide in antifouling paints, after the international ban of the organotin substances. Its replacement requires a very careful market research in terms of alternative substances, their efficacy and prior engagement with the users. Potential severe restrictions of practically all currently available biocidal antifouling products in the New Zealand market would require a very robust justification and most importantly, alternative available solutions that can be applied immediately.

However, during this reassessment the following goals are set to be achieved:

a) Identification of a time period before copper will be revisited as an antifouling agent;
b) Identification of stakeholders’ responsibilities during that period in order to be prepared to assess/support regulatory actions regarding copper at the time it will be revisited. More specifically:
   - Stakeholders to be prepared to demonstrate that specific practices are sufficient to provide safe uses of copper resulting into acceptable environmental concentrations by monitoring and/or other means
   - Collection of information on new active ingredients to be examined as an option for use as the main biocides (copper replacement) in antifouling paints
   - Stakeholders to collect information regarding alternative solutions (biocide-free paints, more frequent and efficient cleaning) and their feasibility; strategies/policies for their implementation in case of decision for replacement of copper after the future reassessment
c) Leaching rate controls options
d) Improvements of application and removal processes.

Copper pyrithione

*Main regulatory actions taken by overseas jurisdictions on copper pyrithione*

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Regulatory actions/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>USEPA (Federal)</td>
<td>Not registered yet. Currently being assessed for registration as a new active ingredient in an antifouling formulation</td>
</tr>
<tr>
<td>Sweden</td>
<td>Is used in antifouling products but due to health related risks is not so far approved for products for amateur use in Sweden. Products with this biocide are currently approved for professionals to be applied on seafaring (except the Gulf of Bothnia) ships (&gt;12 m)</td>
</tr>
</tbody>
</table>
Initially, provisional approval had been granted for 5 years for professional antifouling products containing maximum formulation concentrations of 1.6 % w/w copper pyrithione for application to vessels above 25 metres in overall length. Any such products were allowed to be applied by brush, roller or spray (airless or conventional means). Approval for a product containing 3.8 % copper pyrithione was not recommended.

In 2004, the risk assessment strategy for antifoulant products was revised following an update to the 2000 review of booster biocides. As a result of this revision, the risk assessment for copper pyrithione was revisited, which resulted in the previous restriction for the use only on vessels > 25 m being relaxed and the product containing 3.8 % copper pyrithione has since been granted approval.

Based on the overseas regulatory decisions and its current overall regulatory status, copper pyrithione is initially considered a “green” active ingredient for use in antifouling paints. However, there are restrictions by the UK and Swedish authorities on application by amateur users that trigger concerns regarding human health risks. This aspect will need to be looked at closely during the reassessment in order to identify possible risk mitigation measures.

**Zinc pyrithione**

*Main regulatory actions taken by overseas jurisdictions on zinc pyrithione*

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Regulatory actions/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK (May 2003)</td>
<td>It was recommended that provisional approval for the professional use by brush, roller, spray and aerosol and amateur use by brush and roller of antifouling products containing zinc pyrithione at a maximum concentration of 4% w/w was allowed to continue.</td>
</tr>
<tr>
<td>Sweden</td>
<td>Is used in antifouling products but due to health related risks is not so far approved for products for amateur use in Sweden. Products with this biocide are currently approved for professionals to be applied on seafaring (except the Gulf of Bothnia) ships (&gt;12 m).</td>
</tr>
</tbody>
</table>

Based on the overseas regulatory decisions and its current overall regulatory status zinc pyrithione is initially considered a “green” active ingredient for use in antifouling paints. However, there are restrictions by the UK and Swedish authorities on application by amateur users that trigger concerns regarding human health risks. In addition, there are approved substances in New Zealand with significantly higher concentrations than
those allowed by the UK authority. These aspects will need to be looked at closely in order to identify possible risk mitigation measures.

Zineb

*Main regulatory actions taken by overseas jurisdictions on zineb*

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Regulatory actions/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK (March 2004)</td>
<td>Provisional approval was allowed to continue for both amateur and professional use of antifouling products containing a maximum formulation concentration of 20 % w/w zineb with certain restrictions and controls regarding its use by amateur and professional users (i.e. personal protective equipment, spray application allowed only for professionals etc)</td>
</tr>
<tr>
<td>EU (April 2011)</td>
<td>The overall conclusion from the evaluation is that it may be expected that there are products containing zineb for the product-type 21 (antifouling paints), which will fulfil the requirements laid down in Article 10(1) and (2) of Directive 98/8/EC. This conclusion is subject to: Compliance with the particular requirements of the report (amongst others) The uses that were proposed and supported by the applicant were for a specific product of 4.53% w/w zineb at specific application rates and with certain restrictions regarding its use by amateur and professional users (i.e. spray application allowed only for professionals). Extension of the use pattern beyond those described will require an evaluation at product authorisation level</td>
</tr>
</tbody>
</table>

Based on the overseas regulatory decisions and its current overall regulatory status, zineb is initially considered as a “green” active ingredient for use in antifouling paints. However, there are restrictions by the UK authority and the EU Rapporteur Member (Ireland) on application by amateur users that trigger concerns regarding human health risks. This point will need to be looked at closely during the reassessment in order to identify possible risk mitigation measures.

Red-flagged chemicals

Diuron

*Main regulatory actions taken by overseas jurisdictions on diuron*

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Regulatory actions/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK (October 2001)</td>
<td>The ACP recommended that all uses of diuron in antifouling paints should be revoked on environmental and human health grounds because there was inadequate reassurance that the risk to operators was acceptable</td>
</tr>
<tr>
<td>EU</td>
<td>Not supported for inclusion in Annex I to Directive 98/8/EC as an active substance for use in</td>
</tr>
</tbody>
</table>
While it was proposed that all agricultural uses of diuron where rates exceed 160 g/ha should be suspend due to risks to aquatic environment which are considered unacceptable, this proposed suspension will not affect the registration of antifouling paints. The assessment did not find any reason why the continued registration of these products could not be supported. The human health assessment report raised no concerns in relation to the continued approval of diuron and diuron product registrations. It is noteworthy that the human health assessment does not include exposure modelling for neither agricultural uses nor for antifouling paints application.

It is not permitted to import, sell or use anti-fouling bottom paint containing the biocide diuron on ships shorter than 25 metres.

On the basis of the risks identified and all the consequent regulatory decisions as presented above and the fact that diuron is not registered by major jurisdictions such as the US EPA and the EU, this active ingredient has been flagged “red”. It is noted that the APVMA has not proposed suspension of the use of antifouling paints (as they did for products used in agriculture) containing diuron due to low expected environmental risks. However, this is contradictory to other jurisdictions’ concerns so far; in addition, environmental exposure modelling performed in Australia was based on the OECD ESD standard proposed scenarios and not on Australia specific scenarios which may have lead to risk underestimation. Furthermore, it is noted that no human health risk assessment was performed for identifying the risks to operators (application of paint). This can’t be disregarded given that the ACP in the UK for this reason recommended revocation of all uses of diuron in antifouling paints.

### Chlorothalonil

*Main regulatory actions taken by overseas jurisdictions on chlorothalonil*

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Regulatory actions/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK August 2002</td>
<td>All amateur uses of antifouling products containing chlorothalonil are to be revoked because information from humans indicates that the risk of skin sensitisation is unacceptable. Approvals for the professional use of antifouling products containing chlorothalonil at a maximum concentration of 5% w/w may be continued for professional use by brush, roller and spray, subject to data requirements</td>
</tr>
<tr>
<td>EU</td>
<td>Not supported for inclusion in Annex I to Directive 98/8/EC as an active substance for use in product type 21 (Antifouling products)</td>
</tr>
<tr>
<td>Australia</td>
<td>One antifouling product containing chlorothalonil was found in June 2007 by (Reference) on the PUBCRIS database; currently no antifouling products containing chlorothalonil can be</td>
</tr>
</tbody>
</table>
The only jurisdiction that this active ingredient is registered for use in antifouling paints is Japan, while the UK report recommended that all amateur uses be revoked. On this basis chlorothalonil has been flagged “red”.

**Irgarol 1051**

*Main regulatory actions taken by overseas jurisdictions on Irgarol 1051*

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Regulatory actions/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK (February 2005)</td>
<td>It was recommended that: Approval for professional and amateur use of antifouling products containing Irgarol 1051, on vessels less than 25 m, should be revoked in accordance with standard procedures and timescales. This length restriction is interpreted as revocation of all amateur uses of Irgarol 1051. The use of antifouling products containing Irgarol 1051 by professionals on vessels greater than 25 m, at a maximum concentration of 10 % w/w, for application by brush, roller and spray, may continue subject to conditions and data requirements which should be addressed to timescales specified</td>
</tr>
<tr>
<td>EU (January 2011)</td>
<td>The overall conclusion from the evaluation is that it may be expected that there are products containing Cybutryne (Irgarol 1051) for the product type (PT) 21 (Antifouling) which will fulfil the requirements laid down in Article 5 of Directive 98/8/EC. This conclusion is subject to compliance with the particular requirements of the report (amongst others) The uses that were proposed and supported by the applicant were regarding a specific product of 2.3% w/w Irgarol 1051 at specific application rates and intervals with certain restrictions regarding its use by professional users only (i.e. personal protective equipment). Extension of the use pattern beyond those described will require an evaluation at product authorisation level</td>
</tr>
<tr>
<td>California EPA (August 1996)</td>
<td>Registration of Irgarol 1051 for use in formulating antifouling paints approved. The typical active ingredient concentration in end-use formulations was submitted to be between 1.5% and 3.0%. However, no quantitative environmental and human health risk assessment was performed</td>
</tr>
<tr>
<td>USEPA (Federal)</td>
<td>Reregistration review decision 2015 according to work plan</td>
</tr>
<tr>
<td>Denmark</td>
<td>It is not permitted to import, sell or use anti-fouling bottom paint containing the biocide Irgarol on ships shorter than 25 metres</td>
</tr>
</tbody>
</table>
| Sweden             | The Swedish authorities banned pleasure boat paints containing Irgarol 1051 for use on the east coast from the 1st of January 2001 Irgarol 1051 is registered as an active ingredient in antifouling products on the Swedish market, but it is gradually being phased out (by the time an approval for a product runs out, a
Based on the above list of decisions (restrictions to commercial boats of length >25 m and application/removal by professional users only) and the rationale behind them, Irgarol 1051 has been flagged as “red”.

**Orange-flagged chemicals**

3(2H)-Isothiazolone, 4,5-dichloro-2-octyl-

*Main regulatory actions taken by overseas jurisdictions on 3(2H)-Isothiazolone, 4,5-dichloro-2-octyl-*

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Regulatory actions/Conclusions</th>
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</thead>
<tbody>
<tr>
<td>UK March 2004</td>
<td>Continued approval was recommended for professional products containing 3(2H)-Isothiazolone, 4,5-dichloro-2-octyl-. Antifouling active substances including 3(2H)-Isothiazolone, 4,5-dichloro-2-octyl- were to be reviewed under the Biocidal Products Directive in the second review group. All relevant data including those generated as a consequence of the 2000 UK review will be taken into account.</td>
</tr>
<tr>
<td>EU December 2010</td>
<td>It was recommended that the active ingredient shall be included in Annex I to Directive 98/8/EC as an active substance for use in product type 21 (Antifouling products), subject to the following specific provisions: The active substance as manufactured shall have a minimum purity of 950 g/kg. Antifouling products containing (3(2H)-Isothiazolone, 4,5-dichloro-2-octyl-) shall only be authorized for use by professional operators on commercial vessels or super yachts above 25 m, unless data is provided demonstrating other safe uses (as the applicant supported only these uses). Certain restrictions regarding its use by professional users (i.e. personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by others means). Risks were identified for seawater and marine sediment from maintenance and repair activities and appropriate risk mitigation measures must be taken to protect those compartments along with appropriate warnings in labels and/or safety data sheets. For the in-use phase of antifouling products, a risk has been identified for marinas. Unless safe use according to Article 5 (1) of 98/8/EC can be demonstrated when authorising products, authorities should consider restrictions for marinas, especially in sensitive areas.</td>
</tr>
<tr>
<td>California EPA (February 1999)</td>
<td>Registration of Sea Nine 211 for use in formulating antifouling paints approved. However, no quantitative environmental and human health risk assessment was performed.</td>
</tr>
</tbody>
</table>
Inconsistent information is found within overseas regulatory decision documents regarding the registration of 3(2H)-Isothiazolone, 4,5-dichloro-2-octyl- as an active ingredient in antifouling paints. This active ingredient has been registered in almost all jurisdictions checked. However, in the EU Rapporteur Member’s (Norway) report high environmental risks were identified for marinas and for scenarios where the product is used for only commercial vessels or super yachts > 25 m. Therefore, the active ingredient has been flagged “orange” and extensive modelling with the New Zealand specific scenarios is required for the identification of environmental risks.

**Dichlofluanid**

*Main regulatory actions taken by overseas jurisdictions on dichlofluanid*

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Regulatory actions/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK (January 2003)</td>
<td>The ACP recommended approvals for professional use of antifouling products, containing dichlofluanid at a maximum concentration of 10% w/w and to be applied by brush, roller, spreader or spray be continued, subject to conditions and data requirements. The ACP considered that the skin sensitisation potential of dichlofluanid was of sufficient concern to recommend that the amateur application of antifouling products by spray or aerosol be revoked. However it recommended that amateur application by brush and roller was acceptable with a recommendation for gloves to be worn as a precautionary measure.</td>
</tr>
<tr>
<td>EU</td>
<td>Supported for inclusion in Annex I to Directive 98/8/EC as an active substance for use in product type 21 (Antifouling products). Currently being reviewed by Rapporteur member State UK.</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Registrations expired and not renewed</td>
</tr>
</tbody>
</table>

Due to lack of enough robust information on the risks posed to human health and the environment by the use of this substance in antifouling formulations, dichlofluanid has been flagged “orange” and a full human health and environmental modelling and risk assessments are required.

**Tolyfluanid**

*Main regulatory actions taken by overseas jurisdictions on tolyfluanid*

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Regulatory actions/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU</td>
<td>Supported for inclusion in Annex I to Directive 98/8/EC as an active substance for use in product type 21 (Antifouling products). Currently being reviewed by Rapporteur Member State Finland</td>
</tr>
</tbody>
</table>

Tolyfluanid, to our knowledge, is only registered as an antifouling agent in Japan. In the EU it is still under review and as Rapporteur Member’s (Finland) report has not been released yet and no other complete reviews or reports regarding the risks arising from its use as an antifouling active ingredient are available. On that basis tolyfluanid has been flagged “orange” and full human health and environmental modelling and risk
assessments are required. This may change if, in the meantime, Finland’s report is released and the conclusions are robust enough to trigger another flag.

Ziram

*Main regulatory actions taken by overseas jurisdictions on ziram*

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Regulatory actions/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>Not supported at review and voluntarily withdrawn</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Expired-Registrations not renewed</td>
</tr>
</tbody>
</table>

Ziram was assessed under Part 5 as a new active ingredient in antifouling paints in New Zealand. Due to the lack of scientific tools at that point, quantitative human health and environmental risk assessments were not performed. Moreover, in the evaluation and review report prepared by ERMA New Zealand at that time, it was mentioned that the product was registered in the United States, Canada and the Netherlands. This international status has now changed as the registrations of the product have expired in the Netherlands and to our knowledge ziram is not registered in Canada. Therefore, ziram has been flagged “orange” and full human health and environmental risk assessments are required.

Thiram

Thiram is registered only in Australia and New Zealand. As the reason for withdrawal in the UK is not having industry’s support, thiram is flagged “orange” and full human health and environmental risk assessments are required.

Mancozeb

Mancozeb is not registered by any other jurisdictions except New Zealand. According to the UK review report on zineb there was sufficient evidence to support the argument for “read across” from mancozeb to zineb due to the extremely similar structures of the two molecules and their similar physicochemical endpoints. This will be examined through the reassessment from the toxicological and ecotoxicological aspects and if proved satisfactory, mancozeb may be directly considered as a green flagged active ingredient on the same basis as zineb has been.

Octhilinone

Octhilinone is registered only in the United States and New Zealand as an active ingredient in antifouling paints. There is however an uncertainty on whether this chemical is considered as a preservative or an active ingredient by other jurisdictions. Its use in antifouling paints will be discussed with stakeholders and a decision will be made on whether full human health and environmental risk assessments are required.
Evaluation summary of the NIWA report:

Conclusions

NIWA was commissioned by the EPA to evaluate whether the default scenarios recommended by the OECD Emission Scenario Document (ESD) were suitable for New Zealand conditions. NIWA identified New Zealand specific scenarios for the estimation of environmental concentrations of biocides contained in antifouling paints. The main outcomes showed that:

- The New Zealand specific scenarios are “worse” than the standard OECD ESD regarding the service life of the paints (leaching from vessel hulls).
- According to NIWA’s estimations predicted environmental concentrations of some biocides exceed the environmental exposure limits (EEL) as set by the EPA. Therefore, this report does not only provide scenarios to be used in the antifouling paints reassessment but it provides a reason (grounds) for this reassessment.
- The work performed by NIWA was satisfactory and the disappointing aspect being the poor response from the industry (antifouling paints application and removal facilities, professional users) to NIWA’s survey regarding the application and removal of the paints. The dataset (answers provided by the industry) was not large enough to develop scenarios based around statistically robust ‘average’ values or practices, so ‘best judgment’ calls had to be made by NIWA using the available data in an attempt to develop New Zealand specific scenarios. It was therefore recommended that these scenarios be reviewed and amended as a result of comprehensive feedback from the industry.

Background

The EPA will carry out quantitative risk assessment of antifouling biocides for the reassessment of existing approved substances and for new substances. To enable this, emissions of the substance and its fate within the marine environment have to be estimated. The OECD ESD describes emission scenarios for three parts of the life cycle for antifouling products used on ship and boat hulls: 1) application 2) service life 3) removal. MAM-PEC (Marine Antifoulant Model to Predict Environmental Concentrations) is a model which has been adopted by the OECD to estimate the fate of antifouling substances in marine environments.

The EPA commissioned NIWA to evaluate whether the default scenarios recommended by the OECD ESD are suitable for New Zealand conditions. In their analysis NIWA compared OECD default inputs to the MAMPEC model with New Zealand data. These input data included physical, hydrological, and water quality data and vessel numbers. NIWA used data from 11 ports and 12 marinas which were collected in the Phase I of this project. In Phase II the data collected in Phase I were modeled using three “dummy” test substances, copper and diuron to predict water and sediment concentrations for the ports and marinas. In addition, two surveys were conducted and data were collected from professional operators and private owners regarding application and removal of paints. Based on that, New Zealand specific application and removal scenarios were recommended to provide an integrated emission scenario assessment.
Summary of the main outcomes

In the following sections, the main conclusions of the NIWA reports are discussed for each part of the lifecycle of antifouling paints, application, service life and removal. Application and removal are discussed in a single section ‘Maintenance and repair’.

Service life assessment

Ports

- Estimated antifouling emissions from New Zealand ports were lower than the OECD default values. This arises from lower numbers and smaller size of vessels operating in New Zealand waters;
- Predicted antifouling concentrations (PECs) in receiving waters are higher in New Zealand ports than OECD default values, largely due to the nominal dimensions of the port area within the greater harbour environment.

Recommendation: New Zealand data be used for the service life in ports assessment rather than the OECD default port. The ports to be used in an EPA assessment should be Lyttelton and Milford Sound as they represent realistic worst-case situations.

Marinas

MAMPEC predicted higher antifoulant emissions and higher concentrations in receiving water for many of the New Zealand marinas compared to the OECD defaults. This was largely due to the larger numbers of vessels, larger average vessel size and the marine configuration (typically smaller mouths) in New Zealand than in the OECD defaults.

Recommendation: That New Zealand marina data be used for the service life in marinas assessment rather than the OECD default marina. The marinas to be used in an EPA assessment should be Half Moon Bay (marine) and Kinloch (freshwater).

Other key issues

Leaching rate is a very important input parameter in determining biocide emission rates and PECs. Industry (paint manufacturers) needs to provide the data necessary to derive leaching rates of biocides from specific antifouling products. If such information is not available then assumptions based on a “worst case” approach will be used.

Application factor (the proportion of vessels using paint with specified antifouling biocide) is another key parameter and NIWA used the OECD default (90%) for all biocides tested except copper (95%). For active ingredients except copper the 90% factor may be a conservative assumption as these ingredients are booster biocides to copper. For instance for diuron, predicted concentrations allied most closely to measured values when application factors of 5% and 10% were used. More accurate application factors would require information from industry (paint manufacturers, professional and non-professional users). However, for assessing new antifouling compounds the 90% default provides conservative values relevant if a new product is widely used.
Although the OECD ESD does not require prediction of antifouling compounds in sediments MAMPEC can predict sediment concentrations after 1, 2, 5 and 10 years. The NIWA analyses showed predicted concentrations of copper in sediment much lower than measured concentrations. This is likely due to additional sources of copper emission into marina sediments and accumulation of copper for more than 10 years, i.e. for longer than the longest period modeled by MAMPEC.

Risk Assessment
A preliminary risk assessment was performed by NIWA. PEC values derived by the model using New Zealand specific scenarios were compared to toxicity data from ANZECC & ARMCANZ water quality guidelines and EEL as set by the EPA. PECs of copper exceeded these limits in many ports and marinas. The EEL for diuron was exceeded in some seawater marinas although, an application factor of 90% was used which is likely an overestimate.

Cumulative effects were outside the scope of this project, but NIWA nevertheless recommended that a cumulative input model is required for areas such as the Waitemata Harbour because of the significant number of multiple inputs from the numerous marinas within the harbour.

Recommendation: It is not essential to take cumulative effects into account as, to date, cumulative effects have been beyond the scope of the EPA assessments.

Application and removal assessment
Maintenance & Repair Scenarios
Six maintenance and repair (M&R) scenarios are established based on information from boat paint suppliers, boat yard operators and private vessel owners:

Application – (1) Large commercial vessels (2) Small commercial vessels (3) Pleasure craft;

Removal – (1) Large commercial vessels (2) Small commercial vessels (3) Pleasure craft.

Each of the above scenarios is split into realistic worst case and typical case scenarios.

Other key issues
There are several issues requiring further work:

- Many of the assumptions on the basis of which the above scenarios were defined, were based on survey responses that in many cases were very poor (few or single or no answers). More work is required to acquire essential information for amending the developed scenarios on:
  - Paint loss during spray application and how much overspray ends into the marine environment? Type of location where commercial vessel paint application is performed (e.g. walled dry docks/ slipway/shrouded or enclosed).
  - How much (%) of paint is removed under ultra high pressure water blasting (UHP)? How much (%) abrasive spot blasting is performed in boatyards in New Zealand? Input from experts or additional
research on the fraction of active ingredient in paint removed by abrasion. How many boats (%) are wet sanded in New Zealand? What is the remaining paint thickness?

- How much emission from M&R operations is captured/treated and/or diverted to sewage treatment plant (STP), avoiding emission into the marine environment? Comprehensive industry input and/or site visits may be needed to assess this.
- The estimated loads of antifouling compounds from M&R are provided in terms of kg_{ingredient}/day or per year. These values could be transformed to environmental concentrations (i.e. mg/m^3) for any given marina but only after very careful consideration of the layout of the marina and the form of the antifouling compounds particularly for removal scenarios. Further discussions need to be conducted with NIWA on this matter.

A comparison of M&R emissions to service life emissions was performed and emissions during service life were estimated to be substantially larger than from M&R for most of the scenarios assessed.

**Summarised information required from the industry (maintenance and repair) as identified by the NIWA report**

- Paint loss during application, during spray application and how much overspray ends into the marine environment?
- Type of location where commercial vessel paint application is performed (e.g. walled dry docks/slipway/shrouded or enclosed).
- How much (%) of paint is removed under ultra high pressure water blasting (UHP)?
- How much (%) abrasive spot blasting is performed in boatyards in New Zealand?
- Input from experts or additional research on the fraction of active ingredient in paint removed by abrasion. How many boats (%) are wet sanded in New Zealand?
- How much is the paint thickness remaining of the original paint thickness?
- How much emission from M&R operations is captured/treated and/or diverted to sewage treatment plant (STP), avoiding emission into the marine environment?

The industry will be requested to provide information on the above questions.