What are the ecotoxicology challenges for suppliers who want to place antifouling products on the EU market?

INSIGHT EXPERT FOCUS | 12 December 2022

Yuzhu (Celia) Wei and Hans Marquart, registration and risk assessment experts at Triskelion, outline the challenges of assessing the environmental risks of PT21 products – and look at options for refining the process

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Antifouling products play an essential role in maritime transport and maintaining marine platforms such as oil rigs. Preventing unwanted organisms from attaching to ships and offshore structures saves energy and cuts costs.

The global antifouling market is expected to increase from around $6bn in 2021 to $13bn in 2031. However, placing antifouling products on the market is not easy. In the EU, for example, such products are strictly regulated under the biocidal products Regulation (BPR) and must pass both efficacy and risk assessments to be authorised.

Below, we look at the challenges of bringing antifouling products – or product-type 21 (PT21) under the BPR – to the European market from the regulatory ecotoxicology perspective, and possible refinements.

Environmental risk assessment under the BPR

According to Echa's PT21 product authorisation manual, the release rates of assessed substances in antifouling paints need to be calculated following ISO 10890, or tested in a laboratory using the ASTM D6442, ASTM D6903 or ISO 15181 standard methods.

The determined leaching rate is used to calculate the predicted exposure concentration in the marine antifouling model to predict environmental concentrations (Mampec).

Besides leaching rate, the model includes parameters covering environmental conditions (for example, regional size), substance properties (for example, biodegradation rates) and service conditions (for example, the number of vessels).

Finally, the calculated predicted environmental concentration (Pec) is compared to the predicted no-effect concentration (Pnec) to ascertain the risk. If Pec/Pnec >1, safe use can be demonstrated. If Pec/Pnec <1, the risk is considered unacceptable. Depending on the application of the paint, the risks in different scenarios (such as commercial harbours, marine/freshwater marinas and inland waterways) must be assessed.

Tier 1 environmental risk assessment

In Tier 1 risk assessment, scenarios aim to demonstrate unacceptable environmental risks in both marine and freshwater marinas.

While manufacturers produce paint for different regions that differs, for example, in its composition, thickness and expected lifetime, each type of paint needs to be demonstrated as safe to use in marinas in all core EU

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regions – including those where it is not intended to be used.

For instance, paints for pleasure crafts used in the Atlantic region usually contain more active substances than those in the Baltic region because of a higher fouling pressure. However, the Baltic region also needs to find the risk of these paints acceptable.

This appears to be a logical requirement as the craft is a mobile object and can sail to different areas. But how likely is it that Baltic marinas are filled by pleasure crafts originating in the Atlantic region? The risks in the Baltic region are probably overestimated in this case, and the product intended for the Atlantic region will fail the environmental risk assessment and be banned from the market, regardless that it poses no risk in its target region.

Another challenge is the high background concentration of copper in marine and freshwater areas. Copper is the most common active substance in antifouling products and is also the only substance for which the regional background concentration is required during Pec calculation (as agreed under Council Regulation (EEC) 793/93 on existing substances – EU-RAR).

This means that both the released copper from the antifouling paint and the regional background copper contribute to the final Pec values in the risk characterisation. Given that the regional background concentrations of copper are already close to the corresponding Pnecs, there is only a small margin left for the product leaching rate to demonstrate 'safe use'.

For example, the ratio between the Pec caused by the background value in seawater surrounding harbours/marinas and the Pnec for seawater is already 0.96, only marginally lower than the maximum accepted ratio of 1. Therefore, it is difficult for copper-containing products to achieve 'safe use' in Tier 1.

Meanwhile some other commonly used substances in antifouling paints, such as zinc, are almost ubiquitous in some marinas. The zinc concentration in brackish water marinas can be as high as 26 micrograms per litre (µg/L) – more than seven times higher than the seawater Pnec for zinc.

A higher background concentration of copper and other substances of concern (for example, zinc) may be adopted in the PT21 regulation in the future. It will mean that the margin for released antifouling product will be even smaller for concluding 'safe use' in Tier 1.

The refinement options for high tiers

According to Echa's PT21 product authorisation manual, environmental risk assessment allows for 'refinements' to calculations in higher tiers. However, there is no agreed EU-wide refinement available. Instead, applicants are encouraged to propose and discuss optional refinements with relevant EU member states.

Providing sufficient information for this is challenging because the available literature and data are usually based on local/national results and cannot cover regional environmental risk assessment. The discussion process can also be time-consuming and the proposed refinement may eventually be rejected, or accepted only with additional information.

For example, in the 2006 EU technical experts workshop, the European Council of the Paint, Printing Ink and Artists' Colours industry (Cepe) proposed a correction factor (CF) for the calculated leaching rate in the Tier 2 risk assessment to compensate for the overestimated release of copper over the life of a product. The workshop accepted the CF but additional evidence from the applicants was required.

Ytreberg et al. (2021) disagreed with the application of such a refinement, saying it could encourage unnecessarily high levels of copper in antifouling products and inhibit the innovation of environmentally friendly alternatives. However, hardly any antifouling products are likely to be acceptable without a CF, and the quality and efficacy of alternative solutions is not sufficiently established.

Limiting one environmental problem could lead to an increase in another – such as widespread invasive species and increased energy consumption. Hence a CF is needed now, though a lower value than that initially proposed might be possible.

Other refinement options include considering the volume of boats travelling between marinas. This approach considers that each marina is exposed to paints different to the one intended for each marina. It reduces the overestimation of the risk of high biocide content paints in areas where low biocide content paints are usually used.

Another refinement option is to account for the impact of salinity on the leaching rate determination – something not considered in Tier 1 risk assessment. The leaching rate

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of copper reduces as salinity decreases, therefore, a CF for salinity could be a refinement in Tier 2 assessment.

Meanwhile, the Mampec model calculates the Pec value of the released substance in suspended matter – instead of sediment. But this Pec value is compared with the Pnec for sediment in risk characterisation to determine the risk to sediment-dwelling organisms. Although the released substance in the suspended matter will eventually settle on the top layer of the sediment, the Pec value in suspended matter depends on multiple parameters, such as the suspended matter concentration in the water compartment and water flow velocity. Hence, the impact on the risk assessment of comparing the Pec for suspended matter to the Pnec for sediment is hard to estimate. But if the sediment's top layer is removed to keep the channel water depth, sediment samples could be taken and analysed. The Pec of sediment should be used instead of the Pec for suspended matter.

Conclusions

The main challenges of bringing antifouling – or PT21 – products to the European market are the high ratios between estimated concentrations and limit values in Tier 1, and the lack of agreed refinements in higher tiers. The fact that the assessment does not distinguish, in assessed marinas, between products and high background copper concentrations in the environment, makes it hard for the products to pass the safe threshold value in Tier 1.

Although the environmental risk assessment appears to overestimate the risks from some perspectives, proposing refinements in high tiers can be challenging and time-consuming. Increasing our knowledge of vessels travelling between regions, of actual leaching versus calculated leaching, and of the influence of various factors, may lead to accepted refinement options.

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FURTHER INFORMATION

Harmonisation of leaching rate determination for antifouling products under the BPR, workshop report, December 2006 →

Antifouling biocides in German marinas →

Improved estimates of environmental copper release rates from antifouling products →

Antifouling paints leach copper in excess –study of metal release rates and efficacy along a salinity gradient →

Environmental risk assessment of using antifouling paints on pleasure crafts in European Union waters →

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