I-Tech AB
Förändringens gata 10
431 53 Mölndal
Sweden

I-Tech AB's comments to the consultation on derogation conditions for medetomidine under the Biocidal Products Regulation

In this document, I-Tech AB (hereafter referred to as I-Tech), comments on the renewal of the active substance medetomidine in product-type (PT) 21 (antifouling products) via the conditions set out in Article 5(2) of Regulation No 528/2012 (BPR), i.e., derogations to the exclusion criteria. I-Tech is the sole applicant for medetomidine, which is the active substance in Selektope®.

This text summarises I-Tech´s submission to the public consultation, which comprises (i) a detailed analysis of alternatives[1], (ii) an independent socio-economic analysis (SEA) conducted by the consultant Ricardo Plc on the environmental, economic and wider social impacts of potentially not renewing medetomidine's approval under the BPR and (iii) a further study by Ricardo Plc on the importance of maintaining sufficient chemical diversity in PT21 to effectively mitigate the risks of invasive alien species in European waters.

These analyses support the renewal of approval based on the Article 5(2) criteria, as follows.

Introduction to I-Tech, medetomidine and the issue of 'hard fouling'

The development of medetomidine as a viable antifouling active substance was a key deliverable of the Marine Paint research programme (2003-2011) of the Swedish Foundation for Strategic Environmental Research (MISTRA).[2] Research was conducted by the University of Gothenburg and Chalmers University of Technology and followed the EU and international bans on the use of organotins (i.e., tributyltin 'TBT')

[1] The analysis of alternatives was previously submitted to ECHA in a consultation on potential candidates for substitution (03/11/2023 to 04/01/2024). However, as its content and conclusions remain pertinent to the discussions on exclusion criteria it is attached for the convenience of the decision makers.

[2] https://mistra.org/wp-content/uploads/2023/02/Marine-Paint-FinalReport_2003-2011-ENG.pdf.

for antifouling coatings in the early 2000s. I-Tech was founded as a spin-off company to commercialise medetomidine and received funding from the European Union.[3]

I-Tech currently markets medetomidine – under the commercial name of Selektope® – in biocidal marine coatings that have become the preferred solution for several international paint manufacturers, bringing major benefits to stakeholders in the maritime industry such as ship owners and shipyards. For example, the majority of commercial vessels (e.g., container ships, hospital ships, tankers)[4] built today in South Korea use antifouling coatings containing Selektope®.

'Fouling' (also called 'biofouling') is the settling, growth and/or accumulation of biological matter on hard underwater surfaces such as the hulls of vessels and other marine infrastructure. It can be categorised into 'soft' or 'hard' types depending on the organism(s) involved. **Soft fouling** is comprised of bacteria, slime, diatoms and microalgae whilst **hard fouling** is characterised by organisms with shells or calcareous exoskeletons, such as barnacles, mussels, tubeworms and bryozoans, which attach firmly to surfaces, sometimes penetrating coatings. **Biocidal active substances are usually demonstrated to be effective either against hard or soft fouling and, whilst different biocides are often used in combination in a single coating (as co-biocides), they cannot be used interchangeably**.

Left: Ship hull covered with hard fouling. Right: Comparison of ship hull sections treated with and without Selektope®.

Hull fouling, particularly hard fouling, increases the water resistance (drag) of a vessel in motion due to increased surface friction. In turn, this increased drag leads to higher fuel use (and associated greenhouse gas emissions) as well as increased operating and maintenance costs (including for dry-docking for periodic hull cleaning). Fouling is also an important vector for the transfer of invasive aquatic alien species into new environments and vessels can be denied docking because of excessive fouling.[5,6] Invasive alien species are a threat to marine biosecurity around the globe including in the EU. It is thus essential that effective and sustainable measures are taken to prevent hard fouling on vessels.

[3] Such as via the EU Entrepreneurship and Innovation Programme and the EU SEAFRONT (Synergistic Fouling Control Technologies) project.
[4] Detailed case studies may be found at https://selektope.com/about-selektope/case-studies/.
[5] https://vessel-check.com/knowledge-base/biofouling-risk/#antifoulant-coating
[6] https://www.safinah-group.com/wp-content/uploads/2018/06/PortShield-Antwerp-May-2018-final-edited.pdf

Medetomidine has been approved as an active substance under the BPR for use in antifouling products (PT 21) since 2015. **Medetomidine is one of less than a handful of active substances in PT21 that have been demonstrated to be efficacious against hard fouling**. While the process for Member States authorisation of biocidal products containing medetomidine remains ongoing (and has been subject to numerous delays[7]), temporary authorisations have been granted in 13 EEA countries.[8]

Medetomidine is an innovative, 'next-generation', solution to hard fouling that has significant benefits compared to 'legacy' alternatives (such as copper compounds). Specifically, medetomidine is used in very low concentrations (0.1% compared to up to 50% for some copper-based coatings) and has a unique – non-lethal – mode of action, which repels hard fouling organisms from surfaces by inducing reversible hyperactivity. As such, organisms will not become resistant to it. Paint products formulated with medetomidine can also be significantly smoother than copper-based coatings, reducing their hydrodynamic drag and increasing their relative fuel efficiency.

Given the global nature of the marine biofouling issue and of maritime value chains, any decision on the authorisation of medetomidine should not only consider the current EU market for medetomidine but also consider broader impacts on other geographies and on their trade relations with Europe. **In the case of non-renewal of the active substance approval of medetomidine under the BPR, the numerous vessels treated with Selektope® in other geographies could no longer be 'placed on the EU market'. This would have a negative impact on EU based ship owners.**

Analysis of alternatives

The analysis of alternatives undertaken by the evaluating competent authority reported that there are 12 substances approved in PT21 and considers that 10 of them are a suitable alternative to medetomidine. Unfortunately, this assumption did not consider that, besides medetomidine, **only three of these substances (i.e., tralopyril, copper thiocyanate and dicopper oxide)have been demonstrated to be effective against hard fouling** and that **none of these alternatives has been demonstrated to have a significantly better hazard and risk profile than medetomidine**. For example, tralopyril is a PFAS[9] which may degrade in the environment into trifluoroacetic acid (TFA), a persistent 'arrowhead' PFAS (i.e., a terminal degradation product) that is currently being considered for harmonised classification under the CLP Regulation[10] and is also subject to ongoing scrutiny under EU water legislation.[11] Copper, on the other hand, is also subject to ongoing environmental concerns that have led to restrictions on its use around the world, including in the EU (notably in sensitive regions such as the Baltic sea), while reports of resistance in some species, including invasive alien species, question its efficacy in the long term. Copper thiocyanate and dicopper oxide are also subject to ongoing assessment for potential endocrine disrupting properties.

[7] Application for approval of an antifouling product containing medetomidine was submitted by a paint maker in August 2018. The evaluating member state is the Netherlands and the intention of the applicant was to apply for mutual recognition in 17 EU member states for the submitted product.

[8] Denmark, Estonia, France, Greece, Italy, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Spain.

[9] Per or poly-fluoroalkyl substance – also sometimes called 'forever chemicals'.

[10] Germany submitted a proposal for harmonised classification for accordance check in June 2024 for the following hazard classes: Acute Tox. 3, Skin Corr. 1A, Repr. 1B, Aquatic Chronic 3, PMT, vPvM. https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e188e6e587.

[11] TFA was specifically identified by the EU Council as a relevant parameter for urgent revision of the EU Drinking Water Directive (EU 2020/2184) https://data.consilium.europa.eu/doc/document/ST-11383-2024-INIT/en/pdf/.

By not recognising the specific technical functionality of medetomidine (i.e., to be efficacious against hard fouling), the conclusions of the analysis by the evaluating competent authority, whilst potentially reflecting the general availability of active substances in PT21, **are unrepresentative of the fact that only limited substances with PT21 have been demonstrated to be efficacious against hard fouling**.

I-Tech requests that the European Commission and Member States, when considering the reapproval of medetomidine, carefully consider the available evidence of the efficacy of alternatives specifically against hard fouling and do not assume that substances in PT21 that have only been concluded to be efficacious against soft fouling are suitable alternatives; they are not.

In addition, I-Tech notes that all of the active substances in PT21 that are acknowledged to be efficacious against hard fouling are also subject to ongoing renewal under the BPR. Given the concerns associated with these alternatives (as noted above – and elaborated in other parts of our submission), their future regulatory status should also be considered to be uncertain. **Therefore, it is of the utmost importance that sufficient chemical diversity against hard fouling is maintained in PT21 to ensure that hard fouling, and particularly the risks of invasive alien species, can continue to be effectively managed.**

Further information and assessment on the suitability of alternatives is provided in I-Tech's analysis of alternatives (originally submitted as part of the ECHA process to assess the renewal) and in Chapter four of the socio-economic analysis. In addition, a further assessment of the efficacy of alternatives against hard fouling is included in the study on the importance of chemical diversity in PT21 to mitigate the risk of invasive alien species in European waters.

Medetomidine meets the conditions for derogation under Article 5(2) of the BPR

In light of its critical function in controlling hard fouling, and the fact that there are limited suitable alternatives available, the reapproval of medetomidine is clearly justified.

Specifically, medetomidine is ***"essential to prevent or control a serious danger to human health or the environment"*** (Art. 5(2)(b) BPR), because its approval is vital to ensure that there is sufficient chemical diversity in PT21 that is effective against hard fouling to limit/prevent the transfer of invasive alien species in the event that (i) copper thiocyanate/dicopper oxide are subject to greater restrictions on use, (ii) there is increasing resistance (or tolerance) to copper in invasive species or (iii) in the event that copper thiocyanate/dicopper oxide or tralopyril were not to be re-approved in the future.

The use of biocidal substances, with a range of efficacy spectra and modes of action, is essential to preventing the further spread of invasive alien species in the EU and the decline of marine ecosystems.

Further detailed assessment of the importance of sufficient chemical diversity in PT21 is provided in the study on 'the importance of chemical diversity in marine anti-fouling coatings to mitigate the risk of invasive species in European waters'.

Furthermore, not approving medetomidine ***"would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from its use"***

(Art. 5(2)(c) BPR). The independent socio-economic analysis conducted by the consultants Ricardo Plc (submitted as part of this consultation response), performed using standard ECHA and European Commission methodology, concluded that there are limited to no net benefits to the EU from the non-approval of medetomidine across economic, environmental and wider social impact dimensions, while triggering substantial costs, resulting in a benefit-cost ratio of zero. The European Commission's Better Regulation toolbox[12] suggests that, in order to be economically acceptable, a policy should have a **benefit-cost ratio of greater than one**. Therefore, by default, the non-approval of medetomidine would be disproportionate.

The negative impact is primarily because (i) alternatives do not have a better hazard and risk profile and (ii) any risks associated with the use of medetomidine in marine coatings can be adequately controlled (i.e., with adequate operating conditions and risk management measures). Indeed, the abatement costs for medetomidine emission reduction are estimated to be significantly greater than those for recent REACH restrictions, including for PFOA and PFOA-related substances. The socio-economic analysis also elaborates how the non-renewal of medetomidine would result in a net negative impact on the environment arising from insufficient chemical diversity in PT21.

Full details of the socio-economic impact of a non-authorisation of medetomidine on economic, environmental and wider social dimensions are provided in the socio-economic analysis.

Conclusion

The management of hard fouling is a significant global issue, with aspects ranging from minimising carbon emissions to controlling the environmental risks associated with invasive alien species. Medetomidine is a next-generation biocide that is a solution to many of these challenges, while minimising biocide use.

The current EU market for medetomidine, which has been influenced by the slow pace of regulatory authorisations and approvals in Member States, is not a good indicator of the potential of this European innovation. Non-approval would be a terrible missed opportunity to realise the benefits of medetomidine, that have been widely recognised in other geographies.

This is especially true when considering that risks can be adequately controlled by appropriate operating conditions and risk management measures. The exposure concentrations associated with effects on the endocrine system are far greater than those associated with uses in antifouling coatings (and were instead related to the pharmaceutical uses of medetomidine).

Finally, I-Tech notes that regulatory decisions on substances in PT21 would benefit from a more comparative approach (as recently the case, for example, for anti-coagulant rodenticides). Substance-by-substance regulatory decision making on active substances as and when their existing approvals expire disadvantages those active substances that have earlier renewal dates, and could readily lead to substances with poor environmental and human health properties remaining on the market simply because they are the only ones remaining when regulatory decisions are made.

[12] https://commission.europa.eu/document/download/9c8d2189-8abd-4f29-84e9-abc843cc68e0_en?filename=BR%20toolbox%20-%20Jul%202023%20-%20FINAL.pdf. In particular, cf. "Tool #63. Cost-benefit analysis".

In light of this, I-Tech firmly believes that medetomidine meets the conditions for reapproval under the conditions on Article 5(2) of the BPR, as evidenced by the analysis of alternatives, socio-economic analysis and study on substance diversity on PT21 attached to this submission.

Enc.

1. ANALYSIS TO BIOCIDAL ACTIVE SUBSTANCES MEETING THE SUBSTITUTION CRITERIA UNDER THE BIOCIDAL PRODUCTS REGULATION
2. SOCIO-ECONOMIC ANALYSIS OF THE RENEWAL OF THE ACTIVE SUBSTANCE APPROVAL OF MEDETOMIDINE
3. THE IMPORTANCE OF CHEMICAL DIVERSITY IN MARINE ANTI-FOULING COATINGS TO MITIGATE THE RISK OF INVASIVE SPECIES RISK IN EUROPEAN WATERS