Medetomidine: Large consultation response consistently highlights adverse consequences of non-renewal

Summary of non-confidential stakeholder comments to the European Commission's Public Consultation on the renewal of medetomidine

This document has been prepared on the basis of non-confidential submissions provided to I-Tech after an 'access to documents' request submitted to ECHA and the European Commission.

Key points

- **Lack of suitable alternatives**: Stakeholders emphasized the lack of suitable alternatives to medetomidine in marine anti-fouling coatings, with only two alternatives (dicopper oxide and tralopyril) having a comparable functionality and use profile i.e., to prevent 'hard fouling' on commercial vessels. Non-biocidal hull coatings are not technically feasible on all commercial vessels.
- **Climate goals**: Use of medetomidine aligns with EU and IMO goals to reduce greenhouse gas emissions from shipping by significantly reducing fuel consumption and CO_2 emissions.
- **Threat to EU competitiveness**: Non-renewal of the approval of medetomidine would disproportionally impact the EU shipping industry, preventing vessels using it from being sold to EU owners or flagged by the EU.

Introduction

I-Tech AB markets the biocidal active substance medetomidine – commercial name Selektope® – for use in novel anti-fouling marine coatings. Medetomidine prevents hard fouling on ship hulls and propellers, even whilst idle. The regulatory approval of medetomidine as a biocide in the EU is undergoing periodic renewal.

As part of this renewal process, the European Chemicals Agency (ECHA) concluded that medetomidine should be considered as having endocrine disrupting properties. Biocidal active substances with endocrine disrupting properties may be approved if one or more of the three conditions specified in Article 5(2) of the Biocidal Products Regulation (BPR) are met:

a) There is negligible risk to humans, animals of the environment;
b) the active substance is essential to control a serious danger to human health, animal health or the environment;
c) not approving the active substance would have a disproportionate negative impact on society.

The availability of suitable alternatives is also a key consideration.

A public consultation on whether medetomidine should be considered to meet one or more of the Article 5(2) criteria was held from September to November 2024. This document provides a summary of the key themes presented by stakeholders in non-confidential comments received in the consultation.

Summary of stakeholder comments

A range of industry stakeholders, including shipyards and marine equipment manufacturers, various marine paint manufacturers (in addition to both their European and Global trade associations), ship owners, as well as alternative providers responded to the consultation. I-Tech obtained access to non-confidential submissions after filing an 'access to document' request to ECHA and the European Commission.

In relation to the suitability of alternatives, stakeholders were unequivocal in expressing **significant concerns on the lack of suitable alternatives** to medetomidine as well as questioning the reliability of the Analysis of Alternatives (AoA) conducted by Norway (the evaluating Competent Authority) as evaluated by the Biocidal Products Committee.

Specifically, whilst the AoA concluded that there were many suitable alternatives to medetomidine in PT21, stakeholders observe that, in reality, **only three active substances have principal activity against 'hard fouling'**. The remaining substances are acknowledged to have principal activity against 'soft fouling' (and are often described as co-biocides) and would always need to be formulated alongside an active substance with principal activity against hard fouling in an anti-fouling paint.

Of the three substances with principal activity against hard fouling (dicopper oxide, copper thiocyanate and tralopyril), copper thiocyanate is noted to be used primarily for leisure craft rather than large commercial vessels, which suggests that, in practice, only two alternatives to medetomidine (dicopper oxide and tralopyril) have a comparable functionality and use profile. It is noteworthy that **none of the stakeholder comments available to I-Tech supported the conclusions of the assessment of alternatives reported in the BPC opinion.**

Regarding the non-biocidal anti-fouling alternatives identified in the AoA, several stakeholders conclude that their technical feasibility is overstated and that they cannot currently be considered as suitable alternatives to biocidal-based coatings for all types of commercial vessels. In addition, a stakeholder notes that non-biocidal alternatives have yet to be scrutinised via comprehensive regulatory risk assessments making any regulatory conclusion on their relative safety (in comparison to biocidal products) premature.

In relation to the impacts of a non-renewal, stakeholders highlighted that use of medetomidine aligns with the European Union and International Maritime Organization's (IMO) goals of **reducing greenhouse gas emissions from shipping**. Ship owners using medetomidine emphasized its high efficiency, minimising fuel consumption and CO_2 emissions. In fact, according to a study by Calypso (a ship operator), effective antifouling systems, such as those enabled by Selektope, save the shipping industry over 100 million tonnes of carbon dioxide annually. Additionally, stakeholders noted the advantages of Selektope's effectiveness at very low concentrations, providing protection against hard fouling while minimizing its impact on coating hardness (which is particularly important on propellers).

Finally, stakeholders highlighted that the continued availability of antifouling coatings in the EU is a **concern for the global shipping industry.** This is because if the approval of medetomidine is not renewed, vessels with medetomidine anti-fouling coatings could not be sold to EU owners. Given the advantages of medetomidine over the available alternatives, this is considered as an erosion to the competitiveness of EU industry, including for EU shipyards who could not apply the *de facto* state-of-the-art anti-fouling coatings containing medetomidine.

In conclusion, **stakeholders participating in the public consultation agreed that not renewing the approval of medetomidine in anti-fouling coatings would result in disproportionate negative societal impacts compared to the risks to human health, animal health, or the environment associated with its use**.

In addition, the conclusions of stakeholders align with those of an independent socio-economic analysis that assessed the consequences of a non-renewal decision for medetomidine and which was submitted by I-Tech to the consultation.

Contact information: Please contact Dr. Cecilia Ohlauson, Director Regulatory Affairs & Sustainability at I-Tech for any further queries at cecilia.ohlauson@i-tech.se