

# EU extends approval for Selektope® until 31 December 2026

**I-Tech AB (publ) today provides an update on the EU approval process for its antifouling biocide Selektope® (active substance: medetomidine). The European Commission and the Standing Committee on Biocidal Products (SCBP) have decided to extend the current approval for use in antifouling coatings (product-type 21) until 31 December 2026.**

## **Extension granted again**

According to the European Commission, the extension has been granted because the ongoing assessment could not be finalised within the remaining timeframe, for reasons outside the Company's control.

I-Tech views the decision as confirmation that the Selektope case is receiving significant attention at EU Member State level, and that authorities consider it appropriate to maintain approval while the assessment continues. The extension provides regulatory continuity for Selektope® and its customers during the remaining review period.

## **CEO comment**

*"We welcome the SCBP's decision to extend the approval of Selektope,"* says Markus Jönsson, CEO of I-Tech AB.

*"In our view, this reflects the complexity of the case and the level of attention and scrutiny it is receiving at EU level. The additional extension enables a thorough evaluation and a decision-making process based on robust, scientific evidence. It also provides important regulatory clarity while the process continues."*

## **EU regulatory re-approval process**

Selektope has been approved for use in antifouling coatings in the EU since 2016 and is currently subject to a formal re-approval process under the EU Biocidal Products Regulation. The renewal application has undergone a full scientific evaluation, followed by an EU-level review and ongoing discussions among EU Member States.

I-Tech has consistently supported a stringent, science-based regulatory framework. At the same time, the Company has repeatedly raised concerns about certain aspects of the ongoing re-approval process, including the analysis of alternatives and the interpretation of available scientific data. I-Tech has stated that the analysis of alternatives has not sufficiently reflected technical feasibility, availability, real-world antifouling performance or sustainability impacts, and that conclusions should not be drawn where material scientific uncertainties remain.

Against this background, I-Tech has emphasised the importance of due process, proportionality and decision-making based on complete, up-to-date evidence, and has continued to engage constructively with regulatory authorities throughout the process.



## **Forward-looking actions: investment in a new safety study**

I-Tech is taking proactive steps to support a well-informed, science-based regulatory outcome. The Company is investing in a new *Extended One-Generation Reproductive Toxicity (EOGRT) study*, designed to generate additional data relevant to the safe use of Selektope (medetomidine) in antifouling coatings.

The study is intended to clarify remaining scientific uncertainties and strengthen the overall evidence base relating to possible endocrine effects. Although the study is predominantly intended for use outside the EU, I-Tech expects the results to also be relevant in a European regulatory context. The investment reflects I-Tech's long-term commitment to responsible product stewardship, transparency and evidence-based regulation.

## **Contacts**

Markus Jönsson, CEO

M: +46729-77 96 25

E: [markus.jonsson@i-tech.se](mailto:markus.jonsson@i-tech.se)

## **About I-Tech AB**

I-Tech is a biotechnology company that has developed the antifouling technology Selektope®, an active substance that prevents barnacle attachment on submerged surfaces such as ships and boat hulls. By increasing the anti-barnacle performance in marine paint systems (e.g. antifouling coatings), fuel and maintenance costs are reduced and vessel energy efficiency improved. I-Tech has obtained the necessary regulatory approvals for Selektope® and has several of the world's largest manufacturers of marine antifouling coatings as customers. The company's share is listed for trading on Nasdaq First North Growth Market in Stockholm. The Company's Certified Adviser is Redeye Nordic Growth AB. For more information visit our website [www.i-tech.se](http://www.i-tech.se).

## **Attachments**

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