Press Release
03 November 2026 14:10:00 CET

EU Member States support non-renewal of Selektope approval; limited commercial impact expected

Mölndal, Sweden, [DATE] – I-Tech AB (publ) today notes that EU Member States have voted in favour of the European Commission's proposal not to renew the approval of Selektope® (medetomidine) under the EU Biocidal Products Regulation (BPR). Subject to completion of the formal EU decision-making process, the non-renewal will take effect in accordance with the applicable transition arrangements.

The vote is consistent with the regulatory scenario previously communicated by I-Tech.

The outcome concerns only Selektope's future approval status in the European Union. It is not a global prohibition and does not affect approvals elsewhere, Selektope's performance or commercial track record, or the scientific evidence and operating experience supporting its use under assessed conditions.

Limited commercial impact

Based on the company's current interpretation, approximately 95% of the global commercial fleet is expected to be able to continue applying and operating with Selektope-containing coatings. I-Tech's direct commercial exposure to regional EU demand for Selektope represents approximately 4% of total turnover, and the company therefore expects the direct financial consequences to remain limited and in line with previous assessments and communications to the market.

Selektope's value proposition is primarily linked to international shipping, where shipowners and operators seek effective biofouling-management technologies that help maintain clean hulls, improve fuel efficiency, reduce greenhouse-gas emissions while supporting commercially viable vessel operations.

Continued use and orderly transition within the EU

The vote does not affect vessels already coated with Selektope-containing antifouling coatings and does not require the removal or replacement of existing coatings.

Based on the company's current understanding of the applicable regulatory framework, vessels coated with Selektope-containing coatings may continue to operate internationally, including calls at European ports and transit through European waters.

The principal scenario requiring careful assessment after the transition period is the transfer of a Selektope-coated vessel to an EU-based owner where the vessel is intended to operate exclusively within EU waters. Vessels engaged in international trade, including EU-flagged vessels, are not expected to be affected. Individual circumstances should nevertheless be assessed against the applicable regulatory requirements.

Following adoption and publication of a formal non-renewal decision, the applicable transition arrangements are expected to provide a 180-day period during which Selektope-containing coatings may continue to be supplied and applied within the EU. I-Tech will provide customers with further guidance as the implementation timetable is confirmed.

Following the applicable transition period, Selektope-containing antifouling coatings may no longer be placed on the EU market. This will reduce the range of antifouling products available to EU-based shipyards, while supply and application may continue in all jurisdictions where the relevant approvals remain in place.

Business continues as planned

I-Tech emphasises that the non-renewal is not a finding that Selektope is unsafe under its conditions of use. The decision is based on intrinsic hazard, whereas real-world risk depends on exposure. Selektope has passed human-health and environmental risk assessments for antifouling use.

I-Tech remains committed to supporting customers and shipowners worldwide and to delivering technologies that contribute to more efficient and sustainable shipping. The decision does not alter the company's long-term strategy.

CEO comment

"While we are disappointed by the outcome, it is important to put it into perspective. This is a regional regulatory decision that does not alter Selektope's performance or global relevance. Approximately 95% of the global commercial fleet is expected to be able to continue applying and operating with Selektope-containing coatings. We will support our customers and pursue the appropriate scientific, regulatory and legal avenues."

Next steps

I-Tech is reviewing the outcome and its implications together with external legal and regulatory advisers. The company maintains that important scientific and procedural questions remain regarding the assessment underlying the proposed non-renewal, including the endocrine-disruption classification, the relevance of the evidence to the specific conditions of antifouling use and the assessment of available alternatives.

I-Tech intends to challenge relevant aspects of the assessment through the appropriate scientific, regulatory and legal channels and is evaluating the remedies and procedural options available following adoption of the final decision.

In parallel, I-Tech will continue generating scientific data and evidence, engaging in the relevant scientific and regulatory dialogue, and supporting future regulatory activities and the long-term development of Selektope.

For further information, please contact:

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About I-Tech AB
I-Tech is a biotechnology company developing and commercializing innovative solutions for biofouling prevention. With science and specialist expertise at its core, the company is building a broader technology portfolio to address biofouling challenges across marine industries, supporting improved performance and reduced emissions to air and sea. I-Tech's established technology Selektope® is used in antifouling coatings by leading marine coating manufacturers worldwide.

I-Tech is listed on Nasdaq First North Growth Market Stockholm (ticker: ITECH) and the Certified Adviser is Redeye Nordic Growth AB. For more information, visit www.i-tech.se.

Attachments
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