Bridging the Gap Advancing Regulatory Science Tools for Biofilm Research through Standardisation

UNIC | Environmental Health Research Centre

EUROMIC EUROPEAN NETWORK FOR MIC MANAGEMENT

cost EUROPEAN COOPERATION IN SCIENCE & TECHNOLOGY

RESEARCH & INNOVATION FOUNDATION

CYMIC

Theo Zacharis – 23 Jan. 2025

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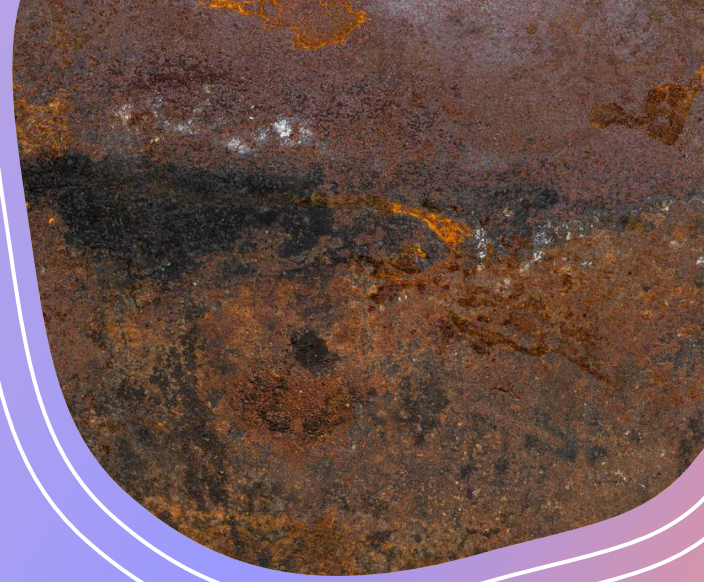
EUROPEAN NETWORK FOR MIC MANAGEMENT

Euro-MIC Action Bridging the Gap Advancing Regulatory Science Tools for Biofilm Research through Standardisation

Theo Zacharis

Agenda



1. Introduction to Regulatory Science
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3. Innovations Outpacing Standards The Need for Enhanced Regulations
4. The Role of Standardisation - CEN/CENELEC Workshop Agreements (CWAs)
5. Anticipated Benefits for EUROMIC COST Action
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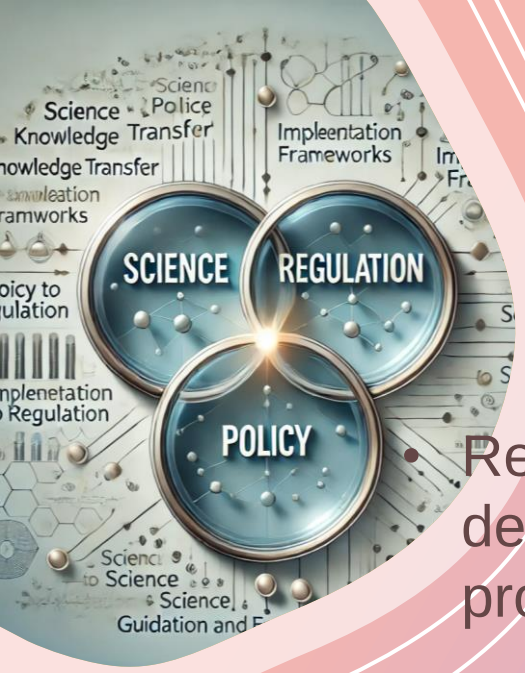
GREEK SCIENTISTS SOCIETY

Theo Zacharis

Greek Scientists Society

Hello

I am
Theo Zacharis



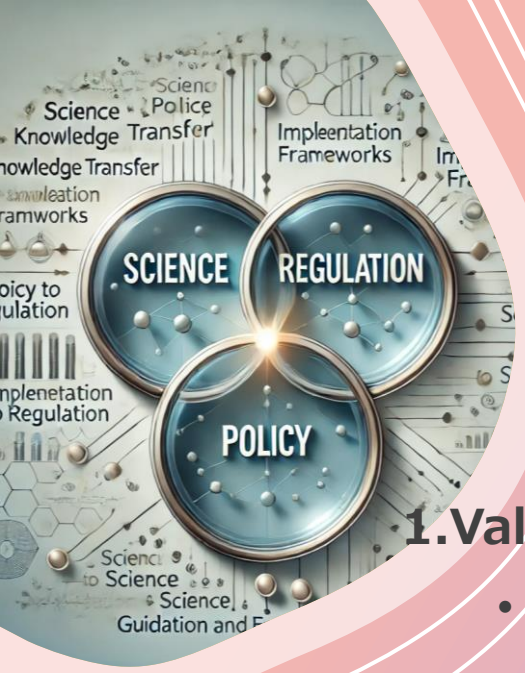
1. Introduction to Regulatory Science

What is Regulatory Science?

- Regulatory Science is the application of **scientific knowledge** and **tools** to develop **standards**, **guidelines**, and **regulatory frameworks** for ensuring product safety, efficacy, and environmental sustainability.

- It bridges the gap between **scientific innovation** and **policy implementation**. Connects cutting-edge scientific advancements with real-world policy and regulatory needs. Ensures that innovative products and methodologies, like those in the biofilm field, are adopted efficiently and safely.

- Balancing innovation with safety, Regulatory Science helps ensure that innovative tools (e.g., anti-biofilm technologies, monitoring tools) meet safety and performance standards before market introduction.



1. Introduction to Regulatory Science

What is Regulatory Science?

Specific Relevance to the Biofilm Industry

1.Validation of New Technologies

- Biofilm-resistant materials, eco-friendly biocides, and advanced detection tools require **standardised testing protocols**.
- Regulatory science provides a **framework** for validating these technologies across industries (e.g., healthcare, water treatment, and shipping).

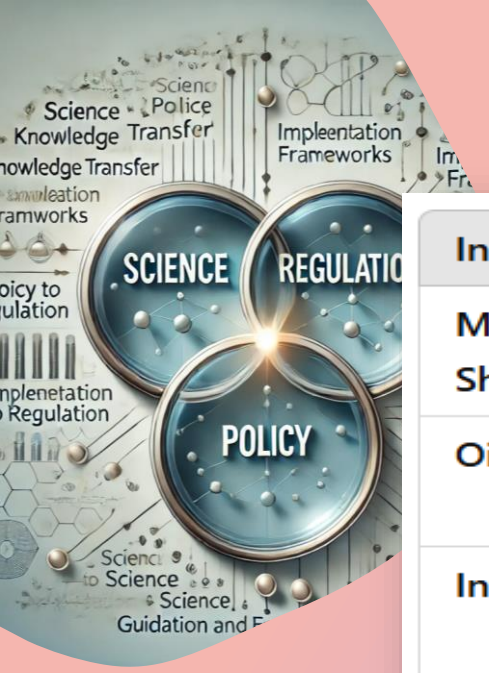
2.Risk Assessment

- Ensures that biofilm-related innovations do not introduce unforeseen risks to public health or the environment (e.g., evaluating the environmental impact of new anti-fouling coatings for marine applications)

2. The Current Landscape of Biofilm Research per Industry

Industries Impacted by Biofilms and Regulatory Gaps

- **Marine and Shipping** Biofouling and microbiologically influenced corrosion (MIC) of hulls, propellers, and underwater pipelines.
- **Oil and Gas** Corrosion in pipelines, tanks, and offshore structures.
- **Infrastructure** Accelerated corrosion in bridges, storage tanks, and water systems.
- **Healthcare** Medical device biofilms leading to infections and reduced device efficacy.
- **Food Processing** Contamination risks and biofilm formation on production equipment.
- **Water Treatment** Biofilms in water distribution systems lead to microbial contamination, reduced water quality, and damage to infrastructure



2. The Current Landscape of Biofilm Research per Industry

Industry	Research Focus Areas	Key Innovations
Marine and Shipping	Anti-fouling coatings, eco-friendly biocides, early detection technologies	Development of sustainable coatings and advanced biofilm monitoring tools
Oil and Gas	MIC mechanisms, biofilm-resistant materials, chemical/biological mitigation	Pipeline protection via novel materials and microbial corrosion inhibitors
Infrastructure	Biofilm impact on concrete/metal, protective surface treatments, real-time monitoring	Smart monitoring devices and durable, biofilm-resistant coatings
Healthcare	Anti-biofilm coatings for devices, biofilm-resistant implants, studies on biofilm-related chronic infections	Advanced coatings for medical devices and deeper understanding of biofilm-infection links
Food Processing	Biofilm control strategies, pathogen biofilms (Listeria, Salmonella), cleaning/disinfection technologies	New disinfection methods and enhanced pathogen detection protocols
Water Treatment	Biofilm-resistant coatings, microbial interactions, filtration technology improvements	Innovative filtration systems and microbial research for cleaner water systems

2. The Current Landscape of Biofilm Research per Industry

Regulations and Standards Across Industries

Industry	Key Regulations	Relevant Standards
Marine and Shipping	IMO Biofouling Guidelines, MARPOL Annex VI	ISO 19030: Hull performance; Lack of MIC-specific standards
Oil and Gas	EPA Regulations, DNV-OS-F101 Offshore Standards	NACE SP21412: MIC mitigation; Lack of global standards for biofilm prevention
Infrastructure	Eurocode, Environmental Impact Assessments (EIA)	ASTM G1: Corrosion testing; No biofilm-specific degradation standards
Healthcare	FDA Standards, EU MDR (Medical Device Regulation)	ISO 10993: Biocompatibility testing; No harmonized biofilm-specific protocols
Food Processing	HACCP Framework, EU General Food Law	ISO 22000: Food safety management; Limited focus on biofilm-specific contamination
Water Treatment	WHO Drinking Water Standards, EU Water Framework Directive	ASTM D4189: Biofilm testing in water systems; Limited biofilm prevention standards in pipelines

Key Innovations in Biofilm Research

1. Advanced Materials		
Development of Anti-Biofilm Coatings	**Marine Applications**	Fouling Release Coatings - Advanced **silicone-based coatings** prevent biofilm attachment on ship hulls (e.g., products like **Intersleek® 1100SR by AkzoNobel**).
		Graphene-Infused Coatings - High-performance coatings reduce biofouling while being environmentally friendly.
	Healthcare Applications	**Hydrogel Coatings**. Used in medical devices like catheters to prevent biofilm-related infections (e.g., **Aquaflex® Hydrogel Coatings**).
		Silver Nanoparticle Coatings. Anti-microbial coatings for implants and prosthetics.
	Infrastructure Applications	**Anti-Corrosion Coatings.** Biofilm-resistant materials applied to bridges and pipelines to mitigate MIC (e.g., **zinc-aluminium-molybdenum-based coatings**).
Introduction of Biofilm-Resistant Materials	**Pipelines**	**Polymeric Liners**. Materials like cross-linked polyethylene (PEX) reduce biofilm adhesion in oil and gas pipelines.
	Medical Devices	**Silicone Rubber with Anti-Biofilm Properties**. Used in prosthetics and heart valves to minimize biofilm formation.
2. Breakthrough Detection Tools		
High-Resolution Imaging		**Confocal Laser Scanning Microscopy (CLSM)**. Widely used in biofilm research to study the 3D structure of biofilms and monitor their growth in real-time.
		Atomic Force Microscopy (AFM). Enables visualization of biofilm surface topography and interactions at the nano-scale.
Real-Time Monitoring Systems		**Electrochemical Sensors.** Detect biofilm activity and thickness in water treatment and industrial systems.
		Biofilm Detection. Chips Devices like BioFlux® by Fluxion Biosciences simulate and monitor biofilm formation in microfluidic environments.
3. Innovative Solutions		
Environmentally Friendly Biocides	**Marine Applications**	**Selektope®** A biodegradable antifouling agent that prevents barnacle settlement on ship hulls without harming marine life.
		Natural Enzyme-Based Biocides Enzymes like DNase target biofilm extracellular matrices without environmental toxicity.
Advanced Cleaning and Disinfection Technologies	**Food Processing**	**Electrolyzed Water Systems.** A non-toxic disinfection method used to remove biofilms from food processing equipment.
		Ultrasonic Cleaning Devices. Breaks down biofilm layers on surfaces in food production
	Water Treatment	**UV-C Disinfection.** Destroys biofilm-forming bacteria in water pipelines and filtration
		Nanotechnology-Based Filtration Membranes. Resist biofilm buildup in reverse osmosis systems.

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3. Innovations Outpacing Standards
The Need for Enhanced Regulations

Breakthroughs in

Biofilm Research

Laboratory Innovations

1. Advanced Materials
- •Peptide-based anti-biofilm agents for precise disruption.
- •Stimuli-responsive coatings activated by pH or temperature.
- •Graphene oxide and nanocomposites with anti-adhesive properties.

2. Detection and Monitoring Tools
- •Biosensors detecting quorum-sensing molecules in real-time.
- •Microfluidic devices for controlled biofilm simulation.
- •Advanced imaging (cryo-EM, super-resolution fluorescence microscopy).

3. Mechanistic Studies
- •CRISPR technology targeting biofilm genes.
- •Synthetic biology for biofilm-degrading enzyme production.
- •Metabolic pathway analysis to find biofilm vulnerabilities.

4. Innovative Mitigation Strategies
- •Enzyme-based biofilm disruption (e.g., dispersin B, DNase).
- •Bacteriophage (phage) therapy for biofilm penetration.
- •Bioelectric systems enhancing antimicrobial efficacy.

5. Environmental and Ecological Research
- •Natural inhibitors from plants or microbes for biofilm control.
- •Studies on biofilm-environment interactions to predict impacts.

3. Innovations Outpacing Standards The Need for Enhanced Regulations

Gaps Between Current Regulations and Innovative Product Solutions

1. Misalignment with Innovation

Outdated Testing Protocols

- Current regulations lack standards for validating advanced anti-biofilm materials like peptide-based coatings and graphene composites.

Slow Update Cycles

- Regulatory frameworks are not updated in sync with new discoveries in biofilm disruption (e.g., phage therapy, enzyme-based methods).

2. Lack of Harmonization Across Industries

Fragmented Regulations

- Each industry (marine, healthcare, etc.) has its own regulatory guidelines, often inconsistent with each other.

Missed Opportunities

- Uniform standards could accelerate adoption of cross-industry innovations like biofilm-resistant materials.

3. Innovations Outpacing Standards The Need for Enhanced Regulations

Gaps Between Current Regulations and Innovative Product Solutions

3. Limited Scope of Current Guidelines

Focus on Traditional Risks

- Current standards primarily address microbial contamination but fail to account for **biofilm-specific challenges** like **MIC and chronic infections**.

Insufficient Support for New Tools

- Innovative detection technologies (e.g., **microfluidic biofilm devices**) and monitoring systems remain under-recognized in approval pathways.

4. Barriers to Adoption

High Validation Costs

- Absence of standardized testing increases costs for companies to **validate novel products.**

Unclear Regulatory Pathways

- **Lack of guidance** on integrating advanced biofilm solutions into existing approval processes.

3. Innovations Outpacing Standards The Need for Enhanced Regulations

Key Innovations Outpacing Standards

Advanced Materials

- Innovations like graphene-based anti-biofilm coatings and stimuli-responsive materials lack standardized validation protocols (sustainable coatings for marine and healthcare sectors have no specific testing requirements)

Detection and Monitoring Tools

- Real-time biofilm monitoring technologies and biosensors are not integrated into regulatory frameworks (electrochemical sensors for industrial systems remain outside standard approval processes)

Innovative Mitigation Strategies

- Breakthroughs such as enzyme-based biofilm disruption and phage therapy are under-regulated (no clear pathways for the validation of phage-based biofilm treatments in healthcare and food industries)

3. Innovations Outpacing Standards The Need for Enhanced Regulations

Gaps in Current Standards

Outdated Protocols

- Existing standards focus on traditional microbial contamination rather than biofilm-specific challenges.

Lack of Harmonization

- Industry-specific regulations create silos, hindering the adoption of cross-sector innovations.

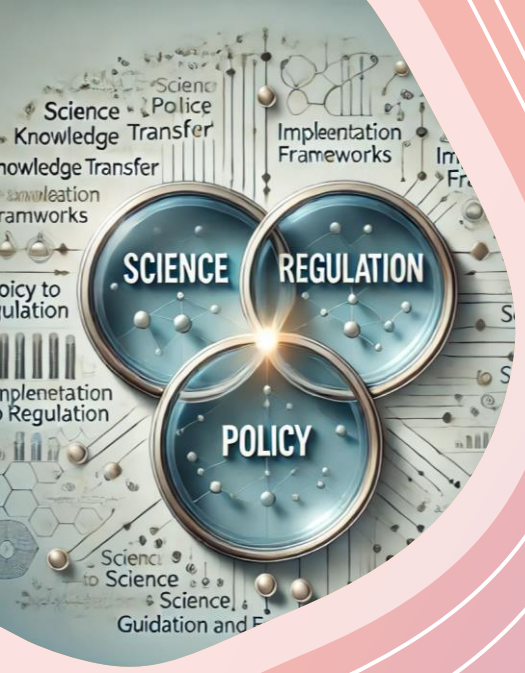
Limited Coverage of New Tools

- Emerging technologies like microfluidic biofilm devices are not recognized by most regulatory bodies.

3. Innovations Outpacing Standards The Need for Enhanced Regulations

Gaps in Current Standards

Innovation	Current Regulatory Gap	Impact of the Gap
Graphene-based coatings	No specific testing standards	Slows adoption in marine and infrastructure sectors
Real-time monitoring tools	Lack of recognition in approval pathways	Limits industrial deployment
Enzyme-based biofilm disruption	Absence of regulatory validation frameworks	Inhibits commercialization in healthcare and water sectors



3. Innovations Outpacing Standards The Need for Enhanced Regulations

Why Enhanced Regulations Are Needed

To Align Innovation with Practice

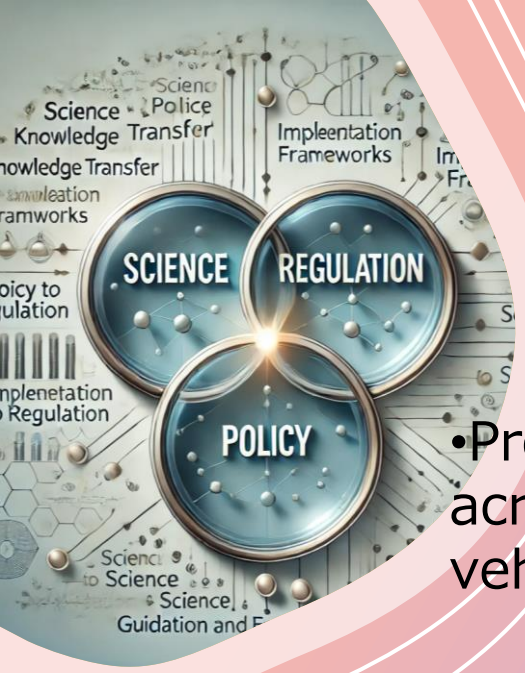
- Ensures validated tools and materials are adopted effectively across industries (standardized guidelines for biofilm-resistant implants can improve healthcare outcomes)

To Promote Safety and Sustainability

- Supports environmentally friendly solutions like enzyme-based biocides and UV-C disinfection.

To Foster Global Collaboration

- Harmonized standards reduce fragmentation, enabling shared innovation across industries.



3. Innovations Outpacing Standards The Need for Enhanced Regulations

Why Enhanced Regulations Are Needed

Driving Innovation

•Provides a structured framework for developing and adopting technologies across industries, e.g. standards for battery efficiency accelerated electric vehicle advancements.

Ensuring Compatibility and Interoperability

•Ensures products, processes, and services work seamlessly together, eg USB standards enable universal connectivity across devices.

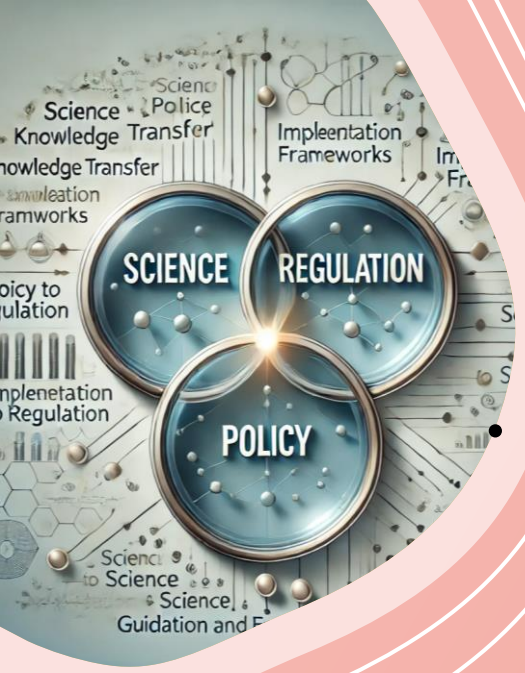
Enhancing Quality and Safety

•Establishes benchmarks for performance, safety, and reliability.

•Protects consumers and the environment, for example, ISO 9001 for quality management builds trust in innovation.

Reducing Barriers to Market Entry

•Simplifies compliance, promoting fair competition and global trade for example, CE marking in Europe ensures products meet essential health and safety standards.



4. The Role of Standardisation - CEN/CENELEC Workshop Agreements (CWAs)

Key Regulatory Tools and Their Roles

Formal Standards

- Authoritative documents developed by recognised organisations (e.g., ISO, IEC). Provide comprehensive technical and performance guidelines for products and services.

Guidelines

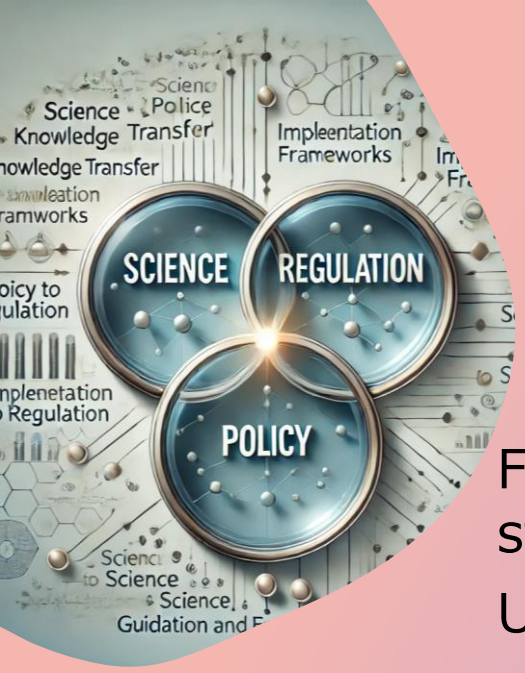
- Non-mandatory recommendations offering best practices. Facilitate compliance and industry alignment.

Technical Specifications

- Documents addressing specific technical details or requirements. Fill gaps where formal standards do not yet exist.

CEN/CENELEC Workshop Agreements (CWAs)

- Consensus-based documents developed quickly to address emerging needs. Serve as pre-standardisation tools.



4. The Role of Standardisation - CEN/CENELEC Workshop Agreements (CWAs)

CEN/CENELEC Workshop Agreements (CWAs): A Fast-Track Approach

What Are CWAs?

Flexible, fast-track documents developed through collaboration among stakeholders.

Used to address emerging challenges before formal standards are adopted.

Benefits of CWAs:

Speed: Developed faster than formal standards.

Flexibility: Adaptable to different sectors and challenges.

Collaboration: Encourage cooperation among industry, academia, and regulators.

Applications of CWAs:

Emerging technologies (e.g., artificial intelligence, renewable energy).

Cross-sectoral solutions requiring rapid consensus.

4. The Role of Standardisation - CEN/CENELEC Workshop Agreements (CWAs)

Steps for Implementing a CEN/CENELEC Workshop Agreement (CWA)

Identify the Need

- Stakeholders (industry, academia, regulators) identify a gap or emerging need for standardisation,, for example, a lack of harmonised testing methods for a new technology.

1.Initiate the Workshop

- A formal proposal is submitted to CEN/CENELEC.
- Interested parties are invited to join and contribute.

2.Draft the Agreement

- Experts collaborate to create a consensus-based draft document.
- Iterative reviews ensure the draft addresses key challenges.

3.Public Consultation

- The draft CWA is shared for feedback from broader stakeholders and the public.
- Comments and suggestions are incorporated into the final version.

4.Approval and Publication

- The final CWA is approved by workshop participants.
- Published as an official document, accessible for use by industries and organisations.

5.Implementation and Monitoring

- Organisations and industries adopt the CWA in their processes.
- Feedback is monitored for potential updates or transition to formal standards.

4. The Role of Standardisation - CEN/CENELEC Workshop Agreements (CWAs)

Steps for Implementing a CEN/CENELEC Workshop Agreement (CWA)

Step	Description
1. Proposal Submission	Propose the development of the WA, outline scope and relevance; ensure support from at least three National Standards Bodies (NSBs).
2. Workshop Establishment	Announce the workshop, invite stakeholders, and agree on the project plan with detailed timelines and deliverables.
3. Drafting the Agreement	Collaboratively draft the WA with stakeholder input through meetings and iterative reviews.
4. Public Consultation	Make the draft publicly available, collect feedback, and incorporate revisions based on stakeholder input.
5. Final Approval	Achieve consensus among workshop participants and submit the final document to CEN/CENELEC.
6. Publication and Dissemination	Officially publish the WA and disseminate it through industry and public channels.
7. Implementation and Monitoring	Monitor adoption, gather feedback, and update the WA if needed; transition to formal standards if applicable.

4. The Role of Standardisation - CEN/CENELEC Workshop Agreements (CWAs)

Estimated Costs and Timeline for Developing a CEN/CENELEC Workshop Agreement (CWA) in the Biofilm Industry

1. **Administrative Costs**:
    1. CEN or CENELEC administrative fees: €5,000–€15,000.
    2. Meeting organisation, moderation, and support: €10,000–€20,000.
    3. Travel and accommodation for participants (if physical meetings): €5,000–€15,000 per meeting.
2. **Technical Work**:
    1. Cost for drafting and reviewing the agreement: €10,000–€30,000, depending on the need for external experts.
    2. Public consultation and feedback integration: €5,000–€10,000.
3. **Publication and Dissemination**:
    1. Design and publication of the final document: €2,000–€5,000.
    2. Communication and outreach efforts: €5,000–€10,000.

Estimated Total: €30,000–€70,000, with costs typically shared among the participating stakeholders, sponsors, and national committees.

4. The Role of Standardisation - CEN/CENELEC Workshop Agreements (CWAs)

Differences between ISO Standards and CEN/CENELEC Workshops

Feature	ISO Standard	Workshop Agreement (WA)
Purpose	Formal, comprehensive standard	Flexible, pre-standardisation tool
Development Time	2–3 years	6–12 months
Scope	Global applicability	European or niche focus
Stakeholders	Broad international consensus	Limited to participating stakeholders
Legal Status	Often mandatory or regulatory	Voluntary
Cost	Higher development cost	Lower development cost
Longevity	Long-term	Temporary (may transition to a formal standard)

4. The Role of Standardisation - CEN/CENELEC Workshop Agreements (CWAs)

How EUROMIC Could Structure Its Participation in a WA or TC

1. Define Clear Objectives

Identify Strategic Goals

Focus on outcomes aligned with EUROMIC's mission, such as:

- •Harmonising testing protocols for MIC.
- •Promoting biofilm-resistant materials.
- •Advancing eco-friendly anti-biofilm solutions.

Set Specific Targets:

Decide on deliverables, such as a CWA document, testing guidelines, or a pathway to formal standards.

2. Assemble an Internal EUROMIC Task Force

Key Members:

Appoint a dedicated group of researchers, technical experts, and industry representatives to contribute to the WA or TC.

Roles and Responsibilities:

- **Lead Coordinator**: Oversees participation, liaises with CEN/CENELEC, and manages timelines.
- **Technical Experts**: Provide data, research, and insights on MIC and biofilms.
- **Policy Advisors**: Ensure compliance with standardisation rules and manage conflict-of-interest risks.
- **Administrative Support**: Handles logistics, documentation, and stakeholder communication.

How EUROMIC Could Structure Its Participation in a WA or TC

3. Engage in Stakeholder Collaboration

Broaden Representation: Collaborate with diverse stakeholders, including:

- National Standards Bodies (NSBs).
- Industry leaders in affected sectors (marine, oil and gas, water treatment).
- Regulatory agencies and policymakers.

Workshops and Meetings: Actively participate in all workshops and ensure consistent representation from EUROMIC.

Public Consultation: Encourage members and stakeholders to review and provide feedback during the public consultation phase.

4. Ensure Compliance with Standardisation Rules

- **Transparency**: Disclose affiliations, funding sources, and potential conflicts of interest during participation.
- **Balanced Representation**: Avoid dominance by a single organisation or stakeholder group by fostering equitable contributions from all participants.
- **Follow CEN/CENELEC Guidelines**: Adhere to the rules and processes outlined in CEN/CENELEC guides for CWAs and standardisation activities.

How EUROMIC Could Structure Its Participation in a WA or TC

5. Leverage Research and Technical Expertise

Provide Evidence-Based Contributions:

- Use EUROMIC's research findings to shape the technical content of the WA or standard.
- Offer data on biofilm-resistant materials, testing methods, and case studies on MIC challenges.

Develop Testing Frameworks:

- Draft and propose reproducible methods that can be adopted across industries.

Highlight Environmental and Societal Benefits:

- Focus on how harmonised biofilm and MIC solutions can improve sustainability and safety.

6. Actively Advocate for the WA/TC

Promote the CWA's Importance:

- Use EUROMIC's network to raise awareness about the WA or TC objectives and its value to stakeholders.

Engage National Standards Bodies:

- Work with NSBs to secure support for the WA and ensure the document has broad adoption potential.

How EUROMIC Could Structure Its Participation in a WA or TC

7. Monitor and Evaluate Impact

- **Post-WA Monitoring**:
  - Track how the WA is implemented in industries and gather feedback for potential updates.
- **Prepare for Transition to Formal Standards**:
  - Use the WA as a foundation for proposing an EN (European Norm) or ISO standard if widely adopted.

8. Maximise Visibility

- **Publications and Communication**:
  - Publish outcomes and findings in peer-reviewed journals, conferences, and industry events.
- **Showcase Leadership**:
  - Highlight EUROMIC's role in the WA development process to strengthen its credibility in the biofilm and MIC sectors.

5. Anticipated Benefits for EUROMIC COST Action

1. Alignment with EUROMIC's Mission

Demonstrates leadership in addressing microbiologically influenced corrosion (MIC) and biofilm-related challenges.

Ensures EUROMIC's research translates into tangible, impactful outcomes.

2. Accelerating Innovation Adoption

Provides harmonised testing methods for MIC and biofilm-resistant technologies.

Facilitates quicker adoption of research findings by industries such as marine, oil and gas, healthcare, and infrastructure.

3. Influence on Regulatory Frameworks

Bridges the gap between scientific innovation and regulatory policies.

Positions EUROMIC as a key contributor to pre-standardisation efforts, shaping future European and global standards.

4. Enhancing Visibility and Credibility

Strengthens EUROMIC's reputation as a thought leader in biofilm and MIC research.

Expands its influence among policymakers, industry leaders, and academic institutions.

5. Anticipated Benefits for EUROMIC COST Action

5. Strengthening Stakeholder Networks
Brings together academia, industry, regulators, and National Standards Bodies (NSBs).Fosters long-term collaborations across sectors and disciplines.

6. Securing Funding and Support
Showcases measurable outcomes that can attract future funding from EU grants or private industry. Demonstrates a clear pathway for turning research into actionable solutions.

7. Pathway to Formal Standards
Acts as a stepping stone toward developing formal EN or ISO standards.
Ensures long-term sustainability and global adoption of EUROMIC's work.

6. Call to Action

Standardisation as a Sustainability Plan for EUROMIC

1. Why Standardisation is Ideal for Sustainability

Aligns with EUROMIC's mission to address microbiologically influenced corrosion (MIC) and biofilm challenges.
Ensures EUROMIC's impact continues beyond the COST Action (Year 4).
Provides long-term value by establishing harmonised standards and influencing policies.

2. Key Options for Sustainability

a. Non-Profit Organisation (NPO) *Example*: Association or Foundation.

Benefits

- Long-term structure for ongoing research, funding, and collaboration.
- Flexible membership for academia, industry, and regulators.

b. Public-Private Partnership (PPP) *Structure*: Collaboration between public institutions (e.g., NSBs) and private stakeholders.

Benefits

- Shared funding and resources.
- Combines public oversight with private sector expertise.

Standardisation as a Sustainability Plan for EUROMIC

c. Contractual Agreement *Structure*: A formal agreement among stakeholders for specific projects (e.g developing a CWA).

Benefits

Low-cost, fast to implement.

Ideal for short-term goals with minimal administrative burden.

Integration with National Standards Bodies (NSBs) *Role*: Partner with NSBs to transition CWAs into formal EN or ISO standards.

Benefits

- Access to NSB resources and networks.
- Ensures alignment with European and international regulatory frameworks.

3. Benefits of a Sustainability Plan

- Provides a pathway for EUROMIC's members to remain engaged post-COST Action.
- Attracts new funding opportunities (e.g., Horizon Europe, industry sponsorships).
- Strengthens EUROMIC's leadership and influence in standardisation and regulatory science.

Thank you!

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