EIC ELMs Portfolio

Deliverable 9.9

Contribution to the regulatory debate in RP2

Project Number: 101071145

Project Acronym: FUNGATERIA

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DELIVERABLE FACTSHEET

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20/01/2025	Silvia Holler, Jose M. Pérez-Pomares	WG Contribution
20/04/2025	KADK, UU	Added project specific contributions (section 2) and conclusion (section 3)

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EXECUTIVE SUMMARY

During RP2, a limited number of activities related to WG on regulation have taken place, mostly under the discussed necessity of re-considering such activities under the perspective of the proposed fusion of the ELSA and Regulatory WGs. Advances have mostly been made in the absence of a formally appointed representative (coordinator) for the Regulatory WG. The major part of the activities developed directly related to the collaboration with the European Medicines Agency (EMA), activities led by the project officer.

FUNGATERIA's contribution has been to highlight the differences in regulatory frameworks between medicine and the built environment, but to draw attention to the fact that ELM development can be a catalyst for emerging areas of overlap between built environment and medical frameworks due to the nature of the technology, especially in early-stage regulation. We also examine how current regulatory frameworks for materials in the built environment are likely to be ill-equipped to handle entities that are simultaneously organisms, materials and technologies across much of the material life-cycle. We identify that ELMs raise compliance concerns across their life phases—from design, cultivation, labelling, marketing, installation and use, through to disposal—particularly regarding biosafety, containment and potential reactivation.

We conclude that these complexities demand a rethinking of classification systems, lifecycle responsibility and adaptive governance tailored to the evolving nature of living materials.

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1 Contribution from the WG REGULATORY

1.1 Collaboration with EMA

Via the Project Officer, the portfolio has engaged with the European Medicines Agency (EMA) to increase its internal awareness on ELMs and address regulatory gaps specific to health-related ELMs products, with a focus on patient translation.

PROJECTS INVOLVED: PRISM-LT, Next-Skins, Bio-HhOST, BioRobot-MiniHeart, SUMO plus new projects added to the portfolio Bioaction, ISOS, and REMEDY; and a Pathfinder Open project Enlight that attended also the January 2024 1st Annual Meeting.

Outputs in RP2:

- attendance of EMA staff (EMA staff from the Regulatory Science and Innovation Task Force, and from EMA SMEs Office) to 1st Annual Meeting January 2024
- contribution to internal EMA documents on ELMs via the PO

Ongoing activities:

- PRISM-LT with the PO and PM has lead the organization of the webinar with EMA representative to be held on February 6, 2025
- Individual projects have provided 3 slides of their presentation and 3-5 questions that they have to EMA. This material has been sent to EMA in December 2024 to finalize the list of panelists and prepare for the discussion.

Future: how to proceed will very much depend on the outcome of the workshop. This is the first time that EMA carries out such an experiment with such an emerging field. It will provide a first model on how to proceed for other emerging areas.

1.2 Considerations of the WG on future actions

Considering the rationales from their respective RP1 reports, we have identified common interests and concerns in different ELM consortia regarding Regulatory issues:

1. WG members agree in the necessity of defining the nature of the different ELMs (identify similarities and common needs) prior to attempt a systematic approach to regulatory representatives and bodies. To discuss whether a single regulatory frame for all ELMS is possible is a must, as it is a continuous alignment with ELSA actions.
2. It is believed that proceeding with a joint mapping (all consortia) of the regulatory landscape in the countries involved and the EU is regarded as the next mandatory action.
3. Discussions on the production, and/or use and/or end-of-life of ELMs (with a special focus on environmental security) have also been considered pertinent. In particular, the use of ELMs has to be always considered from the perspectives of Health, Safety and Security to preserve the rights of the users/consumers (as it is the case for food and medical products regulations).

4. Some of the regulatory actions taken might be in need of support from the Communication WG (e.g. in the case of generating a new state of mind in the EU civil society regarding the use of ELMs and the innovative emerging technologies that create them)

2 Specific contribution from the project

The WG focus during RP2 on engagement with the European Medicines Agency (EMA) has little direct relevance to the FUNGATERIA project. FUNGATERIA targets a different use-case domain with different regulatory frameworks. These operate in fundamentally different ways as they are shaped by different goals, methods, standards, stakeholders and risk profiles (Table.1).

Table 1. Comparison of regulatory framework aspects between medicine and the built environment highlighting key differences.

	Medicine	**Built Environment**
Primary Goal	Protect human health, safety, and efficacy of treatments	Ensure structural safety, durability, human comfort, and environmental performance
Core Regulatory Drivers	Risk of harm to individual patients, population-level safety, bioethics	Risk of structural failure, fire, long-term exposure, public safety
Governing Bodies	EMA (EU), MHRA (UK), FDA (U.S.)	Building codes authorities
	Health authorities, bioethics boards	Local/national construction agencies, environmental regulators, fire
Testing Requirements	Preclinical (lab, animal)	Material certifications (e.g., ASTM, ISO)
	Clinical trials (Phases I–III)	Structural load testing
	GMP (Good Manufacturing Practice)	Fire safety, mold, moisture, acoustic, thermal testing
Documentation Required	Clinical data	Building product declarations
	Dossiers for regulatory approval	Performance data
	Pharmacovigilance plans	Construction method statements, safety plans
Life Cycle Focus	Short to medium term (e.g., drug action and metabolism)	Long-term (decades of use)
		End-of-life (demolition, recyclability, environmental impact)
Standards Development	Bioethical review boards, pharmacological and toxicological standards	Engineering bodies, construction industry standards boards (e.g., ICC, BSI)
User/Patient vs. Occupant	Individuals treated under controlled settings	Broad public exposed in uncontrolled environments over time
Innovation Risk Appetite	Lower—high stakes, requires extensive proof before release	Slightly higher in early phases, especially for sustainable materials pilot

However, within the field of ELMs there might exist emerging areas of overlap between built environment and medical frameworks due to the nature of the technology, especially in early-stage regulation. Some common areas of overlap might be found across:

1. Biological Safety & Biosecurity
2. Hygiene and Contamination Control
3. Material Traceability and Testing Standards
4. Ethics of Living Systems
5. Standards for Sector-crossing Emerging Biotechnologies

With the possibility of ELM technologies straddling multiple regulatory domains, it would be prudent for the WG to consider activities that help to identify possible regulatory blind spots between health and building sectors, to examine the possibility for hybrid frameworks and to seek early dialogue between built environment and medical/biotech regulators. This would enhance the possibilities of contribution from the built environment/design focused projects (FUNGATERIA, Loop-of-Fun, REMEDY) to the WG activities, at the portfolio level, but also help to scope forward and external facing contributions, particularly in the context of developing guidelines and recommendations for blended frameworks to support bio-based innovation, which is increasingly cross-cutting sectors.

This said, the FUNGATERIA project has focused efforts on a continued exploration of the regulatory landscape using the optic of material lifecycle within a built environment context. This builds upon an initial regulatory mapping defined in the previous ELM Portfolio Regulatory WG deliverable (D9.4_Contribution to the regulatory debate in RP1), which took a holistic overview of material life phases (figure 1). Maintaining the material life phase perspective, we have now identified how ELMs, which present unique and novel material challenges and opportunities, raise regulatory and compliance challenges under existing frameworks. In addition, we identify where regulatory developmental focus may need to directed in order to pave the way for ELMs to be accepted, adopted and compliant.

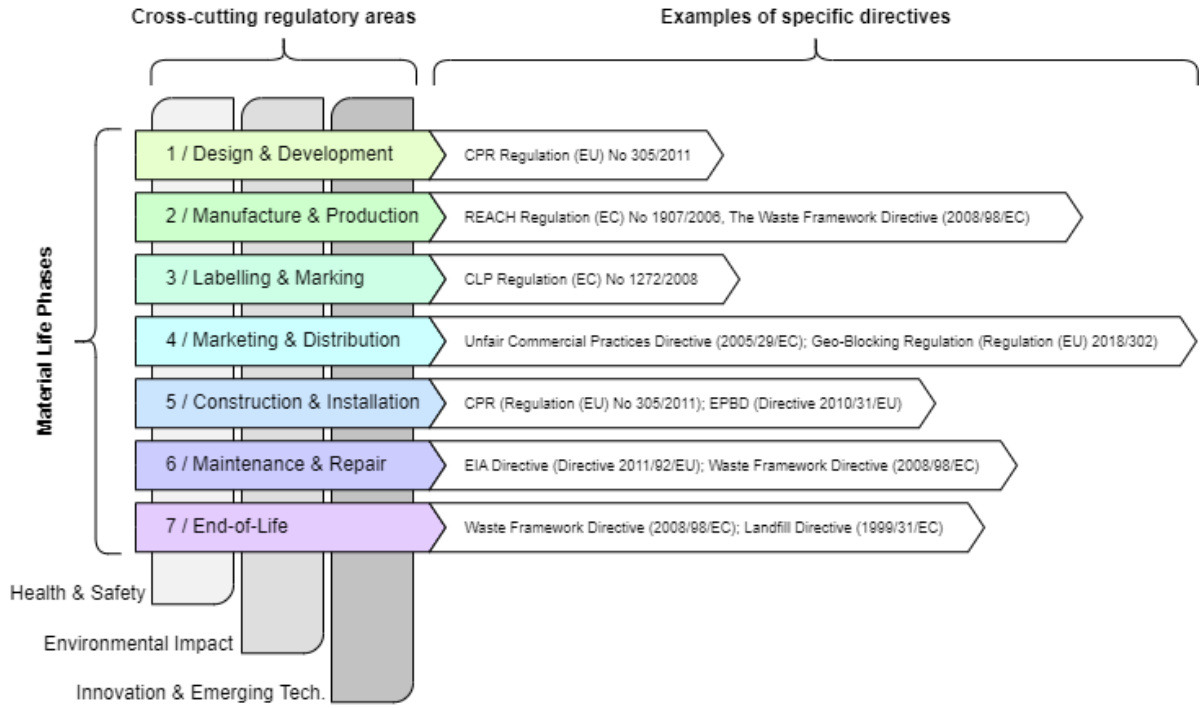

Figure 1. Mapping of regulatory domains and specific directives against material life phases, defined int he previous related deliverable.

ELMs introduce novel material capabilities—such as self-repair, growth and environmental responsiveness—which hold transformative potential for the built environment. However, these same characteristics challenge existing regulatory frameworks across the full life cycle of ELMs, from early development to end-of-life. In the design and development phase, key regulatory hurdles include the classification of ELMs as either organisms or materials, triggering inconsistencies in how genetic engineering regulations and biosafety protocols apply. As manufacture and production scale up, regulatory focus shifts to facility standards, containment of engineered organisms and managing occupational exposure risks, particularly when working with live or reactive systems.

During the labelling and marking phase, ELMs raise issues of transparency and traceability—especially when organisms are dormant or embedded in composite forms. In marketing and distribution, ELMs may encounter regulatory obstacles related to the transport of genetically modified or biologically active materials, especially if anticipating global markets. Compliance must span international treaties (such as the Cartagena Protocol), national biosafety laws and sector-specific agreements that may not account for hybrid bio-materials.

Once in the built environment, ELMs face construction and installation challenges that intersect with conventional building codes. Their living or semi-living nature complicates assessments of fire resistance, structural stability, liability, maintenance protocols and indoor air quality, none of which are currently tailored to biologically active systems. Maintenance and repair of ELMs will likely require ongoing monitoring for biological growth, decay and mold, along with mechanisms for long-term performance validation.

Finally, at end-of-life, ELMs disrupt standard waste management practices. Their degradability may not align with composting infrastructure and they may require new classification systems to distinguish between biodegradable, recyclable or hazardous biological waste. Safe decomposition or engineered “kill switches” must be incorporated to prevent unintended environmental release or regeneration. Across all stages, ELMs demand a fundamental rethinking of compliance—toward frameworks that are adaptive, function-focused, and capable of addressing the hybrid, evolving nature of living materials in architectural and infrastructural contexts.

These regulatory focus areas are summarised in table 2.

ELM Life Stage	Regulatory Focus
1 / Design & Development	Classification of organism and material
	Genetic engineering regulations
	Biosafety protocols
2 / Manufacture & Production	Facility standards
	Biosecurity containment
	Occupational exposure limits
3 / Labelling & Marking	Transparency of material origin and risks
	Traceability
4 / Marketing & Distribution	Transport of bio-based or GM materials
	Compliance with international treaties, national laws and sector-specific agreements
5 / Construction and Installation	Compliance with building codes
	Fire resistance
	Structural safety
	Indoor air quality
6 / Maintenance & Repair	Monitoring for biological growth or decay
	Mold prevention
	Long-term performance validation
7 / End-of-Life	Biodegradability vs compostability
	Waste classification (e.g., organic, hazardous)
	Recycling or safe decomposition/kill protocols

Table 2. Regulatory focus areas that ELMs present related to ELM life stage.

3 Conclusions (WG Regulatory)

ELMs present novel challenges and opportunities by integrating biological systems into the built environment, blurring the boundaries between living and non-living matter. Their dynamic, adaptive and regenerative properties offer fascinating potentials and alternatives to conventional materials, but they also complicate existing regulatory frameworks. These are currently ill-equipped to handle entities that are simultaneously organisms, materials and technologies across much of the material life-cycle. ELMs raise compliance concerns across their life phases—from design, cultivation, labelling, marketing, installation and use, through to disposal—particularly regarding biosafety, containment and potential reactivation. These complexities demand a rethinking of classification systems, lifecycle responsibility and adaptive governance tailored to the evolving nature of living materials.

The preliminary mapping of focus areas requiring regulatory development in the context of ELMs may hold relevance for other projects within the ELM Portfolio – specifically those focused on mycelium-based materials with a built environment/design focus.