EIC ELMs Portfolio

Deliverable 9.4
Contribution to the Regulatory Debate in RP1

Project Number: 101071145

Project Acronym: FUNGATERIA

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DELIVERABLE FACTSHEET

Project Acronym | Number		FUNGATERIA | 101071145	
Deliverable Title:	Contribution to the regulatory debate in RP1		
Deliverable Description:	Report on the activities, outcomes and planned follow up to assess and address the ELMs portfolio needs. This includes contribution to the regulatory debate by engaging early on and continuously with regulatory bodies. Any confidential information related to these activities will be included in the technical report.		
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Date	**Authors**	**Description**
04/01/2024	PA (KADK)	The term 'agency' used in section 2.2 has been replaced with 'behaviour and functionality' and examples provided.

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EXECUTIVE SUMMARY

The work on the regulatory aspects of ELMs needs to be fostered at the ELM Portfolio WG level. The initial effort by the FUNGATERIA project, described in this deliverable, is in anticipation of the prospective WG effort.

The introduction to section 2 briefly outlines the '*why*' we need to engage in regulatory debate. In section 2.1 we have started to identify '*where*' such debate might initially be focused. In the conclusion we outlined further areas that need to be cultivated in order to develop a comprehensive plan for engaging with the regulatory debate.

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1 Contribution from the WG Regulatory

1.1 Status of the ELMs Portfolio Regulatory WG

So far, no leader for the ELMs Regulatory WG has been appointed; accordingly, no meetings on this aspect of the portfolio have been jointly implemented by the ELMs consortia. Work on this aspect of the Portfolio will commence with the appointment of a leader for the ELMs Regulatory WG in RP2.

2 Specific contribution from the members of the project

FUNGATERIA has conducted some preparatory work in anticipation of effort starting within the ELM Portfolio Regulatory WG in RP2.

ELMs represent a new material frontier with significant implications and transitions anticipated across areas of design, production, use and end-of-life. In addition, ELMs exhibit new properties and functionalities that challenge established relationships between conventional materials and their users and environments. These differences will drive the need for revised/new regulatory directives and/or frameworks across the ELM value chain. The precursor for such changes is an engagement in regulatory debate.

2.1 Preliminary Mapping

FUNGATERIA is taking a holistic view of the ELM being developed – from design to end-of-life. We have therefore conducted a preliminary mapping of the regulatory landscape through the optic of Material Life Phases (MLP). The aim of this mapping is to help determine where to focus initial regulatory debate activities. Through this mapping we can identify specific directives for each of the MLP areas and cross-cutting regulatory domains (Fig.1).

In addition to the cross-cutting and specific regulatory areas shown, there are spheres of debate that can influence regulatory decisions, which should be considered and will, no-doubt, cross-over with other ELM Portfolio WG activities – specifically across ELSA, Technology, Communication, Environment & Sustainability WGs. In particular, the ethics surrounding design, use, disposal, ownership and rights of living materials, need to be considered both in general and on a use-case basis. Public perception and acceptance of ELMs could influence regulatory decisions. Addressing public concerns, providing accurate information, and ensuring transparency in the development and use of ELMs would likely be important factors surrounding the regulatory debate.

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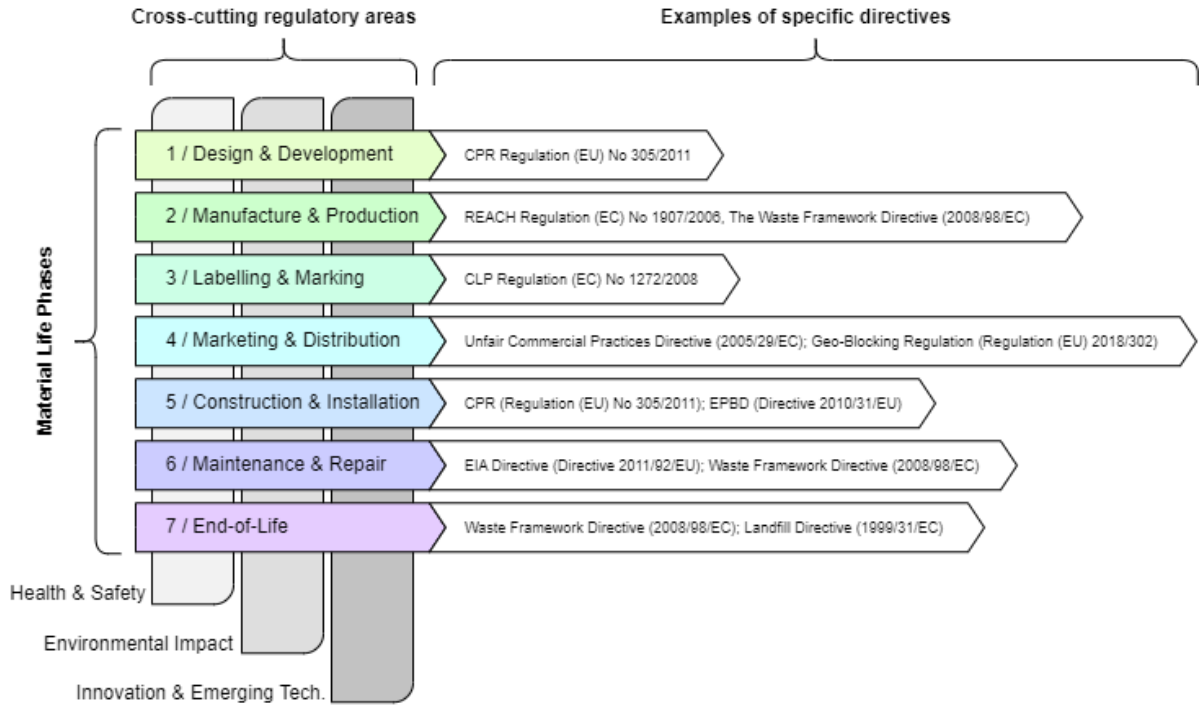

Figure 1. Mapping of regulatory domains and specific directives against material life phases.

2.2 ELM Regulatory debate – preliminary focus areas

ELMs represent a novel development area in materials and current regulations are insufficient to address the unique challenges that they pose. The lack of adequate regulation, and specific regulations governing ELMs, will require regulators to update policies to ensure the safe development and deployment of ELMs. This, in turn, will also build public trust. At this stage in the project, we feel it will be most beneficial to focus efforts in the general regulatory areas that are cross-cutting in Figure 1.

1. **Health & Safety** – questions and risks need to be evaluated regarding the potential harm to human health and safety through exposure to these materials when used in construction, as for the FUNGATERIA proposed use-cases, or other contexts for the ELM Portfolio projects.
2. **Environment impact** – a primary area of environmental impact will likely focus on the release of genetically modified organisms (GMOs) into the environment, which could have unintended consequences, such as disrupting ecosystems or outcompeting native species. Debate will need to be informed through risk/benefit analyses, definitions of containment protocols, end-of-life protocols and potential consequences of accidental releases.
3. **Innovation & Emerging Technologies** – specific areas of debate for this area should revolve around ensuring the responsible, equitable and sustainable production, use and disposal. In addition, regulatory debate will likely also need to consider issues of ownership and liability as

we move towards materials demonstrating new kinds of behaviour and functionality such as growth, self-organisation, self-repair and environmental responsiveness.

3 Conclusions

The work on the regulatory aspects of ELMs needs to be fostered at the ELM Portfolio WG level. The initial effort by the FUNGATERIA project, described in this deliverable, is in anticipation of the prospective WG effort.

The introduction to section 2 we briefly outlined the '*why*' we need to engage in regulatory debate. In section 2.1 we started to identify '*where*' such debate might initially be focused. In the coming phases of the project, and in collaboration with the Regulation WG, efforts should elaborate upon this initial starting point and extend this preliminary scope to consider the questions of '*when*' and '*whom*'. It is evident that this is a complex and nuanced area of operation and will require the development of a detailed plan setting out aims, objectives, actions, goals relative to specific stakeholders and areas of the regulatory landscape.