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New Organs on Command: The Regulatory Prospects of 3D Bioprinting Technology in the European Union

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Abstract

This article examines the evolving legal landscape of bioprinting in the European Union, focusing on the regulatory challenges posed by the hybrid nature of bioprinted products. These constructs – simultaneously biological and synthetic – defy conventional legal classifications and are conceptualised here as biosthetics. The analysis explores how existing EU regulatory instruments – including the ATMP Regulation, MDR, GDPR and SoHO Regulation – apply to bioprinting technologies across research and development as well as clinical implementation. The article argues that current frameworks, while comprehensive, remain fragmented and insufficiently adaptive to address the ontological and operational complexities of biosthetics entities. Three regulatory scenarios are presented: continued reliance on mode-of-action classification, incremental amendments to existing laws and the development of a novel regulatory model tailored to bioprinting. Ultimately, the article advocates for a paradigm shift towards anticipatory, participatory and ethically grounded governance that can respond to the challenges and promises of biomedical technologies in the biosthetics age.

***Keywords**:* 3D bioprinting; techno regulation; harmonization; European Union; adaptive regulation.

1. Introduction

This article examines the regulatory landscape of tissue engineering in the European Union to showcase the regulatory prospects for 3D bioprinting technology, a burgeoning field with the potential to revolutionise healthcare by creating human tissues and organs. Advances in tissue fabrication and the critical shortage of transplantable organs rest on the promise that 3D bioprinting holds in addressing this issue, along with advancements in personalised medicine, drug testing and disease management. The legal and regulatory perspectives, ethical considerations and societal outlooks are more than relevant as technology evolves. According to a study prepared for the European Parliament, there are numerous reasons for regulating bioprinting, such as safety concerns, ethical issues, quality and safety standards, economic and social impact, protection of health rights and equality.[1]

This article addresses the research gap in the insufficient understanding of regulatory requirements and the lack of a comprehensive regulatory framework for 3D bioprinting. It examines the relevant legislation and explores whether the European Union can effectively regulate 3D bioprinting technology to ensure safety, efficacy and ethical compliance while fostering innovation.

Section 2 details the technology's processes, applications and future potential. Section 3 builds on the dominant narratives shaped by Brownsword, Lessig, Somsen, Jasanoff, Yeung and Bennet Moses, to name a few. Section 4 examines the correlation between these narratives and the current EU regulatory landscape applicable to biomedical technologies and their relevance to bioprinting. Section 5 offers legal perspectives on bioprinting, including potential regulatory pathways and specific challenges.

[1] Ferrari, "Additive Bio-Manufacturing," 88.

The main finding of the article posits that there is piecemeal legislation that can only address specific aspects of technology. However, due to the dual nature of bioprinted products, the European Union might not be equipped to handle the complexities of 3D bioprinting technology.[2] The mentioned dual nature that combines biological and synthetic materials introduces unique challenges that existing classifications could not address as they may not adequately capture the functional and compositional nuances of bioprinted products. In my previous work, I used the term 'biosthetics' to describe the novelty of the technology and its implication for normative approaches to it.[3] This tension between non-organic and organic or synthetic and natural components of bioprinting comes into the spotlight as it challenges the definition of life in the biological and legal sense. The natural focuses on biological and physical while, as Jasanoff observes, the legal focuses on entitlements of life that come with scientific breakthroughs.[4] Besides this, bioprinted products can serve various therapeutic and cosmetic applications. They can also be a component of medical devices and prosthetics. Thus, the article identifies three potential scenarios for 3D bioprinting in the European Union.

The primary methodology employed is doctrinal legal research, augmented by normative analysis and insights from regulatory theory. The article rigorously analyses existing EU legal frameworks to interpret their implications for the emerging field of 3D bioprinting. By scrutinising legal texts and pertinent definitions, it assesses the current legal landscape's adequacy in addressing the complexities of bioprinting. Furthermore, it adopts a normative perspective, advocating for adaptive regulation as a more fitting legal strategy in response to the dynamic nature of bioprinting technologies. Additionally, the analysis employs a narrative-based approach to critique and compare prevailing regulatory paradigms, including harmonisation and adaptive regulation, through a constructivist lens that emphasises the intersection of legal scholarship and governance theory. This multifaceted methodological framework aims to illuminate the evolving regulatory challenges posed by bioprinting and propose pathways for more effective legal oversight.

2. Bioprinting Technology

Bioprinting uses 3D printers to print human tissue layer by layer, fusing living human cells into scaffolds in a controlled environment. It is a biofabrication technology that can overcome the difficulties of producing an exact mimic of native tissues since authors agree that placing multiple types of cells in a designed matrix could bring us closer to making more complex human tissues.[5] To bioprint effectively, besides the bioprinting machine, ink made of human cells and a hydrogel to provide a living environment for the cells are also essential. The CAD file contains the blueprint of the tissue we want to print, and bioinks must be precisely placed in the scaffold. The CAD files or blueprints for tissue printing allow for the creation of anatomical structures that, in function and design, mimic natural organs and tissues. Bioprinting is a patient-specific technology where printed tissues mimic the patient's and thus reduce the chances of rejection.[6]

The process starts by extracting cells from the patient to create ink. Cells are autologous when the donor and recipient are the same person. In the case of autologous cells, the immune system recognises them as non-hostile and does not attack them after transplantation. The extracted cells are then differentiated, cultivated and replicated to create bio-ink or cell ink.[7] Scaffolds play a critical role in bioprinting tissues. The purpose of scaffolds is to support the cells placed in designated positions. It provides an environment where they can live, bind and form tissues. Depending on the type of technology, there are different types of scaffolds.[8] Conditional to their properties, scaffolds can be synthetic or natural, whereas 'synthetic hydrogels have become more readily adopted than natural polymers because of their greater water absorption capacity, longer shelf life, and wide varieties of chemical resources that are available'.[9]

Printing an entire organ is still not feasible due to the complexity of tissue structures within organs.[10] Fully functional organs require various components that must be printed, such as connective tissues, vascularisation and neural systems.[11] Currently,

[2] This should not be understood as 'dual use', which refers to the concept of certain technologies being applicable to both civilian and military purposes. This implies that innovations developed for peaceful applications could also be adapted for warfare or other forms of conflict.
[3] Đuković, "No Sharp Line"; Đuković, "Regulating Biomedicine."
[4] Jasanoff, Reframing Rights.
[5] Xia, "Tissue and Organ," 1.
[6] Agarwala, "A Perspective on 3D Bioprinting Technology."
[7] Faramarzi, "Patient-Specific Bioinks," 1701347.
[8] Bishop, "3-D Bioprinting Technologies," 189.
[9] Dell, "3D Bioprinting Using Hydrogels," 2596.
[10] Mirshafiei, "Advancements in Tissue and Organ 3D Bioprinting," 112853.
[11] Mandrycky, "3D Bioprinting," 12.

'in situ' 3D bioprinting uses a bioprinter to 'directly pattern cells and other bioactive materials at the targeted site' to print skin, cartilage, muscles and bone regeneration.[12]

Incorporating cells into 3D constructs enables personalised drug testing and disease management. Companies such as Aspect Biosystems are developing bioprinted lung tissue and exploring treatments for diseases such as type 1 diabetes. Advances in personalised prosthetics include bioprinted ears using bioink for cartilage, combining precision and autologous reconstruction.[13] In Europe, 3D bioprinting is transforming medicine. The BRIGHTER project at the Institute for Bioengineering of Catalonia (IBEC) is developing functional tissues such as skin with sweat glands and hair follicles for medical use and as alternatives to animal testing. Partnering with Goethe University Frankfurt, the project also focuses on neural tissue printing, tracheal scaffolds and cardiac repair for patient-specific implants.[14]

Researchers are further creating organ-on-chip models to simulate human organ environments, reducing animal testing and accelerating drug development.[15] Some of the so far approved tissue-engineered products in the European Union are RenNovaCell™ Skin autologous (epithelial cell) harvesting device as skin graft for vitiligo, Spherox Human autologous (chondrocyte) spheroids for cartilage defect in adults and CardioCel® Acellular collagen matrix-based scaffold for cardiovascular treatment.[16]

These examples highlight the diverse and impactful applications of 3D bioprinting, underscoring its potential to transform healthcare and biomedical research. Research and investment in this promising technology are growing, and it is only a matter of time before scientists perfect the methods to print the entire transplantable organ. At the same time, regulators should prepare to address the technology and prepare healthcare systems and markets for its impact. As noted earlier, this technology is related to tissue engineering and regenerative medicine; accordingly, the regulatory approaches and frameworks for these technologies apply to bioprinting. However, this article will show that this is only partly the case.

The European Medicines Agency (EMA) classifies bioprinted products under the Advanced Therapy Medicinal Products (ATMP) framework. This framework is part of Regulation (EC) No 1394/2007 and Directive 2001/83/EC, providing the legal basis for ATMPs in the European Union. This framework encompasses gene therapies, somatic cell therapies and tissue-engineered products, ensuring that they undergo rigorous evaluation for safety, efficacy and quality. The classification under the ATMP framework allows for a comprehensive and centralised assessment by the EMA involving the Committee for Advanced Therapies (CAT). The CAT issues scientific recommendations on the classification of ATMPs and follows scientific developments to ensure these innovative therapies meet stringent standards.[17]

The two main phases in the lifecycle of biomedical technology are research and development (R&D) and clinical deployment in patient care. These phases are typically regulated under different systems, involving distinct regulatory authorities, such as ethics committees and research funders in the R&D phase and agencies such as the EMA and national health regulators in the healthcare phase. This article examines 3D bioprinting technology in both phases due to the translational integration between the phases, as it is a crucial process of connecting different phases of medical research and patient care. Specifically, it highlights the importance of ensuring that valuable insights, data and risk assessments derived from R&D are effectively transferred to the clinical phase, where these findings can directly impact patient care. Conversely, it also emphasises the necessity of channeling information from the clinical experience into R&D initiatives. This reciprocal flow of information enhances the regulatory framework, enabling a more agile and evidence-based approach to healthcare regulations. For instance, post-market surveillance data, including real-world patient outcomes, can provide critical feedback that informs future research and policy-making. By fostering this integration, healthcare systems can better adapt and respond to emerging evidence and patient needs, ultimately improving health outcomes. It is worth noting that while the ethical concerns in the biomedical R&D phase revolve around the responsible conduct of experimentation, balancing scientific advancement with the minimisation of harm and safeguarding the autonomy of research participants through rigorous consent protocols, the patient care phase shifts the ethical lens towards ensuring equitable access, clinical transparency and the prioritisation of individual well-being, thereby underscoring a transition from population-level innovation ethics to the intimate obligations of personalised therapeutic responsibility.

[12] Mahmoudi, "In Situ 3D Bioprinting," e00260.
[13] Jovic, "3D Bioprinting," 609836.
[14] López, "Reducing Animal Testing."
[15] Ingber, "Human Organs-on-Chips," 467–491.
[16] Parkkavi Sekar, "Current Standards and Ethical Landscape."
[17] For more detailed information, visit the EMA's page on advanced therapy medicinal products: https://www.ema.europa.eu/en/human-regulatory-overview/advanced-therapy-medicinal-products-overview.

Biomedical technology, with its potential to revolutionise healthcare, poses significant regulatory challenges. The narratives surrounding technological progress and neutrality shape regulatory frameworks and influence perspectives on the governance of these innovations. By contrasting different regulatory approaches and highlighting the importance of ethical, social and legal considerations in biomedical technology regulation, the next section of the article explores the theoretical framing as narratives within which legislation will be examined.

3. Dominant Discourses in Technology Regulation

One of the predominant discourses in technology regulation is the belief in technological progress as a catalyst for a better future. This perspective posits that technological advancements inherently lead to societal improvements, thus warranting minimal regulatory interference. Proponents of this view often argue that regulation stifles innovation and delays the benefits that new technologies can bring. Techno-regulation refers to intentionally influencing individuals' behaviour by embedding norms into technology; it thus extends beyond the traditional legal frameworks.[18] Design-based regulation involves shaping the environment or products to manage behaviour or mitigate risks. Van den Berg and Leenes found that this approach can be more effective than traditional regulation in specific contexts, as it can directly shape behaviour without needing external enforcement.

Lessig's famous assertion that 'code is law' affirms that technology can be a form of regulation. Thus, regulatory frameworks should be agile and responsive to technological developments as technology drives societal progress.[19] For Koops, techno-regulation is an intentionally built-in mechanism influencing people's behaviour.[20] Techno-regulation also incorporates the concept of 'nudge', developed by behavioural economist Thaler and legal scholar Sunstein. For them, a nudge 'is any aspect of the choice architecture that alters people's behaviour predictably without forbidding any options or significantly changing their economic incentives'.[21] Porter advocates innovation-friendly regulation, suggesting that well-designed regulation can spur technological advancement by creating new standards and requirements where governments should act as catalysts and challengers, not as controllers.[22] Friedman advocated minimal regulatory intervention in technological markets, as regulation can impede innovation and economic growth.[23]

While there is no doubt that technological advancement leads to societal progress, Brownsword and Somsen emphasise the importance of regulatory frameworks that can keep pace with those advancements. They argue that regulation should guide the progress to benefit society.[24] Brownsword discusses the concept of techno-regulation, where technology itself serves as a regulatory mechanism. This involves embedding regulatory techniques within the design of biomedical technologies to influence behaviour. However, he cautions against relying solely on techno-regulation, warning that it can undermine moral and legal principles by shifting the focus from human agency to technological control as 'the techno-regulation approach fails to respect the values of the moral community or the community of rights'.[25] Brownsword argues for a nuanced regulatory framework that would promote innovation based on protecting ethical and social values and respecting human rights principles – the so-called 'bioethical triangle'.[26]

Since the beginning of the new millennium, the focus has shifted to examining how new technologies can be utilised as tools for regulation.[27] The central idea is that studying regulation should take priority over merely analysing the law. This leads to the essential question of how much technology influences regulation. According to Lessig, regulation is a comprehensive term encompassing a wide range of actions that precede the formalisation of certain behaviours into legal norms. Thus, regulation becomes the framework for behaviour, with the law being just one part of it.[28]

Exploring the concept of design-based regulation, where regulatory techniques are embedded in technology design to influence behaviour, Yeung argues that this approach can have significant implications for constitutional rights and freedoms (such as freedom of expression, the right to privacy, freedom from inhuman and degrading treatment and the right to bodily integrity

[18] van den Berg, "Abort, Retry, Fail," 67.
[19] Lessig, Code, 121.
[20] Koops, "Criteria for Normative Technology," 157–158.
[21] Thaler, Nudge, 8.
[22] Porter, The Competitive Advantage of Nations, 82.
[23] Friedman, Capitalism and Freedom.
[24] Brownsword, "Law, Innovation and Technology," 73.
[25] Brownsword, Rights, Regulation, and the Technological Revolution, 24.
[26] Brownsword, Rights, Regulation, and the Technological Revolution, 32.
[27] Brownsword, "So What Does the World Need Now?" 24.
[28] Lessig, Code, 122.

and autonomy), requiring careful consideration of ethical and social impacts.[29] She cautions that the decisions we make to reach our goals could alter the vision of the society we aspire to create.

Francis Fukuyama warns of biotechnology's potential threats to human dignity, calling for regulatory frameworks that protect ethical and social values.[30] Jasanoff challenges the notion of technological determinism, which assumes that technology independently shapes social structures and cultural values. She argues that this view overlooks the complex interactions between technology and society, where societal values and norms influence technological development. She calls for a more nuanced understanding of the co-evolution of technology and society, where regulation plays a critical role in mediating this relationship.[31] In her work, Jasanoff highlights the ethical dimensions of technological regulation, arguing for 'technologies of humility' in regulatory frameworks, which would involve recognising and addressing the limitations and uncertainties inherent in technological development.[32] This approach emphasises the need for a more participatory and democratic process in regulating new technologies.

Further critiques of the unrestrained technological progress narrative come from Ulrich Beck and his concept of 'reflexive modernisation'.[33] Beck argues that the rapid pace of technological change can lead to the disintegration of traditional institutions and the emergence of new risks. He calls for a reflexive approach to regulation capable of responding to these emerging challenges. The management of risk and uncertainty is a critical aspect of technology regulation. Baldwin and others focus on risk-based regulation, which controls behaviour by quantifying and managing risks.[34] This approach is prevalent in environmental protection and public health, where regulators set standards and enforce compliance through penalties for non-compliance.

Another critical narrative is a 'regulatory lag', where law lags behind technology as legal frameworks have difficulties adapting to changing circumstances;[35] thus, 'the regulatory framework becomes disconnected'.[36] In biomedical technology, one example is regulating human embryonic stem cell (hESC) research. While some EU countries have embraced stem cell research, others have stringent regulations that limit its scope. The lack of a unified regulatory approach has created disparities in research opportunities and clinical applications across member states.[37]

Given that bioprinting technology is still in the research stage, we should look forward to the potential of the technology to end the public health crisis that is the organ shortage. As Bennett Moses suggests, there needs to be an institutional connectedness and careful consideration of regulatory mechanisms.[38] Brownsword and Somsen emphasise the importance of authors thinking creatively and attentively about how regulation and technology are evolving, as we need to find more effective ways to apply the law.[39]

Addressing 'regulatory lag' is a difficult task, as technologies constantly evolve and so regulatory frameworks must be flexible and capable of evolving with technological developments. Additionally, they also have to ensure transparency, the involvement of relevant stakeholders and risk-based and value-based approaches. This is crucial for the above-presented evolving nature of bioprinting. Unlike static, one-size-fits-all regulatory models, adaptive regulation acknowledges uncertainty and change – especially in fast-evolving sectors such as technology, climate policy or finance. Some of the key characteristics are iterative policy-making, where the rules are updated over time based on feedback and new evidence, and stakeholder engagement, which means that regulators collaborate with industries, researchers and communities. It rests on the monitoring and real-time data that help assess effectiveness and adjust accordingly when needed. Instead of one uniform standardised oversight, there can be several risk-based systems where the distinction between high-risk and low-risk technologies can be established. In that way, the risk assessments and resources are allocated efficiently, focusing on the end goal of the regulation: saving human lives. The described approach highlights the need for regulation that accounts for the complex interplay between biology and technology.

[29] Yeung, "Are Human Biomedical Interventions Legitimate?" 840.
[30] Fukuyama, Our Posthuman Future.
[31] Jasanoff, The Ethics of Invention.
[32] Jasanoff, "Technologies of Humility," 224.
[33] Beck, World at Risk.
[34] Baldwin, Understanding Regulation, 83.
[35] Bennett Moses, "Agents of Change," 763.
[36] Brownsword, "So What Does the World Need Now?" 27.
[37] For reference, see the different levels of scrutiny in hESC research in Europe at The Hinxton Group – an International Consortium on Stem Cells, Ethics, and Law at http://www.hinxtongroup.org/index.html.
[38] Bennett Moses, "Agents of Change," 788.
[39] Brownsword, "Law, Innovation and Technology," 73.

Adaptive societal governance refers to systems of public decision-making and institutional coordination capable of adapting to rapid, complex societal changes. Mourby and others propose this approach as a framework that allows greater flexibility and innovation in evaluating novel technologies. This approach involves ongoing feedback and adjustments to regulatory frameworks based on new evidence and technological developments. The Adaptive Societal Governance (ASG) supposes that 'a self-organising network of scholars and interested parties could carry out the multi-modal (meta)analyses needed to understand societal constructions of ideas inherent to our understanding of "life".'[40] Adaptive regulation in medicinal products is recognised in several jurisdictions besides the European Union, such as India, Japan, the United States and Australia.[41]

This exploration of dominant regulatory discourses reveals the deeply intertwined relationship between law, technology and society, particularly in the context of emerging biomedical innovations such as 3D bioprinting. By drawing on various perspectives – from techno-regulation and design-based governance to adaptive regulation – this section has demonstrated how competing narratives frame both the perceived promises and the regulatory challenges of technological advancement. These discourses do more than reflect abstract theories; they actively shape the design, application and legitimacy of regulatory frameworks. In this sense, law is not merely a tool for governance but a dynamic space where these visions of progress, risk and ethics are negotiated and contested. For a technology as transformative and complex as bioprinting, recognising these narratives helps to clarify the normative foundations on which future regulation must be built. As this field advances, the challenge will be to develop governance models that are not only scientifically and ethically robust but also responsive to societal expectations and capable of evolving alongside technological change.

3.1. Regulatory Approaches Embodied in the Biomedical Technology Legal Landscape

The described narratives on regulation show that several approaches shape the regulatory framework in the European Union: minimal regulatory involvement, balancing precaution and innovation, ethical considerations, centralised and decentralised regulation, harmonisation (which creates a uniform regulatory environment across member states), public participation, risk and value assessments and, finally, adaptive regulation. These approaches reflect a range of scholarly perspectives discussed earlier, from Friedman's advocacy for limited intervention to Jasanoff's participatory 'technologies of humility' model.

In the institutional and regulatory context of the European Union, some authors identify techno-regulation as the general approach, triggered by the focus of regulation on the product.[42] The focus is on the product, and the aim of the European Union is political and economic integration, which is animated by the goal of market harmonisation.[43] This aligns with Lessig's argument that 'code is law' and Koops' emphasis on built-in behavioural control mechanisms. However, it also brings into view Brownsword's critique of techno-regulation, where embedding rules in technology risks undermining moral agency and the values of the rights community. The European Union's aim of political and economic integration, animated by market harmonisation, reflects Porter's view that governments can act as catalysts for innovation by creating new regulatory standards. Other authors find that internal market harmonisation is a dominant frame for EU regulation, where risk analysis remains a vital framing device. This reflects Baldwin's concept of risk-based regulation and Beck's reflexive modernisation, both of which emphasise the need to manage uncertainty through responsive institutional frameworks. At the same time, rights and ethics legitimise the regulatory framework.[44]

However, as human tissues, blood and organs cannot be regarded as products,[45] measures such as the Blood Safety Directive, the Human Tissue Directive and the Human Organs Directive are based on health protection provisions,[46] indicating a departure from pure market logic and recognition of ethical dimensions – resonating with Brownsword's 'bioethical triangle' approach. If the harmonisation of rules in human materials is based on the risk-regulation system and consumer safety, then market rationale in regulation prevails. Yet, as Yeung notes in her analysis of design-based regulation, this can pose challenges to fundamental rights such as bodily integrity and autonomy, requiring careful ethical evaluation.

It is clear that the European Union does not have exclusive constitutional competence to regulate areas such as technology and health, but it still does so. How? Two fundamental principles of EU law allow the European Union to exercise competencies: the principle of proportionality and the principle of subsidiarity. Additionally, the harmonisation process rests in Article 114 of

[40] Mourby, "Biomodifying the 'Natural'," 1.
[41] Mourby, "Biomodifying the 'Natural'," 13.
[42] Brownsword, "Law, Innovation and Technology," 31.
[43] Consolidated version of the Treaty on the Functioning of the European Union, OJ C 326, art. 114.
[44] Bache, "The Defining Features," 8.
[45] Hervey, European Union Health Law, 343–48; Bache, "The Defining Features," 18.
[46] Consolidated Version of the Treaty on the Functioning of the European Union, *Official Journal of the European Union* C 326/47 (2012), art. 168.

the Treaty on the Functioning of the European Union (TFEU), which authorises the approximation of laws to ensure internal market functioning.[47]

Moreover, Article 168 of the TFEU ensures high human health protection. The Charter of Fundamental Rights (the Charter) includes provisions relevant to health technologies, such as the right to dignity, the right to physical integrity, and the prohibition on genetic discrimination and human cloning. Under the title of Solidarity, the Charter protects the right to health.[48] These provisions reflect Fukuyama's emphasis on protecting human dignity in biotechnology governance and Yeung's concerns about maintaining rights within technologically mediated regulation.

In this manner, the European Union has adopted numerous instruments regulating biomedical technologies. Thus, bioprinting as a novel technology can be subject to a range of EU regulations, directives and guidelines, including Council of Europe documents. The legal landscape sets safety, performance, clinical evaluation, conformity assessments and post-market surveillance requirements. This multi-layered setup reflects Bennett Moses' call for institutional connectedness in emerging technologies and aligns with Mourby and colleagues' adaptive societal governance, promoting feedback-based adjustments in regulation.

The described regulatory approaches overlap. For example, the previously mentioned ATMP Regulation 2007 covers many new product categories in the European Union, including gene therapy, somatic cell therapy and tissue-engineered products. Additionally, it introduces a centralised procedure through CAT, with representatives from each member state performing regular assessments of new technologies.[49] This responsiveness exemplifies Beck's reflexive modernisation and Mourby's adaptive regulation. It also allows for amendments and updates to reflect rapid scientific and technological advancements and empowers the European Commission to adopt delegated acts to modify annexes and other regulatory aspects.[50]

Complemented by the Good Manufacturing Practice Guidelines, national and EU legislation is 'open to an adaptive approach by regulators',[51] implying regulatory flexibility via conditional marketing authorisation, scientific advice and accelerated assessment.[52] These mechanisms echo the iterative policy-making and stakeholder collaboration described in adaptive regulatory models, and align with Brownsword and Somsen's call for creative legal thinking that evolves with technology. To unmask this, we do not have to go further than the recitals, which provide the background, the reason and the context of the regulation. Recitals also explain the considerations taken into account when adopting legal solutions. While they do not have legal force, they provide an insight into the substantive part of the regulation.

The ATMP Regulation harmonises legislation across EU member states, balancing precautionary measures with innovation.[53] This dual goal reflects Porter's vision of regulation as a driver of innovation and Brownsword's insistence on embedding ethical safeguards in law. The regulation promotes high ethical standards and donor anonymity while respecting fundamental rights and referencing the Oviedo Convention, echoing Fukuyama's concern with dignity and Jasanoff's emphasis on ethical, democratic governance.

The regulation employs a centralised approach to authorising ATMPs through the EMA while allowing for national-level considerations. It mandates comprehensive risk and value assessments, including pharmacovigilance and cost-effectiveness evaluations, aligning with Baldwin's framework of managing risk through structured oversight. Recital 21 encourages open consultation with all stakeholders, embodying Jasanoff's 'technologies of humility' and reinforcing participatory legitimacy in regulation.

Another example is Regulation 2024/1938, which sets standards for the quality and safety of substances of human origin (SoHO).[54] Like the ATMP Regulation, it integrates precaution, innovation, ethical principles, harmonisation, transparency and adaptability. While earlier directives (Directives 2002/98/EC and 2004/23/EC) had harmonised regulation to a degree,

[47] Consolidated Version of the Treaty on the Functioning of the European Union, *Official Journal of the European Union* C 326/47 (2012).
[48] Charter of Fundamental Rights of the European Union, *Official Journal of the European Union* C 326/391 (2012) art. 35.
[49] EMA, "Adaptive Pathways."
[50] Regulation (EC) No 1394/2007 of the European Parliament and the Council of 13 November 2007 on Advanced Therapy Medicinal Products, *Official Journal of the European Union* L 324/121 (2007), arts. 24 and 25a.
[51] Mourby, "Biomodifying the 'Natural,'" 15.
[52] Detela, "EU Regulatory Pathways for ATMPs."
[53] ATMP Regulation, l. 5.
[54] Regulation (EU) 2024/1938 of the European Parliament and the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC, *Official Journal of the European Union* L 170/1 (2024), SoHO Regulation, ll. 5 and 6.

divergences remained. This regulation aims to close those gaps, echoing Bennett Moses' concern over regulatory lag. It balances precaution and innovation by establishing high safety standards while supporting structured clinical outcome monitoring, reflecting Beck's concern with emergent risk and Yeung's emphasis on real-time evidence.

The EU SoHO platform fosters transparency and coordination[55] while national authorities retain the flexibility to address local needs, supporting Mourby's adaptive governance framework. Ethical considerations and public involvement are central, including voluntary, unpaid donations and public awareness campaigns, aligning with Brownsword's moral agency and Jasanoff's participatory ideals. While establishing centralised oversight through national competent authorities and an EU-wide SoHO Coordination Board, the regulation also accommodates local implementation.[56] This hybrid model reflects the adaptive, inclusive approach advocated by many scholars and addresses the challenges of governing bioprinting and similar biomedical innovations in a fragmented legal environment.

It is clear that, over the last couple of decades, the European Union has developed a comprehensive framework for regulating technologies. That framework adopts a precautionary and risk-based regulatory approach to harmonising the market. Its legal framework emphasises safety, ethical responsibility, transparency and support for innovation. However, it is only slowly and selectively moving towards a more adaptive regulatory approach. While the European Union has traditionally favoured a precautionary and rule-based regulatory style, there are signs of movement toward adaptive regulatory practices, particularly in high-tech and biomedical sectors. Still, this shift is gradual, sector-specific and often tempered by institutional conservatism and political complexity.

4. Legal Perspectives on Bioprinting and Biosthetics

The European Union maintains a dual-track regulatory ecosystem for biomedical technologies, one that governs upstream R&D activities and innovation, and regulates downstream deployment in healthcare settings for patient care. Each phase involves distinct authorities, compliance pathways and legal instruments – but with increasing emphasis on translational integration, where data and risk management flow between the two. Each phase also follows separate compliance pathways – for instance, clinical trials are governed by the Clinical Trials Regulation (EU 536/2014), while the deployment of approved medical technologies in hospitals falls under Medical Device Regulation (MDR 2017/745) or In Vitro Diagnostic Regulation (IVDR 2017/746). These frameworks come with their own legal instruments, including approval procedures, safety documentation, ethical guidelines and post-market monitoring rules. Translational integration refers to the bridging of these phases, ensuring that insights, data and risk assessments generated during R&D are carried forward into the patient care phase and vice versa. This integration allows for more responsive, evidence-informed regulation, where post-market surveillance data (e.g. real-world patient outcomes) can be fed back into future R&D and policy design.[57] Finally, data and risk management flow between the two, highlights the increasingly continuous nature of regulatory oversight: rather than seeing R&D and patient care as isolated, modern EU frameworks aim to connect them through shared health data systems (such as EHDS), real-world evidence and iterative regulatory evaluations that adapt over time. This flow promotes a safer, more efficient and innovation-friendly biomedical ecosystem.

The legal framework governing bioprinting in the European Union is multifaceted, intersecting with both biomedical R&D and clinical healthcare regulation. Due to their hybrid nature – being part biological and part synthetic – bioprinted products challenge conventional regulatory categories. These products, which this article terms biosthetics, require particular legal attention because they blur the lines between tissue-engineered medicinal products, medical devices and human biological materials. Their classification and regulatory pathway therefore depend not only on function and risk, but also on how law conceptualises their ontological status.

Bioprinted products containing human cells and tissues fall under the SoHO Regulation (EU 2024/1938), which ensures standards for safety, ethical sourcing and quality. This regulation sits at the intersection of clinical care and biomedical innovation, and directly applies to bioprinted constructs intended for therapeutic use. Where bioprinted constructs exhibit biological activity – such as regenerating or replacing tissues – they may be classified as Advanced Therapy Medicinal Products (ATMPs) under Regulation (EC) No 1394/2007. This designation requires centralised authorisation through the EMA, bringing strict oversight regarding clinical evaluation, risk assessment and long-term monitoring.

[55] SoHO Regulation, ll. 36 and 73.
[56] SoHO Regulation, ll. 49 and 50.
[57] Cioeta, "A New Platform."

Conversely, when the primary function of a bioprinted construct is structural or mechanical, such as a scaffold with limited biological activity,[58] it may fall under the Medical Device Regulation (EU) 2017/745. The key legal determinant here is the product's principal mode of action.[59] This creates ambiguity for many bioprinted constructs that combine both mechanical support and biological integration – again underscoring their biosthetic identity. In these cases, regulators must determine on a case-by-case basis whether medicinal product, device or combination product rules apply.

In the research and development context, Directive 2001/83/EC lays the foundation for medicinal product regulation, and its provisions on manufacturing practices, marketing authorisation and pharmacovigilance are directly relevant to bioprinted tissues used as therapeutic interventions. Directive 2004/23/EC further provides requirements for the handling and use of human tissues and cells, ensuring traceability and safety from donation through application. Together, these legal instruments establish core principles for regulating the life-cycle of bioprinted constructs.

Regulation (EU) No 536/2014 provides a framework for conducting clinical trials in the European Union, ensuring the safety and rights of participants. Requirements for the conduct of clinical trials include Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP). The regulation mandates centralised trial registration, ethics committee approval, informed consent and continuous monitoring. Its applicability to bioprinting becomes particularly significant when human-derived cells – especially pluripotent stem cells – are involved. Ethics approvals must address not only the provenance of biological material, but also the long-term risks and uncertainties specific to biosthetic constructs.[60] GCP demands informed consent and data integrity,[61] while GMP enforces stringent controls on production processes, including documentation and traceability – elements that are particularly critical for bioprinting, where each construct may be personalised and produced in small batches. This presents challenges for applying mass-production standards to individualised therapeutic products.[62]

Furthermore, the integration of digital data in bioprinting adds a regulatory layer. The creation of bioprinted constructs relies on numerous data types. By analysing the bioprinting process and technology, it is possible to extrapolate the following data: imaging, genomic, histological, biomaterial, physiological, anatomical, disease-specific and clinical. These data must be handled according to Article 35 of the GDPR, which safeguards personal and health-related information. Especially when creating personalised biosthetics constructs, AI tools or algorithms to optimise the design or predict tissue behaviour may invoke future obligations under the AI Act.

The Patient Rights in Cross-border Healthcare Directive and the now-repealed Directive 95/46/EC (replaced by the GDPR) underscore the need for patient privacy, data transparency and safe clinical care when bioprinting technologies are deployed across borders. Regulation (EU) 2021/2282 on Health Technology Assessment (HTA) is also increasingly relevant, particularly for evaluating cost-effectiveness and integrating bioprinted therapies into public health systems.

5. Conclusion: Rethinking Regulation in the Age of Biosthetics

The analysis presented in this article underscores the pressing need for a reorientation of regulatory frameworks in response to the ontological and practical complexities introduced by bioprinting technologies. As the European Union continues to rely on codified regulatory instruments – such as the MDR, the GDPR and ATMP Regulation – it becomes increasingly evident that these instruments, while comprehensive and grounded in principles of risk mitigation, patient safety and ethical oversight, lack the flexibility necessary to respond effectively to fast-paced technological innovation.

This rigidity is not without cause. As discussed in the broader scholarly discourse, the EU regulatory model is shaped by foundational legal principles (proportionality, subsidiarity and legal certainty), bureaucratic complexity and a precautionary ethos rooted in diverse ethical cultures across member states. These characteristics contribute to a structurally conservative regulatory environment that excels in stability and coherence, yet often struggles with anticipatory governance and rapid

[58] A bioprinted scaffold for bone regeneration that primarily provides structural support and is supplemented with natural materials could be considered a medical device.
[59] Ferrari, "Additive Bio-Manufacturing."
[60] Regulation (EU) No 536/2014 of the European Parliament and the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, *Official Journal of the European Union* L 158/1 (2014), art. 29.
[61] Regulation (EU) No 536/2014 of the European Parliament and the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, *Official Journal of the European Union* L 158/1 (2014) art. 47.
[62] "ATMP Regulation," art. 5; Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, bk. 46f.

responsiveness. Scholars such as Brownsword, Somsen and Jasanoff have highlighted the need for regulatory systems to evolve alongside the technologies they govern, advocating for reflexive, participatory and rights-driven regulatory approaches.

Bioprinted products – here defined as biosthetics – epitomise the epistemic and material hybridity that challenges existing legal definitions. These constructs simultaneously embody characteristics of biological living matter and synthetically engineered materials, thereby destabilising traditional regulatory binaries such as natural/artificial, medicinal product/device and product/process. The European Union's reliance on the 'principal mode of action' test as a primary classifier is illustrative of the limitations of applying categorical logic to technologies that are inherently integrative and hybrid.

In light of these dynamics, three regulatory pathways for bioprinting within the European Union can be envisaged. The first, a continuity model, retains the current fragmented system where legal classification hinges on functional assessments – most notably the principal mode of action. While this strategy preserves institutional stability, it risks inconsistent regulatory outcomes and imposes interpretive burdens on national authorities. The second pathway proposes targeted reforms to existing legal instruments, such as amending the MDR, ATMP Regulation and SoHO Regulation, to explicitly incorporate bioprinting and delineate clearer guidance. However, this option faces practical constraints due to the European Union's procedural complexity and the need for consensus across 27 member states.

The third and most forward-looking trajectory involves constructing a dedicated regulatory framework for bioprinting and similar hybrid biomedical technologies. This novel architecture would draw upon the principles of adaptive governance, incorporating dynamic risk assessment, stakeholder co-governance and real-world evidence into regulatory design. Such a framework would recognise the biosthetics ontology of 3D bioprinting technologies and respond accordingly with modular, flexible and ethically embedded legal instruments. It would also enable the use of regulatory sandboxes, early scientific advice and conditional approval mechanisms, thereby aligning more closely with the innovation ecosystem.

Ultimately, the governance of bioprinting in the European Union demands more than technical classification; it requires a conceptual shift. The law must become a co-productive partner in innovation, capable of evolving with scientific advances, mediating between market dynamics and ethical imperatives, and supporting the translation of biotechnological potential into socially legitimate outcomes. The concept of biosthetics introduced in this article not only captures the ontological novelty of bioprinting but also signals the need for a jurisprudence that embraces hybridity, uncertainty and the co-construction of regulatory meaning. Such a shift will be essential if the European Union aims to maintain its leadership in biomedical innovation while safeguarding fundamental rights, democratic values and public trust.

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