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CAN HUMAN-CENTRICITY OF EU AI ACT BE STANDARDIZED ACROSS BORDERS?

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Abstract
Can human-centricity of EU AI act be standardized across borders? This question sits at the intersection of legal harmonization, technological fluidity, and ethical imperative, defining the scope and viability of the European regulatory experiment in global digital governance. The quest for standardization reflects a complex policy ambition to assert normative influence while managing intrinsic technological uncertainty. Achieving cross-border uniformity necessitates a framework adaptable to varying socio-political contexts and technological interpretations.

Keywords: EU AI Act, Ethics, AI regulation, trustworthy AI, uniformity, human centricity

Introduction

The European Union has clearly set itself apart as a worldwide leader in advocating a human-centric approach to Artificial Intelligence (AI). This leadership position is viewed as a strategic maneuver to differentiate the EU market from technology-driven models focused purely on speed or economic utility, particularly those originating from the United States or China. The EU's commitment is rooted in a constitutional tradition that prioritizes individual rights and democratic oversight over technological advancement, seeking a balance between innovation and protection) [Carnevale, p.1]. The policy evolution leading to the AI Act was deliberate, designed to build public confidence in AI technologies by ensuring transparency and accountability at every stage of development.

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The European Commission, as the main proponent of this idea, stresses that AI should not only be technically-powerful but also socially-beneficial, operating on a "tangible foundation of trust" [Carnevale, p.1]. This concept of trust transcends mere technical safety and encompasses the ethical integration of AI into complex societal structures, requiring continuous monitoring and validation mechanisms. The inherent demand for trustworthiness implies a necessary focus on process consistency and continuous ethical review, a requirement that immediately poses challenges for any regulatory framework based on static, snapshot conformity assessments) [Carnevale, p.1]. Trust is considered the necessary precondition for widespread public and industrial adoption of AI technologies, especially in sensitive sectors like healthcare and justice, which are central to the EU's regulatory focus.Concept is at the heart of the very first sentences of such important papers as "Building Trust in Human-Centric Artificial Intelligence" and "Ethics Guidelines for Trustworthy AI" by the High-Level Expert Group on Artificial Intelligence (HLEGAI) [Carnevale, 30].These foundational documents, formulated prior to the legislative process, set the political and ethical tone, establishing a trajectory that valued fundamental rights protection equally with economic competitiveness.The HLEGAI guidelines specifically detailed a set of requirements for Trustworthy AI, including technical robustness, data governance, transparency, and accountability, laying the conceptual groundwork that the AI Act would later attempt to translate into legally binding obligations.It is, so far, the most significant legislative embodiment of the principle to be found in the groundbreaking Artificial Intelligence Act (AI Act) [Hacker; Carnevale, 22], a first-of-its-kind regulatory framework whose main objective is to enable the placement of AI systems that are safe, transparent, and respectful of fundamental rights in the EU market.

The global impact of this legal undertaking is considerable, as its extraterritorial scope reflects the EU's aspiration to define the worldwide standard for AI ethics and governance, a phenomenon often referenced as the "Brussels effect" by regulatory scholars. This regulation attempts to convert abstract ethical principles into concrete legal requirements, distinguishing it structurally from non-binding frameworks pursued by other global powers. The Act seeks to achieve legal

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certainty and market harmonization by introducing a horizontal framework that preempts fragmented national regulatory approaches across Member States) [Carnevale, p.1].

Nevertheless, the shift of AI to more integrated and collaborative forms at a very high speed is a big challenge for the regulatory ambition to control it. The fundamental uncertainty accompanying the rapid speed of AI development, particularly generative models and complex, adaptive systems, calls for interventionist approaches that can respond dynamically to emergent risks, rather than relying solely on pre-determined rules. Regulators face the challenge of parsing the components of what precisely to regulate—hardware, data, algorithm, or the socio-technical interaction itself—when the technology is rapidly morphing. Moreover, the speed of change creates information asymmetry, making it difficult for governments and regulatory bodies to anticipate risks or fully comprehend the systems they are tasked with governing. The notion of Symbiotic AI (SAI)—where humans and AI systems interact in a reciprocal relationship that goes beyond the traditional controller-tool relationship—challenges the limits of present regulations models [Carnevale, p.3]. SAI conceptually disrupts the neat division of labor and control upon which traditional product safety and liability laws are founded, demanding a reconsideration of the legal definitions of autonomy and agency. In this context, the difficulty in assigning responsibility is compounded by the political decision to withdraw the proposed AI Liability Directive (AILD), which sought to harmonize fault-based liability rules across the EU.

In a symbiotic relationship, as predicted by Licklider and now happening in healthcare and creative works, the boundary between user and tool becomes less clear, therefore new ethical and conceptual are raised such as those of responsibility, control, and the nature of "intelligent" collaboration [Carnevale, p.5-6]. SAI, often described as a "collaborative teaming framework" [Carnevale, p.2], creates opacity regarding causality, moving accountability away from a single, identifiable actor towards a chain of distributed influence. For instance, when AI offers up-to-the-minute guidance that subtly changes human behavior in a high-stakes environment, the traditional legal mechanism of human oversight fails to capture the co-constructed nature of the resulting decision. The

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complexity of tracing fault in this reciprocal relationship highlights the deep inadequacy of applying rigid, ex-ante (before-the-fact) regulatory frameworks designed for static artifacts to dynamic, evolving socio-technical systems) [Carnevale, p.1].

This paper claims that the EU AI Act is a major step towards AI governance. It represents the boldest worldwide endeavor to formalize human-centric AI in the form of binding law, transitioning from ambiguous ethical principles to quantifiable, albeit sometimes problematic, legal obligations.The Act's comprehensive and horizontal scope offers a baseline for safety and rights protection that is internationally unique, establishing a robust foundation for legal certainty across the Digital Single Market.) [Carnevale, p.1].However, its current fixed and product-safety-inspired design, as embodied in the Act, has drawbacks in terms of creating a truly human-centered environment for SAI.The reliance on the established framework of product safety laws, specifically the conformity assessment structure [Hacker, p.7], imposes a regulatory mindset suited for unchanging hardware rather than continuously adaptive software.) [Carnevale, p.1] This design creates a structural friction, particularly regarding civil liability, as product safety only addresses strict liability for defective goods, failing to cover negligence or unlawful conduct arising from dynamic AI process failures.

The EU AI Act's inflexible, risk-based categories and its attempt to find a firm ontological basis for AI are at odds with the symbiotic nature of the dynamic, contextual, and relational human-AI interaction.The Act's deterministic model struggles precisely because the risk profile of a symbiotic system is a variable, tied to its evolving context of use, rather than a constant determined by its initial classification. The lack of a stable foundational definition for advanced AI, which is neither purely a tool nor truly an autonomous entity, destabilizes the legal mechanism requiring clear categorization.There is a governance gap here that we propose to fill with the regulatory framework being supplemented by a constructivist approach to SAI, as argued by Carnevale et al. [Carnevale, p.6-9].

The identified governance gap arises from the discrepancy between the Act's static, rule-based approach and the inherent variability and dynamism of SAI systems.The constructivist model is introduced as the necessary theoretical and practical supplement, offering a methodology better suited for regulating

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technological complexity and uncertainty[Lea, G. R. (2020)] . The latter, which interprets symbiosis as a process emerging from socio-technical interactions rather than a pre-existing state, has the required openness, awareness of context, and emphasis on shared responsibility which are compatible with the EU human-centric vision in the era of advanced, symbiotic AI.) [Carnevale, p.1].

By focusing on the socio-technical process of development and deployment, the constructivist framework provides the theoretical basis for a flexible regulatory approach that can adapt to different technologies and application niches, reflecting the reality that there is "no single understanding of AI" in practice. [Lea, G. R. (2020)] . This focus on process and interaction is critical for achieving true human-centricity, moving beyond simple procedural compliance to embedded ethical practices) [Carnevale, p.1].

Materials and Methods

This paper applies conceptual analysis and interdisciplinary synthesis to evaluate if the EU AI Act's regulatory framework is in line with the Symbiotic AI (SAI) paradigm. The methodology necessitates combining philosophical critiques regarding the nature of intelligence with concrete legal analysis concerning regulatory feasibility and definitional clarity.Conceptual analysis allows for the deep examination of terms like ‘autonomy,’ ‘risk,’ and ‘control’ as they transition from ethical principles (HLEGAI) to legal mandates (AI Act), revealing points of friction.The method is aimed at locating central conflicts and suggesting a single solution by combining legal and philosophical viewpoints. The goal is to develop a normative solution that is both theoretically sound and practically actionable within the existing European regulatory infrastructure.The study has been carried out in four consecutive stages, which are described below) [Carnevale, p.1].Problem Identification and Literature Selection.The first stage was a targeted review of contemporary literature to delineate the research problem. This step focused on identifying key academic and policy texts that critically engaged with both the regulatory mechanisms of the AI Act and the advanced theoretical frontier of human-AI collaboration. As the direct and most relevant sources, two landmark texts were chosen to serve as the foci of this study:

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1. Hacker (2023): AI Regulation in Europe: From the AI Act to Future Regulatory Challenges.

This working paper presents a thorough, critical, and up-to-date legal analysis of the EU AI Act's framework, its substantial provisions, and the areas where it is considered to be lacking. Hacker's work provides the necessary empirical grounding on the Act's structural elements, focusing on mechanisms like the risk-based approach, conformity assessments, and specific articles related to high-risk classification.

In essence, it is the source that helps to understand the legal framework of regulation.

2. Carnevale et al. (2024): A human-centred approach to symbiotic AI: Questioning the ethical and conceptual foundation.

This journal article dives into the philosophical and conceptual aspects of SAI and proposes a constructivist approach as a way to govern it. Carnevale et al. directly address the ontological and ethical challenges posed by symbiotic systems, arguing that traditional control-based models are philosophically unsound when applied to truly reciprocal human-AI relationships. It is the primary source used to understand the inherent challenges of SAI and the methodological solution proposed. These works were selected because one emphasizes the concrete reality of the regulation while the other explores the theoretical frontier of AI development that questions the former.

Conceptual Analysis -the methodology core was a thorough conceptual examination of both articles. This stage involved rigorous textual scrutiny aimed at mapping the core arguments and underlying assumptions of each author, particularly concerning definitions and regulatory efficacy. The activities involved in this were: Close Reading and Thematic Extraction: The researchers systematically examined both works to locate and extract key arguments, concepts, and critiques. From Hacker's paper, the themes of risk-based approach, definitional issues, high-risk classification, and liability in the value chain were the major ones. These themes represent the practical legal and economic challenges facing industry implementation of the AI Act, specifically concerning compliance costs and legal uncertainty caused by overbreadth. From Carnevale

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et al., the themes such as the life-artefact divide, spectrum of intelligence, socio-technical interdependence, and the constructivist approach were pointed out. These philosophical themes highlight the deeper, structural inability of a deterministic legal framework to accommodate the fluid, emergent properties of advanced AI systems.

Critical Examination of Internal Coherence: The authors' arguments' logic and consistency were reviewed. For example, Hacker's criticism of the AI Act's definition was checked against his suggested remedy, and Carnevale et al.'s fundamental objections to SAI were measured against their proposed constructivist framework.This examination ensured that the critiques levied against the AI Act were substantiated by corresponding, viable theoretical or legal alternatives proposed by the authors.There are interdisciplinary synthesis and gap analysis carried out.The themes obtained from the two works were merged to find not only the consonance points but also the disagreements between them. This stage involved.

Confronting Regulation with Reality: The AI Act's stipulations and layout, as explained by Hacker, were put side by side with the philosophical and operational features of SAI, as explained by Carnevale et al..The synthesis clearly indicated the gap in governance - the discrepancy between the AI Act's deterministic model and SAI's dynamic nature.This dissonance arises because deterministic models prioritize ex-ante compliance and predictability, whereas SAI’s socio-technical nature requires continuous, context-aware, post-market monitoring.

Triangulation of Critiques: The criticisms of both authors were compared.It was determined that Hacker's practical, legal critiques (e.g., overbroad definition) were supported by Carnevale et al.'s philosophical critiques (e.g., the difficulty of finding a rigid ontological foundation for SAI).This triangulation reveals that the practical problem of over-regulation (legal ambiguity) shares a common root with the philosophical problem of definition (ontological ambiguity), suggesting a solution must address the core conceptual instability of advanced AI.This triangulation helped to clarify the central problem.

The last stage in the methodology was to come up with a normative solution based on the synthesis. The constructivist approach suggested by Carnevale et al. was seen as a possible connecting point for the local governance gap. Its features such

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as adaptability, awareness of the context, and emphasis on the process were thoroughly linked to the particular regulatory weaknesses pointed out by Hacker. Then, the FAIR project's evaluation framework was introduced as a tangible means to put into effect this constructivist approach in the wider context of the AI Act compliance regime.The FAIR framework, which mandates continuous attestation and multidisciplinary review [Wells et al. (2025)], offers a scalable, auditable mechanism for embedding process-focused ethics into the Act's existing legal structure.

There are some limitations of the study.The study described here is mainly a conceptual, qualitative research based on the in-depth examination of two critical articles.This qualitative approach allows for deep structural analysis but does not provide empirical data on the economic impact or practical enforcement challenges faced by deployers in specific Member States. Its scope is intentionally limited to the high-level structural interplay between the AI Act and SAI.While it puts forward a principled argument and policy recommendations, a lot more empirical and legal research will be needed to work out the detailed technical standards and to figure out the economic impact of the proposed constructivist methodology.This necessity for further research underscores the incremental and experimentalist nature of AI governance, where high-level policy must be continuously refined through sector-specific application and technical standardization.

The European Union's adherence to a human-centric model of Artificial Intelligence is not a newly introduced idea with the AI Act but rather the result of a long-term policy evolution. This approach contrasts with technology-first or market-driven regulatory philosophies, asserting that technological development must serve societal values rather than dictate them. The focus on human rights protection represents a strategic alignment with the foundational principles of the EU legal order, ensuring legitimacy and public acceptance for innovative technologies.The approach places the human being, their rights, and their well-being as the core of technological development and usage.This foundational principle utilizes a dual normative framework: human rights as both guaranteed legal protections under the EU Charter and as ethical values derived from the moral nature of human beings.This duality ensures that compliance is demanded

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on both legally binding and normative ethical grounds, reinforcing the concept of global trustworthiness.

The European Commission has been the advocate of this route for a long time, stressing "communication between societal stakeholders and technology developers to establish a tangible foundation of trust in AI" [Carnevale, p.1].Establishing this trust requires robust mechanisms for transparency and accountability that extend across the entire AI lifecycle, ensuring continuous governance rather than episodic checks.[7]This basic rule was one of the main points in the Commission's 2018 communication, "Building Trust in Human-Centric Artificial Intelligence" [Carnevale, 20], thus it set the political and ethical tone for all the following regulatory initiatives.The most profound development of this concept can be found in the "Ethics Guidelines for Trustworthy AI" prepared by the High-Level Expert Group on AI (HLEGAI) [Carnevale, 30]. The HLEGAI guidelines were crucial for formalizing the conceptual basis of trustworthy AI, providing a set of non-technical and technical requirements aimed at ensuring respect for human autonomy and fundamental rights.The main advantage of this model is its use of the double normative role of human rights fundamental.This incorporation of fundamental rights serves as a necessary rights-based counterbalance to potentially unchecked, purely market-driven innovation.These rights, on the one hand, are legal protections guaranteed by the European Union's constitutional framework and on the other hand, they are ethical values emanating from the inherent moral nature of human beings, which, although not always legally binding, are very important for ensuring global trustworthiness [Carnevale, p.2].The attempt to fuse legal and ethical compliance distinguishes the EU approach, transforming what might otherwise be purely technical standards into mechanisms for upholding societal values.

Additionally, the EU's model takes a pluralistic ethical stance and depends on a set of interrelated principles—like respect for human autonomy, avoidance of harm, fairness, and explicability—which help in the construction of a "good AI society" [Carnevale, p.2]. This reliance on pluralistic principles suggests an evolving ethical landscape that should ideally be supported by adaptable regulatory tools, moving beyond simple non-maleficence to proactive promotion of societal goods.The subsequent legislative effort aims to codify these principles,

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establishing clear criteria against which the ethical claims of AI systems can be legally verified.

The Artificial Intelligence Act (AI Act) is the main instrumental law aiming to convert this moral vision into a legally binding reality.The AI Act initiated by the European Commission in April 2021, is intended to establish "a comprehensive and harmonized framework for the development, deployment, and oversight of artificial intelligence across the EU" [Hacker, p.5].The comprehensive nature of the Act aims to prevent market fragmentation and provide clear legal certainty for developers and deployers operating within the single market.The range of its intervention is large, and similar to the General Data Protection Regulation (GDPR), it declares an extraterritorial effect, that is, its provisions apply to providers and users of AI systems anywhere if the output is used in the Union, irrespective of their location [Hacker, p.6]. This extraterritorial reach is central to the EU's strategy of setting global standards—the "Brussels effect"—allowing its digital governance standards to influence technological design and policy beyond its immediate borders.However, commentators suggest that the actual external impact of the AI Act may align more with experimentalist governance than with deterministic standard-setting, implying a cooperative and open-ended interaction with other global approaches.

The structural heart of the AI Act is a risk-based approach that adjusts the regulatory requirements to the level of risk the AI system poses to health, safety, and fundamental rights [Hacker, p.6].This tiered approach is a pragmatic compromise, intended to concentrate regulatory efforts on the most dangerous applications while minimizing regulatory burden on low-risk systems to encourage innovation. The concept is that the stringent compliance requirements must be proportional to the assessed potential for harm.The Act categorizes AI systems into four categories:

Prohibited AI: The activities that are considered as unacceptable and are direct violations of EU values, such as social scoring of individuals by public authorities or, with a few highly controversial exceptions, real-time remote biometric identification in publicly accessible areas (Art. 5 AI Act) [Hacker, p.6].These prohibitions reflect the EU's zero-tolerance policy towards systems deemed to fundamentally undermine democratic values and fundamental rights.

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High-Risk AI: Systems that are utilized in the sectors that are deeply affected and are listed in Annexes II and III of the Act like administration and justice, biometrics, medicine, employment, and essential private services such as credit scoring [Hacker, p.6].The inclusion of sectors like healthcare and finance acknowledges the potential for significant, life-altering impacts on individuals stemming from biased or erroneous AI decision-making.This category embodies the "heart of the planned AI regulation" [Hacker, p.6].Limited-Risk AI: Systems that have certain transparency obligations like chatbots or deepfakes where users have to be informed that they are dealing with an AI (Art. 52 AI Act) [Hacker, p.7].These transparency obligations, while less burdensome than high-risk requirements, are critical for establishing trust by providing the user with the necessary information to comprehend and question AI-generated decisions. Minimal or No Risk: The rest of the AI applications which are largely left without regulation so as not to be hampered in terms of innovation [Hacker, p.7].The intention here is explicitly to foster investment and creativity by avoiding over-regulation of benign or simple software applications.

For high-risk AI systems, providers must adhere to a rigorous set of requirements to ensure human-centricity and safety throughout the lifecycle of the system [Hacker, p.6].These include conducting risk assessments, using high-quality datasets, ensuring comprehensive documentation and record-keeping, providing transparency to users, enabling effective human oversight, and implementing robustness and cybersecurity measures [Hacker, p.6].These requirements mandate a substantial organizational shift for high-risk AI providers, requiring the integration of quality management systems and comprehensive technical documentation comparable to medical device or aviation regulations.This system is largely modeled on product safety laws, with conformity assessments—mostly self-certification—being the approval process's central role [Hacker, p.7]. The reliance on the product safety model dictates an ex-ante (before placement on the market) assessment structure, focusing on the AI system's compliance at the point of deployment. However, this deterministic, fixed compliance model fundamentally struggles to address the challenges posed by Symbiotic AI, which changes dynamically post-deployment. The human-centered principle is the core idea behind the high-risk system requirements.The necessity of human control is

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the direct legal example of the idea that humans should be the ones in charge ascertaining that an AI system is not functioning in a fully autonomous manner that could result in the loss of human autonomy [Hacker, p.6].This legal mandate for human oversight, however, becomes conceptually tenuous in SAI, where the AI system is not merely a tool but an integrated, co-creative partner.The assumption of clear human control fails when the boundary between user and tool is deliberately blurred in a reciprocal relationship.

Correspondingly, user-friendly regulations make sure that users get honest information thereby giving them the power to comprehend and question AI-generated decisions.The Act bases its operation on the triple of health, safety, and fundamental rights thus, it is in line with the ethical demand of "non-maleficence" and "justice" promoted by the HLEGAI guidelines.The EU's method stresses several main points.Through the formation of a horizontal, ex-ante regulatory framework, it is trying to avert a situation where regulation varies greatly from one member state to another and thus, provide legal certainty.The accent on fundamental rights incorporates a strong, rights-based counterbalance to the innovation that is purely market-driven.The requirement for Fundamental Rights Impact Assessments (FRIAs) for deployers of certain high-risk systems exemplifies this commitment, serving as a key accountability and risk measure tool that market surveillance authorities are expected to prioritize.

Besides that, the extraterritorial extent of the initiative is a manifestation of the desire to spread its digital governance standards to other regions, a process which is termed as the "Brussels effect" by the researchers [Hacker, p.6].To put it simply, the AI Act is the boldest worldwide endeavor to formalize human-centric AI in the form of law thus making a move from vague ethical principles to concrete legal obligations.However, this solid structure is going to be challenged by the next frontier of AI development: Symbiotic AI.The subsequent chapter will examine the conceptual and practical difficulties of SAI in relation to this deterministic, rule-based regulatory model.

Symbiotic AI (SAI), a concept where humans and AI systems jointly work in a mutually co-influencing partnership, is a paradigm that challenges the limits of the regulatory framework of the EU AI Act.The inherent reciprocity of SAI, where both human and machine agents are capable of influencing the other's

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decision-making [Carnevale, p.3], directly conflicts with the Act's implicit model of a clear, hierarchical human "controller" and an obedient AI "tool" [Hacker, p.6].Although the Act offers a detailed regulatory framework for less complex AI applications, its deterministic, product-safety-inspired model is not flexible enough to cater for the dynamic, situational, and relational aspects of real human-AI symbiosis.

The fixed nature of product safety laws, which are designed to assess inherent dangers in static objects, cannot account for emergent risks that arise only through continuous, contextual socio-technical interaction. The failure to provide clear guidance for monitoring AI performance after initial deployment confirms the limitations of this ex-ante structure. SAI imagines the evolution of the traditional human "controller and control, into a reciprocal relationship between two agents potentially equal in decision-making, capable of mutually influencing one another" [Carnevale, p.3].It is not simply a case of advanced automation but rather a "collaborative teaming framework" [Carnevale, p.2] in which, for instance, an AI not only performs tasks but also offers the most up-to-the-minute guidance that changes human behavior, or a brain-computer interface like Neuralink that learns and adapts from your neural processes, thus reducing human control of the system [Carnevale, p.3].The dynamic adaptation inherent in these systems means their risk profile can shift dramatically over time, making an initial risk classification based on static annexes rapidly obsolete.This degree of closeness creates a "sociotechnical interdependence" [Carnevale, p.2] that the AI Act's present format cannot handle, a problem that unfolds in three main areas.

Distinguishing Life, Artifacts, and Adaptive Intelligence is essential. The chief difficulty is at the very base of the word "symbiosis".Symbiosis, as a biological term, implies a life-to-life relationship, forcing a challenging conceptual leap when applied to non-living, artificial constructs.When the biological concept, which means a life-to-life relationship, is applied to AI artefacts, it raises deep philosophical questions.The traditional distinction going back to Aristotle is that living beings have an autonomous principle of movement and self-finality (entelechy), whereas artefacts "are moved by external forces" [Carnevale, p.4].

This distinction underpins much of Western legal theory regarding non-contractual liability, where artifacts are generally treated as tools whose faults

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must be traced back to a human designer or manufacturer. However, the line between the two is blurred because of the presence of AI and robotics which challenge this distinction by being capable of self-development and learning. The capacity for autonomous adaptation and learning—a key feature of advanced AI—undermines the definition of an artifact as something merely "moved by external forces".However, this adaptation still lacks the fundamental drive for self-preservation associated with living systems. As Carnevale et al. put it, the technologies like LLMs are missing the most basic aspect of life: the instinct for self-preservation (conatus or Wille zum Leben) [Carnevale, p.5]. They may self-improve, but not in pursuit of their own "good" or continued existence [Carnevale, p.5].

The "insurmountable gap" here makes it difficult to apply biological concepts such as symbiosis directly to AI, leaving the foundational idea of SAI on shaky ontological ground which, in turn, creates regulatory ambiguity in defining and classifying such systems.The instability of the AI system's ontological status—neither purely artifact nor truly alive—directly challenges the legal categorization required by the AI Act. This instability validates the necessity for a constructivist governance approach, which regulates AI not based on its intrinsic nature but based on the socio-technical processes and choices that define its function and risk profile.The first problem to be solved first is the conceptual one: how can AI such as those with symbiotic possibilities be governed in a legislative framework which is essentially deterministic?.

Governance features of the AI Act reveal a "governance gap" brought about by the foundational variability of SAI that lie within the Act's deterministic framework.The Act's inflexible, rule-based manner of working which brings the desired results in the cases of unchanging products is at odds with the fluid character of symbiotic systems.The Overbroad Definition of AI: One of the major shortcomings of the Act is its definition of an AI system being extremely broad on the basis of the notion "autonomy". While the EU aligned its broad definition with the OECD framework, this intentional breadth creates significant legal uncertainty for developers, operators, and users, potentially leading to widespread over-regulation [Madiega, T. (2024)]. According to Hacker, the definition of the system could very well encompass "smart meters, scheduling tools, rule-based

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systems and almost any advanced software," even an electric toothbrush [Hacker, p.9].

The problem of this imprecise delineation is that it could turn the AI Act into a de facto "Software Act". The risk here is that the Act, designed to regulate the specific and severe hazards posed by autonomously learning systems, instead imposes a substantial compliance burden on simple algorithmic software that poses none of these particular risks. For example, the American Chamber of Commerce in the EU (AmCham) explicitly suggested adopting a narrower definition, focusing strictly on "high-risk" AI applications to avoid over-regulation of general software [Madiega, T. (2024)]. In that case, it would weaken the AI focus, and impose a substantial burden of compliance on technologies that do not pose any of the particular risks of advanced, adaptive AI.

Static Classification for Dynamic Systems: The main tool of the Act—the method of determining that a system is high-risk based on the preset use-cases given in the static annexes (e.g., employment, medicine) [Hacker, p.9]—is inappropriate for SAI. The reliance on static annexes fails to capture systems whose functions, risk levels, and degree of autonomy evolve continuously through interaction and adaptation. For complex, novel technologies, the lack of clarity regarding which applications fall under the high-risk umbrella further hinders effective implementation. The use of a symbiotic system in a high-risk area can be for a low-risk accessory function, or the risk profile of that system may change dynamically through learning. Hacker suggests that, **"completely different AI risk profiles do indeed coexist within high-risk areas"** (Hacker, p.9). This observation underscores the inefficiency of the current regulatory mechanism, which mandates identical, stringent ex-ante compliance for all systems within a listed sector, irrespective of their actual contextual risk contribution. The static approach misdirects regulatory resources by treating all applications within Annexes II and III as uniformly high-risk. It means that if a symbiotic AI is used to arrange the doctor's appointments you are subjecting it to the same stringent requirements as a symbiotic AI that conducts operations. This is the misdirection of regulatory resources that is not in line with the Act's own risk-based logic. The fundamental discord between the deterministic regulatory structure and the dynamic nature of SAI is summarized in the following structural comparison:

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The Conflict Between Product Safety Model and AI Liability

Regulatory Model Feature	AI Act (Product Safety Foundation)	Symbiotic AI (Dynamic Liability Requirement)	Source of Governance Friction
Risk Assessment Trigger	Static, based on pre-set, fixed use-cases (Annexes II/III)	Dynamic, context-dependent, and evolving through continuous interaction	Misapplication of resources; failure to capture emergent, post-deployment risk
Civil Liability Principle	Strict liability for defective products (Revised PLD)	Need for harmonized fault-based liability (AILD withdrawal leaves vacuum)	Difficulty assigning fault and causality in non-contractual, distributed SAI processes
Governance Focus	Ex-ante conformity assessment and technical documentation	Continuous ethical assessment and real-time human-AI interaction monitoring	Risk of procedural compliance displacing ongoing ethical review and accountability

The Risk of Abstract Ethics: The last element of the governance gap is the human-centric potential for turning into a box-ticking exercise. The emphasis on ex-ante documentation, while necessary, carries the inherent risk that compliance efforts prioritize generating paperwork over genuinely embedding ethical considerations into the continuous socio-technical process. This procedural focus contrasts sharply with the understanding that the realization of Trustworthy AI is explicitly defined as a continuous process spanning the system's entire life cycle.

Carnevale et al. warn that an ethics solely based on following abstract principles is **"overly abstract and unnecessary,"** it doesn't give clarity or guidance and hence is very susceptible to being exploited [Carnevale, p.9-10]. This deficiency is amplified by the ambiguity in terminology, particularly the interchangeable use of keywords such as transparency, explainability, and interpretability within the regulatory interpretations, hindering the establishment of quantifiable fairness metrics. The AI Act's obligations such as impact assessment on fundamental rights have this risk if they are regarded just as procedural steps that hinder the integration of the living socio-technical process where the AI operation is a

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part.While Fundamental Rights Impact Assessments (FRIAs) are intended to be vital accountability tools, they risk becoming mere procedural hurdles if they focus only on the static design phase rather than requiring continuous monitoring throughout deployment. A procedural approach risks displacing embedded ethics by focusing compliance solely on the documentation of abstract fairness principles, rather than verifying the actual ethical robustness of the adaptive system over time.

This gap is especially deep in SAI where morals have to be present in the ongoing, real-time interaction, not just in the documentation done before deployment. The continuous interaction characterizing SAI demands continuous ethical assessment and monitoring, a principle supported by researchers developing tools like capAI, which seek to translate high-level ethics into verifiable, operational criteria throughout the AI system's lifecycle.To sum up, the concept of SAI reveals a profound conflict: the EU AI Act is trying to govern a dynamic, socio-technical phenomenon with a static, product-oriented toolkit.An argument will be presented in the next section that bridging this gap involves a fundamental change in regulatory method from a deterministic to a constructivist basis.

Results and Discussions

The examination above has highlighted an unequivocal and significant finding: a fundamental gap in governance exists between the regulatory framework of the EU AI Act and the practical and philosophically-informed realities of Symbiotic AI (SAI). This gap is a direct consequence of the AI Act's inability to reconcile the need for legal certainty—demanding fixed definitions and static risk assessments—with the intrinsic nature of advanced, adaptive AI systems that defy clear categorization and evolve unpredictably.The deterministic, product-safety-approach embodied within the Act is a major and notable advance in the regulation of specific AI systems, however, the complex, contextual, and socio-technical nature of human-AI symbiosis inherently trouble the core of regulatory processes embodied in the Act.

The outcomes from our investigation are crystallized around three essential tensions:

1. The Foundational vs. the Constructed: Attempting to find stable ontological

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ground for SAI, either in biology or a stable definition of intelligence, takes on philosophical challenges [Carnevale, p.4-6].

The difficulty in assigning a stable nature to AI, due to the insurmountable gap between artifacts and living systems [Carnevale, p.5], necessitates a conceptual retreat from regulating 'what AI is' to regulating 'how AI is made and used'. The AI Act, as a legal mechanism, necessitates clear definitions for regulation, however, SAI does not lend itself to clear-defined categorization.

2. Static rules vs. Dynamic systems: The AI Act assumes a static, use-case-based annexes mechanism to trigger high-risk obligations [Hacker, p.9], ultimately not fit for SAI systems whose functions, risks, and degree of autonomy can change continuously through interactions.

The inefficiency and resource misdirection caused by the static classification model confirms the failure of the deterministic model to govern emergent risks. The necessary approach must regulate the dynamism, not the fixed category.

3. Abstract compliance vs. Embedded ethics: The regulations encapsulated in the AI Act cautions against ex-ante conformity assessments being codes of practice that abstract ethics to a checklist of requirements that may or may not ensure ethical outcomes.

This tension highlights the need for continuous, process-focused compliance rather than a procedural box-ticking exercise, particularly in the complex realm of human-AI collaboration. The identified tensions compel the adoption of an alternative methodological lens to preserve the human-centric mandate.The constructivist approach offers this framework.We claimed that a constructivist model as defined by Carnevale et al. offers the required theoretical framework along with the practical toolkit to be a supplement to the AI Act's articles.The constructivist label captures the core idea that engineering choices in AI are deeply bounded by, and infused with, theories of intelligence, values, and socio-technical context, meaning AI is heavily a product of choices rather than a natural kind [Lea, G. R. (2020)].

Constructivism, by rethinking symbiosis not as a state already set but as a series of processes created through socio-technical interactions, can bring the much-needed adaptability, awareness of context, and distributed responsibility focus that the Act is missing. This emphasis on interaction aligns with concepts of social

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constructivism where the AI acts as a "More Knowledgeable Other" (MKO), scaffolding and co-constructing knowledge through dialogue and iterative refinement, fundamentally altering the traditional controller-tool relationship. To operationalize this constructivist mandate—shifting regulatory focus from the static product to the dynamic process—a concrete evaluation framework is required that can function within the existing compliance ecosystem.The evaluation framework of the FAIR project makes this theoretical approach operational by offering a comprehensive methodology for the assessment of the human-centric nature of SAI systems in their specific usage contexts. FAIR-AI (Framework for the Appropriate Implementation and Review of AI), developed by a multidisciplinary consortium of stakeholders including patients, providers, and developers, was specifically designed to bridge the gap left by frameworks that are often "overly theoretical, lack practical and actionable guidance". Its multidisciplinary nature ensures that the defined risk categories and transparency requirements (like the AI Label) are both legally compliant and practically relevant to the specific context of use[Wells et al. (2025)].

The dimensions indicated by the FAIR project (AI Model, Symbiosis, Data, Proportionality, Governance) should be integrated into AI Act implementation guidelines, particularly for the assessment of complex and adaptive AI systems. FAIR-AI requires a comprehensive evaluation across key risk categories: Development and Validity, Usefulness, Workflows and Human Oversight, Ethics and Equity, and Legal and Regulatory Compliance. This extensive scope ensures that compliance is not limited to technical documentation but includes ethical performance and contextual use.The framework's structure institutes the constructivist requirement for continuous ethical engagement. Specifically, for systems designated to move forward, a Safe AI Plan is developed, mandating continuous monitoring through a regular attestation by the business owner, which verifies alignment with the approved use case and ensures that underlying data and related workflows have not substantially changed[Wells et al. (2025)]. This requirement for documented attestation institutionalizes the concept of embedded ethics, shifting the legal focus from a one-time conformity check to a perpetual, auditable process. The table below maps the constructivist principles to the functional components of the FAIR-AI framework, illustrating how the

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theoretical approach can be practically integrated into the regulatory structure of the EU AI Act:

Mapping Constructivist Principles to the FAIR-AI Framework

Constructivist Principle	**FAIR-AI Evaluation Component**	**Regulatory Outcome for SAI**
Contextual Awareness	Inclusion/Exclusion Criteria, Usefulness, Workflows, and Human Oversight	Ensures assessment aligns with the specific socio-technical setting of deployment and use
Process Orientation	Continuous Monitoring and Business Owner Attestation Requirements	Shifts regulatory focus from initial deployment to lifecycle ethical robustness and risk management
Distributed Responsibility	Governance dimension, Clear Protocols, AI Label Transparency	Enables joint liability and accountability across the entire AI value chain (mandating downstream transparency)
Multidisciplinarity	Leveraging diverse stakeholders (patients, providers, developers)	Synthesizes legal, ethical, and practical expertise, combating the risks of abstract compliance

Conclusion

With the EU AI Act, the European Union has set out a monumental and pioneering example of how to frame the human-centric imperative of artificial intelligence in the form of binding law.Key to this is its risk-based, ex-ante regulatory architecture, which, according to our assessment, delivers a very important groundwork for the establishment of trust and protection of basic rights in the AI era. But, as it was presented in this article, the decisiveness of this product-safety-inspired regulatory model inherently entails a considerable governance void when confronted with the dynamic, contextual, and relational nature of Symbiotic AI (SAI). The difficulty of the Act in grappling with the very changeability of SAI at its core, the existence of a static classification system and

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the risk that ethics become an abstract form of compliance without any real world implications, are aspects that may result in the human-centric AI ecosystem to be postponed in the case of the most advanced forms of human-machine collaboration. The major insight from this examination is that overcoming this gap necessitates a radical change in the underlying methodology. We claimed that a constructivist model as defined by Carnevale et al. offers the required theoretical framework along with the practical toolkit to be a supplement to the AI Act's articles. Constructivism, by rethinking symbiosis not as a state already set but as a series of processes created through socio-technical interactions, can bring the much-needed adaptability, awareness of context, and distributed responsibility focus that the Act is missing.The evaluation framework of the FAIR project makes this theoretical approach operational by offering a comprehensive methodology for the assessment of the human-centric nature of SAI systems in their specific usage contexts. Hence, to make sure that the EU regulatory framework is still adequate and remains at the forefront globally, we list a number of recommendations for further policy work:

Support and Incorporate Constructivist Methods: In cooperation with standard-setting institutions such as CEN-CENELEC, the European Commission should provide guidance which encourages the implementation of assessment frameworks that are flexible and aware of the context. This guidance should explicitly endorse a shift towards governance that focuses on continuous ethical assessment and post-market monitoring, recognizing that static, ex-ante checks are insufficient for adaptive systems. The dimensions indicated by the FAIR project (AI Model, Symbiosis, Data, Proportionality, Governance) should be integrated into AI Act implementation guidelines, particularly for the assessment of complex and adaptive AI systems. The integration of these dimensions provides practical, auditable metrics for demonstrating compliance with the human-centric mandate, thereby resolving the risk that ethical obligations devolve into abstract, non-verifiable procedural steps.

The AI Act's AI Definition Needs a Clarification: Proposed law changes to the AI Act would benefit from a more accurate definition of AI, such as including **"a capacity to learn and adapt autonomously"** as pointed out by Hacker. By centering the definition on adaptive capacity, the regulation structurally

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prioritizes the systems most likely to engage in true SAI, thereby creating a necessary legal bridge between the static text of the Act and the dynamic reality of technology development. In this way, the Act's focus would be on the particular hazards of advanced AI, and simple automated software could be excluded from the scope of the law. This refinement immediately addresses the "Software Act" critique by ensuring regulatory resources are focused efficiently on the high-risk applications that pose emergent societal hazards, rather than being diluted by over-regulating simple rule-based systems. Besides, this would align the legal definition with those dynamic processes that the constructivist approach evaluates.

Safe Harbours and Codes of Conduct to Be Process-Focused: With the AI Act, Article 69 as the starting point, regulators can push forward the creation of sector-specific codes of conduct, which when given the green light, can serve as the safe harbour for the issuers from liability.Regulatory sandboxes, established under Article 57, provide an ideal controlled environment for testing and validating these process-focused codes of conduct and innovative AI systems for a limited time before market placement.[1] These sandboxes facilitate empirical learning, aligning with the concept of experimentalist governance by allowing the regulatory framework to evolve responsively. These codes should be evaluated not only in terms of the technical results but also the robustness of the defined processes for continuous ethical assessment, stakeholder engagement, and context monitoring—features of the constructivist approach, which should be at the core of the codes.Successful processes demonstrated in the sandbox environment can be formalized into these codes, providing legal certainty (safe harbour) based on dynamic, context-aware compliance, thereby resolving the abstract ethics critique. This ensures that the governance mechanism is designed to handle emergent risks inherent in complex, adaptive systems.

Improve AI Value Chain Governance: The primary task, commitment, or goal should be the enforcement of Article 28 regarding the AI value chain. Article 28 mandates that distributors, importers, or deployers may be treated as high-risk providers if they substantially modify the system or put their name on it, formalizing accountability across the supply chain. However, effective enforcement depends on robust contractual clarity.[12]In order to control the

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distributed responsibility that is characteristic of SAI, it is necessary to have clear, feasible measures for information-sharing protocols and joint liability models. Since SAI results in inherent sociotechnical interdependence, the legal framework must move towards legally supported joint liability models, particularly in the vacuum created by the withdrawal of the AILD proposal. Mandatory, detailed information-sharing protocols are essential for overcoming information asymmetry throughout the supply chain , promoting secure collaboration and visibility into models.

By doing this, the constructivist insight that responsibility is a chain running through the entire socio-technical system and not a single point within it, can be the legal basis. To sum up, the move towards a human-centric AI society is not accomplished by passing the AI Act; it only goes on to a new, more intricate stage.The EU, through the embracing of the constructivist paradigm, can hence evolve its oversight from that of a stationary rulebook for products to a dynamic framework that allows for responsible socio-technical practices. Acting like this will not only safeguard the Act's viability when there is rapid technological growth but also reaffirm the EU's position as a global lighthouse for a digital future that is innovative as well as human-centered without any doubt.

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