

EU AI Act

Fostering Agentic Al

March 2025



Contents



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Executive Summary





Risk Levels Matter

The EU AI Act doesn't regulate agentic AI itself—it regulates how it's used. Some uses are banned, some are high-risk, and others have fewer rules.



Humans Stay In Control

The Act emphasizes human oversight, while we see Guardrails as a promising approach to ensure safety.



Al Must Be Transparent

Agentic AI needs to explain its decisions. Companies must document how their AI works and make sure users understand it.



Global Impact

The EU's rules could become a global standard. Companies using agentic AI should follow them to avoid legal risks and access European markets.

Key Themes

Safeguarding Technological Advancements

The development of agentic artificial intelligence (AI), characterized by its autonomous decision-making capabilities, has catalysed profound transformations across industries. Amid the accelerating advancements in large language models and multimodal systems, the European Union (EU) has introduced the AI Act, a groundbreaking regulatory framework designed to govern AI's development and deployment.

Central to the Act is its risk classification approach, which categorizes AI applications based on their intended use and potential societal impact rather than the mere presence of agentic AI. This whitepaper examines the interplay between the EU AI Act and the evolving landscape of agentic AI, focusing on regulatory, ethical, business, and societal implications.



Agentic Al versus EU Al Act



Agentic Al

Autonomy: Operates independently, making decisions based on programming, learning, and environmental inputs.

Goal-Oriented Behaviour: Pursues specific objectives, optimizing actions to achieve desired outcomes.

Environment Interaction: Adapts strategies by perceiving and responding to changes in its surroundings.

EU Al Act

Autonomy: Article 14 ensures human oversight for high-risk AI systems, enabling monitoring and control to prevent risks to health, safety, or fundamental rights.

Goal-Oriented Behaviour: Article 13 mandates transparency, allowing users to interpret outputs and ensure alignment with intended objectives.

Environment Interaction: Article 9 requires a risk management system to assess and mitigate risks from Al systems' dynamic interactions with their environment.

Ethical and Societal Considerations

Beyond technical and regulatory aspects, the use of agentic AI raises ethical and societal concerns. Their deployment in sensitive areas such as law enforcement or education demands careful consideration of fairness, accountability, and inclusivity.

The EU AI Act emphasizes transparency, risk classification, and human oversight, ensuring that AI technologies enhance societal well-being without exacerbating inequalities or undermining fundamental rights.

Importantly, the use case—not the agentic AI capability itself—dictates risk classification, reinforcing the need for a balanced regulatory approach.

Moreover, global influence must be considered. If the European approach to agentic AI governance becomes a benchmark, it could shape international regulatory trends.



Introduction to Agentic Al



1 Input

Sensors

Control Centre

Effectors

Actions

Environment

Key Components

- Input: Data, instructions, or triggers originating from users or systems (e.g., API calls).
- Control Centre: The core decision-making hub, often powered by advanced AI models (e.g., LLMs, multimodal architectures).
- Actions: The outcomes executed by effectors, from physical movements to database updates.

- Sensors: Tools that collect environmental data, such as cameras, microphones, or API queries, providing additional context for decision-making.
- Effectors: Mechanisms that execute actions, including robotic arms, digital scripts, or software automation tools.
- 6 Environment: The ecosystem where Al operates, which could be physical (factories, logistics networks) or digital (cloud-based Al services).



Risks Specific to Agentic Al

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Non-Deterministic



Risk-First Approach

Fundamental Rights

Health & Safety

Type

Autonomy and Control

Automated decision-making may limit human oversight and intervention, impacting trust and accountability.

Complexity and Unpredictability

Highly adaptive models can produce varied outputs for similar inputs, posing challenges in safety-critical applications.

Flexible and Adaptive

Able to learn from data, adapt to new situations and handle uncertainty, often resulting in varied outcomes for similar inputs.

Limited Flexibility

May not account for individual nuances, potentially impacting fairness and equality.

Over-Reliance

Businesses may become overly dependent on agentic AI, failing to detect environmental shifts requiring different responses.

Predictable Behaviour

As models grow more complex, ensuring clear, interpretable decision-making becomes increasingly difficult.



Dos and Don'ts



DO



Ensure clear accountability structures for Al-driven decisions.



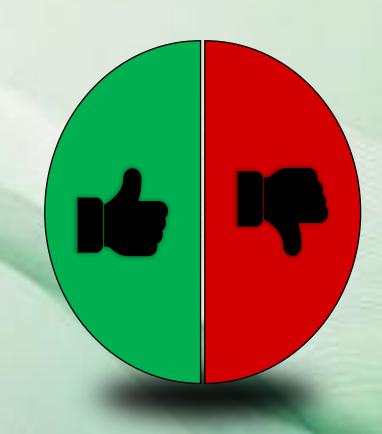
Implement riskadaptive governance that matches the use case classification.



Maintain transparency in agentic Al interactions with humans and systems.



Embed fail-safes that allow for human intervention when necessary.



DON'T



Assume that all agentic Al use cases fall into a single risk category—context matters.



Over-rely on agentic Al without clear human oversight mechanisms.



Neglect the broader ecosystem risks, such as Al biases and regulatory inconsistencies.



Treat agentic Al governance as identical to standard Al governance—it requires tailored approaches.



Appendix – Third-Party Opinions by Karushkov ...



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Opinion 1

The autonomy of an AI agent can significantly increase the benefits for the respective company that utilises it. In addition, the learning functionalities of the agent, and, say, its reasoning capabilities can easily turn out to be a competitive advantage from risk assessment standpoint. In any case, however, the AI agent needs to be subject to human oversight when addressing the European market. You may take a look at some video content on some AI related practicalities at my LinkedIn page

http://linkedin.com/in/mitkokarushkov-3533882.



Opinion 2

The risk assessment, as far as AI agents are concerned, shall be seen in two main directions, as follows: first, the risk assessment capabilities of the agent itself, and, which is crucial - the reliability of the results such risk assessment functionalities. The other main direction is the risk status of the AI agent. This is to be carefully considered from the standpoint of the relevant market and societal sector, as well as from the functionalities and interface perspectives. In parallel, it is vital to estimate which statutory risk category the AI agent corresponds to. For details on such or similar regulatory or compliance solutions, please contact US at: sofia@karushkov.com, or visit our website: www.karushkov.com.

"One aspect involves looking at the risk status of the AI agent." Karushkov







Introduction

The EU AI Act: A Risk-Based Framework for Responsible Innovation

'Dynamic risk classification needed'

"As AI Agents evolve, their classification under the EU AI Act will shape their adoption. Clear, adaptable frameworks are key to ensuring both innovation and compliance in this fast-moving landscape."

Patrick Orsos, Managing Director, mgoIT



Introduction to Agentic Al

2. Evolution of AI Agents

'Paradigm shift in concept of legal identity'

"Al agents test the boundaries of current legal models. They are less creatures of the law of agency and better analysed through legal concepts of identity. If your agent is you – how will you ID and control it?."

Charles Kerrigan, Partner, CMS UK



Risks Specific to Agentic Al

Risks posed by AI Agents

'Al Governance framework recalibration needed by boards'

"Boards and C-suites must recalibrate AI governance frameworks to address the complexities of multiagentic AI, ensuring regulatory consonance while fortifying cyber-ethics resilience against adversarial exploits and liability exposure."

Prof. Ingrid Vasiliu-Feltes, MD EMBA, Founder and CEO, Institute for Science, Entrepreneurship and Investments







Risks Specific to Agentic Al

Risks posed by AI Agents

'Autonomous nature necessitates human oversight'

"Agentic AI's key risk is losing human control, leading to unpredictable, self-directed actions misaligned with human goals. This starts with the wrong input of data and complete lack of correcting and aligning the AI to perform as it should be."

Michael Boevink, Founder, Boevink Group



Risks Specific to Agentic Al

Risks posed by AI Agents

'Trust forms the bedrock of responsible AI'

"Al transparency is the cornerstone of trust. By making Al systems understandable and accountable, we ensure ethical use, foster innovation, and build a future where technology unequivocally serves humanity's best interests."

Colin Crone, Director, ISOCO(UK) Ltd



Conclusion

Ethical and Societal Considerations

"Unaffordable not to keep a human-in-the-loop"

"Keep an expert human in the loop to monitor and control the Al agent to make sure it does not cause harm. In 2012, Knight Capital Group suffered a \$440 million loss within ~30 minutes due to a malfunctioning algorithm."

Doug Hohulin, Business Associate, Al & Partners







Introduction to Agentic Al

2. Evolution of AI Agents

'Sustainability supported by societal-focused Agentic solutions'

"Sustainability is the cornerstone of future progress—innovative solutions must harmonize economic growth with environmental responsibility. Embracing green technologies and ethical practices today ensures a thriving, resilient world for generations to come."

Lisa Ventura MBE, Founder, Cyber Security Unity



Introduction

The Role of Large Language and Multimodal Models

'Define clear human intervention points'

"Ensure AI decision-making is interpretable, allowing users to understand suggestions. Define clear human intervention points and implement a 'Human-in-the-Loop' review for critical decisions to enhance transparency and accountability."

Nadine Soyez, Founding Partner & Al Accelerator, Designing Al Heroes



Risks Specific to Agentic Al

Risks posed by AI Agents

'Risk-based analysis of agents facilitates an Agent Economy'

"The EU AI Act has potential to facilitate the agent economy by encouraging risk-based analysis of the wide variety of agents that will appear, promoting public confidence. The challenge is to avoid impeding the agent economy through excessive regulation. The EU AI Office has the opportunity to chart a course that favors the former while avoiding the latter."

Maury Shenk, Founder & CEO, LearnerShape







Risks Specific to Agentic Al

Risks posed by AI Agents

'Regulation accelerates Agentic Al adoption'

"The EU AI Act not only regulates AI but also accelerates its adoption—AI Agents, when classified appropriately, can drive innovation while mitigating risks, ensuring responsible deployment amid evolving large-language and multimodal advancements."

Anandaday Misshra, Founder & Managing Partner, AMLEGALS



Implementation Steps

10 Dos and Don'ts for Agentic Al

'Al Literacy complements risk-management protocols'

"Company should provide training course to all staff about the risk-classification of AI including forbidden practise. This should be part of AI-Literacy and implemented in the training process of the company."

Ina Schöne, Founder, Data Privacy and Al



Risks posed by AI Agents

'Risk-based approach needed for multimodal healthcare AI agents'

"The EU AI Act fosters reasonable oversight for AI agents, ensuring safe deployment while mitigating risks—especially for high-risk models like multimodal healthcare AI agents, where transparency and accountability are crucial for trust and safety."

Osama Al-Zadjali, CEO, AFAQ AI









Risks Specific to Agentic Al

Risks posed by AI Agents

'Al Agents with ethical safeguards unlock new opportunities'

"Al agents are not just about automation—they amplify human capabilities, unlocking new opportunities for creativity and problem-solving. Companies that prioritize ethical Al adoption will lead the future of innovation and trust."

Hande Ocak Başev, President, WSI London



Conclusion

Regulatory Perspectives

'Safeguards a prerequisite to AI Agent adoption in healthcare'

"Healthcare seeks to become more proactive. Agentic Al systems, where agents can be additional members of the healthcare team, could help to promote this transition so long as appropriate safeguards are in place."

Guy Parsons, Clinical AI Expert and Digital Health Advisor



Implementation Steps

10 Dos and Don'ts for Agentic Al

'Value lies in developing risk-aligned agentic solutions'

"It is imperative to develop methods that enable AI Agents to provide benefits universally while maintaining acceptable levels of risk."

Jonathan Osborne, Associate Director, Cognizant







Risks Specific to Agentic Al

Risks posed by AI Agents

'Autonomous nature demands greater transparency'

"By definition agentic systems have agency - some freedom in how they operate. So, it's vital that every model output in an agentic system is transparent, explainable and contestable."

Mike Oaten, CEO, Tikos



Introduction to Agentic Al

2. Evolution of AI Agents

'Server-based AI systems can achieve sustainability goals'

"At Leafcloud, we redefine this problem as an opportunity. By placing server-based AI systems directly in buildings, we utilize the generated heat for water and space heating. This circular model not only reduces total CO2 emissions but also creates cost effective cloud."

David Kohnstamm, Founder, Leafcloud





Thanking Our Corporate Partners

























































<u>Anandaday Misshra</u>, As a legal professional with over 27 years of experience, Anandaday Misshra specializes in data privacy, artificial intelligence, Goods and Services Tax (GST), international arbitration, international laws, and strategic dispute resolution across diverse jurisdictions. My career is dedicated to assisting organizations in navigating the complexities of legal compliance within an ever-evolving regulatory landscape.

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Colin Crone, Colin Crone is a seasoned expert in artificial intelligence frameworks currently serving as the Director at ISOCO(UK). With extensive experience in implementing and auditing management systems, Colin specialises in ISO 42001, Al management systems. His expertise extends to security, resilience, risk assessment, and treatment. He is also an panel of experts memeber with BSI and ISO, contributing to projects and standards development in Al (editor of ISO/EIC 8183 Artificial intelligence — Data life cycle framework) and cybersecurity. Colin's work is driven by a commitment to ensuring that businesses can operate transparently and securely, even in the face of difficult times.

<u>Daniel Ballin</u>, Daniel Ballin is a versatile professional who has launched large scale ventures and award winning products, from conception to final deployment and ownership. Highly motivated and a confident communicator at all levels, with a proven record of innovative thinking and of delivering commercial and technical solutions to meet complex customer requirements in existing and nascent markets. I have consistently led innovative products through a successful of balance of structure and creativity, whilst understanding what is important to the customer and end-user





<u>David Kohnstamm</u>, David Kohnstamm is the co-founder, resident thermodynamics expert, and Chief Sustainability Officer at Leafcloud, where his expertise in servers and thermal dynamics plays a pivotal role in shaping the company's vision and the design of Leaf sites. His work focuses on transforming server heat into a reusable resource, leveraging his background as an engineer with a passion for building and innovation. David's journey into the tech world began in engineering, building solar boats and electric bikes. He then transitioned to energy management, arriving at the intersection of IT hardware and thermal management through trialing various immersion cooling solutions. Captivated by the potential of reusing server heat on a large scale, he co-founded Leafcloud in 2019 to bring this vision to life. David's innovative approach and dedication to sustainability have not only propelled Leafcloud forward but also made him a sought-after speaker at industry events worldwide. His insights and the company's groundbreaking work have been featured in the documentary "Clouded II: Does Cloud Cost the Earth?", highlighting the environmental impacts of cloud computing. Outside of his professional endeavors, David is an avid cycle-smith, a proud father of two, and enjoys board games.

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<u>Ginés Sánchez</u>, Ginés Sánchez is an Industrial Engineer with eight years of experience in tech startups as both an operator and investor. Passionate about innovation, he has supported and scaled multiple ventures. Now, Ginés is focused on redefining Al for a sustainable and trustworthy future, merging technology with impact to drive positive change.

<u>Guy Parsons</u>, Guy Parsons has over a decade of experience as a clinician, researcher, and leader in healthcare, Guy is passionate about delivering a healthier future for the world. Driven to realise the transformative power of technology in global healthcare he has built and led international teams to develop safe and effective clinical AI for implementation at scale.

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Prof. Ingrid Vasiliu-Feltes, MD EMBA, Prof. Dr. Ingrid Vasiliu-Feltes is a visionary leader operating at the intersection of academia, business, government and not-for-profit sectors, recognized globally for her deep tech diplomacy and digital ethics efforts. With over two decades of executive experience, she has held numerous high-impact leadership roles and has extensive complex system integration expertise, driving the development of responsible, inclusive, diverse, sustainable AI, blockchain and other deep tech innovation ecosystems at a regional, national or international level. Her unique background positions her as a thought leader on how emerging or frontier technologies are posing unique ethical challenges and are reshaping law, regulatory frameworks, corporate governance, risk management, compliance and enterprise digital strategy. She is an alumna of MIT, Harvard, Stanford, Columbia University, and University of Miami's Herbert Business School. She is a Lean Six Sigma Master Black Belt, holding executive certifications in AI, Blockchain, Finance, Mediation, Tech Diplomacy, Human Rights, and Ethics. She has served as an expert advisor to numerous Fortune 100 and 500 companies, US DOD, IEEE, NIST, and EU, UN or G20-affiliated organizations, guiding them on strategic decisions around digital transformation, digital risk governance, digital trust, and digital cyber-ethics orchestration."





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Zafar Imran, Zafar Imran has a track record of successfully managing Value Engineering teams & Cloud Adoption for customers. Successful track record of helping 500+ customers in the EMEA, ECEMEA & APAC region towards their Digital Transformation projects across Public, MRD, CMUT, Oil & Gas, E& C, FSI industries. Zafar Imran has 30+ years of experience with global organizations and MNCs in APAC, EMEA and ECEMEA.





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Utilising top-tier research data



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