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Navigating AI in the UK and EU markets

Roadmap to help you to navigate the divergent approach to the regulation of AI across the UK and EU

January 2023

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Contents

Introduction

Artificial Intelligence (AI) has rapidly evolved around the world without a clear agenda underpinning its development.

Lately, there has been an increased acknowledgment of the need to support innovation with proper procedures and regulations. In this document we have set out an overview of the UK and EU markets' existing and upcoming regulatory frameworks.

The information in this publication is accurate as of 24th January 2023.

Regulation of AI in the UK

Regulation of AI in the UK

UK Government Policy

[in discussion]

Key takeaways:

The Government's aim is not to define AI but instead to propose a number of core principles to require developers and users to ensure that: AI is used safely, AI is technically secure and it functions as designed, there is appropriate transparency, an identified legal person is responsible for AI, and that its use complies with guidance issued by regulators. The Government's plan is for each of the individual sector regulatory bodies to issue sector-specific guidance, to try to prevent unnecessary restrictions.

Applies to:

- Developers, public and commercial users of AI within the UK on a sector by sector basis.

"Pro-Innovation Approach":

- The approach aims to drive business confidence, promote investment, boost public trust and ultimately drive productivity across the economy.

- The framework will be context-specific, pro-innovation and risk-based, coherent, and proportionate and adaptable.

- Examples of sectors where the pro-innovation approach is being discussed in its application focus on financial services, legal and medical sectors.

- The UK Government is set to publish a White Paper in early 2023, setting out its pro-innovation approach to AI governance.

Financial Services:

The UK's principles-led approach to financial services regulation, which is less prescriptive and more adaptive in nature, can be interpreted to incorporate AI. However, in the absence of substantive AI case law, to support compliance, businesses await practical guidance from the regulators. The PRA and Financial Conduct Authority (FCA) are yet to deliver official guidance but the FCA is in consultation on the subject until 10 Feb 2023.

Life sciences and medical devices:

The Medicines and Healthcare products Regulatory Agency (MHRA) announced the 'Software and AI as a medical device' change programme in 2021. Prioritising safety for the patient, its regulatory focus includes providing clear requirements for AI device manufacturers and ensuring manufacturers can demonstrate compliance. Transparency is key, but can only be achieved if the AI language after a period of learning can still be interpreted by humans. Likewise it will be challenging to measure outcomes from the AI not least because human application will be person-specific.

Regulation of AI in the UK

National AI Strategy

[presented to Parliament Sept 2021]

Key takeaways:

The strategy will be a three pillar approach - the 3 main aims of the strategy are to invest and plan for the long-term needs of the AI ecosystem, support the transition to an AI-enabled economy, and ensure the UK gets the national and international governance of AI technologies right.

Applies to:

- The public

- UK businesses in all sectors (who might benefit from the adoption of AI)

- Scientists, researchers, entrepreneurs, innovators who build, and use AI technologies in the UK

"Pillar 1: Invest in the long-term needs of the AI ecosystem":

- Seeks to maintain the UK's position as one of the global AI superpowers

- Ensures the UK continues to lead in the research, development, commercialisation and deployment of AI

by investing, planning, securing, unlocking the key inputs that support AI innovation.

"Pillar 2: Support the transition to an AI-enabled economy":

- Captures the benefits of AI innovation in the UK

- Ensures AI technologies benefit all sectors and regions

by the Government backing up the domestic design, development of new AI technologies, pushing British businesses to adopt these, and commercialising them into products and services.

"Pillar 3: Governing AI effectively":

- Ensures the UK gets the national and international governance of AI technologies right

- Seeks an effective governance regime that supports scientists, researchers and entrepreneurs to innovate

by leading to deploy a safe and ethical AI framework which governs its own use of the technology.

Regulation of AI in the UK

UK GDPR

[in force]

Key takeaways:

UK GDPR applies to organisations that process personal data. In terms of AI, there is the potential for making decisions from data solely based on automated means without any humans being involved, or for profiling purposes. Article 22 of the UK GDPR sets out additional provisions on those organisations which carry out solely automated decision-making, including profiling, that have legal or similarly significant effects in order to protect individuals from those activities.[1]

Applies to:

- Automated individual decision-making

- Profiling

Exceptions:

Automated decision-making and profiling can only be conducted where the outcome is:

- Necessary for the entry into or performance of a contract; or
- Authorised by domestic law applicable to the controller; or
- Based on the individual's explicit consent.

If any of the processing falls under Article 22, ensure that:

- Individuals are informed about the processing;
- Simple procedures are in place to request human input in the decision-making or challenge a decision;
- Regular checks are carried out on the systems to make sure these work as intended.

In 2021 the government launched a **consultation** that included the possibility of removing Article 22. The vast majority of respondents opposed the proposal to remove Article 22, noting that the right to human review of an automated decision was a key safeguard. The government decided not to remove, but instead to consider adaptations to Article 22 to clarify the circumstances in which the Article must apply and cast it as a right to specific safeguards as opposed to an outright prohibition.

[1] *Relevant ICO guidance on this topic is here: Rights related to automated decision making including profiling | ICO.*

Regulation of AI in the EU

Regulation of AI in the EU

The Artificial Intelligence Act

[final text adopted 6 Dec 2022]

The scope of the Act is wide, covering a variety of technologies that can generate outputs such as content, predictions, recommendations, or decisions influencing 'environments they interact with'. It prioritises data governance and quality and human oversight capabilities pre-and post-market.

Key takeaways:

Organisations will need to consider what category of risk their AI technology falls into and then take appropriate action. Technologies / AI systems that fall within the 'unacceptable' risk category will be banned under the AI Act.[2]

Applies to:

- Providers of AI systems in the EU.

- Non-EU organisations that supply / provide AI systems into the EU.

- Users of AI systems who are located within the EU.

Risk based approach:

- **Unacceptable Risk** – AI systems creating unacceptable risk are banned. These types of AI include use of real-time remote biometric identification systems in publicly accessible spaces by law enforcement except where strictly necessary for a narrow range of purposes. Another example of this type of AI is using subliminal techniques to materially impact on an individual's behaviour that causes or is likely to cause harm. Using these AI systems can result in a fine of up to 6% of global revenue or €30m.

- **High Risk** – These types of AI include use in critical infrastructure, education, product safety, employment rights and law enforcement. A conformity assessment is required and organisations will be subject to additional obligations, including record keeping, human oversight, cybersecurity, risk management system, data requirements and post market monitoring. Failing to implement these obligations can result in a fine of up to 4% of global revenue or €20m.

- **Limited Risk** – Providers will need to inform users that they are engaging with AI. Failing to comply with this transparency requirement can result in a fine of up to 4% of global revenue or €20m.

- **Minimal Risk** – No additional requirements – these types of AI can be freely used.

[2] *Summary of the regulatory framework proposal is here: Regulatory framework proposal on artificial intelligence | Shaping Europe's digital future (europa.eu).*

Regulation of AI in the EU

The AI Liability Directive

[awaiting Committee decision]

Key takeaways:

Designed to work hand-in-hand with the AI Act, the AI Liability Directive is intended to put in place a framework addressing responsibility (and the availability of compensation) for harm caused by AI.

Applies to:

- The proposed Directive covers national liability claims based on the fault or omission of any person (providers, developers, users), for the compensation of any type of damage covered by national law and for any type of victim (individuals, companies, organisation etc).

- The proposed Directive does not apply to contractual or criminal liability.

Why do we need it?:

- Guarantees must be put in place alongside technological advances to ensure EU consumers benefit from the highest standard of protection.

- Current national liability rules are not equipped to handle claims for damage caused by AI-enabled products and services.

- Provides greater certainty to businesses utilising AI technology around what types of claims and compensation are possible.

- It will include damage caused by AI systems, irrespective of whether they are **High Risk** or not according to the EU AI Act (once implemented).

Regulation of AI in the EU

Revised Product Liability Directive

[proposed, expected late 2023]

Key takeaways:

The new proposal adds provisions requiring business to disclose evidential information that a claimant would need to prove their case in court, but includes safeguarding to ensure the protection of trade secrets. It also lays down the updated rules for businesses operating through circular business models.

Applies to:

- All products as well as software updates

Why do we need it?:

- Growing tendency of consumers purchasing products directly from non-EU countries without there being a manufacturer/importer based in the EU.

- Directive ensures there should always be a business or legal representative based in the EU that can be held liable for defective products bought directly from manufacturers outside the EU. This approach aims to create a "more level playing field"[3] between EU and non-EU manufacturers.

- Lays down rules for businesses operating through circular business models.

[3] *New liability rules on products and AI to protect consumers (europa.eu).*

Regulation of AI in the EU

EU GDPR

[in force]

Key takeaways:

EU GDPR establishes that individuals have the right not to be subject to a decision based solely on automated means, if the decision produces legal effects concerning individuals or significantly affects individuals in a similar way. Algorithm-based decisions may not make use of special categories of data, unless individuals have given consent or the processing is allowed by EU or national law. Organisations must, at least, inform individuals of the right to human intervention and make the required procedural arrangements, as well as allow to express individuals' point of view and inform individual's right to challenge the decision.[4]

Applies to:

• Automated individual decision-making

• Profiling

Exceptions:

• This type of decision-making may be allowed if the use of algorithms is permitted by law and suitable safeguards are provided.

• The decision is necessary, i.e. there must be no other way to achieve the same goal to enter or perform a contract.

• Individuals give explicit consent.

In both instances, the decision taken needs to protect your rights and freedoms, by implementing suitable safeguards.

[4] *Relevant European Commission guidance on this topic is here:* *Can I be subject to automated individual decision-making, including profiling? (europa.eu).*

Regulation of AI in the EU

EU Data Governance and Data Act

[in force]

Key takeaways:

Seeks to increase trust in data sharing, strengthen mechanisms to increase data availability and overcome technical obstacles to the reuse of data.

Applies to:

- EU citizens and companies

Why do we need it?

- Make more data available and enable data sharing across sectors and EU countries.

- Leverage the potential of data for the benefit of European citizens and businesses.

- Powerful engine for innovation and new jobs.

- Society as a whole will benefit from more evidence-based policies and better solutions to common challenges.

- Businesses will benefit from costs reduction for acquiring, integrating and processing data, and from lower barriers to enter markets. They will also see a reduction in time-to-market for innovative products and services, which will enable small and large firms to develop novel data-driven products and services.

Timeline

EU / UK

Early 2023

UK Government White Paper due, setting out its pro-innovation approach to AI governance.

September 2023

EU Data Governance Act will apply from September 2023.

2023/2024

Expect EU Revised Product Liability Directive and AI Liability Directive in force.

2023/2024

AI Act expected to become EU law but with 2-3 year grace period before fully enforceable

10 February 2023

FCA's consultation closes for feedback.

Throughout 2023

AI Act steps: Draft report, Committee vote, Trilogue, Plenary vote to take place before Act can be adopted.

2025-2026

Transition period ends for the proposed EU AI / Product Liability Directives - Member states have 2 years to implement into national law.

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Links: *National AI Strategy - GOV.UK (www.gov.uk).*   *European Data Governance Act | Shaping Europe's digital future (europa.eu).*
Liability Rules for Artificial Intelligence (europa.eu).   *The European Commission proposes revision of the Product Liability Directive -*
Ecommerce Europe (ecommerce-europe.eu).   *Artificial intelligence act | Think Tank | European Parliament (europa.eu).*

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