European Commission Outlines Proposed Regulation for Artificial Intelligence

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Proposed Regulation for Artificial Intelligence

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The feedback period for the European Commission (EC) proposal for the Regulation of artificial intelligence (AI) (COM (2021)206) (proposed Regulation) closed on 6 August 2021, during which time 304 pieces of feedback were received, marking another milestone in pursuit of the first EU legal framework specifically focused on AI.

The proposed Regulation follows the EC's strategy for AI, as outlined in its coordinated plan on Artificial Intelligence for Europe in 2018 and its AI White Paper in 2020. The proposed Regulation seeks to balance the safety and fundamental rights of EU consumers while improving the AI investment and innovation landscape. Although the proposed Regulation may change significantly before its entry into force, entities that use (or plan to start using) AI should be prepared to comply with a comprehensive regulatory framework in Europe.

Who will the proposed Regulation apply to?

The proposed Regulation will employ a risk-based approach to the controls it will place on the use of AI systems, depending on the intended purpose of the AI system and apply directly to all Member States. It defines AI as "software that is developed with one or more of […] techniques and approaches […] and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with". The EU considers that this definition should prove pragmatic and flexible as technologies advance over time.

The proposed Regulation will apply as long as the AI system is placed on the EU market or its use affects people located in the EU. Specifically, the proposed Regulation applies to:

- AI system providers that place AI systems on the market or into service in the EU irrespective of the place of establishment of such providers
- Users (i.e., consumers) of AI systems located in the EEA
- AI system providers and users located in a third country, where the output of the AI system is used in the EU

The proposed Regulation is potentially far-reaching, containing obligations for AI system providers and users alike, and will have implications for a large number of companies operating in or selling into the EU.

A risk-based approach

The proposed Regulation categorises uses of AI systems by risk to individuals. The risk categories are on a sliding scale, from "Minimal Risk" to "Unacceptable Risk." The below non-exhaustive list shows the broad scope of society that may be impacted by "high risk" AI (from a person's interaction with emergency services to visa applications), and highlights the broad scope of businesses that will need to understand and comply with the proposed Regulation when it comes into force.

Categories and Treatment of AI Systems Under the Proposed Regulation			
Category	**Definition**	**Defined Scope**	**What the proposed Regulation requires**
Minimal Risk	AI systems that present a minimal risk to users' rights or safety, and do not fall in any other risk category	• Examples include AI-enabled spam filters • The EC notes that "the vast majority" of AI systems will fall into this category	No specific requirements
Limited Risk	AI systems that pose specific manipulation risks, and do not fall into the High Risk or Unacceptable Risk categories	AI systems used to and/or for the purposes of: • Interacting with individuals • Detecting emotions or determining association with (social) categories based on biometric data • Generating or manipulating content (e.g., "deep fakes")	Providers should make users aware that they are interacting with and/or viewing content generated by an AI system

Categories and Treatment of AI Systems Under the Proposed Regulation

Category	Definition	Defined Scope	What the proposed Regulation requires
High Risk	AI systems that are deemed a high risk to the health and safety or fundamental rights of individuals	AI systems used to and/or for the purposes of: • Producing safety components of products subject to third-party ex ante conformity assessments (e.g., toys, medical devices, and protective equipment) • Using remote biometric identification in public spaces • Managing and operating essential public infrastructure networks, such as supply of utilities • Providing emergency first response services, e.g., firefighters and medical aid • Accessing educational and vocational training institutions • Recruiting (e.g. screening or filtering applications, or evaluating candidates in the course of interviews or tests) • Evaluating creditworthiness • Evaluating the eligibility for public assistance benefits • Producing assessments or predictions for evidence in the investigation, detection or prosecution of a criminal offence • Predicting the occurrence of crimes or social unrest • Examining asylum and visa applications • Assisting judges at court (with the exception of ancillary tasks) • Other high risk AI systems as added by the European Commission following the pre-defined criteria and process	Providers must comply with certain restrictions and requirements. For example, providers must: • Undergo a conformity assessment of the AI-system (either by a third party or undertaken as a self-assessment) • Have adequate risk assessment and mitigation systems • Keep detailed documentation • Maintain appropriate human oversight • Ensure a high level of robustness, security, and accuracy • Consider that they may be required to notify an independent body • Be registered in an EU database before a declaration of conformity is signed, after which the AI system bears the "CE marking". This certification process must be repeated if any substantial changes occur • Be subject to ongoing monitoring (i.e., after the high-risk AI system is on the market) by various supervisory authorities (including a newly created European Artificial Intelligence Board (AI Board)) of their compliance with the proposed Regulation, while in parallel providers and users may report serious incidents These stringent requirements are intended to will help to ensure transparency for both users and supervisory authorities, while high evidentiary requirements will help ensure the "trustworthiness" of AI that the proposed Regulation seeks to build. On the other hand, the compliance burdens of providers of high-risk AI systems will increase, and businesses using these systems will need to ensure their compliance with the proposed Regulation, or face potentially significant penalties (as discussed below).

Categories and Treatment of AI Systems Under the Proposed Regulation

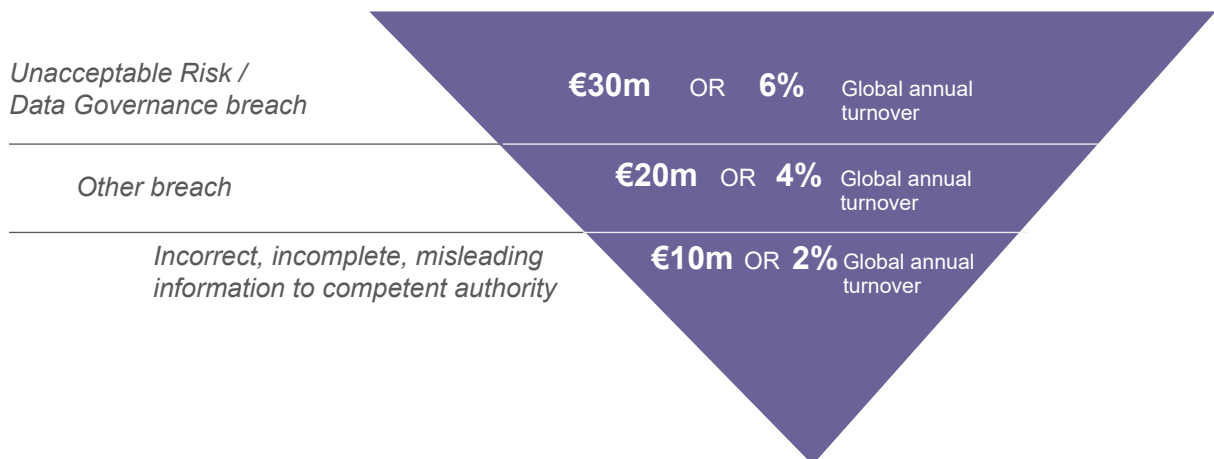| Category	Definition	Defined Scope	What the proposed Regulation requires
Unacceptable Risk	AI systems that are considered a clear threat to the safety, livelihood, and rights of individuals	AI systems used to and/or for the purposes of: • Manipulating human behaviour or circumventing free will • Exploiting or manipulating individuals to target their vulnerabilities or special circumstances • Contributing to governmental social scoring • Using biometric identification in publicly accessible spaces for law enforcement purposes (subject to certain exemptions)	Prohibited

AI Board and AI supply chain

The proposed Regulation introduces the AI Board and provides for oversight by national supervisory authorities, as well as providing for post-market monitoring and market surveillance requirements. The AI Board, chaired by the EC, will be able to assist in collaboration, ensure uniformity of practices, and issue guidance to national supervisory authorities.

The proposed Regulation imposes obligations on certain authorised representatives who are mandated by providers outside the EU (e.g., to keep and provide information and documentation on request by a national supervisory authority) and any users, importers, distributors, or involved third parties of the AI system. As such, the proposed Regulation covers the entire AI chain in some way.

Enforcement

The proposed Regulation sets forth the following tiers of fines:

Unacceptable Risk / Data Governance breach	**€30m** OR **6%**	Global annual turnover
Other breach	**€20m** OR **4%**	Global annual turnover
Incorrect, incomplete, misleading information to competent authority	**€10m** OR **2%**	Global annual turnover

Notably, the highest of these fines is higher than the penalties of up to 4% of global annual turnover under the General Data Protection Regulation (GDPR). This level of penalty is intended to ensure that all entities involved in bringing AI systems to the public pay significant attention to the proposed Regulation. Upon implementation of the proposed Regulation, entities are likely to spend more time and resources on ensuring AI compliance throughout their business units and supply chains. In some cases, particularly where high-risk AI systems are involved, entities will likely employ specific AI compliance officers to oversee AI-related activities.

The response so far and next steps

While it is important for businesses to understand the proposed Regulation as currently drafted, tracking the proposed Regulation's development will be equally critical. European bodies have already considered the proposed Regulation, and have noted a variety of concerns and recommendations, which may have a tangible impact on the final form of the proposed Regulation.

Though the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) "strongly welcomed" the overarching purpose of the proposed Regulation, the bodies published a joint opinion expressing some concerns. The opinion warned that the exclusion of international law enforcement co-operation may result in circumvention of the regime, whilst recommending that the proposed Regulation clarify the application and alignment of the proposed Regulation's scope with EU data protection frameworks.

The Council of the European Union (the Council) also published a progress report on 18 June 2021 in consideration of the proposed Regulation. The report noted that in particular that, whilst it identified general support among the Member States for the proposed Regulation's objectives, the definition of AI systems may be too broad (perhaps inappropriately including more traditional software systems in its scope) and that the definition of high-risk AI systems (see: A risk-based approach above) should be more tightly defined. The Council noted that for both issues, discussions and debate is still ongoing with national experts.

Now the feedback period has elapsed, and whilst the EC considers the feedback received, the proposed Regulation will be further considered by the European Parliament (specifically assigned to the Committee on Internal Market and Consumer Protection), Member States, and a large number of stakeholders. Following this, the European Parliament and Member States will need to adopt the proposal as law. Once adopted, the proposed Regulation will be directly applicable across the EU. The content of the proposed Regulation will not likely be finalised for a number of months, while the co-legislators and the Commission discuss and agree on its text. While no clear timeline has been set, the EC has allowed for a 24-month transition period for compliance following finalisation.

The UK and AI

The proposed Regulation will not apply directly in the UK following Brexit, but will apply to UK residents de facto. The proposed Regulation will apply if an AI system is placed on the EU market or its use (or output) affects people located in the EU.

The UK government's legislative approach to AI Regulation is currently unknown. However, given its recent publications and statements on AI Regulation (see below), the government is unlikely to elect to adopt some or all of the proposed Regulation into UK law to remain in line with the EU. The government has made clear that it sees the UK's competitiveness in fostering development in AI systems as critical to the economy (with the recent AI Counsel Roadmap report identifying AI as delivering an estimated 10% increase in UK GDP by 2030), and it identifies that public trust in AI lies at the heart of this. But the government recently indicated that it does not necessarily consider that a new, wholesale AI regulatory framework is required, and has instead focused on reviewing deficiencies in existing Regulations. For example:

- On 22 September 2021, the UK government published its national AI strategy. The strategy sets out a 10-year framework to drive national innovation and growth in AI, and is focused on three pillars: investment in the AI ecosystem; supporting the transition to an AI-enabled economy; and effective national and international governance for AI. The strategy includes plans for a white paper on pro-innovation AI governance and Regulation, expected in early 2022, and a consultation on copyright and patents for AI.

- Earlier in September 2021, the UK government launched a wide-ranging consultation on reform of the UK data protection regime, which seeks views on a number of proposals to reduce the regulatory burden on using personal data for AI development, testing, and implementation.

- In March 2021, the UK Intellectual Property Office (IPO) published the consultation outcome following its Call For Views in 2020 on AI and intellectual property (IP). This outcome demonstrated the UK government consideration of developing and adapting existing IP legislation to align with developments in AI technology, rather than legislate on AI independently. For more information, please see Latham's blog post on the consultation outcome.

- In December 2020, the House of Lords' Liaison Committee published a report titled AI in the UK: No Room for Complacency. The report suggests that identifying gaps in AI Regulation rather than developing a new regulatory framework is preferable.

- In May 2020, the ICO published guidance titled "Explaining Decisions Made with AI". This was followed in July 2020 by the ICO's Guidance on AI and data protection, which aims to assist organisations with ensuring compliance with data protection law when developing and deploying AI technology. Beyond this, the ICO has produced a range of guidance on the data protection implications of AI.

Latham & Watkins will continue to provide updates on the regulation of AI in the UK and the EU. Follow the firm's Latham.London blog for the latest news.

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