

TOWARDS A EUROPEAN LEADERSHIP ON TRUSTWORTHY ARTIFICIAL INTELLIGENCE?

How to find the right balance between innovation and fundamental rights in the “AI Act”

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Abstract

In April 2021, the European Commission presented its AI package. This package consists of a Communication on Fostering a European Approach to Artificial Intelligence, the Coordinated Plan with Member States: 2021 Update, and a proposal for an AI Regulation laying down harmonised rules for the EU (Artificial Intelligence Act).

In the following pages, firstly, the increasingly prominent role of AI technology in different fields and sectors is discussed with a specific focus on its potential from an economic point of view. Secondly, the current role of EU in the global race for artificial intelligence is explained through a comparative analysis of the three main players - the United States, China and the EU. The comparative analysis takes into consideration several factors such as the regulatory model, amount of private and public investment in the field, number of publications and AI patents registered.

Thirdly, the European regulatory framework on AI is briefly outlined by recalling and discussing the main milestones until 2020. Finally, the new Artificial Intelligence Act (AI Act) presented by the European Commission in April 2021 is explained and discussed. The proposal has been regarded as a first possible answer to the above-mentioned regulatory gap and, therefore, praised for its ambitious goal to regulate this new and fast-developing field. However, the AI Act has also raised several concerns. This part not only introduces the EC's proposals for a regulation on AI, but it also presents and discusses its major critical points.

To conclude, the European and international debate around the EC proposal is briefly presented and the most recurrent opinions with regards to the EC proposal are briefly outlined.

1. The potential of artificial intelligence for our society

AI is markedly changing all aspects of our daily life and it is very difficult to imagine a segment of society that will not be transformed in the years to come by these new technologies. Thanks to the intense research activity in the field of AI, nowadays, several intelligent technologies, such as computer vision, natural language understanding, decision support systems, machine learning and robotics, are reaching levels of maturity so as to be able to be applied in different sectors and business contexts and to increasingly consolidate the interest of companies in them¹.

This is a growing interest which is confirmed by the exponential growth registered by the AI market in recent years. According to the latest release of IDC (International Data Corporation)² Worldwide revenues for the artificial intelligence (AI) market, including software, hardware, and services, is estimated to grow 15.2% year over year in 2021 to \$341.8 billion. The market is forecast to accelerate further in 2022 with 18.8% growth and remain on track to break the \$500 billion mark by 2024. Among the three technology categories, AI Software occupied 88% of the overall AI market. However, in terms of growth, AI Hardware is estimated to grow the fastest in the next several years. From 2023 onwards, AI Services is forecast to become the fastest growing category.

Therefore, these are numbers that testify how companies are increasingly using AI as a new factor for industrial growth and as a lever for competitiveness and to achieve benefits in terms of greater reliability, greater quality and safety, lower operating costs and higher revenues and profits. AI technology helps companies to raise the quality of human work, to free up workers from repetitive, onerous and dangerous tasks, to increase turnover and profits and to acquire new customers, as well as to limit risks and improve efficiency in general. Consider, for example, the real-time identification of fraudulent transactions or predictive maintenance in the manufacturing sector or even faster and more reliable delivery of consumer goods by a service company. However, AI is not only used to optimize the contribution of human work, but also to amplify human intelligence, providing contextual knowledge from data that the human mind alone could not access and / or process.

In the European Parliament study "Opportunities of Artificial Intelligence"³ we read that AI will lead to a strong increase in labor productivity (between 11% and 37% by 2035) due to innovative technologies enabling more efficient workforce-related time management.

However, the benefits deriving from AI do not only concern the industrial world but affect society as a whole. For example, for citizens, artificial intelligence could mean better

¹ [I-Com, THE WAY TO DIGITAL MADE-IN-EUROPE Promoting European values in the global digital arena, December 2020](#)

² [IDC \(2021\)](#)

³ [European Parliament, Opportunities of Artificial Intelligence, June 2020](#)

healthcare, safer cars and other transport systems, and also tailor-made, cheaper and longer-lasting products and services. It can also facilitate access to information, education and training. Furthermore, AI used in public services can reduce costs and offer new possibilities in public transport, education, energy and waste management and could also improve the sustainability of products⁴. In fact, AI could contribute to achieving the European Green Deal goals and UN Sustainable Development Goals. For instance, concerning climate action, an analysis by PwC and Microsoft found that the use of AI for environmental applications has the potential to reduce global greenhouse gas emissions by between 1.5% and 4% by 2030⁵.

Moreover, AI and machine learning have the capabilities to address also major health challenges, such as the current pandemic. In fact, AI technologies and tools has played a key role in every aspect of the COVID-19 crisis response from prediction and tracking of the spread of the virus to diagnosis and development of therapies and vaccines and in the improvement of healthcare systems. In general, AI systems have the great potential to accelerate the lead times for the development of vaccines and drugs. Therefore, many life science companies resort to artificial intelligence for drug discovery.

Finally, among the various areas in which AI brings benefits, we also mention security and cybersecurity. AI is predicted to be used more in crime prevention and the criminal justice system, as massive data sets could be processed faster, prisoner flight risks assessed more accurately, crime or even terrorist attacks predicted and prevented. It is already used by online platforms to detect and react to unlawful and inappropriate online behavior.

However, AI applications also bring significant ethical, trust and legal challenges, for example, related to security, robustness and resilience of AI systems privacy and data protection; transparency and accountability of AI systems; fairness, discrimination and explainability of AI systems; and liability issues. Therefore, the European commission is trying to define a clear legal framework on AI that tries to give answers to all the complex issues related to this new technology.

2. The EU in the global race for AI

The global race for artificial intelligence sees three main players - the United States, China and the EU. It is three countries that have shown different approaches to the development, implementation and regulation of AI, outlined in their respective strategies. China's strategy is mainly focused on the role of the state, which protects and invests in those businesses that have made it to the top after an initial phase of fierce domestic competition.

⁴ <https://www.europarl.europa.eu/news/en/headlines/society/20200918STO87404/artificial-intelligence-threats-and-opportunities>

⁵ [European Parliament, Opportunities of Artificial Intelligence, June 2020](#)

On the other hand, the US gives a much more prominent role to the market and the investments made by big corporations, maximizing space for innovation through lighter public regulation. The US strategy relies to a greater extent on voluntary self-regulation, and the protection of values that they consider as “core”, such as freedom, human rights or the rule of law. Finally, the EU is trying to develop legislation that paves a third way between the other two models, promoting what is dubbed as “ethical and trustworthy AI”. Its strategy aims at fostering cooperation between the public and private sector, as well as ensuring a set of values that are considered to be key (e.g., transparency, accuracy, robustness and non-discrimination)⁶.

However, comparing the EU to China and United States, a pattern of a clear competitive disadvantage seems to emerge. Especially the gap in the overall amount of investments appears to be the most reason for Europe lagging.

According to Stanford University estimates⁷, in 2020 the US continued to have a dominant position in private AI investment. In specific, US companies invested \$23.6 billion in AI, compared to China’s \$9.9 billion. Chinese investment level in 2020 is less than half that of the United States. It is important to note, however, that China has strong public investments in AI. In fact, both the central and local governments in China are spending heavily on AI R&D. The level of European private investments, on the other hand, is much lower and amounts to only \$2 billion (Figure 1).

Moreover, also in terms of AI publications and patents, the EU has a gap especially with China. Almost 60% of all AI patenting firms are from China, versus 14% from the US and 7% from South Korea and the European Union. However, Chinese firms have fewer patents on average compared to the US companies. In fact, the average number of patent applications filed by Chinese firms is 1.6 vs 3.2 for US ones⁸.

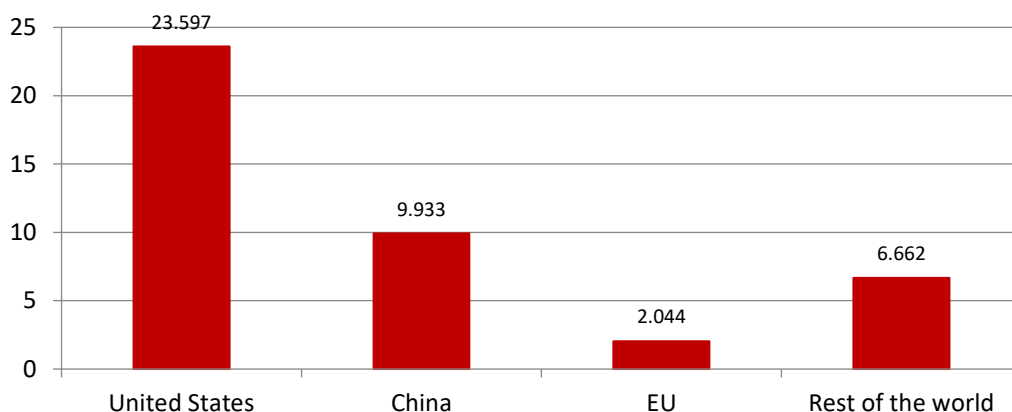
⁶ PromethEUs, THE N(EU) WAY TO ARTIFICIAL INTELLIGENCE (2020)

⁷ [Stanford University, Artificial Intelligence Index Report 2021](#)

⁸ [Joint Research Centre \(JRC\), AI Watch TES analysis of AI Worldwide Ecosystem in 2009-2018 \(2020\)](#)

Figure 1: Private Investment in AI (2020, million \$)

Source: Artificial Intelligence Index Report 2021, Stanford University



As of 2019, China led in the share of peer-reviewed AI publications in the world, after overtaking the European Union in 2017 (Figure 2). It published 3.5 times more peer-reviewed AI papers in 2019 than it did in 2014—while the European Union published just 2 times more papers and the United States 2.75 times more over the same period.

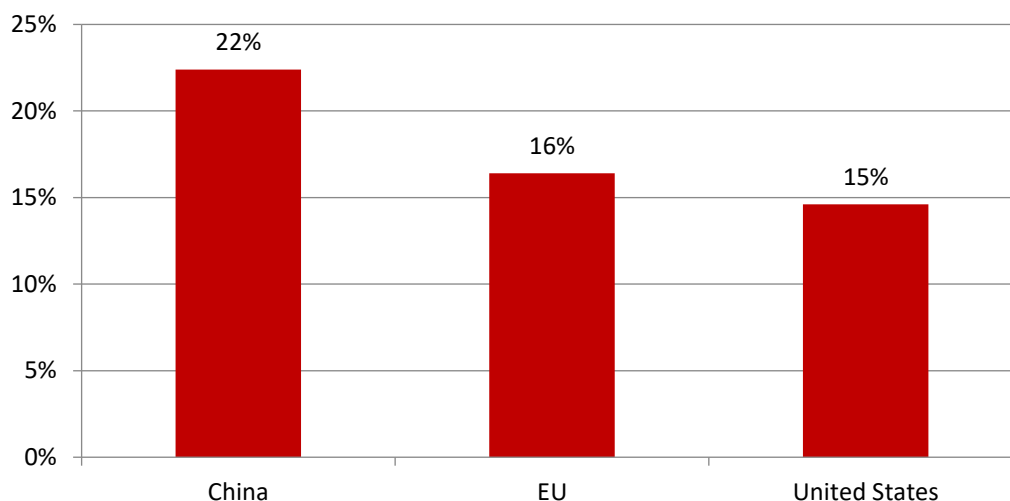
Also in the AI journal publications China has had the largest share in the world since 2017, with 18.0% in 2020, followed by the United States (12.3%) and the European Union (8.6%). Moreover, China overtook the United States in the share of AI conference publications in the world in 2019. China’s percentage of AI conference publications in 2019 is almost nine times higher than it was in 2000. Instead, the share of conference publications for the European Union peaked in 2011 and continues to decline.

In addition to the traditional avenues for publishing academic papers (discussed above), AI researchers have embraced the practice of publishing their work (often pre-peer review) on arXiv, an online repository of electronic preprints. In 2020, the US led in the share (32.5%) of AI-related publications on arXiv in the world, followed by the EU (18.7%) and China (15.7%). However, China is catching up with the United States. In fact, its share of AI-related publications on arXiv is increasing year on year. On the contrary, the share of publication counts by the European Union has remained largely unchanged⁹.

⁹ [Stanford University, Artificial Intelligence Index Report 2021](#)

Figure 2: Peer-reviewed AI publications (2019, % of world total)

Source: Artificial Intelligence Index Report 2021, Stanford University



3. The EU legal framework on AI: the main milestones until 2020

The start of EU's pro-active approach towards AI can be set on 25 April 2018, when the European Commission presented the Communication "AI for Europe", that can be considered as the starting point of the pro-active approach towards AI within the EU. The new approach was based on three main pillars. The first one includes placing the EU at the cutting-edge of technological developments, encouraging uptake of AI by the both the public and private sectors, increasing the EC annual investments in AI by 70% under the Horizon 2020 Research and Innovation Program, strengthening AI research centers across Europe and supporting the development of AI applications in key sectors. The second one aims at preparing EU for socio-economic changes brought about by AI, supporting business-education partnerships to attract and keep more AI talent in Europe and implementing training and retraining schemes for professionals. Finally, the third one focuses on ensuring an appropriate ethical and legal framework.

Following, on June 2018, the EC announced the appointment of several experts to the High-Level Expert Group on Artificial Intelligence (AI HLEG). The group's aim was to support the implementation of the EU Communication on AI published in April 2018 and make recommendations on how to address mid-and long-term challenges and opportunities related to AI. In the same month the EC also launched the AI Alliance, a multi-stakeholder forum with the scope to provide feedback to the AI HLEG. Moreover, the *Coordinated Plan on AI*, published on 7 December 2018, required Member States to adopt AI strategies, including budget figures, to be possibly and significantly increased in the following years.

In April 2019, the AI HLEG presented the *“Ethics Guidelines for Trustworthy AI”*.¹⁰The document offers guidance to all stakeholders and sets a framework for achieving trustworthy AI, and that by identifying a list of ethical principles and providing guidance on how to translate such principles in socio-technical systems. According to the *Guidelines*, trustworthy AI should be: (a) lawful, complying with all applicable laws and regulations; (b) ethical, ensuring adherence to ethical principles and values; and (c) robust, both from a technical and social perspective, since, even with good intentions, AI systems can cause unintentional harm. In June 2019 the AI HLEG presented the report *“Policy and investment recommendations for trustworthy Artificial Intelligence”*, which highlights the need for: (a) boosting the uptake of AI across sectors in the EU, and the need for higher investments in the field, (b) fostering and scaling AI solutions by enabling innovation and promoting technology transfer; (c) setting up public-private partnerships to foster sectoral AI ecosystems

Moving on, February 2020 sets the start of the Von der Leyen Commission’s digital proposals. The latter include two Communications (Shaping Europe’s digital future & A European Strategy for data), a white paper (Artificial Intelligence: a European Approach to excellence and trust) and two reports (B2G Expert Group Report: Towards a European Strategy on business-to-government data sharing for the public interest and the Commission Report on Safety and liability implications of AI, the Internet of Things and Robotics). The first communication, Shaping Europe’s digital future, sets three objectives that will ensure a digital transformation which respects European values, namely: (a) a technology that works for people; (b) a fair and competitive economy, (c) an open, democratic, and sustainable society. The second Communication’s aim is to make Europe emerge as a leader in the data economy, providing for a single market for data and a larger role for European companies. With this communication the EC acknowledges EU’s potential in the data economy, but it enlists several issues holding the EU back, namely: (a) availability of data; (b) imbalances of market power; (c) data interoperability and quality; (d) data governance; (e) data infrastructures and technologies; (f) empowering individuals to exercise their rights; (g) skills and data literacy; and (h) cybersecurity.

With regards to the abovementioned white paper, titled *“Artificial Intelligence: a European Approach to excellence and trust”*, it can be said that its main goal is to create an *“ecosystem of excellence”* and an *“ecosystem of trust”* with regards to AI in the EU. Among several planned actions, the EC aims to revise the 2018 Coordination Plan and work with MSs to ensure that at least one digital innovation hub per MS has a high degree of specialization in AI.

¹⁰ The publication of the guidelines was preceded by a first draft of the document in December 2018, on which more than 500 comments were received through an open consultation.

For the other ecosystem, the Commission assesses the main risks associated with AI and, according to the white paper, an AI application is high-risk when it meets the following two cumulative criteria: 1) it is employed in a sector where, given the characteristics of the activities typically undertaken, significant risks can be expected to occur (for instance, healthcare, transport, energy and parts of the public sector); 2) the AI application in the sensitive sector is used in such a manner that significant risks are likely to arise. The use of AI applications for employment processes, biometric identification and other intrusive surveillance purposes would always be considered as high-risk. Mandatory requirements for high-risk applications would cover the following areas: 1) training data; 2) data and record-keeping; 3) information to be provided 4) robustness and accuracy; 5) human oversight; 6) specific requirements for certain specific applications, such as biometric identification. With regards to enforcement, the EC set out a mixed approach: the requirements would be at least in part verified under prior conformity assessments, while ex post controls could be enforced by national authorities. On the other hand, a voluntary labelling scheme, allowing the economic operators to signal the trustworthiness of their products or services would be applied for non-high risk applications of AI. To be noted that 14 EU countries have published a non-paper on AI¹¹, asking EU Commission to strike the right balance between managing risks and supporting technological innovation, and to create a common framework where trustworthy and human-centric AI can grow in accordance with EU principles.

Ahead of anticipated legislative proposals from the European Commission, in June 2020, the European Parliament established AIDA – a special committee on Artificial Intelligence in a Digital Age - with the objective of analyzing Artificial Intelligence’s impact on the EU economy. In July 2020 the AI HLEG presented two relevant documents with regards to AI regulation. On 17 July 2020 the group presented their final Assessment List for Trustworthy Artificial Intelligence (ALTAI), which is intended for self-evaluation purposes. After a piloting process (that took place from 26 June until 1 December 2019) the list was then revised and became “a tool to support AI developers and deployers in developing Trustworthy AI” as it provides an initial approach for the evaluation of Trustworthy AI. Secondly, on 23 July, 2020, the AI HLEG presented their Sectoral Recommendations on Trustworthy Artificial Intelligence (AI). The latter focuses its analysis on three sectors, namely:

1. Public Sector: within this sector the main suggestions are (i) promote data and algorithmic literacy amongst the public administration (ii) make sure AI-enabled e-Government services are accountable and traceable and allow ex post verification (iv) Promote interoperability to enable efficient communication between jurisdictions

¹¹ The countries which published the non-paper are Denmark, Belgium, the Czech Republic, Finland, France Estonia, Ireland, Latvia, Luxembourg, the Netherlands, Poland, Portugal, Spain and Sweden. See: <https://em.dk/media/13914/non-paper-innovative-and-trustworthy-ai-two-side-of-the-same-coin.pdf>

2. Healthcare: within this sector the main suggestions are: (i) promote AI skills applicable in healthcare, (ii) establish an inclusive AI development and policy framework, (iii) the importance of the availability of high-quality health data, (iv) possible concerns with regards to trade-off between access to quality treatment and privacy, (v) create a European Health Data Space
3. Manufacturing and Internet of Things (IoT): within this sector the main issues that were considered were: (i) create a strategy that promotes new skills and lifelong learning, (ii) promote the deployment of human-centric AI systems in manufacturing and industrial IoT, (iii) enhance collaboration between the EU, MSs, the AI industry, (iv) create a European data-driven ecosystem in AI, manufacturing and industrial IoT, (v) keep diversity and inclusion in the AI field.

In the period between 20 February 2020 and 14 June 2020 the EC carried out a public consultation with the give stakeholders the opportunity to express their views on the questions raised and policy options proposed in the White Paper on Artificial Intelligence. The stakeholders contacted by the EC were: AI developers and deployers, companies and business organisations, Small and Medium-sized Enterprises (SMEs), public administrations, civil society organisations, academics, and citizens. The results of such public consultation were then discussed, among many other topics, during the “Second European AI Alliance Assembly” which started on 9 October 2020. The assembly focused especially on the European initiative to build an Ecosystem of Excellence and Trust in the AI field. During this conference several aspects of the AI phenomenon were analysed, among many other the main ones were: (a) the idea of “ecosystem of excellence”, (b) AI tools that can help fight the pandemic, (c) the uptake of the AI in the public sector, (d) biometric identification, (e) AI and liability issues, (f) requirements for trustworthy AI, and finally (g) conformity assessment, standards, and high-risk AI applications.

With regards to more recent development, in April 2021 the Impact Assessment of the Regulation on Artificial intelligence became public. This report assesses the case for an EU regulatory framework for the development and use of AI systems and examines the impact of different policy options.¹² The impact assessment identifies six main problems linked to the development of AI, namely: (a) risks to safety and security of citizens, (b) of violations of citizens’ fundamental rights and Union values, (c) lack of powers, procedural frameworks and resources by the Authorities to ensure compliance to the rules in AI development, (d) legal uncertainty and complexity on how existing rules apply to AI systems, (e) mistrust in AI and reduction of global competitiveness of the EU economy, (f) obstacles for cross-border AI single market and threats to EU’s digital sovereignty. Moreover the report analyses which policy options are viable based on the following main dimensions: (a) The nature of the EU legal act

¹² To be noted that the use of AI for exclusive military purposes remains outside the scope of the present initiative due to its implications for the Common Foreign and Security Policy (CFSP).

(no EU intervention/ EU act with voluntary obligations/ EU sectoral legislation/ horizontal EU act); (b) Definition of AI system (voluntary/ ad hoc for specific sectors/ one horizontal definition); (c) Scope and content of requirements and obligations (voluntary/ ad hoc depending on the specific sector/ risk-based/ all risks covered); (d) Enforcement and compliance mechanism (voluntary/ ex ante or ex post only/ ex ante and ex post); (e) Governance mechanism (national, national and EU, EU only). The impact assessment analyzed the policy options through an evaluation against the economic and societal impacts, with a particular focus on impacts on fundamental rights.

4. The EU Commission's regulatory approach for Artificial Intelligence: an overview on the “AI Act”

To help further define its vision for AI and to turn Europe into the global hub for trustworthy AI, the European Commission published its AI package in April 2021. This package consists of¹³:

- a Communication on Fostering a European Approach to Artificial Intelligence;
- the Coordinated Plan with Member States: 2021 update;
- a proposal for an AI Regulation laying down harmonized rules for the EU (Artificial Intelligence Act).

With the Artificial Intelligence Act¹⁴, described as “the first ever legal framework on AI” and a new Coordinated Plan with Member States, the EU Commission intend to guarantee the safety and fundamental rights of people and businesses, while strengthening AI uptake, investment and innovation across the EU.

In specific, the AI Act will make sure that Europeans can trust in AI by imposing tailored obligations on actors at different parts of the value chain, while the updated Coordinated Plan¹⁵ will use funding allocated through the Digital Europe and Horizon Europe programmes, as well as the Recovery and Resilience Facility that foresees a 20% digital expenditure target, and Cohesion Policy programmes, to:

- Create enabling conditions for AI's development and uptake through the exchange of policy insights, data sharing and investment in critical computing capacities;
- Foster AI excellence 'from the lab to the market' by setting up a public-private partnership, building and mobilising research, development and innovation capacities, and making testing and experimentation facilities as well as digital innovation hubs available to SMEs and public administrations;

¹³ <https://digital-strategy.ec.europa.eu/en/policies/european-approach-artificial-intelligence>

¹⁴ https://eur-lex.europa.eu/resource.html?uri=cellar:e0649735-a372-11eb-9585-01aa75ed71a1.0001.02/DOC_1&format=PDF

¹⁵ https://ec.europa.eu/commission/presscorner/detail/en/IP_21_1682

- Ensure that AI works for people and is a force for good in society by being at the forefront of the development and deployment of trustworthy AI, nurturing talents and skills by supporting traineeships, doctoral networks and postdoctoral fellowships in digital areas, integrating Trust into AI policies and promoting the European vision of sustainable and trustworthy AI globally;
- Build strategic leadership in high-impact sectors and technologies including environment by focusing on AI's contribution to sustainable production, health by expanding the cross-border exchange of information, as well as the public sector, mobility, home affairs and agriculture, and Robotics.

In detail, the AI ACT establishes a list of prohibited certain practices for all AI systems as violating EU values and fundamental rights. The regulation follows a risk-based approach, differentiating between uses of AI that create (i) an unacceptable risk, (ii) a high risk, and (iii) low or minimal risk. The prohibitions cover practices manipulate persons through subliminal techniques or exploit the fragility of vulnerable individuals, and could potentially harm the manipulated individual or third person. Moreover, the proposal also prohibits AI-based social scoring for general purposes done by public authorities and the use of 'real time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement.

The Regulation contains also specific rules for AI systems that create a high risk to the health and safety or fundamental rights of natural persons. In specific, requirements for high-risk AI systems include implementing a risk management system for the entire life cycle of a high-risk AI system to eliminate or reduce risks through adequate design and development, implementing mitigation and control measures, providing information and training, and conducting testing. The obligations imposed on businesses distinguish between providers of high-risk AI systems, product manufacturers, authorized EU representatives appointed by non-EU providers, importers, distributors, users, and other third parties involved in the AI value chain.

Providers of high-risk AI systems are responsible for ensuring the compliance of their systems with the AI Regulation, implementing a quality management system, drawing up the relevant technical documentation, keeping logs generated by their high-risk AI systems, complying with conformity assessment and registration obligations, taking corrective actions as required and cooperating with authorities. Manufacturers of products covered by EU legislation, and including high-risk AI systems, are responsible for compliance as if they were the provider of the high-risk AI system. Distributors, importers, users and other third parties will also be subject to providers' obligations if they place a high-risk AI system on the market or into service under their name or trademark, modify the intended purpose of a high-risk AI system already on the market or in service or make a substantial modification to a high-risk AI system. In that case, the original provider is relieved of responsibility.

The AI Act also imposes obligations on users of high-risk AI systems. They must use such systems in accordance with the instructions for use, ensure that input data is relevant, and monitor the operation of the high-risk AI system based on the instructions¹⁶.

People can be deceived by some systems (such as chatbots) into thinking that they are dealing with a human. In those cases, the AI Act merely imposes transparency requirements to ensure that the affected person is aware of being exposed to an AI application¹⁷. In specific, transparency obligations will apply for systems that (i) interact with humans, (ii) are used to detect emotions or determine association with (social) categories based on biometric data, or (iii) generate or manipulate content ('deep fakes').

In addition to the obligations imposed on the development, distribution and use of AI systems, the AI Act contains various measures intended to support innovation in this area. It encourages national competent authorities to set up regulatory sandboxes and sets a basic framework in terms of governance, supervision and liability. It also contains measures to reduce the regulatory burden on SMEs and start-ups.

Regarding the governance aspects, the proposal establishes at Union level a European Artificial Intelligence Board (the 'Board'), composed of representatives from the Member States and the Commission. The Board will facilitate a smooth, effective and harmonised implementation of this regulation by contributing to the effective cooperation of the national supervisory authorities and the Commission and providing advice and expertise to the Commission. It will also collect and share best practices among the Member States. At national level, Member States will have to designate one or more national competent authorities and, among them, the national supervisory authority, for the purpose of supervising the application and implementation of the regulation. The European Data Protection Supervisor will act as the competent authority for the supervision of the Union institutions, agencies and bodies when they fall within the scope of this regulation.

Moreover, relatives to ex post market surveillance, the proposal establishes that Providers of high-risk AI systems must establish and document an appropriate post-market monitoring system to continuously check compliance with regulatory requirements. They must report serious incidents and malfunctioning to the market surveillance authority of the Member State where the incident or the associated breach of fundamental rights occurred. Market surveillance authorities must require the relevant operators to take appropriate measures or even to withdraw the AI system when the AI system is in breach of the regulation or when the AI system, while in line with the regulation, presents a risk for health, safety, human rights or a public interest¹⁸.

¹⁶ <https://www.nortonrosefulbright.com/en/knowledge/publications/fdfc4c27/eu-to-propose-new-artificial-intelligence-regulation>

¹⁷ <https://www.eipa.eu/the-artificial-intelligence-act-proposal-and-its-implications-for-member-states/>

¹⁸ Ibidem

Finally, the AI Act encourages the creation of codes of conduct to foster the application of requirements applicable to high-risk AI systems to other AI systems based on appropriate specifications and solutions and includes measures to ensure the effective implementation of the regulation through effective, proportionate, and dissuasive penalties for infringements of the provisions.

5. The European and international debate around the EC proposal for a regulation on artificial intelligence

Since its publication in April 2021, the European Commission Proposal for a Regulation on Artificial Intelligence (AI) has been the source of an increasingly intense debate among stakeholders, both on European and international level.

On the one hand, stakeholders and experts have praised the Commission for its efforts to lay down a harmonised framework in the field of AI, while at the same time several have recognized the proposal as a first steps in defining a new regulatory approach in the field of AI.

Another aspect of the abovementioned proposal that has been praised is its risk-based approach, (GAIRG, IBM) and the definition of high-risk use of AI technology. Some experts argued especially in favour of the broad definition of high-risk systems as those potentially impacting health, safety, and fundamental rights, because of the possible flexibility to expand in the future and include further and broader technologies or cases.

Moreover, as revealed by the public consultation carried out by the European Commission, there is a widespread appreciation among stakeholders when it comes to the focus on human rights, and the explicit goal to create a regulatory framework that will be able to protect them in the field of AI.

Furthermore, the proposal is also seen as a crucial step in establishing the EU's leading role in the field of AI regulations. As observed by several experts who expressed their views in the abovementioned public consultation, the proposal is a first and important step for the EU in trying to regulate in a uniformed way a field, AI, that is becoming increasingly relevant both for the economy and people's daily life (EQUINET).

On the other hand, however, the discussed proposal was also followed by numerous concerns. A first issue, which emerged in the international debate, is the "broad and vague" character of the proposal, which is seen as a limit to "effectively boost the impactful development and use of AI made in Europe" (CLAIRE).

With regards to the proposal several stakeholders pointed out the need for a further refined scope in order to ensure legal certainty; but the same applies to other aspects of the

regulation such as the obligations falling upon actors or the several aspects of “high-risk” AI systems. The AI proposal is said to include several terms and several provisions that need further clarification. At the same time, others criticize the definition of AI technologies because of its focus on a specific set of technologies that are being used rather than on the uses and applications of technology itself.

Another problematic element of the regulation is that according to some it doesn’t provide sufficient guarantees (especially when it comes to monitoring, compliance, and enforcement) that AI-induced harm on fundamental rights such as non-discrimination can be effectively identified, prevented or remedied. Stakeholders believe that, in its current form, the AI proposal falls far short of measures that will ensure people a meaningful protection from harmful AI systems, both in the EU and globally.

Finally, some critics focus on the compliance costs, paperwork and administrative burdens that will fall on companies if the new regulatory framework is enforced. Several voices argue that high compliance costs will have a negative impact on businesses, that would be particularly true for SMEs and start-ups, and this will eventually hinder innovation and competition in the field.

CONCLUSIONS

In the coming years, many segments, if not all, of the economy and daily life will probably be affected by the development of AI technologies and their applications. As the first attempt to codify the rules for the uptake of this technology, the proposal of an Artificial Intelligence Act is therefore held to be of crucial importance. However, because of this, expectations from stakeholders and the public are very high when it comes to how the above-mentioned regulation will regulate this increasingly prominent field. The general attention is especially focused on how the AI Act will balance the necessity to reinforce the European AI market and the need to establish a solid framework for the protection of European citizens and the development of trustworthy AI technologies.

The European Union will not be able to effectively establish itself as a global leader in the field of AI regulation, unless it first achieves a leading role in the development of AI technologies. While the focus on protecting human rights in the digital field is deemed as extremely important, it has been noted that the EU is slowly falling behind on AI development when compared to other countries, such as China, the US and even the UK. What European institutions need to take into consideration is that if the race in AI development accelerates and the gap between the EU and the other countries becomes even wider, this will most

certainly affect the chances for the EU to establish itself as a leading force in the regulatory framework for AI.

While it is important to continue to thoroughly analyse the AI proposal to ensure fundamental rights are effectively safeguarded, the European Union should also work towards a better coordination in the field. To achieve this, it is of crucial importance that the EU, MSs and stakeholders act fast to boost the competitiveness of the European AI market and preserve its role globally. The need to enhance AI development, however, should not prevent the EU from continuing to carefully assess the possible risks of this technology, translating it into the AI regulatory proposal.

Creating a balanced regulatory framework in the field of AI is of paramount importance, yet, as mentioned, to achieve such a result, coordinating efforts at different levels, from the EU down to the regional and local levels is an essential factor. A key element for this cooperation will be a close collaboration between the private and the public sectors. Moreover, dialogue and exchanges between the EU and national legislations should be further developed before provisions at different levels end up contradicting each other or pursuing different goals. Consequently, the possibility of a multilateral governance approach should be further analysed.

To conclude, despite the overall positive comments and praise that the AI Act has drawn so far, there is clearly still room for improvement, starting from more detailed definitions. Therefore, it goes without saying that EU institutions are called on to carry out a difficult task, finding the right balance between the different interests and demands will not be easy. Promoting the model of trustworthy AI and creating within the EU a space where this field can grow and improve, while, at the same time, reinforcing the trust of citizens, may seem an ambitious plan. Nevertheless, finding the right balance between these different needs appears to be the only way towards creating a legal framework that will be able to respond to the speed of this fast-growing technology. Regulating this field is certainly a challenging task, yet a necessary one, given that AI is here to stay.