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SPECIAL ISSUE

European Law and Digital Technologies

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5

FEDERICA GIOVANELLA
Introduction to the Special Issue

10

ALESSANDRO CATANO
Data protection at the gate: personal data of third-country nationals in the EU Entry/Exist System

35

SARA GARSIA – BILGESU SUMER
The European digital identity wallet as a tool to increase individual autonomy: from theory to critical reality

60

GIULIA FORMICI
Transatlantic debate on AI-powered facial recognition technologies: EU and US regulatory models

80

XIATONG BING – ANNE OLOO
Affective computing-based attention monitoring in AI education: a comparative analysis of children's biometric data protection in China and the EU

104

SONIA SFORZA

Central bank digital currencies and privacy: a comparative analysis of regulatory approaches in the EU and China

126

RAFFAELE AMBROSINO

Governance profiles of secondary use of health data in the EHDS

146

GIOIA CODOGNOTTO

Contradictions of Twin Transitions: The Environmental Impact of AI Systems from the European Union Perspective

164

GABRIELE FRANCO

Through the Artificial Intelligence Act: cross-sectional study on a pro-innovation law

182

FABIO SEFERI

AI regulatory sandboxes as legal transplants: governance, regulatory learning and legal-technical interaction

202

GIULIA FANTONI

The Right to Good Administration and Foundation Models: A European Governance Perspective and Best Practices

222

GIOVANNI CHIECO

AI in the Legal Market: Addressing Legal Ambiguity Through a Consumer-Centric Lens

240

BEATRICE MARONE

Escaping the regulatory lasagna: how the AI liability legislation must molt to survive

260

EDOARDO D. MARTINO – VERONICA ZERBA

Tokenising property

THROUGH THE ARTIFICIAL INTELLIGENCE ACT: CROSS-SECTIONAL STUDY ON A PRO-INNOVATION LAW

Gabriele Franco¹

TABLE OF CONTENTS:

I. THE NEW EU LEGAL FRAMEWORK ON AI - II. THE AI ACT AS A PRO-INNOVATION LAW - III. EXPLICIT INNOVATION MEASURES; III.1. AI REGULATORY SANDBOXES; III.2. TESTING AI SYSTEMS IN REAL-WORLD CONDITIONS; III.3. MEASURES AND DEROGATIONS FOR SMES, START-UPS AND SPECIFIC OPERATORS - IV. IMPLICIT INNOVATION MEASURES; IV.1. EXCEPTIONS TO THE MATERIAL SCOPE OF APPLICATION; IV.2. THE RISK-BASED APPROACH; IV.3. AI LITERACY - V. ASSESSMENT OF EFFECTIVENESS AND FUTURE PERSPECTIVES.

On August 1, 2024, Regulation (EU) 2024/1689 (the AI Act) entered into force, establishing the new EU regulatory framework for artificial intelligence (AI). This has reignited the debate on whether EU legislation support or, conversely, constrains innovation. Public and academic narratives about the AI Act's market impact often overlook a set of innovation-oriented measures provide by the law that could at least partially compensate for the potential restrictive effects arising from compliance obligations. This paper offers a cross-sectional study of the AI Act aimed at systematically identifying and examining those measures that are capable of supporting technological development, particularly in the business and workplace context. Methodologically, it introduces two conceptual categories to frame these measures, distinguishing between "explicit innovation measures" and "implicit innovation measures". Building on legal doctrine and empirical evidence from other regulated sectors, the article also advances a preliminary assessment of the likely effectiveness of these measures. The study also considers the proposed amendments to the AI Act contained in the Digital Omnibus on AI.

Keywords: Artificial Intelligence Act - AI Act - pro-innovation regulation - regulatory sandboxes - AI literacy - risk-based approach - digital omnibus

I. THE NEW EU LEGAL FRAMEWORK ON AI

On August 1, 2024, Regulation (EU) 2024/1689² came into force, establishing the new EU regulatory framework for artificial intelligence (the AI Act)³. In comparative terms, it is the first international legislation aimed at comprehensively governing the technical and social

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² Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), in O.J. L of July 12, 2024.

³ For a preliminary overview see, *ex multis*, G. Finocchiaro, F. Donati, F. Paolucci, O. Pollicino (eds.), *La disciplina dell'intelligenza artificiale* (1st ed. 2025); S. Calzolaio, A. Iannuzzi, E. Longo, M. Orofino, F. Pizzetti, *La regolazione europea dell'intelligenza artificiale nella società digitale* (1st ed. 2025); C.N. Pehlivan, N. Forgó, P. Valck (eds.), *The EU Artificial Intelligence (AI) Act: A Commentary* (1st ed. 2024); G. Taddei Elmi, A. Contaldo (eds.), *Intelligenza artificiale. AI Act - Regolamento (UE) 1689/2024. Il nuovo scenario giuridico europeo* (1st ed. 2024); G. Cassano, E.M. Tripodi (eds.), *Il Regolamento Europeo sull'Intelligenza Artificiale. Commento al Reg. UE n. 1689/2024* (1st ed. 2024); A. Mantelero, G. Resta. G.M. Riccio (eds.), *Intelligenza artificiale. Commentario*, (1st ed. 2025).

phenomenon of artificial intelligence (AI). This harmonized set of rules governs the placing on the market, putting into service and the use of “AI systems”⁴ by providers⁵ and deployers⁶, with specific obligations for other operators as well⁷. The AI Act tailors the type and content of its rules to the scope and intensity of the risks that may arise from the provision and use of AI. Building on this risk-based approach, the regulation lays down prohibitions, requirements, and obligations, with specific provisions applying to general-purpose AI models⁸. The regulation becomes applicable progressively: on February 2, 2025, Chapters I and II became effective, followed by Chapters III (Section 4), V, VII and XII, and Article 78⁹ on August 2, 2025, while most of the provisions will apply from August 2, 2026¹⁰.

The stated goal of the AI Act is to introduce a legal framework to enable and facilitate the spread and development of this technology in the internal market, while supporting an anthropocentric and trustworthy vision of AI and ensuring respect for fundamental rights and EU values¹¹. However, the regulation’s attempt to express the tension between supporting innovation and protecting rights in a balanced rationale has generated intense debate. There is controversy over the ability of the AI Act to strike an appropriate trade-off between innovation and the protection of rights. In other words, there are growing concerns about whether the AI Act is a regulation that can support innovation or whether, by contrast, it may hinder it.

II. THE AI ACT AS A PRO-INNOVATION LAW

Economic and legal scholars have long debated the relationship between innovation and regulation¹². This is a structurally ambivalent relationship, as regulation can both hinder and

⁴ Pursuant to Article 3(1)(1), «a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments». On this point, see OECD, *Recommendation of the Council on Artificial Intelligence*, 2019, OECD/LEGAL/0449 and OECD, *Explanatory memorandum on the updated OECD definition of an AI system*, OECD Artificial Intelligence Papers, 8 (2024); EU Commission, *Commission Guidance on the definition of an artificial intelligence system as set out in Regulation (EU) 2024/1689 (AI Regulation)*, Brussels, July 29, 2025, C(2025) 5053 final.

⁵ «[A] natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge» (Article 3(1)(3)).

⁶ «[A] natural or legal person, public authority, agency or other body using an AI system under its authority except where the AI system is used in the course of a personal non-professional activity» (Article 3(1)(4)).

⁷ Including, in particular, importers (ex Article 3(1)(6), «a natural or legal person located or established in the Union that places on the market an AI system that bears the name or trademark of a natural or legal person established in a third country») and distributors (ex Article 3(1)(7), «a natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market»).

⁸ Articles 51 et seq. On this topic, see EU Commission, *Approval of the content of the draft Communication from the Commission – Guidelines on the scope of the obligations for general-purpose AI models established by Regulation (EU) 2024/1689 (AI Act)*, July 18, 2025, C(2025) 5045 final.

⁹ Except for Article 101.

¹⁰ Article 6(1) and the corresponding obligations will become effective on August 2, 2027.

¹¹ Article 1(1).

¹² *Ex multis*, N.A. Ashford, R.P. Hall, *The importance of regulation-induced innovation for sustainable development*, in *Sustainability*, 3 (1, 2011); S. Ambec, M.A. Cohen, S. Elgie, P. Lanoie, *The Porter hypothesis at 20: can environmental regulation enhance innovation and competitiveness?*, in *Review of Environmental Economics and Policy*, 7 (1, 2013); J.

enable innovative processes¹³. On the one hand, there is the intensity and complexity of the obligations and requirements imposed by regulations¹⁴; on the other, their ability to create ecosystems that foster trust and new technological demand¹⁵. Ultimately, the impact of regulation on innovation is an empirical question, to be assessed on a case-by-case basis¹⁶. This also means that interpretations that automatically portray digital regulation as an obstacle to innovation should be avoided¹⁷.

The debate on the ability of EU legislation to support or, conversely, limit innovation has returned to the forefront with the approval of the AI Act. This applies especially in the business and workplace context. Several factors may explain this renewed interest, including: i) the exponential growth of the global AI market, including in terms of adoption and impact on employment¹⁸; ii) the new “space race” for economic and political hegemony over AI technologies at the international level¹⁹; iii) the divergent approaches to AI regulation

Pelkmans, A. Renda, *Does EU regulation hinder or stimulate innovation?*, CEPS Special Report, 96 (2014); R. Engberg, P. Altmann, *Regulation and technology innovation: a comparison of stated and formal regulatory barriers throughout the technology innovation process*, in *Journal of Technology Management & Innovation*, 10 (3, 2015); N. Martin, C. Matt, C. Niebel, K. Blind, *How data protection regulation affects startup innovation*, in *Information Systems Frontiers*, 21 (6, 2019); B.Q. Cunha, F. Donadelli, *Mapping the relationship between regulation and innovation from an interdisciplinary perspective: A critical systematic review of the literature*, in *Regulation & Governance*, 19 (1, 2024); W. Zhang, B. Zhu, Y. Li, D. Yan, *Revisiting the Porter hypothesis: a multi-country meta-analysis of the relationship between environmental regulation and green innovation*, in *Humanities and Social Sciences Communications*, 11 (1, 2024).

¹³ «[...] the impact of a regulatory framework on innovation, competitiveness and investment depends on two contradicting factors. On the one hand, the additional compliance costs and administrative burdens make AI projects more expensive and hence less attractive for companies and investors. From an economic point of view, whether the obligations are imposed on the user or on the developer is irrelevant, since any costs the developer has to bear will eventually be passed on to the user. On the other hand, the positive impact on uptake is likely to increase demand even faster, and hence make projects more attractive for companies and investors. The overall impact will depend on the balance of these two factors» (EU Commission, *Impact assessment accompanying the proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (artificial intelligence act) and amending certain union legislative act*, 2021).

¹⁴ For a more detailed discussion of the negative effects of AI regulatory policies based on the precautionary principle, see D. Castro, M. McLaughlin, *Ten ways the precautionary principle undermines progress in artificial intelligence*, Information Technology and Innovation Foundation, 2019.

¹⁵ A similar debate interested the General Data Protection Regulation. See, *ex multis*, K. Blind, C. Niebel, C. Rammer, *The impact of the EU General data protection regulation on product innovation*, in *Industry and Innovation*, 31 (3, 2024).

¹⁶ J. Pelkmans, A. Renda, *Does EU regulation hinder or stimulate innovation?*, *cit.*, 26.

¹⁷ In this regard, see A. Tartaro, A.L. Smith, P. Shaw, *Assessing the impact of regulations and standards on innovation in the field of AI*, arXiv:2302.04110 (2023).

¹⁸ By 2030, AI will contribute \$15.7 trillion to the global economy, with the potential to increase GDP in local economies by up to 26% (PwC, *PwC's 2024 Global AI Jobs Barometer*). From another perspective, the adoption of generative AI solutions could add between \$2.6 trillion and \$4.4 trillion per year to the global economy (McKinsey & Company, *The economic potential of generative AI: The next productivity frontier*). Globally, 78% of organisations use AI in at least one business function (McKinsey & Company, *The state of AI: How organisations are reworking to capture value*). In the EU, 41.17% of large enterprises used AI technologies in 2024 (Eurostat, *Use of artificial intelligence in enterprises*). In Italy, also in 2024, 59% of large companies had an active AI project (Artificial Intelligence Observatory of the Politecnico di Milano). On the employment front, AI could create 97 million new jobs globally by 2025, compared with the loss of 85 million jobs (World Economic Forum, *Future of Jobs 2020*). The adoption of generative AI solutions could also automate activities that account for 60-70% of today's working time (McKinsey & Company, *The economic potential of generative AI: The next productivity frontier*).

¹⁹ See, for example, Y. Walter, *Managing the race to the moon: Global policy and governance in Artificial Intelligence regulation - A contemporary overview and an analysis of socioeconomic consequences*, in *Discover Artificial Intelligence*, 14 (4, 1, 2024).

compared to the United States and China; iv) the lack of pre-existing EU harmonisation legislation, as in the case of Regulation (EU) 2016/679 (the GDPR).

These circumstances may have led to the perception that the AI Act will represent a barrier to technological innovation in the field of AI in Europe²⁰. While recognizing the significant effort required to comply with the AI Act, as well as other factors that might negatively impact the market, another dimension of the law's content deserves attention. This perspective is often overlooked in narratives about the regulation's impact on the market. Within the AI Act, alongside those that can be defined as "protective measures," there are several "innovation measures" that could compensate, at least in part, for the potential restrictive effects on innovation arising from the law.

This paper offers a cross-sectional study of the AI Act to systematically detect and collect those measures capable of supporting and incentivizing technological development. Methodologically, two conceptual categories are suggested to classify these measures. The first includes "explicit innovation measures", while the second encompasses "implicit innovation measures". As it is not possible to provide an exhaustive analysis of each of these measures in this article, they will be examined from the perspective most relevant here – namely, their ability to facilitate and/or support innovation. Finally, some concluding remarks will be offered, including some predictions of the effectiveness of the measures based on comparative analysis.

III. EXPLICIT INNOVATION MEASURES

The "explicit innovation measures" category includes those measures that the AI Act expressly identifies as such. These are «*measures to support innovation, with a particular focus on SMEs, including start-ups*», which constitute an integral component of the subject matter of the AI Act²¹ and to which Chapter VI of the regulation is dedicated. This systematic inclusion is particularly significant, both in terms of the mentioned balancing rationale and in terms of the empowerment of such measures.

²⁰ On this point, incidentally, it suffices to refer to M. Draghi, *The Future of European Competitiveness (Part B): In-depth Analysis and Recommendations*, September 2024: «[...] while the ambitions of the EU's GDPR and AI Act are commendable, their complexity and risk of overlaps and inconsistencies can undermine developments in the field of AI by EU industry actors. The differences among Member States in the implementation and enforcement of the GDPR [...], as well as overlaps and areas of potential inconsistency with the provisions of the AI Act create the risk of European companies being excluded from early AI innovations because of uncertainty of regulatory frameworks as well as higher burdens for EU researchers and innovators to develop homegrown AI. As in global AI competition 'winner takes most' dynamics are already prevailing, the EU faces now an unavoidable trade-off between stronger ex ante regulatory safeguards for fundamental rights and product safety, and more regulatory light-handed rules to promote EU investment and innovation, e.g. through sandboxing, without lowering consumer standards. This calls for developing simplified rules and enforcing harmonised implementation of the GDPR in the Member States, while removing regulatory overlaps with the AI Act [...]. This would ensure that EU companies are not penalised in the development and adoption of frontier AI. [...] While it is early to fully gauge the impact of these landmarks regulations, their implementation must avoid producing administrative and compliance burdens and legal uncertainties as the GDPR's and must be enforced within shorter timeframes and more stringent processes for compliance provisions».

²¹ Article 1(2). On this point, see P. Van Eecke, B. Reegenhardt, *Article 1. Subject Matter*, in C.N. Pehlivan, N. Forgó, P. Valck (eds.), *The EU Artificial Intelligence (AI) Act: A Commentary*, cit., 18, which notes that «*Chapter VI contributes to the objective to create a legal framework that is innovation friendly*» through the measures provided for therein and analysed in the following paragraphs.

III.1 AI regulatory sandboxes

The AI Act defines AI regulatory sandbox as «*a controlled framework set up by a competent authority which offers providers or prospective providers of AI systems the possibility to develop, train, validate and test, where appropriate in real-world conditions, an innovative AI system, pursuant to a sandbox plan for a limited time under regulatory supervision*»²². Inspired by the success of sandboxes in various sectors, including fintech, and responding to calls from national AI strategies for the establishment of AI-specific sandboxes²³, the AI Act institutes this measure to provide «*a controlled environment that fosters innovation and facilitates the development, training, testing and validation of innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority*»²⁴. Notably, by requiring each Member State to ensure that its competent authorities establish at least one AI regulatory sandbox at national level to be operational by August 2, 2026²⁵, the AI Act introduces a *de facto* mandatory pro-innovation measure²⁶.

AI regulatory sandboxes – which can be established in physical, digital or hybrid form and may host both physical and digital products²⁷ – are pioneered by the AI Act with the aim of: i) improving legal certainty for regulatory compliance; ii) supporting the sharing of best practices through cooperation with authorities; iii) promote innovation and competitiveness and facilitate the development of an AI ecosystem; iv) contribute to evidence-based

²² Article 3(1)(55).

²³ N. de Andrade, *Article 57. AI Regulatory Sandboxes*, in C.N. Pehlivan, N. Forgó, P. Valck (eds.), *The EU Artificial Intelligence (AI) Act: A Commentary*, cit., 882.

²⁴ Article 57(5). In this paper, the analysis is limited to the context of the AI Act. For a broader overview see, *ex multis*, D.A. Zetzsche, R.P. Buckley, J.N. Barberis, D.W. Arner, *Regulating a revolution: from regulatory sandboxes to smart regulation*, in *Fordham Journal of Corporate & Financial Law*, 31 (23, 1, 2017); H.J. Allen, *Regulatory sandboxes*, in *The George Washington Law Review*, 579 (87, 3, 2019); B.R. Knight, T.E. Mitchell, *The sandbox paradox: balancing the need to facilitate innovation with the risk of regulatory privilege*, in *South Carolina Law Review*, 445 (72, 2, 2020); S. Ranchordas, *Experimental lawmaking in the EU: regulatory sandboxes*, in University of Groningen Faculty of Law Research Paper Series, 1 (12, 2021); OECD, *Regulatory sandboxes in artificial intelligence*, in OECD Digital Economy Papers, 356 (2023); S. Ranchordas, V. Vinci, *Regulatory sandboxes and innovation-friendly regulation: between collaboration and capture*, in *Italian Journal of Public Law*, 107 (16, 1, 2024); R. Nabil, *Artificial intelligence regulatory sandboxes*, in *Journal of Law, Economics and Policy*, 295 (19, 2, 2024); H.J. Allen, *Regulatory sandboxes: One decade on*, 2025, SSRN 5365057.

²⁵ Article 57 also allows for the establishment of AI regulatory sandboxes jointly between authorities of Member States, and additional sandboxes at regional or local level, or jointly with the competent authorities of other Member States.

²⁶ «*This clear and compulsory requirement for the implementation of AI regulatory sandboxes makes this provision concrete and actionable, ensuring that this new and innovative concept becomes a living reality in all Member States. The level of concreteness and actionability of this provision further strengthens the importance of its goals, namely the fostering of innovation, the development of an AI ecosystem and the acceleration of access to markets for European AI providers and deployers*» (N. de Andrade, *Article 57. AI Regulatory Sandboxes*, cit., 891). In the EU Commission's proposal this measure was not envisaged as mandatory, thus demonstrating the «*confidence that institutions have in regulatory sandboxes in the context of European technological developments*» (E. Perrone, *Regulatory Sandboxes. Spazi di sperimentazione normativa per l'intelligenza artificiale*, in *Media Laws*, 237 (1, 2025) – translated by the author). With regard to the changes made during the approval procedure, it has been emphasised that the rules on sandboxes ended up becoming «*very important for identifying, especially at Member State level, an innovative way to apply the new rules on AI*» (E. Longo, *Gli spazi di sperimentazione normativa o anche regulatory sandboxes nell'AI Act*, in S. Calzolaio, A. Iannuzzi, E. Longo, M. Orofino, F. Pizzetti, *La regolazione europea dell'intelligenza artificiale nella società digitale*, cit., 113 – translated by the author).

²⁷ Recital 138.

regulatory learning; v) facilitate and accelerate access to the EU market for AI systems, in particular when provided by SMEs²⁸. However, these goals are not placed on the same level. The main aim is to promote innovation and contribute to the development of an AI ecosystem: the others appear to serve as means to achieve this primary objective, as is also evident from the systematic placement of the rules on the regulatory sandbox in Chapter VI²⁹.

Providers participating in AI regulatory sandboxes benefit from several significant advantages, including: i) the establishment of a qualified relationship and privileged exchanges with authorities with a view to compliance with the AI Act³⁰; ii) the release of written proof of successfully completed activities and an exit report on activities carried out, results and learning outcomes that can be used to demonstrate compliance with the regulation³¹; iii) the non-application of administrative fines in the event of infringements of the AI Act for providers who comply with the specific plan³² and the terms and conditions of participation and follow the guidance provided by the authorities in good faith³³; iv) a facilitated regime for the further processing of personal data lawfully collected for other purposes for development, training and testing in the sandbox of certain AI systems in the public interest³⁴. The practical implementation of these objectives is entrusted to the EU Commission, which is tasked with adopting implementing acts specifying the detailed arrangements for the creation, development, implementation, operation and supervision of regulatory sandboxes, outlining common principles and key outcomes that should be respected through these acts³⁵.

AI regulatory sandboxes have the potential to promote innovation and achieve the other goals outlined in the AI Act. Of course, this capacity will take time to be assessed. The adoption of implementing acts delegated to the Commission will also have to be awaited³⁶,

²⁸ Article 57(8) and Recital 139.

²⁹ N. de Andrade, *Article 57. AI Regulatory Sandboxes*, cit., 888.

³⁰ Article 57(6)(7).

³¹ Article 57(7).

³² The «*sandbox plan*» is «*a document agreed between the participating provider and the competent authority describing the objectives, conditions, timeframe, methodology and requirements for the activities carried out within the sandbox*» (Article. 3(1)(54)).

³³ Article 57(12). In N. de Andrade, *Article 57. AI Regulatory Sandboxes*, cit., 892, reference is made to the exemption in terms of a «*safe harbour*». The provision is without prejudice to liability under applicable EU and national law for any damage inflicted to third parties as a result of the experimentation taking place in the sandbox. Furthermore, «*[w]here other competent authorities responsible for other Union and national law were actively involved in the supervision of the AI system in the sandbox and provided guidance for compliance, no administrative fines shall be imposed regarding that law*».

³⁴ Article 59 and Recital 140. To further explore this topic, see T. Binder, I. Eisenberger, *Article 59. Further Processing of Personal Data for Developing Certain AI Systems in the Public Interest in the AI Regulatory Sandbox*, in C.N. Pehlivan, N. Forgó, P. Valck (eds.), *The EU Artificial Intelligence (AI) Act: A Commentary*, cit., 900, which also investigates the relationship between this provision and the relevant rules of the GDPR.

³⁵ N. de Andrade, *Article 58. Detailed Arrangements for, and Functioning of, AI Regulatory Sandboxes*, cit., 898, which also explains that «*[t]he rationale behind the need for these implementing acts is to 'avoid fragmentation across the Union', that is, contribute to the harmonization of procedures for setting up and running AI regulatory sandboxes. Ensuring that the rules of governance for AI sandboxes are consistent across Member States helps promote a level playing field for all stakeholders interested in participating in this type of program, while avoiding 'sandbox shopping'*». Similarly, E. Perrone, *Regulatory Sandboxes. Spazi di sperimentazione normativa per l'intelligenza artificiale*, cit., 260.

³⁶ E. Perrone, *Regulatory Sandboxes. Spazi di sperimentazione normativa per l'intelligenza artificiale*, cit., 268.

but the basis appears well-grounded and valid³⁷, enabling a mandatory measure for encouraging innovation³⁸.

III.2 Testing AI systems in real-world conditions

Testing in real-world conditions is defined as «*temporary testing of an AI system for its intended purpose in real-world conditions outside a laboratory or otherwise simulated environment, with a view to gathering reliable and robust data and to assessing and verifying the conformity of the AI system with the requirements of [...] Regulation and it does not qualify as placing the AI system on the market or putting it into service within the meaning of [...] Regulation, provided that all the conditions laid down in Article 57 or 60 are fulfilled*»³⁹. Accordingly, the AI Act introduces a specific regime to allow providers and potential providers of high-risk AI systems listed in Annex III to test such systems in real-world conditions outside a regulatory sandbox⁴⁰. The aim is to accelerate the development and placement on the market of these systems, while considering their potential consequences on individuals⁴¹.

To this end, a framework of safeguards and requirements is established for providers and potential providers interested in such testing⁴². These cumulative conditions include: i) the

³⁷ N. de Andrade, *Article 57. AI Regulatory Sandboxes*, cit., 892, for whom «*these provisions represent a significant and welcome regulatory innovation within the AI Acts*». For E. Longo, *Gli spazi di sperimentazione normativa o anche regulatory sandboxes nell'AI Act*, cit., 136 this is instead «*one of the most courageous gambles of the new AI Regulation*» (translated by the author). Furthermore, C. Cavaceppi, *Sviluppo e ricerca - Innovazione e sostegno - Sandboxes normativi - Spazi di prova in condizioni reali (artt. 57, 58, 59, 60)*, in G. Taddei Elmi, A. Contaldo (eds.), *Intelligenza artificiale. AI Act - Regolamento (UE) 1689/2024. Il nuovo scenario giuridico europeo*, cit., 169 also highlights the possibility that sandboxes could become «*ethical reference spaces where the relationship between artificial intelligence and human rights can be framed from the design stage onwards*» (translated by the author).

³⁸ The proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI) presented by the EU Commission on November 19, 2025 proposes changes to Article 57, *inter alia*, by providing the legal basis for the AI Office to establish a sandbox on EU level.

³⁹ Article (3)(1)(57).

⁴⁰ As clarified in T. Binder, I. Eisenberger, *Article 60 Testing of High-Risk AI Systems in Real-World Conditions Outside AI Regulatory Sandboxes*, in C.N. Pehlivan, N. Forgó, P. Valck (eds.), *The EU Artificial Intelligence (AI) Act: A Commentary*, cit., 928, «*[r]eal-world testing may be conducted within and outside AI regulatory sandboxes; Article 60 regulates the latter. [...] providers must comply with Article 60 in both situations, as made clear by Article 76(2). According to Article 76(2), the market surveillance authorities shall verify the compliance with Article 60 where AI systems are tested in real world conditions in an AI regulatory sandbox*».

⁴¹ Recital 141.

⁴² Outlined in Article 60. The need to impose strict rules to protect subjects undergoing testing in real-world conditions stems from the different conditions that characterise these cases compared to regulatory sandboxes: in the case of testing in real-world conditions, the competent authorities cannot exercise enhanced regulatory oversight or impose safeguards (T. Binder, I. Eisenberger, *Article 60 Testing of High-Risk AI Systems in Real-World Conditions Outside AI Regulatory Sandboxes*, cit., 928). It is precisely because tests carried out outside regulatory sandboxes are supervised only by the provider or deployer that it is understandable why the legislator has not expressly provided for specific requirements for informed consent for participation in testing in real-world conditions within sandboxes. However, it can be expected that, in the agreements to be concluded between authorities and participants pursuant to Article 58(4), in the case of testing in real-world conditions within a regulatory sandbox, consent requirements similar to those laid down in Article 61 will be considered, «*thus making such requirements de facto applicable also to testing within a sandbox. This would be especially warranted to safeguard the human dignity and personal integrity of the subjects, which should be respected regardless of where the testing takes place*» (S.Y. Esayas, L. Tosoni, *Article 61. Informed Consent to Participate in Testing in Real World Conditions Outside AI Regulatory*

drawing up of a real-world testing plan⁴³, which shall be submitted and approved, together with the testing, by the authority; ii) the recording of tests in an EU database, subject to certain limited exceptions; iii) being established in the EU, or having appointed a legal representative who is; iv) the implementation of adequate safeguards applicable under EU law as a necessary condition for the transfer of data collected and processed for testing purposes to third countries; v) the provision of time limits for the duration of testing (six months, extendable by a further six months)⁴⁴; vi) the application of additional safeguards in the case of persons belonging to vulnerable groups; vii) in the case of deployers' participation, the fulfilment of appropriate information obligations and the conclusion of a written agreement defining the roles and responsibilities of the parties; viii) effective supervision by competent personnel involved in the tests; ix) the implementation of supplementary safeguards to ensure that the predictions, recommendations and decisions of the AI system can be effectively reversed and disregarded; x) ensuring the possibility of withdrawal from the trials at any time, without prejudice and without justification on the part of the individuals, recognising their right to request the immediate and permanent deletion of their personal data; xi) requesting the informed consent⁴⁵ of individuals to participate in the testing. This latter guarantee is covered by a specific regime⁴⁶, which outlines the conditions for obtaining it and the related documentation requirements⁴⁷. This combination of provisions strikes a balance between promoting innovation and respecting fundamental rights, which is the essence and objective of the regulation⁴⁸.

Sandboxes, in C.N. Pehlivan, N. Forgó, P. Valck (eds.), *The EU Artificial Intelligence (AI) Act: A Commentary*, cit., 951).

⁴³ This is «a document that describes the objectives, methodology, geographical, population and temporal scope, monitoring, organisation and conduct of testing in real-world conditions» (Article 3(1)(53)).

⁴⁴ On the comparison between this limit and the provisions for AI regulatory sandboxes, see T. Binder, I. Eisenberger, *Article 60 Testing of High-Risk AI Systems in Real-World Conditions Outside AI Regulatory Sandboxes*, cit., 936.

⁴⁵ Defined as «a subject's freely given, specific, unambiguous and voluntary expression of his or her willingness to participate in a particular testing in real-world conditions, after having been informed of all aspects of the testing that are relevant to the subject's decision to participate» (Article 3(1)(59)).

⁴⁶ Article 61.

⁴⁷ For further analysis, see S.Y. Esayas, L. Tosoni, *Article 61. Informed Consent to Participate in Testing in Real World Conditions Outside AI Regulatory Sandboxes*, cit., 942, which also examines interactions with other regulations, including the GDPR. More generally, and along the same lines, it has been noted that this provision «raises [...] the level of diligence required of AI providers during the testing phase: it does not merely ensure the technical compliance of AI systems, but aims to ensure that the information process meets high standards of clarity and completeness. It establishes detailed requirements for informed consent, reflecting a legislative commitment to the protection of individual rights, in line with other key legal documents of the European Union» (G. Pollio, G. Crea, *Sviluppo e ricerca - Partecipazione - Prove reali - Spazio sperimentazione* (artt. 61, 62, 63), in G. Taddei Elmi, A. Contaldo (eds.), *Intelligenza artificiale. AI Act - Regolamento (UE) 1689/2024. Il nuovo scenario giuridico europeo*, cit., 180 – translated by the author).

⁴⁸ «Article 61 of the AI Act is intrinsically linked to Article 60 [...]. Together, these provisions embody and further the central objective of the AI Act, in the sense that they aim to strike a balance between the promotion of innovation and respect for the interests and fundamental rights of individuals. While real world testing aims 'to accelerate the process of development and the placing on the market of the high-risk AI systems', the requirements for free and informed consent in Article 61 ensure that such testing is conducted in a way that respects individuals, especially their rights to human dignity and personal integrity» (S.Y. Esayas, L. Tosoni, *Article 61. Informed Consent to Participate in Testing in Real World Conditions Outside AI Regulatory Sandboxes*, cit., 945).

The rules dedicated to test in real-world conditions, while differing from those for AI regulatory sandboxes⁴⁹, therefore appear to introduce an (optional) framework capable of facilitating innovation in the field of AI within a perimeter that guarantees security and fundamental EU rights and values⁵⁰.

III.3 Measures and derogations for SMEs, start-ups and specific operators

Articles 62 and 63 complete the Chapter on measures in support of innovation by adopting an operator-based approach. As such, attention is focused on specific operators based on their intrinsic features, assessed in relation to the AI market.

Article 62 addresses the interests of SMEs, including start-ups⁵¹, which are providers or deployers of AI systems. The provision lays down obligations for Member States and the AI Office (but not only for them), aimed primarily at developing capacity for SMEs, reducing regulatory burdens and improving market access⁵². More specifically, Member States are required to undertake a series of actions to «*promote and protect innovations*»⁵³. These actions, which in most cases also extend to other parties (deployers, other innovators, local public authorities, other relevant stakeholders), include: i) priority access to AI regulatory sandboxes⁵⁴; ii) organising targeted awareness-raising and training activities on the application of the AI Act⁵⁵; iii) the provision of dedicated channels of communication with these entities to provide advice and answer questions on the implementation of the

⁴⁹ In addition to the differences already mentioned, for the purposes of this article, attention is drawn to Article 60(9), which provides that providers remain liable for any damage caused during their testing in real world conditions. This is in line with Article 57(12) regarding liability for damages in the context of regulatory sandboxes. However, the exemption from administrative penalties for violations of the AI Act does not apply to testing in real world conditions. For this reason, «*[t]esting in real-world conditions in an AI regulatory sandbox may be more attractive to some (prospective) providers*» (T. Binder, I. Eisenberger, *Article 60 Testing of High-Risk AI Systems in Real-World Conditions Outside AI Regulatory Sandboxes*, *cit.*, 940).

⁵⁰ The Digital Omnibus on AI proposes amendments to the testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes pursuant by Article 60, *inter alia* extending this regime to high-risk AI systems covered by Section A of Annex I and creating a legal basis for interested Member States and the EU Commission, on voluntary basis, to enter into written agreements to test high-risk AI systems referred to in Section B of Annex I in real world-conditions.

⁵¹ For an overview, also in terms of the historical evolution of the text of the AI Act, with regard to the concepts of SMEs and start-ups, see T. Binder, I. Eisenberger, *Article 62. Measures for Providers and Deployers, in Particular SMEs, Including Start-Ups*, in C.N. Pehlivan, N. Forgó, P. Valck (eds.), *The EU Artificial Intelligence (AI) Act: A Commentary*, *cit.*, 965, where it is argued that «*[t]he final Article 62 [...] refers to 'SMEs' in general, thus including medium-sized enterprises as well. This is a more appropriate approach to fostering innovation, as it covers more addressees*».

⁵² T. Binder, I. Eisenberger, *Article 62. Measures for Providers and Deployers, in Particular SMEs, Including Start-Ups*, *cit.*, 964, which points out that Article 62 should be considered in the context of the EU's general measures to promote and support SMEs. Along the same lines, see G. Pollio, G. Crea, *Sviluppo e ricerca - Partecipazione - Prove reali - Spazio sperimentazione (artt. 61, 62, 63)*, *cit.*, 181.

⁵³ Recital 143.

⁵⁴ The incentive is linked to a location criterion – being aimed at SMEs, including start-ups, with their registered office or a branch in the EU – and requires that the eligibility conditions and selection criteria for regulatory sandboxes be met, without precluding other providers from accessing AI regulatory sandboxes.

⁵⁵ «*This provision is in line with the Commission's objectives to avoid disproportionate burdens on SMEs in the AI Act and to create a digitally literate population and highly skilled digital professionals. Furthermore, this provision helps to overcome the problem that SMEs and start-ups often lack skilled employees because they cannot afford to invest adequately in the training of their employees*» (T. Binder, I. Eisenberger, *Article 62. Measures for Providers and Deployers, in Particular SMEs, Including Start-Ups*, *cit.*, 966).

regulation; iv) facilitation of participation in the standardisation development process. This provision then requires notified bodies to take into account the specific interests and needs of providers that are SMEs, including start-ups, when setting fees for conformity assessment, «*reducing those fees proportionately to their size, market size and other relevant indicators*»⁵⁶. Also under the logic «*to address the specific needs of SMEs, including start-ups*»⁵⁷, the AI Office is required to take action by: i) providing standardised templates for the areas covered by the AI Act; ii) developing a single information platform with easy to use information on the regulation; iii) organising communication campaigns to raise awareness of the obligations under the AI Act; iv) promoting the convergence of best practices in public procurement procedures in relation to AI systems.

Article 63 focuses, instead, on microenterprises within the meaning of Recommendation 2003/361/EC. Given the very small size of these operators, and «*in order to ensure proportionality regarding costs of innovation*», these operators are allowed to fulfil «*one of the most costly obligations, namely to establish a quality management system, in a simplified manner which would reduce the administrative burden and the costs for those enterprises without affecting the level of protection and the need for compliance with the requirements for high-risk AI systems*»⁵⁸. Once again, the measure clearly reflects a pro-innovation stance⁵⁹, as it is designed to reduce potentially disproportionate regulatory burdens for smaller businesses while ensuring simplified compliance for them⁶⁰.

IV. IMPLICIT INNOVATION MEASURES

The AI Act also encompasses a set of provisions which, although not expressly defined as «*measures in support of innovation*», can directly or indirectly encourage progress in the field of AI. These measures, which can be classified as “implicit innovation measures”, find their rationale from the purpose of the regulation, as outlined in Article 1(1), which makes explicit reference to the promotion of innovation⁶².

⁵⁶ Recital 143 also extends the intervention in question to the EU Commission and Member States.

⁵⁷ Recital 143 specifies that «*[m]edium-sized enterprises which until recently qualified as small enterprises within the meaning of the Annex to Commission Recommendation 2003/361/EC should have access to those support measures, as those new medium-sized enterprises may sometimes lack the legal resources and training necessary to ensure proper understanding of, and compliance with, [...] Regulation*».

⁵⁸ Recital 146. The EU Commission is tasked with developing guidelines to specify the elements of the quality management system that micro-enterprises should comply with in this simplified manner.

⁵⁹ «*Article 63 aims for a regulatory balance that safeguards safety and trust without hindering innovation with undue obligations on microenterprises. Instead of applying the same strict standards across the board, it offers a degree of leeway specifically for microenterprises in terms of quality management, thereby encouraging AI innovation even among the smallest companies*» (A. Zarra, *Article 63. Derogations for Specific Operators*, in C.N. Pehlivan, N. Forgó, P. Valck (eds.), *The EU Artificial Intelligence (AI) Act: A Commentary*, cit., 973).

⁶⁰ A. Zarra, *Article 63. Derogations for Specific Operators*, cit., 975, which also reports the data from the study supporting the impact assessment of the AI Act, according to which the total costs for setting up a quality management system range from approximately €193,000 to €330,000.

⁶¹ The Digital Omnibus on AI propose adding legal definitions for micro, small and medium-sized enterprise (SME) and small mid-cap enterprise (SMC) to the definitions in Article 3, extending regulatory privileges for SMEs to SMCs on technical documentation and putting in place a quality management system that takes into account their size, and extending the derogation from micro-enterprises to SMEs to comply with certain elements of the quality management system in a simplified manner.

⁶² The same reference also appears in Recital 1. On this point, see also P. Van Eecke, B. Regenhardt, *Article 1. Subject Matter*, cit., 18, according to which «*[t]he promotion of AI-driven innovation is closely linked to the Data Act, the*

IV.1 *Exceptions to the material scope of application*

After defining the scope of the regulation from a material, personal and territorial perspective⁶³, Article 2 establishes a list of scenarios in which the regulation does not apply. Two cases are particularly relevant here, both concerning research activities.

The first provides that the AI Act does not apply to «*AI systems or AI models, including their output, specifically developed and put into service for the sole purpose of scientific research and developments*»⁶⁴. The exclusion aims to «*support innovation, [...] respect freedom of science, and [...] not undermine research and development activity*» and its exceptional nature is confirmed by the express subjection of the AI Act rules to «*any other AI system that may be used for the conduct of any research and development activity*»⁶⁵.

The second, instead, excludes from the scope of the regulation «*any research, testing or development activity regarding AI systems or AI models*», but only «*prior to their being placed on the market or put into services*»⁶⁶. This exception⁶⁷ shares the same rationale⁶⁸ and complements the exemption for scientific research by focusing on commercial research, testing and development activities⁶⁹. In this case, however, a logical-temporal limit is introduced: only research, testing and development activities regarding AI systems or AI models before their commercialisation or deployment are exempt, with the obligation to comply with the AI Act if an AI system falling within the scope of the regulation is placed on the market or put into service as a result of such research and development activities⁷⁰.

Data Governance Act, Common European Data Spaces, and other initiatives under the EU strategy for data, which are intended to establish trusted mechanisms and services for the reuse, sharing and pooling of data that are essential for the development of data-driven AI models of high quality». For M. Orofino, *Obiettivi, ambito di applicazione e principi fondamentali dell'AI Act*, in S. Calzolaio, A. Iannuzzi, E. Longo, M. Orofino, F. Pizzetti, *La regolazione europea dell'intelligenza artificiale nella società digitale*, cit., 37, «*according to the EU's intentions, regulation should not be seen as a limitation (or obstacle) to private activity, but as an essential tool for strengthening citizens trust*» (translated by the author).

⁶³ For an overview of the discipline, see P. Van Eecke, B. Regenhardt, *Article 2. Scope*, in C.N. Pehlivan, N. Forgó, P. Valck (eds.), *The EU Artificial Intelligence (AI) Act: A Commentary*, cit., 22; M. Orofino, *Obiettivi, ambito di applicazione e principi fondamentali dell'AI Act*, cit., 33; M. Bassini, *Oggetto, campo di applicazione e ambito territoriale*, in G. Finocchiaro, F. Donati, F. Paolucci, O. Pollicino (eds.), *La disciplina dell'intelligenza artificiale*, cit. 113; L. Marafioti, *Caratteri essenziali e ambito di applicazione del regolamento*, in G. Cassano, E. M. Tripodi (eds.), *Il Regolamento Europeo sull'Intelligenza Artificiale. Commento al Reg. UE n. 1689/2024*, cit., 369.

⁶⁴ Article 2(6). The law does not define the meaning of «*specifically*» and «*[t]his could prove challenging, as research can explore potential scenarios where a research project might have both scientific and practical applications, calling into doubt the applicability of the exemption*» (P. Van Eecke, B. Regenhardt, *Article 2. Scope*, cit., 43).

⁶⁵ Recital 25 also specifies that «*any research and development activity should be carried out in accordance with recognised ethical and professional standards for scientific research and should be conducted in accordance with applicable Union law*».

⁶⁶ Article 2(8). The provision also clarifies that such activities should be carried out in accordance with applicable EU law and that testing in real world conditions does not fall within the scope of this exclusion.

⁶⁷ According to Recital 25, the exclusion does not affect the application of the rules on regulatory sandboxes and testing in real-world conditions.

⁶⁸ For M. Orofino, *Obiettivi, ambito di applicazione e principi fondamentali dell'AI Act*, cit., 45, «*this objective must also be interpreted as a limit on the intervention of Member States, which cannot exploit the exclusion to adopt national regulations that unduly restrict research activity*» (translated by the author).

⁶⁹ P. Van Eecke, B. Regenhardt, *Article 2. Scope*, cit., 44.

⁷⁰ Recital 25. M. Orofino, *Obiettivi, ambito di applicazione e principi fondamentali dell'AI Act*, cit., 45 qualifies the exception referred to in paragraph 6 as an absolute derogation and that provided for in paragraph 8 as a partial derogation.

The exclusion of scientific and commercial research and development activities from the scope of the AI Act can be considered as a key measure from a pro-innovation perspective, freeing these innovative processes from regulatory compliance duties. Moreover, the partial nature of the exemption for commercial activities also allows research activities to be set up in a logic of by-design and by-default compliance, in the absence of an immediate compliance burden, thus enabling the identification and testing of the best solutions to ensure innovation and (subsequent) sustainable compliance.

IV.2 *The risk-based approach*

The risk-based approach – which, together with the ethical guidelines for trustworthy AI developed by the High-Level Expert Group on Artificial Intelligence appointed by the EU Commission⁷¹, constitutes the foundation of the AI Act – is outlined in recital 26⁷². The latter explains the rationale behind this approach («[i]n order to introduce a proportionate and effective set of binding rules for AI systems»)⁷³, the *modus operandi* («[t]hat approach should tailor the type and content of such rules to the intensity and scope of the risks that AI systems can generate») and the results of its application («[i]t is therefore necessary to prohibit certain unacceptable AI practices, to lay down requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems»). The pyramid identified by this approach provides for: i) certain AI practices that pose an unacceptable risk – and are therefore prohibited – strictly listed by the regulation⁷⁴; ii) high-risk AI systems that qualify as such according to the classification criteria referred to in Article 6 and Annexes I and III, for which several requirements and obligations should be met⁷⁵; iii) certain AI systems specifically indicated in Article 50, which are subject to transparency obligations⁷⁶.

⁷¹ Recital 27.

⁷² For further analysis, in addition to the references cited below, see P. Dunn, *The Artificial Intelligence Act: a tile in the EU's digital risk-based approach*, in G. Finocchiaro, F. Donati, F. Paolucci, O. Pollicino, *La disciplina dell'intelligenza artificiale*, cit., 141; G.M. Marsico, *L'approccio basato sul rischio*, in G. Cassano, E.M. Tripodi (eds.), *Il Regolamento Europeo sull'Intelligenza Artificiale. Commento al Reg. UE n. 1689/2024*, cit., 377.

⁷³ «Hence, the underlying objective of the AI Act's risk-based approach is to strike an optimal (or proportionate) balance between innovation and the benefits of AI systems on the one hand, and the protection of fundamental values such as safety, health and fundamental rights on the other» (M. Ebers, *Truly Risk-based Regulation of Artificial Intelligence How to Implement the EU's AI Act*, in *European Journal of Risk Regulation*, 685 (16, 2, 2025), which refers to G. De Gregorio, P. Dunn, *The European Risk-based Approaches: Connecting Constitutional Dots in the Digital Age*, in *Common Market Law Review*, 473 (59, 2, 2022), who emphasises that this objective, albeit by different means, is the same as that pursued primarily by EU risk-based digital policies, including GDPR).

⁷⁴ Article 5. For further analysis, see EU Commission, *Commission Guidelines on prohibited artificial intelligence practices established by Regulation (EU) 2024/1689 (AI Act)*, Brussels, February 4, 2025, C(2025) 884 final.

⁷⁵ For the criteria for classifying high-risk systems, see Article 6.

⁷⁶ Article 50 AI Act.

Under this risk-based approach, the legislator predetermined the risk associated with AI systems⁷⁷ following a top-down approach⁷⁸. Turning this theoretical pyramid upside down, this means that an AI system that does not fall within the risk categories listed in the AI Act is not bound by the regulation⁷⁹. Although not free from criticism⁸⁰, this methodological choice can also be viewed from a different perspective, as far as it is of interest here. By preselecting only certain AI systems as risky, the legislator has effectively left all AI systems not expressly referred to in the regulation⁸¹ free from constraints, thus also promoting the related innovative processes.

IV.3 AI literacy

The AI Act defines AI literacy as the «*skills, knowledge and understanding that allow providers, deployers and affected persons, taking into account their respective rights and obligations in the context of [...] Regulation, to make an informed deployment of AI systems, as well as to gain awareness about the opportunities and risks of AI and possible harm it can cause*»⁸². The law therefore requires providers and deployers to take «*measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalfs: this should be done taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used*»⁸³. The AI literacy requirement, although not appearing in the initial text of the

⁷⁷ The only exception to this rule is that provided for in Article 6(3), which allows an AI system not to be considered high risk «*where it does not pose a significant risk of harm to the health, safety or fundamental rights of natural persons, including by not materially influencing the outcome of decision making*», provided that at least one of the conditions listed in the provision is met and subject to the counter-exception in the case of AI systems that perform profiling of natural persons.

⁷⁸ «*In this case, the shift from a bottom-up to a top-down interpretation of risk-based regulation [...] reached its apex. The categories of risk are defined directly by the EU Commission and set in stone within the law. The list of “unacceptable”, and therefore prohibited, AI systems is directly set by the law and is independent of any a posteriori risk assessment by providers or users of those systems. The definition of high-risk technologies is also already defined by the law: in this case, the category is seemingly less stiff and more open to ex post change, since a procedure to amend the Annex III is possible. However, it is once again up to the EU Commission to make the necessary adjustments. The AI Act sets a range of risk criteria: however, in this case, they are meant as a guide for the Commission itself, and not for the targets of regulation*» (G. De Gregorio, P. Dunn, *The European Risk-based Approaches: Connecting Constitutional Dots in the Digital Age*, cit., 492). Similarly, G.M. Marsico, *L'approccio basato sul rischio*, cit., 383. Both sources also highlight the difference in approach compared to the GDPR.

⁷⁹ «*The spectrum embracing the set of AI applications with minimal risk is very broad and offers both the interpreter and the operator an opaque, albeit vast, range of application possibilities*» (G. De Gregorio, P. Dunn, *The European Risk-based Approaches: Connecting Constitutional Dots in the Digital Age*, cit., 491).

⁸⁰ On this point, see the observations in M. Ebers, *Truly Risk-based Regulation of Artificial Intelligence How to Implement the EU's AI Act*, cit. and in C. Novelli, *L'Artificial Intelligence Act Europeo: alcune questioni di implementazione*, in *Federalismi*, 95 (2, 2024).

⁸¹ With a view to the voluntary application of the AI Act, rules on codes of conduct have been introduced. For further analysis, see N.E. Vellinga, J.M. Bonnici, *Article 56. Codes of Practice*, in C.N. Pehlivan, N. Forgó, P. Valck (eds.), *The EU Artificial Intelligence (AI) Act: A Commentary*, cit., 871.

⁸² Article 3(1)(56).

⁸³ Article 4.

regulation⁸⁴, became a cross-referenced provision in the AI Act⁸⁵. Despite being included in the Chapter containing the general provisions of the law, it is considered to apply only in cases of «*rights and obligations in the context of [...] Regulation*» and not whenever there is an «*AI system*» within the meaning of the AI Act⁸⁶. These training activities are aimed at the staff of providers and deployers, as well as «*other persons dealing with the operation and use of AI systems on their behalf*»⁸⁷. To address the potential vagueness of certain elements of the obligation – such as the «*sufficient*»⁸⁸ or «*adequate*»⁸⁹ level of AI literacy and the concept of «*measure*»⁹⁰ to be taken⁹¹ – the EU Commission has provided initial guidance on what the minimum requirement for compliance with the AI Act should be⁹². The regulation also provides incentives for the adoption of measures to support compliance with the new requirement⁹³. First, it should be noted that it is the AI Act itself which suggests that the AI literacy obligation (also) serves as a measure to support innovation⁹⁴. The law clarifies that this provision was introduced «*[i]n order to obtain the greatest benefits from AI systems while protecting fundamental rights, health and safety and to enable democratic controls*», also pointing out that «*the wide implementation of AI literacy measures and the introduction of appropriate follow-up actions could contribute to improving working conditions and ultimately sustain the consolidation, and innovation path of trustworthy AI in the Union*»⁹⁵.

Second, and more generally, the AI literacy requirement can operate as a pro-innovation measure from multiple perspectives. Acquiring an adequate level of AI literacy could be a significant factor in stimulating innovation, as it can help remove a bottleneck to innovation

⁸⁴ A provision on AI literacy appeared for the first time in the EU Parliament's negotiating position in June 2023. However, several significant changes were made to the originally proposed version. On this point, see M. Paolini e Silva, A. Tamò-Larrieux, O. Ammann, *AI Literacy Under the AI Act: Tracing the Evolution of a Weakened Norm*, in SSRN Electronic Journal, 2 (2025).

⁸⁵ See the provisions on technical documentation (Article 11), human oversight (Article 14) and the right to explanation of individual decision-making (Article 86).

⁸⁶ This is the interpretation proposed in T. Cabral, *AI Literacy Under the AI Act: An Assessment of its Scope*, in SSRN Electronic Journal, 1 (2025).

⁸⁷ Article 4. On this point, the EU Commission has clarified that these subjects are not employees, but persons who fall within the organisational sphere in a broad sense, such as contractors, service providers and clients (EU Commission, *AI Literacy - Questions & Answers*).

⁸⁸ Article 4.

⁸⁹ Recital 91.

⁹⁰ Article 4.

⁹¹ E. Fernandes, W. Holmes, S. Zhgenti, *Article 4. AI Literacy*, in C.N. Pehlivan, N. Forgó, P. Valck (eds.), *The EU Artificial Intelligence (AI) Act: A Commentary*, cit., 93.

⁹² EU Commission, *AI Literacy - Questions & Answers*. Further aspects clarified concern, for example, the format of training.

⁹³ On the one hand, one of the tasks of the European AI Board is to «*support the Commission in promoting AI literacy, public awareness and understanding of the benefits, risks, safeguards and rights and obligations in relation to the use of AI systems*» (Article 66(1)(f)); on the other hand, the EU Commission, through the AI Office, and the Member States are called upon to facilitate the development of voluntary codes of conduct «*to advance AI literacy among persons dealing with the development, operation and use of AI*» (Recital 20, which is applied in the subsequent Article 95(2)(c)).

⁹⁴ For an analysis of some outstanding issues on the interpretation and application of AI literacy rules, see L. Paseri, M. Durante, U. Pagallo, *The Legal Challenges of AI Literacy Between Enforcement and Compliance*, in *Media Laws*, 1 (1, 2025).

⁹⁵ Recital 20.

by bridging the technical skills gap that is often widespread in many countries⁹⁶ and professional sectors⁹⁷. In addition, a higher level of AI competence can facilitate and speed up the adoption of this technology in the workplace⁹⁸. Through appropriate AI literacy training, employee confidence in AI can be strengthened, thereby making the adoption of algorithmic systems faster and more scalable in business⁹⁹. At the same time, such training may serve as a precondition for reducing implementation costs and preventing potential failures in implementation processes. Making training compulsory further increases the likelihood of achieving these outcomes¹⁰⁰.

V. ASSESSMENTS OF EFFECTIVENESS AND FUTURE PERSPECTIVES

This cross-sectional study of the AI Act has highlighted the existence of a variety of measures that may support and encourage technological development, particularly in the EU business and employment context. A number of innovation measures within the AI Act, both explicitly and implicitly, have been identified and analysed. However, there are also other measures that can be considered to have implicitly positive effects on innovation. These include, for example: i) lower penalties for SMEs, including start-ups¹⁰¹; ii) the regime of (non-)application of the AI Act for AI systems already placed on the market or put into service¹⁰²; iii) the gradual application of the AI Act rules¹⁰³, which has been defined *ex ante* by the EU lawmaker.

⁹⁶ A relevant analysis in this regard is offered by S. Denkowska, K. Fijorek, G. Wegrzyn, *Formal and Non-Formal Education and Training As an Instrument Fostering Innovation and Competitiveness in EU Member Countries*, in *Journal of Competitiveness*, 12 (3, 2020).

⁹⁷ In this regard, an interesting perspective is provided by C. Chatzichristos, G. Chatzichristos, I. Borremans, S. Gruyaert, I. De Vos, M. De Vos, F. De Backere, *Bridging the AI-Literacy Gap in Health Care: Qualitative Analysis of the Flanders Case Study*, *J Med Internet Res* 2025;27:e76709.

⁹⁸ In this regard, analysing the issue at the level of educational programmes, see T. Schultheiss, U. Backes-Gellner, *Does updating education curricula accelerate technology adoption in the workplace? Evidence from dual vocational education and training curricula in Switzerland*, in *The Journal of Technology Transfer*, 49 (1, 2024).

⁹⁹ For further analysis regarding the application of this requirement in the workplace, see G. Franco, *AI Literacy: l'alfabetizzazione sull'intelligenza artificiale nel prisma degli obblighi di formazione sul lavoro*, in *Il Lavoro nella giurisprudenza*, 7(2025).

¹⁰⁰ The Digital Omnibus on AI proposes transforming the obligation for providers and deployers of AI systems with regards to AI literacy to an obligation on the EU Commission and the Member States to foster AI literacy.

¹⁰¹ Article 99(6). A Buchta, *Article 99. Penalties*, in C.N. Pehlivan, N. Forgó, P. Valck (eds.), *The EU Artificial Intelligence (AI) Act: A Commentary*, *cit.*, 1348 explains that «[f]or SMEs, the fines are capped at lower amounts, balancing the need for enforcement with the recognition of their limited financial capacity to avoid stifling innovation while ensuring that AI systems are developed and used responsibly». The Digital Omnibus on AI proposes extending these regulatory privileges on penalties for SMEs to SMCs.

¹⁰² Article 111 provides, *inter alia*, that the AI Act applies «to operators of high-risk AI systems [...] that have been placed on the market or put into service before 2 August 2026, only if, as from that date, those systems are subject to significant changes in their design». The rationale for this provision is «to ensure legal certainty, ensure an appropriate adaptation period for operators and avoid disruption to the market, including by ensuring continuity of the use of AI systems» (Recital 177). A. Winkelmeier, C. Korab, *Article 111. AI Systems Already Placed on the Market or Put into Service and General-Purpose AI Models Already Placed on the Market*, in C.N. Pehlivan, N. Forgó, P. Valck (eds.), *The EU Artificial Intelligence (AI) Act: A Commentary*, *cit.*, 1446 clarifies that «[d]ue to a lack of special provisions in Article 111, compliance obligations for AI systems other than high-risk or GPAI systems – such as primarily the obligations in Article 50 – are relevant from the date of application of the act onwards».

¹⁰³ See the timetable set out in Article 113. On this point, see C.N. Pehlivan, *Article 113. Entry into Force and Application*, in C.N. Pehlivan, N. Forgó, P. Valck (eds.), *The EU Artificial Intelligence (AI) Act: A Commentary*, *cit.*,

It is not yet possible to prove that these measures will be sufficient to support and stimulate the AI market in the EU, thereby offsetting any limiting effects resulting from compliance burdens. However, some preliminary assessments could be made from an *ex ante* perspective. For those provisions whose effects on innovation are difficult to evaluate in the abstract (e.g. the risk-based approach and the exceptions to the material scope of application), the actual impact will depend on how stakeholders and authorities approach the new legal framework, both from an implementation and an enforcement perspective.

For other provisions, experience from different sectors and/or jurisdictions may provide a basis for more informed predictions. This could apply in particular to provisions on AI literacy¹⁰⁴.

Similarly, with regard to regulatory sandbox, useful parameters for prediction can be drawn from experiences of countries that have adopted this measure in specific industries, specifically fintech. The adoption of sandboxes has produced significant positive effects, particularly in terms of venture investment¹⁰⁵, regulatory certainty, companies-regulator collaboration, and credibility¹⁰⁶, but also in operational continuity and patent ownership¹⁰⁷. Comparative, multi-jurisdictional and multi-sector analyses of regulatory sandboxes regimes also allows for the identification of factors that can contribute to the production of positive impacts on innovative markets through these measures. These include, among others: the establishment of structured and clear regulatory framework for sandbox projects (setting out conditions for regulatory exemptions, application procedures, assessment criteria and exit strategies); systematic updates to these frameworks; the availability of adequate funding and support for innovators; the promotion of diversified and inclusive participation; and transparent reporting¹⁰⁸.

As a further consideration, the success of these measures also depends on broader systemic factors, such as the availability of adequate investment programmes and economic support for the market. In this respect, the example of other countries can also serve as a useful benchmark, in particular those with more advanced AI market, such as China and the United

1468 («Rebalancing technological innovation with regulatory oversight, the AI Act, through its risk-based approach and phased implementation, strives to ensure that AI systems are deployed safely and ethically across the EU while providing sufficient time and guidance for stakeholders to conform to the new rules»). The Digital Omnibus on AI proposes postponing the application of obligations for high-risk AI systems (scheduled for August 2, 2026) through a mechanism linking the application of these requirements to the availability of standards, common specifications and guidelines from the EU Commission, with deadlines of December 2, 2027 and August 2, 2028 (depending on the AI system concerned).

¹⁰⁴ See the arguments already set out above in this regard.

¹⁰⁵ See J. J. Goo, J. Y. Heo, *The Impact of the Regulatory Sandbox on the Fintech Industry, with a Discussion on the Relation between Regulatory Sandboxes and Open Innovation*, in *Journal of Open Innovation: Technology, Market, and Complexity*, 6 (2, 2020), which considered nine countries in the study (United Kingdom, Singapore, Hong Kong, Australia, India, Canada, Malaysia, The Netherlands, and Japan).

¹⁰⁶ See J. Kálmán, *The Role of Regulatory Sandboxes in FinTech Innovation: A Comparative Case Study of the UK, Singapore, and Hungary*, in *FinTech*, 4 (2, 2025).

¹⁰⁷ See G. Cornelli, S. Doerr, L. Gambacorta, O. Merrouche, *Regulatory sandboxes and fintech funding: evidence from the UK*, in *Review of Finance*, 28 (1, 2024).

¹⁰⁸ Z. Aydın, O. Yardımcı, *Regulatory sandboxes and pilot projects: Trials, regulations, and insights in energy transition*, in *Engineering Science and Technology, an International Journal*, 56 (2024), 12-15. The study covered twelve countries (Australia, Austria, Belgium, Canada, France, Germany, Italy, the Netherlands, Norway, Singapore, the UK and US).

States. In these jurisdictions, however, approaches to AI regulation differ significantly from the EU model¹⁰⁹, in some cases extending even to forms of deregulation¹¹⁰. This divergence represents an important factor to consider in any comparative analysis.

In conclusion, when assessing whether the identified pro-innovation measures will be able to boost innovation in the field of AI in Europe, the practical implementation phase and the enforcement policies adopted at the EU and national levels will play an important role. In this regard, Italy adopted national regulation on AI with Law No. 132/2025, whose provisions should be interpreted and applied in accordance with the AI Act¹¹¹. However, the regulation's attempt to reconcile measures to protect fundamental rights with those to support innovation remains valid. This makes the AI Act a law that is also commendable in its pro-innovation dimension.

¹⁰⁹ For a preliminary comparative overview see, *ex multis*, J. Chun, C.S. de Witt, K. Elkins, *Comparative Global AI Regulation: Policy Perspectives From the EU, China, and the US*, arXiv:2410.21279 (2024); M. Nimrod, *Global Perspectives on AI Governance: A Comparative Overview*, in Third International Conference on Hybrid Human-Artificial Intelligence co-located with (HHAI 2024), Malmö (2024); F. Heymann, K. Parginos, A. Hariri, G. Franco, *Regulating Artificial Intelligence in the EU, United States and China - Implications for energy systems*, in 2023 IEEE PES Innovative Smart Grid Technologies Europe (ISGT EUROPE), Grenoble (2023).

¹¹⁰ See, for instance, the America's AI Action Plan issued under Executive Order 14179 in July 2025. For a detailed analysis, K.M. Belikova, *The global race for artificial intelligence: regulatory and other acts governing the development and application of artificial intelligence in the United States of America*, in *Lobbying in the Legislative Process*, 4 (3, 2025).

¹¹¹ Law No. 132 of September 23, 2025, "*Disposizioni e deleghe al Governo in materia di intelligenza artificiale*", in O.J. No. 223 of September 25, 2025. The law i) sets out principles on research, experimentation, development, adoption and application of AI systems and models; ii) promotes the correct, transparent and responsible use of AI in an anthropocentric dimension, aimed at seizing its opportunities; iii) ensures the monitoring of economic and social risks and the impact of AI on fundamental rights (Article 1). Applying the pro-innovation reading proposed in this article this law, Article 8 on scientific research and experimentation in the development of AI systems in the healthcare sector is notable. Pursuant to this provision, processing of both personal data and special categories of personal data, carried out by a number of public and private entities, is of significant public interest. The obligations to inform patients are also simplified, providing for the possibility of secondary use of data, including health data, without the need to obtain a second consent, for scientific research purposes, provided that de-identification measures are applied. Furthermore, without prejudice to the obligation to provide a notice, the law legitimises the reuse of both personal and health data to apply anonymisation, pseudonymisation or synthesis measures to them, where this is carried out for the purposes of scientific research or for the planning, management, control and evaluation of healthcare.

