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AI Regulatory Sandboxes as Legal Transplants: Governance, Regulatory Learning and Legal-Technical Interaction

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This article analyses the AI regulatory sandboxes architecture under the AI Act through the lenses of "legal transplantation", advocating for a multilevel examination of their legal, institutional, and functional implications. AI regulatory sandboxes are conceived as controlled spaces for developing, training, validating, and testing AI systems subject to regulatory supervision. The article explores three key dimensions for their implementation, as key factors for a successful "transplant": governance, regulatory learning, and legal-technical interaction. Thus it first examines multilevel coordination problems at the interface between EU institutions, national and sub-national governments, and sectoral regulators, supporting harmonisation and structures of accountability. Then, it addresses the AI regulatory sandbox as a regulatory learning instrument, through which competent authorities may adapt not only the applicable rules but also their practices and regimes in response to sandbox experimentation. Lastly, the article addresses the fundamental issue of "substantial modification" in AI systems and the role of AI regulatory sandboxes in testing and supporting its assessment.

Keywords: AI regulatory sandboxes – AI Act – artificial intelligence — AI regulation – legal transplants

I. Introduction

This article examines AI regulatory sandboxes[1] envisaged under the EU AI Act[2] through the lens of legal transplantation, asking under which legal, institutional, and operational conditions this "double transplant" can succeed in EU and national legal orders. AI regulatory sandboxes are treated not merely as innovation-support tools, but as a legal

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[1] For a comprehensive work on regulatory sandboxes, see F. Bagni and F. Seferi (eds.), *Regulatory sandboxes for AI and Cybersecurity. Questions and answers for stakeholders*, CINI's Cybersecurity National Lab, (2025).

[2] Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj (last visited Jan. 26, 2026). The AI Act has the purpose to promote the uptake of human-centric and trustworthy AI, while ensuring an important level of protection of fundamental rights, health and safety in the EU (refer to Article 1).

institution that has been first transplanted from national and sectoral experimentation into EU law and will then be transplanted again into Member States' frameworks through the AI Act's mandatory obligation to establish at least one national sandbox by 2 August 2026.[3]

Methodologically, the article combines doctrinal analysis of the AI Act with insights from the broader literature on legal transplants and regulatory experimentation, complemented by a structured reading of existing sandbox schemes and guidance at EU and national level. Starting from the legal definition of AI regulatory sandboxes, the study identifies the core features of this instrument. Then, it identifies and analyses three dimensions that need closer consideration for evaluating the degree of success of such transplantation: i.e. governance, regulatory learning, and legal-technical interaction. The argument is grounded in comparative and multi-level reasoning, drawing on selected use cases and policy documents to extract recurring operational practices.

In this view, the structure of the article reflects this threefold analytical focus. Section II frames regulatory sandboxes as legal transplants, distinguishing them from broader notions of legal diffusion and underscoring the "double transplant" dynamic specific to AI sandboxes under the AI Act. Section III then turns to governance, unpacking the multilevel coordination challenges that arise between EU-level bodies (in particular the AI Board and the AI Office), national competent authorities, and regional or local actors, as well as across sectoral regulators already operating sandbox schemes. Section IV focuses on regulatory learning, conceptualising AI regulatory sandboxes as structured experimentation spaces that should generate regulatory feedback and inform both national policy cycles and the EU-level review and impact-assessment processes foreseen by the AI Act. Section V addresses legal-technical interaction by zooming in on the contested notion of "substantial modification" of AI systems and exploring how sandbox activities can support the assessment, documentation, and risk management of such modifications along the AI system lifecycle. Finally, Section VI provides concluding reflections on AI regulatory sandboxes as hybrid instruments of legal and institutional transformation.

II. FRAMING SANDBOXES AS LEGAL TRANSPLANTS

II.1 *Brief remarks on legal diffusion and transplantation*

Legal transplants refer to the process by which a law or legal institution developed in one country is adopted or borrowed by another country or legal system, often with adaptations to suit the new local context.[4] While legal borrowing has resulted to be a common and effective process, "legal transplant" is a contested term, with research preferring

[3] Refer to Article 57(1) of the AI Act.

[4] J. W. Cairns, *Watson, Walton, and the History of Legal Transplants*, in Georgia Journal of International and Comparative Law 41(3), 637 (2013).

expressions such as "legal diffusion"[5] – albeit the growing success of the metaphor provided by the meaning of "transplantation".

Although both "legal diffusion" and "legal transplants" pertain to the phenomenon of transferring and moving laws or regulatory models across borders, the term "legal transplant" points not only to the act of borrowing but also to the challenges of adaptation and institutional integration faced by these models in their new environment. The legal transplantation debate focuses on the fact that a successful transfer relies on adjustments to legal, cultural, and policy contexts in understanding that not all institutions can be easily transported.[6]

The regulatory sandbox concept is a strong exemplary case today: its transfer and application from one sector or jurisdiction to another perfectly illustrates both the promise and the hard realities of legal transplantation in action. In this sense, regulatory sandboxes may be considered a form of "legal transplant".[7] Such frameworks allow for the controlled testing of innovative products under the oversight of a regulatory authority.[8] They were introduced in the financial sector, after an initial establishment in the United Kingdom, where the Financial Conduct Authority (FCA) launched its first regulatory sandbox in 2016 to support fintech innovation.[9] This first initiative has since inspired a wide range of applications in several jurisdictions and sectors, with financial services still being a key pillar.[10] Regulatory sandboxes can be considered as mechanisms for "structured experimentalism".[11] This represents another factor for adopting a "legal transplant" lens in analysing regulatory sandboxes: it is not only a specific law or *corpus* of laws, but a regulatory method – a legal institution and practice in itself – that is diffused, borrowed, and adapted into different legal systems and jurisdictions.[12]

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[5] T. S. Goldbach, *Why Legal Transplants?*, in Annual Review of Law and Social Science, 15:583-601 (2019).

[6] J. W. Cairns, *cit.*

[7] This has been already analysed by Ford and Ashkenazy, who write that "[t]ransplants from one regulatory regime to another require careful thought, if they are to achieve the objectives the new context's regulators have in mind for them"; see C. Ford and Q. Ashkenazy, *The Legal Innovation Sandbox*, in The American Journal of Comparative Law, 72:3, 559 (2024). A more recent article has also shown how this is valid with respect to comparing U.S., EU and Chinese models, in particular by noting that "[t]hese models are not converging toward a single standard; rather, they reflect endogenous responses to regulatory, political, and economic constraints. This framework provides a useful lens for evaluating potential regulatory transplants, legal harmonization efforts, and the risks of conceptual misappropriation": see A. Stazi and R. Jovine, *A Comparative Analysis of Regulatory Sandboxes: Models, Evolution and Strategic Implications in EU, USA and China*, in Comparative Law Review, 16:2, 65 (2025).

[8] For an account of AI sandboxes, see Datasphere Initiative, *Sandboxes for AI. Tools for a new frontier*, Report (2025).

[9] For more information on the FCA Sandbox refer to: https://www.fca.org.uk/firms/innovation/regulatory-sandbox (last visited Jan. 26, 2026).

[10] F. Seferi, *A comparative analysis of regulatory sandboxes from selected use cases: Insights from recurring operational practices*, in F. Bagni and F. Seferi (eds.), *cit.*, (2025).

[11] D. A. Zetzsche, R. P. Buckley, J. N. Barberis, and D. W. Arner, *Regulating a revolution: From regulatory sandboxes to smart regulation*, in Fordham J. Corp. & Fin. L., 23:31-103 (2017).

[12] Several studies have also mapped how regulatory sandboxes have been diffused to different contexts and geographies; see, e.g., A. Attrey, M. Lesher and C. Lomax, *The role of sandboxes in promoting flexibility and innovation in the digital age*, Going Digital Toolkit Note No. 2 (2019); World Bank Group, *Global Experiences from Regulatory Sandboxes*, Fintech Note No. 8 (2020); Baker McKenzie, *A guide to regulatory fintech sandboxes internationally* (2021).

These efforts have led to a consolidation of such practice at EU level also.[13] In particular, the AI Act includes provisions on AI regulatory sandboxes in Chapter VI, which focuses on measures to support innovation. Albeit not being the only EU Regulation that foresees regulatory sandboxes in the digital domain,[14] the AI Act covers a key role since it mandates Member States to ensure that their competent authorities establish at least one AI regulatory sandbox at national level by 2 August 2026.[15] Thus, it is the only Regulation that clearly sets a mandatory provision regarding the establishment of such a scheme at national level in the EU.

Such obligatoriness underscores a distinctive feature of AI regulatory sandboxes, a case of a "double" transplant: first, the regulatory sandbox as a framework was transplanted from sectoral (thus, external) utilisation into EU law; second, due to their mandatory establishment at national level, AI regulatory sandboxes will be permanently transplanted further into national frameworks.[16]

II.2 *AI regulatory sandboxes under the AI Act*

The AI Act defines AI regulatory sandboxes as "controlled framework[s] set up by a competent authority[17] which offer 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".[18]

Starting from the "legal" definition, we can identify an array of features of AI regulatory sandboxes – thus, acknowledging how they have been "transplanted" into the AI Act. First, it is a *controlled framework*, thus assuming that the experimentation should be carried

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[13] They are included as one of the approaches within the EU Better Regulation Toolbox, specifically under Tool #69 on emerging methods and policy instruments.

[14] Other two key examples being the interoperability regulatory sandboxes under the so-called Interoperable Europe Act (Regulation (EU) 2024/903 laying down measures for a high level of public sector interoperability across the Union, 22.3.2024, ELI: http://data.europa.eu/eli/reg/2024/903/oj (last visited Jan. 26, 2026)), and cyber resilience regulatory sandboxes under the so-called Cyber Resilience Act (Regulation (EU) 2024/2847 on horizontal cybersecurity requirements for products with digital elements, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj (last visited Jan. 26, 2026)).

[15] Refer to Article 57(1) of the AI Act.

[16] This is also similar to the concept of "double transplantation" included in the taxonomy created by Ferreri and DiMatteo, who consider this as the case in which a country transplants a specific area of law and then uses that transplantation in the making of a broader law"; see S. Ferreri and L. A. DiMatteo, *Terminology Matters: Dangers of Superficial Transplantation*, in Boston University International Law Journal, 37:1, 54 (2019).

[17] Refer to Article 3(48) of the AI Act for the definition of "national competent authority", for which it relates to "a notifying authority or a market surveillance authority; as regards AI systems put into service or used by Union institutions, agencies, offices and bodies, references to national competent authorities or market surveillance authorities in this Regulation shall be construed as references to the European Data Protection Supervisor".

[18] Refer to Article 3(55) of the AI Act. On a systematic analysis of AI regulatory sandboxes under the AI Act, refer to L. Cotino Hueso, *Sandbox, controlled spaces and real-world testing of artificial intelligence systems in the regulation. Measures for SMEs, startups and micro-enterprises*, in L. Cotino Hueso and D. Galetta (eds.), The European Union Artificial Intelligence Act. A systematic commentary, Editoriale Scientifica, 867 ff. (2025). See also J. Ponce and A. Cerrillo-i-Martínez (eds.), *The EU Artificial Intelligence Act and the Public Sector - Humans and AI Systems in Public Administration in the light of the European Regulation on Artificial Intelligence of 2024*, EPLS Vol. CXXVIII (2025).

out in a protected manner, within specific safeguards. Such controlled framework is set up by a competent authority, posing the need also for a legal basis defining the scope, operational procedures and roles of the different actors involved.[19]

Second, the scheme foresees, at a minimum, the involvement of at least two *types of actors* with different *roles*: (i) the competent authority – in particular, the market surveillance authority – who establishes the framework and oversees experimentation; and (ii) the (prospective) AI provider who participates in experimentation with its innovative AI system.

Third, the *type of activities* that may be conducted are namely four: development, training, validating and testing of innovative AI systems. This highlights how AI regulatory sandboxes may be used in different moments in the systems' development lifecycle, also posing the issue of defining the right types of experimentation to be conducted in each activity.

Fourth, experimentation is carried out pursuant to a specific *sandbox plan*. The sandbox plan holds a key role, since it contains the details of the main elements of sandbox participation, such as objectives, conditions, timeframe, methodology and requirements for the activities conducted within the AI regulatory sandbox.[20]

Fifth, participation in the sandbox is *limited in time*. This ensures that such protected environment and controlled regulatory regime do not apply indefinitely to a specific project, giving it an undue condition with respect to other market players.

Sixth, participation in the AI regulatory sandbox may include *testing in real-world conditions*,[21] that is "the 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 [the AI Act]".[22]

All these features contribute to placing AI regulatory sandboxes in alignment with the types of regulatory sandboxes established in other sectors or geographies. The AI Act, however, does not expressly foresee the possibility of derogating or having possible legal leeway or exemptions from specific norms: this has indeed been a core feature of certain legal traditions on regulatory sandboxes.[23] This is also a core feature of experimental regulation at large, which implies the testing, piloting or trial of a new product, service, approach or process, in such a way as to generate and gather evidence that can inform the design or administration of a regulatory regime.[24] It remains to be seen how AI regulatory

[19] G. Mobilio and M. Giannelli, *Legal basis for regulatory sandboxes: Key aspects for a coherent theoretical and practical framework*, in F. Bagni and F. Seferi (eds.), *cit.*, 29-43.

[20] Refer to Article 3(54) of the AI Act.

[21] Refer to Article 58(4).

[22] Refer to Article 3(57) of the AI Act, for which consistent practices should be ensured across the EU through the cooperation between national competent authorities with respect to testing in real-world conditions.

[23] See, e.g., regulatory sandboxes established in Germany through experimentation clauses; refer to the German Federal Ministry for Economic Affairs and Energy, *Making space for innovation: The handbook for regulatory sandboxes* (2019).

[24] For an overview framing of regulatory sandboxes within experimental regulation, see also E. Longo and F. Bagni, *From legal experimentation to regulatory sandboxes: The EU's pioneering approach to digital innovation and regulation*, in F. Bagni and F. Seferi (eds.), *cit.*, 18-28. See also F. Costantini, *Società dell'Informazione e "diritto*

sandboxes will be deployed and evolve with respect to granting (or not) the availability of derogating from norms.

To prevent regulatory fragmentation within the EU,[25] the European Commission is mandated to adopt implementing acts that will define the provisions governing the "establishment, development, implementation, operation, and supervision of the AI regulatory sandboxes".[26] They will provide the ground rules of "orderly transplant" of the EU framework of AI regulatory sandboxes into Member States' legal frameworks. However, such acts should also provide for flexibility to establish and operate AI regulatory sandboxes at national level.[27] This is indeed a particular moment in time where, considering that the implementing acts and national AI regulatory sandboxes are under development, the diffusion of the legal institution is currently underway. This connects also to the role of legal culture(s) in shaping the success or failure of legal transplants.

Thus, as the implementation and operation of AI regulatory sandboxes generates more data from August 2026 onwards, more empirical sources will be available to assess their success. It is however important to highlight at present how such transplant may be carried out by defining some key dimensions based on the analysis of the legal text of the AI Act and of existing sandbox schemes.

III. GOVERNANCE: NAVIGATING MULTILEVEL COORDINATION

III.1 *Supra-national level*

Albeit mandating the setup of AI regulatory sandboxes at the national level, the AI Act institutes key bodies at the supra-national level to ensure coherent and effective implementation across the EU: first, the European AI Board, which comprises representatives from each EU Member State.[28] Its main function is to secure the uniform application of the AI Act by enabling cooperation between Member States and acting as an essential platform for gathering and exchanging regulatory and technical knowledge. The need of cross-border coordination is embedded in AI regulatory sandboxes since they should facilitate cooperation between national competent authorities of different Member

tecnologico". Il caso delle norme "sperimentali", in R. De Giorgi (ed.), *Limiti del diritto. Prospettive di riflessione e analisi*, 617-629 (2018).

[25] For a first analysis on advantages and pitfalls of a possible harmonised EU legal framework for regulatory sandboxes see D. Ahern, *Regulatory Lag, Regulatory Friction and Regulatory Transition as FinTech Disenablers: Calibrating an EU Response to the Regulatory Sandbox Phenomenon*, in European Business Organization Law Review, Vol. 22 (2021).

[26] Refer to Article 58(1) of the AI Act, see F. Bagni and F. Seferi, *Commento all'Articolo 58*, in A. Mantelero, G. Resta, G. M. Riccio, *Intelligenza Artificiale - Commentario (I edizione)*, Commentari IPSOA, Wolters Kluwer (2025). The draft implementing act was made available by the European Commission for public consultation from 2 December 2025 to 13 January 2026: more information available at https://digital-strategy.ec.europa.eu/en/consultations/commission-seeks-feedback-draft-implementing-act-establish-ai-regulatory-sandboxes-under-ai-act (last visited Jan. 13, 2026).

[27] Refer to Article 58(2)(c) of the AI Act.

[28] Refer to Article 65 of the AI Act.

States.[29] The AI Board also provides important advice and guidance on draft delegated or implementing acts, such as the ones on AI regulatory sandboxes. National competent authorities are themselves directly required to harmonise their activities with respect to sandboxes through the AI Board [30] and to submit annual reports on sandbox implementation to it and the AI Office.[31]

The latter is also a key actor in the supra-national layer of governance. Indeed, the European Commission, through the AI Office, is mandated to adopt the implementing acts containing the detailed arrangements on AI regulatory sandboxes (see subsection II.2). In addition, the AI Office supports governance bodies in Member States by facilitating information exchange and providing technical support, advice, and tools for the establishment and operation of AI regulatory sandboxes.[32] It also actively coordinates with national authorities to promote cooperation among Member States regarding sandboxes and will maintain a publicly available list of all planned and existing sandboxes.[33]

The AI Office is also key since it receives notifications from national competent authorities regarding possible (temporary or permanent) suspensions of testing due to unmitigated risks.[34]

Moreover, another venue of required coordination concerns AI models. The extent to which model testing will occur within AI regulatory sandboxes, and how much (if any) attention general-purpose AI (GPAI) models[35] will be given, has yet to be clarified. However, since oversight of GPAI models lies with the European Commission, specifically the AI Office, coordination and responsibility mechanisms should be defined for those cases where the development, training, validation or testing of an innovative AI system in a national (or sub-national) AI regulatory sandbox may require an evaluation of the GPAI model on which it is based.[36] We would thus have the inclusion of a EU-level body in the operation of a national (or sub-national) AI regulatory sandbox.[37] This is important for the establishment of AI regulatory sandboxes, in particular with respect to

[29] Refer to Article 57(13) of the AI Act.
[30] Refer to Article 57(14) of the AI Act.
[31] Refer to Article 57(16) of the AI Act.
[32] Worth of mentioning, in this sense, is the EUSAiR project, i.e. the two-year Coordination and Support Action launched by the AI Office under the Digital Europe Programme in December 2024, which will support the implementation of AI regulatory sandboxes across the EU; for more information refer to: https://eusair-project.eu/ (last visited Jan. 14, 2026).
[33] Refer to Article 57(15) of the AI Act.
[34] Refer to Article 57(11) of the AI Act.
[35] As defined in Article 3(63), a GPAI model is "an AI model, including where such an AI model is trained with a large amount of data using self-supervision at scale, that displays significant generality and is capable of competently performing a wide range of distinct tasks regardless of the way the model is placed on the market and that can be integrated into a variety of downstream systems or applications, except AI models that are used for research, development or prototyping activities before they are placed on the market".
[36] For example, as referred to in Article 75(1) of the AI Act, "[w]here an AI system is based on a general-purpose AI model, and the model and the system are developed by the same provider, the AI Office shall have powers to monitor and supervise compliance of that AI system with obligations under [the AI Act]". In this case, the AI Office covers the role and has the powers of a market surveillance authority.
[37] This has been noted in the so-called Digital Omnibus on AI Regulation Proposal, i.e. the proposal for amendments to the AI Act, through which the AI Office may be given the possibility of establishing EU-wide AI regulatory sandboxes with respect to GPAI systems. For more information visit: https://digital-strategy.ec.europa.eu/en/library/digital-omnibus-ai-regulation-proposal (last visited Jan. 26, 2026).

their operating procedures, which should in case include such possibilities of coordination and collaboration with the AI Office and clarify which actor retains which responsibility. Ultimately, in the supranational layer, the legal transplant of AI regulatory sandboxes is mediated by EU-level coordinating bodies that act as the primary "host environment" for the new instrument, shaping how it will later take root in national systems. Through the AI Board's harmonising role and the AI Office's power to adopt implementing acts, issue guidance, and aggregate reports, the transplant is channelled into a shared governance framework that reduces the risk of divergent national interpretations of the sandbox model. At the same time, open questions around GPAI oversight show that this host environment is still evolving, so that sandboxes function simultaneously as transplanted instruments and as experimental interfaces feeding back into the further refinement of the EU-level legal architecture that received them.

III.2 *National level*

Effective national coordination is foundational for the successful operation of AI regulatory sandboxes. National competent authorities are the central actors in sandbox operation.[38] Indeed, each Member State shall establish or designate at least one notifying and one market surveillance authority as national competent authorities under the AI Act.[39]

In addition, robust inter-agency cooperation with other relevant national authorities is essential, in particular with regard to national data protection authorities (DPAs): this is the case for those innovative AI systems that involve the processing of personal data.[40] Other authorities providing or supporting access to data may also be involved insofar as the AI system admitted for experimentation within the sandbox falls under their supervisory remit. This provision is also linked to the possibility of further processing personal data within sandboxes with the aim of developing AI systems for public interest.[41] The provision lays down the possibility of processing "personal data lawfully collected for other purposes"[42] for the development, training, and testing[43] specific AI systems under

[38] National competent authorities, as defined under Article 3(48) of the AI Act, are notifying authorities meaning "the national authorit[ies] responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring" (refer to Article 3(19)), or market surveillance authorities meaning "the national authorit[ies] carrying out the activities and taking the measures pursuant to Regulation (EU) 2019/1020" (refer to Article 3(26)).

[39] Refer to Article 70(1) of the AI Act. For a more detailed analysis see E. Longo and F. Seferi, *Commento all'Articolo 70*, in P. Perri, G. Vaciago and G. Ziccardi, *Commentario Regolamento sull'Intelligenza Artificiale,* Giuffrè Francis Lefebvre, *forthcoming*.

[40] Refer to Article 57(10) of the AI Act.

[41] Refer to Article 59 of the AI Act.

[42] Refer to Article 59(1) of the AI Act.

[43] It is interesting to notice how, contrary to the activities foreseen by the AI Act for AI regulatory sandboxes (see paragraph II.2), the provision on further processing of personal data does not include the validation of AI systems (thus including only development, training, and testing). This opens a discrepancy when it comes to legally performing such activity within the sandbox.

specific conditions.[44] Multi-authority collaboration will most probably be a necessity with overlapping oversight, considering that the horizontal nature of AI application means that AI systems often lie at the intersection of various legal frameworks (e.g., medical devices, financial services, employment, critical infrastructure, cybersecurity). [45] Seamless collaboration between AI-specific national competent authorities and established sectoral regulators can be streamlined by either (i) coordinating multi-agency windows of applications on specific topics,[46] or (ii) by creating dedicated venues or committees within AI regulatory sandboxes where different (sectoral) regulators convene to oversee specific participating projects.[47]

Another aspect concerns existing regulatory sandboxes. As previously mentioned, before the AI Act had been adopted, several sectoral bodies had already launched their own regulatory sandboxes tailored to specific domains such as finance, healthcare, or mobility – and the trend is not slowing down.[48] While these efforts have provided valuable insights, they also risk contributing to fragmentation if not properly aligned. A coordinated approach is needed to ensure that such pre-existing initiatives can be integrated into an overall strategy:[49] such nested approach to sandboxing brings an increased need for common risk assessment and management methodologies across different frameworks, in view of harmonising activities and legal outputs of such sandboxes.[50]

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[44] For a more complete analysis of the matter, also with respect to the overlaps with GDPR requirements, see D. Baldini and K. Francis, *AI Regulatory Sandboxes between the AI Act and the GDPR: The role of Data Protection as a Corporate Social Responsibility*, CEUR Workshop Proceedings, vol. 3731 (2024); and D. Baldini, *Legislative intersection perspectives on regulatory sandboxes: Navigating the interplay between the AI Act and the GDPR*, in F. Bagni and F. Seferi (eds.), *cit.*, 70-84.

[45] C. Novelli, P. Hacker, S. McDougall, J. Morley, A. Rotolo, and L. Floridi, *Getting Regulatory Sandboxes Right: Design and Governance Under the AI Act,* Working Paper, SSRN, June 30 (2025).

[46] Ibidem.

[47] For example, the Dutch proposal for an AI regulatory sandbox foresees a three-pillar structure: a core coordination team, a panel of experts for addressing domain-specific questions, and multi-session sandbox processes. This offers a practical model for structuring such inter-agency collaboration and integrating diverse expertise at the national level. For more information refer to: https:// www.autoriteitpersoonsgegevens.nl/en/documents/proposal-dutch-regulatory-sandbox (last visited Jan. 26, 2026).

[48] For example, in Italy two of the most well-known schemes include: (i) the Financial Services Sandbox scheme, established by the Decree of the Ministry of Economy and Finance 100/2021 and involving the market surveillance authorities in banking, insurance and financial markets (for more information refer to: https://www.bancaditalia.it/focus/sandbox/ (last visited Jan. 26, 2026)); and (ii) "Italy Experimentation", a more general and cross-sectoral framework Introduced by Article 36 of Legislative Decree 76/2020 (Urgent measures for simplification and digital innovation) converted by Law 120/2020 (for more information refer to: https://innovazione.gov.it/progetti/sperimentazione-italia/ (last visited Jan. 26, 2026)). For a critical assessment of such schemes see N. Maccabiani, *An empirical approach to the Rule of Law: the case of Regulatory Sandboxes*, in Osservatorio sulle fonti, n. 2 (2020); G. Lo Sapio, *Il regolatore alle prese con le tecnologie emergenti. La regulatory sandbox tra principi dell'attività amministrativa e rischio di illusione normative*, in Federalismi.it, n. 30 (2022); M. Trapani, *L'utilizzo delle sandboxes normative: una ricognizione comparata delle principali esperienze di tecniche di produzione normativa sperimentali e il loro impatto sull'ordinamento*, in Osservatorio sulle fonti, XV, n. 3 (2022); M. Romboli, *Sandbox normativa e temporanea disapplicazione delle regole amministrative*, in Il Diritto Amministrativo (2022); M. Milanesi, *Lo sviluppo delle sandbox regolatorie italiane tra dubbi e opportunità. Requiem per l'art. 223 dello «Schema definitivo di Codice dei contratti pubblici»*, in Federalismi.it, n. 15 (2023); N. Pini, *La regulatory sandbox nell'ordinamento italiano: profili critici e prime applicazioni*, in Queste istituzioni, n. 3 (2023).

[49] As noted also in Article 57(4) of the AI Act.

[50] On the role of regulatory sandboxes as risk management instruments see F. Seferi, *A working experimentation model for cyber resilience regulatory sandboxes*, in Joint National Conference on Cybersecurity Proceedings (ITASEC and SERICS) (2025).

All this considered, at the national level, the transplant of AI regulatory sandboxes becomes a question of how this externally driven legal institution can be integrated into existing administrative structures, sectoral regimes, and data-protection arrangements without generating fragmentation. Authorities must re-configure their cooperation practices, risk-assessment methodologies and data-access setups so that the incoming sandbox scheme complements, rather than conflicts with, pre-existing frameworks. Because many Member States already host sectoral sandboxes, the AI Act's sandbox is effectively transplanted into a crowded ecosystem, and its success hinges on whether national actors can nest this new, EU-mandated layer within domestic experiments, turning overlapping schemes into a coordinated family of transplants instead of isolated, competing organs.

III.3 *Sub-national level*

The AI Act explicitly acknowledges the possibility of establishing additional AI regulatory sandboxes at regional or local level.[51] These sandboxes need however to be considered within the overall national system. One of the focal points is governance and accountability: this demands that it is made clear who should establish and operate the scheme. National competent authorities, charged with placing into effect and ensuring compliance with the provisions of the AI Act, offer bespoke guidance and legal clarification through the national sandbox. The issue is that if only regional or local authorities have responsibility for establishing and operating the scheme, then this may extend their duties beyond those established under the AI Act. According to this perspective, national competent authorities should continue to participate in the regional and local sandboxes and maintain a certain degree of accountability and oversight regarding their operation. Regional and local authorities may also have the opportunity for greater involvement, depending on the functions and powers assigned to them by their respective Member States.

All this considered, diverse types of mechanisms may be weighed. Where national competent authorities are subject to administrative capacity constraints, or subsidiarity considerations mandate experimentation on a localised scale, decentralisation of operational responsibilities to local or regional authorities can be both a practical and attractive solution. Such delegation should not be ad hoc or de facto, however, but rather clearly delineated, legally formalised, and supported by procedural safeguards. It is only through such formalisation that integrity in the regulatory system can be maintained with accountability and legal certainty of involved parties. Local and regional authorities, when they are given responsibility for running sandbox schemes within their areas, will have to

[51] In Italy, a prominent case is the one of Tuscany with the Regional Law 57/2024, which regulates digital innovation and the protection of digital citizenship rights in the region (available at: https://raccoltanormativa.consiglio.regione.toscana.it/articolo?urndoc=urn:nir:regione.toscana:legge:2024-12-09;57 (last visited Jan. 26, 2026)). Such regional law provides for the first transposition of sandboxes at the Italian regional level, in particular for AI regulatory sandboxes as defined by the AI Act. Indeed, Article 25(2) defines regulatory sandboxes as "a tool for studying and experimenting with processes and technologies in particularly innovative fields, including AI and cybersecurity".

do so within the competences allocated to them. That might involve, for example, the administration of sectoral pilot schemes or access arrangements to local infrastructures or datasets. [52]

While regional and local authorities may be tasked with monitoring sandbox regime day-to-day operations (functioning, thus, as coordinating bodies), the ultimate responsibility for regulation-related monitoring must rest within the national competent authorities. They are indeed the institutional actors best positioned to ensure consistency, proportionality, and policy conformity to national and supranational policy objectives. To maintain this decentralised model of implementation, national competent authorities will need to take an active role in constructing and disseminating the "secondary" rules that govern sandbox activity, for overall harmonisation and consistency of practices. These rules could include standardised entry criteria for participating, procedural guidelines for evaluation, data-exchange protocols, and indicators for measuring regulatory effect. The success of including local and regional authorities in the sandbox environment requires a governance system based on open delegation of responsibilities, legal formalisation of delegation agreements, and strong coordination tools backed by national supervision.

Finally, at the sub-national level, the sandbox transplant is further differentiated as regional and local authorities become potential operators of additional schemes, raising the issue of how far operational responsibilities can be devolved without undermining the integrity of the transplanted institution. Regional and local sandboxes can tailor the transplanted model to specific territorial needs and infrastructures, but they must remain normatively anchored to the national competent authorities through clearly formalised delegation, accountability chains, and harmonised "secondary rules" on entry, procedures, data exchange and metrics. In this perspective, decentralisation is framed as a controlled extension of the transplant into local legal tissues, where national supervision and common standards ensure that experimentation at the periphery does not mutate the core design of the AI regulatory sandbox as transplanted by the AI Act.

IV. REGULATORY LEARNING: ITERATIVE POLICY FEEDBACK

IV.1 *The regulatory learning space*

One of the core objectives of AI regulatory sandboxes is to enable regulatory learning and iterative policy-making. [53] AI regulatory sandboxes need not only to enable experimentation but also the development of tools and infrastructures necessary for testing AI systems: this includes metrics such as accuracy, robustness, and security that are

[52] For example, the role of dataset provisioning from public administration is key in the Zurich AI Innovation Sandbox (for more information refer to: https://www.innovationsandbox.ai/ (last visited Jan. 26, 2026)). For a detailed analysis on the Zurich AI Innovation Sandbox, see R. von Thiessen, *Learnings from the AI Sandbox in Zurich: A practical perspective*, in F. Bagni and F. Seferi (eds.), *cit.*, 177-191.

[53] Refer to Article 57(9)(d) of the AI Act, i.e. the contribution of AI regulatory sandboxes to evidence-based regulatory learning.

relevant for regulatory learning, along with provisions to safeguard essential rights and handle societal impacts.[54]

In brief, regulatory learning is the process through which evidence is collected in order to adapt the existing and applicable regulatory policy and framework:[55] it enables technology regulation to effectively respond to and accommodate rapid developments in both the capabilities and applications of regulated technologies.[56] Regulatory learning occurs when regulators acquire knowledge of the issues and possibilities offered by new technologies and innovations, as well as regarding any loopholes or shortcomings in existing regulatory and supervisory frameworks. Such a mechanism is even more pertinent in industries where innovative technologies can offer solutions to social problems. Regulatory learning allows decision makers to learn more about the possible risks as well as benefits and decide whether new interpretations or amendments to current laws are necessary to cope with technological advancements.[57]

The type of regulatory change should also be framed with respect to the specific geographic and sectoral scope (see also Section III). Although Member States are required to document regulatory learning from sandboxes through exit reports[58] and annual reports,[59] they could also implement broader evaluation mechanisms. Therefore, individual EU countries should consider going beyond the formal requirement and analyse how various aspects of the current EU regulatory framework impact businesses and consumers within sandboxes.[60]

IV.2 *Integration into broader AI governance*

To fully harness the regulatory potential of AI regulatory sandboxes, their outcomes must be systematically integrated into the broader governance and implementation architecture of the AI Act. These sandboxes are not intended to be isolated experimental exercises with narrow relevance to specific innovators or individual national regulators.[61] Rather,

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[54] Refer to Article 58(2)(i) of the AI Act.

[55] K. Kert, M. Vebrova, and S. Schade, *Regulatory learning in experimentation spaces*, European Commission, Joint Research Centre (2022), for which "[r]egulatory learning refers to the collection and use of any evidence or knowledge that is relevant to current or future regulatory policy, generated in the process of experimenting with an innovative solution" (p. 2).

[56] D. Lewis, M. Lasek-Markey, D. Golpayegani, and H. J. Pandit, *Mapping the Regulatory Learning Space for the EU AI Act*, in Computers and Society (2025).

[57] European Commission, *Staff Working Document, Regulatory learning in the EU: Guidance on regulatory sandboxes, testbeds, and living labs in the EU, with a focus section on energy*, Brussels, Belgium, p. 6 (2023).

[58] Refer to Article 57(7) of the AI Act.

[59] Refer to Article 57(16) of the AI Act.

[60] E. Longo, *Gli spazi di sperimentazione normativa o anche regulatory sandboxes nell'AI Act*, in F. Pizzetti, S. Calzolaio, A. Iannuzzi, E. Longo, and M. Orofino, *La regolazione europea dell'intelligenza artificiale nella società digitale*, 2025, Giappichelli Editore – Torino.

[61] Methodological concerns regarding the generalizability of the results and outputs stemming from regulatory sandboxes has been raised frequently; S. Ranchordás and V. Vinci, *Regulatory Sandboxes and Innovation-friendly Regulation: Between Collaboration and Capture*, in Italian Journal of Public Law, Vol. 1/2024.

they should function as structured and strategic sites of regulatory learning, providing real-world insights that inform the EU's evolving legal framework for artificial intelligence.[62]
Integrating sandbox outputs into the broader evaluation and review process under the AI Act is essential. This foresees periodic reviews to assess its implementation, proportionality, and effectiveness in light of technological and societal developments.[63] Findings from regulatory sandboxes should offer empirical data on how AI systems perform in practice, where compliance challenges emerge, and whether the current risk-based classification and risk categories are fit for purpose. In this view, a key factor is to establish reliable, standardised success and failure metrics that are applicable across different sandbox projects, by developing clear and consistent procedures for translating sandbox outcomes into concrete regulatory action, such as rule modifications or updated guidance documents.[64]
Such insights are particularly valuable when feeding into regulatory impact assessments (RIAs), which are fundamental tools for ensuring that new legislative proposals or regulatory revisions are proportionate, targeted, and effective.[65] RIAs are central to evidence-based policymaking in the EU legal system. They provide a structured method for evaluating the potential economic, social, and environmental impacts of new or revised regulatory measures. In the context of AI governance, integrating sandbox findings into RIAs would ensure that any future amendments to the AI Act or related legislative instruments are grounded in real-world experimentation and stakeholder feedback.[66]
To support this continuous learning and regulatory calibration, knowledge-sharing mechanisms must be institutionalised. A centralised, accessible digital platform will be established by the AI Office where all sandbox reports, tools, methodologies, and key findings should be published in a standardised and comparable format.[67] This platform should serve as both a repository and a dynamic knowledge hub, facilitating the replication of good practices, enabling benchmarking across Member States, and fostering inclusive engagement from industry, academia, and civil society. Moreover, a formalised institutional learning cycle is needed to ensure that sandbox findings systematically inform regulatory strategy. A dedicated annual AI Board meeting could serve such purpose, with a specific mandate to review sandbox outcomes and develop cross-cutting policy recommendations.

[62] On the possible role of AI regulatory sandboxes within broader governance of high-risk AI systems, see J. Truby, R. D. Brown, I. A. Ibrahim, and O. Caudevilla Parellada, *A Sandbox Approach to Regulating High-Risk Artificial Intelligence Applications*, in European Journal of Risk Regulation, vol. 13, n. 2, pp. 270-294 (2022).
[63] Refer to Article 112 of the AI Act.
[64] C. Novelli, P. Hacker, S. McDougall, J. Morley, A. Rotolo, and L. Floridi, *cit.*.
[65] C. M. Radaelli and F. de Francesco, *Regulatory Impact Assessment*, in R. Baldwin, M. Cave, and M. Lodge (eds.), *The Oxford Handbook of Regulation*, 279-301 (2010).
[66] Indeed, regulatory sandboxes could add value in other instruments for regulatory quality, since they are placed between ex-ante ones (like RIAs) and ex-post evaluations; S. Ranchordás, *Experimental Regulations and Regulatory Sandboxes: Law without Order?*, University of Groningen Faculty of Law Research Paper Series n. 10, 10 (2021).
[67] Refer to Article 57(17) of the AI Act.

IV.3 *Learning as an institutional transplant*

The regulatory learning dimension of AI regulatory sandboxes illustrates a particular complexity in the transplantation process: it concerns not a discrete regulatory rule or instrument, but rather a methodological and institutional shift in how regulatory authorities understand and relate to emerging technologies. When regulatory sandboxes are transplanted into new jurisdictions, the regulatory learning apparatus itself must be adapted to fit (and expand) existing institutional cultures, policy cycles, and evidence-based decision-making traditions.[68] This represents a transplant of regulatory practice rather than regulatory form.

The AI Act's embedding of regulatory learning within AI regulatory sandboxes reflects an acknowledgment that the sustainable transplantation of sandboxes depends on integrating their outputs into established governance architectures.[69] At the EU level, this integration occurs through the European AI Board's coordination role and the AI Office's function as a centralised repository of sandbox knowledge (see also subsection III.1). At the national level, however, the transplant faces contextual pressures: individual Member States possess different bureaucratic capacities, policy formulation windows, and established sectoral regulatory traditions.[70] A Member State's ability to translate sandbox findings into concrete regulatory adaptation may depend on the openness of its legislative cycle, the sophistication of its regulatory impact assessment practices, and the institutional embedding of evidence-based policymaking within its tradition of administrative law. Thus, at the national level, learnings from sandboxes may also be tied to the opening of formal windows within the policy lifecycle.[71]

The legal transplant literature has recognised that successful institutional transfers require not merely the formal adoption of a new instrument, but its integration into existing administrative feedback loops and decision-making structures.[72] In the case of AI regulatory learning through sandboxes, this means that merely establishing sandbox schemes and generating empirical data is insufficient: the success of the transplant depends

[68] Thus, in terms of "learning that can complement the long-term learning processes of the traditional policy cycle", A. Guio Español and P. D. Koenig, *Regulatory sandboxes for AI in the majority world: A learning-centric approach to legal adaptation*, in Cambridge Forum on AI: Law and Governance, 1:e42, 1 (2025).

[69] The potential for and scalability of regulatory learning has indeed been proposed in the draft implementing act as a selection criterion for admitting (prospective) providers in AI regulatory sandboxes (Article 3(3)(b), *supra*, note 26).

[70] D. Ahern, *Operationalising AI regulatory sandboxes under the EU AI Act: The triple challenge of capacity, coordination and attractiveness to providers,* in Cambridge Forum on AI: Law and Governance, 1:e35, 2025.

[71] See, e.g., the experience of the "France Expérimentation" initiative. Such framework identifies two types of obstacles to innovation: (i) a regulatory blockage, where flexibility can be more easily achieved by involving the specific market regulator; (ii) a legislative blockage, which requires the opening of a specific participation window, often linked to the timing of the official policy formulation cycle of legislative bodies, such as the prospect of an appropriate legislative vehicle (vote on a bill by the Parliament). This shows how regulatory adaptation still has different timeframes and complexities depending on the requirement. For more information, refer to: https://www.modernisation.gouv.fr/simplifier-la-vie-des-usagers-et-des-agents/france-experimentation/modalites-de-fonctionnement (last visited Jan. 26, 2026).

[72] Y. Marique and E. Slautsky, *Resistance to Transplants in the European Administrative Space: An Open-Ended Reading of Legal Changes*, in Review of European Administrative Law (REALaw), 1:7-36 (2021).

on whether and how Member States institutionalise mechanisms for converting sandbox findings into policy adaptation.[73]

Furthermore, the regulatory learning transplant involves a specific challenge with respect to sectoral variation. Sandboxes operating in the financial sector may generate learning applicable across fintech, while AI regulatory sandboxes cut horizontally across multiple regulatory domains. The success of this transplant thus depends on designing knowledge-integration mechanisms that account for both the need for sectoral sensitivity and for horizontal coherence in AI governance.[74]

V. LEGAL-TECHNICAL INTERACTION: SUBSTANTIAL MODIFICATION

V.1 *Defining substantial modification*

A substantial modification is defined as "a change to an AI system after its placing on the market or putting into service which is not foreseen or planned in the initial conformity assessment carried out by the provider and as a result of which the compliance of the AI system with the requirements [for high-risk AI systems] is affected or results in a modification to the intended purpose for which the AI system has been assessed".[75] This relates to modifying a product, either physically or digitally, in ways that can alter its nature and characteristics, not having been considered during the initial risk assessment: such changes could potentially affect the product's safety, and therefore should be considered as a substantial modification, with the product being considered as a new one.[76]

In this view, a substantial modification would require a new conformity assessment to the high-risk AI system whose intended purpose has been changed, or whose overall compliance posture with the AI Act has been affected. However, for high-risk AI systems that continue to adapt post-market deployment or after being put into service, modifications and performance changes anticipated by the provider at the time of the initial conformity assessment and documented in the technical documentation shall not be considered a substantial modification.[77]

Thus, inclusion of the possible changes in the technical documentation qualifies them as "non substantial". Indeed, to ensure suitable traceability for high-risk AI systems, logging

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[73] A. Guio Español and P. D. Koenig, *cit.*, 8-13.

[74] For a deeper dive on policy implications see OECD, *Regulatory Sandboxes in Artificial Intelligence*, Digital Economy Papers, No. 356 (2023).

[75] Under Article 3(23) of the AI Act.

[76] Refer to Recital 35 of Regulation (EU) 2023/988 on general product safety, 23.5.2023, ELI: http://data.europa.eu/eli/reg/2023/988/oj (last visited Jan. 14, 2026). The recital also clarifies that "[i]n order to ensure compliance with the general safety requirement laid down in this Regulation, the person that carries out that substantial modification should be considered as the manufacturer and subject to the same obligations. That requirement should only apply with respect to the modified part of the product, provided that the modification does not affect the product as a whole. In order to avoid an unnecessary and disproportionate burden, the person carrying out the substantial modification should not be required to repeat tests and produce new documentation in relation to aspects of the product that are not impacted by the modification. It should be up to the person that carries out the substantial modification to demonstrate that the modification does not have an impact on the product as a whole."

[77] Refer to Article 43(4) of the AI Act.

must record events that help identify situations involving substantial modification to the system.[78] Additionally, these provisions are to be applied alongside more specific rules found in certain Union harmonisation legislation based on the New Legislative Framework.[79] For instance, Regulation (EU) 2017/745 specifies that certain changes are not considered modifications affecting compliance with applicable requirements; this remains applicable to high-risk AI systems classified as medical devices under that regulation.[80]

In any case, the European Commission will provide further guidance on the practical implementation of the requirements and provisions regarding substantial modification under the AI Act.[81]

V.2 *The role of AI regulatory sandboxes*

In addition to the development, training, validation and testing of AI systems before they are placed on the market or put into service, AI regulatory sandboxes should also cover the supervision of AI systems with respect to the notion and occurrence of substantial modification.[82] This is connected also to the support that should be given within AI regulatory sandboxes to understand and prepare for the conformity assessment obligations.[83]

AI regulatory sandboxes may help in clarifying which changes should be accounted for in the record-keeping obligation and technical documentation, thus identifying which qualify as "non substantial". For the modification to clarify as substantial, it must be unforeseen or unplanned in the context of the initial conformity assessment.[84] This may place a burden on (prospective) providers to engage in proactive and comprehensive risk assessment and scenario planning before an AI system is introduced to the market.[85] By anticipating potential future updates, concept, model and semantic shifts, and evolving use cases during the design and development phases, providers can incorporate these possibilities into their initial conformity assessment.

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[78] Refer to Article 12(2)(a) of the AI Act.

[79] Refer to Recital 84 of the AI Act.

[80] Refer to Article 16(2) of Regulation (EU) 2017/745 on medical devices, 5.5.2017, ELI: http://data.europa.eu/eli/reg/2017/745/oj (last visited Jan. 14, 2026).

[81] Refer to Article 96(1)(c) of the AI Act.

[82] Although not specified in an Article, such provision is included under Recital 139 of the AI Act. This aspect was although covered by the draft implementing act, which provides for a sandbox project to be eligible for participation if "the system will be subject to substantial modification" (Article 3(2)(b), *supra*, note 26).

[83] Refer to Article 58(2)(e) of the AI Act.

[84] Indeed, alterations that are integral to the system's predefined learning process are not regarded as substantial modifications; see Bird&Bird, *European Union Artificial Intelligence Act: a guide*, 28 (2025).

[85] Risk assessment and management is important also when implementing the AI Act's requirements – thus transitioning risk categorisation from a scope-oriented to a scenario-based model of multiple factors –, for the assessment of risk significance and when implementing internal risk management requirements; on the matter, see C. Novelli, F. Casolari, A. Rotolo, M. Taddeo, and L. Floridi, *AI Risk Assessment: A Scenario-Based, Proportional Methodology for the AI Act*, in Digital Society, 3:13 (2024).

In this view, risk assessment activities within AI regulatory sandboxes have a determining role.[86] Future methodologies for such risk assessments should, in this view, consider and place a key focus on substantial modification. This strategic analysis would help to prevent such changes from later being classified as "substantial modification", thereby avoiding the associated regulatory triggers and potential re-assessment burdens. Thoroughly conducting risk and impact assessment on AI systems within AI regulatory sandboxes may also support in identifying strategies and recommendations to include in the proactive management process of the system: this can be key for enhancing the continuous monitoring and evaluation mechanisms of the (prospective) providers and deployers.
Another aspect to consider is post-modification participation in the sandbox: i.e., if and how substantially modified AI systems should be allowed for participation in AI regulatory sandboxes. Since the AI system has already been placed on the market or put into service, sandbox participation may focus more on validation and testing, with the aim of ensuring that the new risk posture of the system is correctly defined. Moreover, potential participation of substantially-modified systems may pose a tension also with respect to the formal admission procedure and to the selection criteria defined for assessing applications. Principles on defining such criteria will be included in the upcoming implementing acts:[87] however, commonly they include core criteria such as degree of innovativeness, public interest or societal benefit, and level of maturity of the product.[88] For example, in this view, a more comprehensive analysis of what constitutes an "innovative" AI system should be carried out to ensure that this does not rule out substantially-modified systems for products already deployed.

V.3 *The "technical" frontier of transplantation*

The concept of substantial modification in the AI Act represents a particularly complex site of legal transplantation because it requires alignment between legal categories and technical realities. When AI regulatory sandboxes are established across Member States, they must operationalise the notion of substantial modification in ways that are both legally coherent and technically meaningful. This creates a transplant challenge that is genuinely novel: it is not simply a matter of importing a legal concept developed in another jurisdiction or sector, but of establishing shared understanding of a technical phenomenon (the modification and evolution of AI systems in deployment) through a fundamentally legal-administrative framing.[89]

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[86] A. Alaassar, A. Mention, and T. H. Aas, *Exploring how social interactions influence regulators and innovators: The case of regulatory sandboxes*, in Technological Forecasting and Social Change, Vol. 160 (2020). Their research has shown how social interactions within regulatory sandboxes (in particular, in the financial sector) increase both the legitimacy and risk management capabilities of regulated entities, and the understanding of legal constraints and risks stemming from enabling technologies of regulators.
[87] Refer to Article 58(1). See also *supra*, note 26.
[88] F. Seferi, *A comparative analysis of regulatory sandboxes from selected use cases: Insights from recurring operational practices*, in F. Bagni and F. Seferi (eds.), *cit.*, 149-151.
[89] See M. E. Kaminski, *Regulating the Risks of AI*, Boston University Law Review Vol. 103:1347 (2023), on a more general analysis of (AI) risk regulation itself as a legal transplant.

This creates a second-order transplant challenge: AI regulatory sandboxes must not only operationalise existing legal categories but must themselves become laboratories for refining those categories. The legal-technical interaction dimension shows that sandboxes are expected to support understanding and preparing for conformity assessment obligations, whilst clarifying which changes should be accounted for. This is a form of regulatory learning, but it is distinctly technical in character: it concerns the translation of legal thresholds into operational metrics and assessment procedures.[90]

The transplantation challenge is amplified by the heterogeneity of technical expertise and practices across Member States and sectoral contexts. An AI system in healthcare may undergo modifications that are routine and anticipated in that domain but would constitute substantial modifications if transferred to a critical infrastructure context. National competent authorities operating sandboxes will need to develop and adopt shared methodologies,[91] also in view of assessing substantial modification, while accounting for sectoral variation without creating de facto harmonisation failures.

Furthermore, the notion of substantial modification invokes a legal-technical gap that transcends traditional regulatory transplantation challenges. Whereas the transplantation of governance structures or institutional learning mechanisms can be achieved through legal-administrative means, the transplantation of a meaningful, operationally coherent understanding of when AI system modifications trigger regulatory reassessment requires alignment between legal institutions, technical standards, and practical expertise. This alignment cannot be achieved through legal text alone; it demands that AI regulatory sandboxes serve as sites of collaborative knowledge production between regulators, developers, and technical experts.[92]

VI. Conclusion

AI regulatory sandboxes, as defined in the AI Act and elaborated here further in this article, are a paradigmatic innovation of the EU's new technology regulatory governance. Instead of merely being compliance facilitators, they are hybrid instruments that combine innovation, regulation, and institutional transformation. Their architecture combines a logic of experimentation and iterated learning extending beyond the regulatory border and into the interior of how institutions perceive, process, and learn from technological transformation. This article has analysed AI regulatory sandboxes through the lenses of "legal transplants", thus regarding the moving of a rule or a system of law from one country or jurisdiction to another. AI regulatory sandboxes however provide for a

[90] Novel research has explored the possibility of using "technical" sandboxes for regulatory learning in the AI Act space, see T. Deckenbrunnen, A. Buscemi, M. Almada, A. Capozucca, G. Castignani, *The Bathtub of European AI Governance: Identifying Technical Sandboxes as the Micro-Foundation of Regulatory Learning*, (2026) arXiv:2601.04094.

[91] Refer to Article 58(2)(i) of the AI Act.

[92] On the knowledge gap between regulatory authorities and the technical specifics of the field to be regulated, see H. Ruschemeier, *Thinking Outside the Box? Regulatory Sandboxes as a Tool for AI Regulation* (2024), available at: http://dx.doi.org/10.2139/ssrn.4787008 (last visited Jan. 27, 2026).

"double" transplant activity since they were first introduced in EU law from widely growing adoption in mainly sectoral and national legislation, and they will be further transplanted into national legal frameworks in a permanent manner due to their mandatory establishment in EU Member States by 2 August 2026.

In this view, three core dimensions have been analysed as key for the success of such diffusion: governance, regulatory learning, and legal-technical interaction. From a governance point of view, sandboxes entail robust multilevel coordination at the EU, national, and sub-national levels, and horizontal coordination among sectoral regulators, so that regulatory experimentation does not equate with fragmentation. As far as regulatory learning is concerned, the true regulatory potential of sandboxes lies in the formalisation of feedback loops into broader legislative and governance cycles. Their output should not be stuck in the silos of individual projects or Member States but rather feed back into the evolving EU AI governance system: interpretive direction, conformity templates, and even future redraft of the AI Act itself. Moreover, coupling technical and legal efforts, AI regulatory sandboxes will play a pivotal role in discovering grey areas of AI Act's application, such as supporting in the assessment of possible substantial modifications to AI systems. Harmonised approaches, standardised measures, and distributed knowledge-sharing architectures will be critical.