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“AI Regulatory Sandbox Pilot Project”

Final report of the Bundesnetzagentur, the Federal Commissioner for Data Protection and Freedom of Information and the Hessian Ministry for Digitalisation and Innovation

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für Digitalisierung und
Innovation

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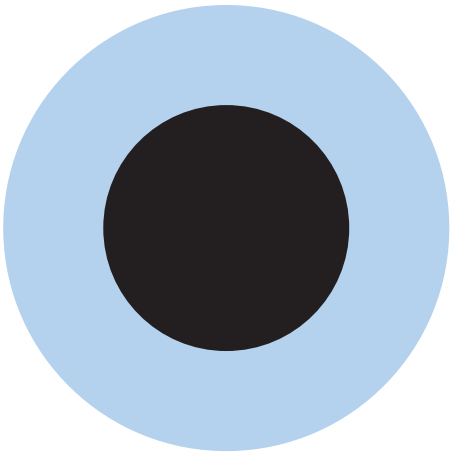

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1. Executive Summary

In a forward-looking pilot project, the Bundesnetzagentur, the Federal Commissioner for Data Protection and Freedom of Information and the Hessian Ministry for Digitalisation and Innovation have tested the implementation conditions for “AI regulatory sandboxes”. The European AI Act requires all Member States to establish at least one AI regulatory sandbox by August 2026. These are intended to provide regulatory sandboxing (i.e. development and testing with regulatory support in a controlled environment to examine new complex legal issues) and make it easier for providers to develop innovative AI products that comply with the requirements of the AI Act and other relevant legislation in Europe.

Based on two use cases, the pilot project has successfully identified the expectations of companies from an AI regulatory sandbox procedure, narrowed down the range of services of AI regulatory sandboxes and resolved organisational issues concerning the structure of these new testing facilities.

The project results show that:

- developing clear selection criteria for participating AI projects is important as regulatory sandboxes are intended to promote exemplary cases of new AI product developments and innovative implementations of the AI Act;
- confidentiality, professional communication and informative documentation are key success factors;
- a maturity model concerning the state of development of participating AI projects could be helpful for structuring the individual requirements;
- particular attention needs to be paid to synergy effects and a good balance between the different objectives pursued by an AI regulatory sandbox. The underlying goals should ideally go hand in hand: on the one hand the AI regulatory sandbox procedure should foster AI innovation for German, European and international companies in the European market; on the other hand it should facilitate evidence-based fine-tuning and amendments to statutory regulations and supervisory practice (“regulatory learning”). Regarding the fostering of innovation, companies primarily expect regulatory guidance. In addition, the regulatory sandbox must actively structure and enable the utilisation of sandboxing findings for the purpose of regulatory learning.

Further issues from the pilot project concern networking with other AI (regulatory) sandboxes (including other types) and any necessary provisions against market distortion. In addition, the way in which insights from regulatory sandbox procedures are channelled to authorities and policymakers should also be specified.

2. Object of study

> *"AI regulatory sandboxes established under paragraph 1 shall provide for 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. Such sandboxes may include testing in real world conditions supervised therein."*
> *(Article 57(5) EU AI Act)*

The term "(regulatory) sandbox" for the practical testing of technical solutions is not a new one. By contrast, "**AI regulatory sandboxes**" within the meaning of the European AI Act are controlled environments for the development and testing of products with integrated components of artificial intelligence (AI). This can either refer to an extension of existing technologies of a product already certified prior to implementation or a novel product in the development phase.

A legal definition of the term "AI regulatory sandbox" as a regulatory instrument of AI supervisory law – below we refer to "**AI[Act] regulatory sandbox**" – can be found in Article 3(55) of the AI Act.[1] However, especially the German term for regulatory sandbox "Reallabor" (verbatim: real-world laboratory) is not used exclusively in a regulatory sense. Other institutions in Germany, largely ones exclusively fostering innovation, also are referred by this term, without necessarily fulfilling a regulatory function. Regulatory sandboxes as a general concept already existed in Germany prior to the establishment of the AI[Act] regulatory sandboxes. The same applies for experimentation clauses: these allow statutory requirements to be temporarily suspended to facilitate flexible testing of new regulatory procedures and legal frameworks in a protected space under real world conditions. As well as these core activities (regulatory learning, fostering of innovation, testing), regulatory sandboxes can also offer further support, for example by providing an environment for training, testing and validating AI systems. Which of these possible functions [see Figure 1] will characterise an AI[Act] regulatory sandbox, also in contrast to other types of (regulatory) sandboxes in a broader sense, is a question that remains to be answered.

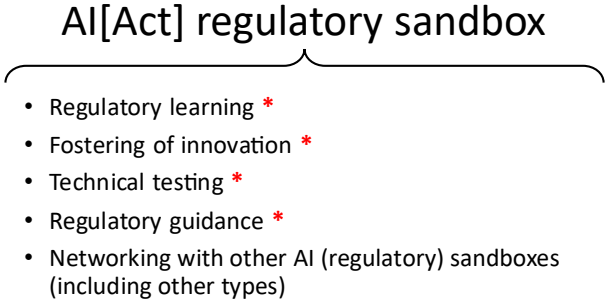

Fig. 1: Possible functions of a regulatory sandbox [* = i.a.w. AI Act]

[1] The EU AI Act has set out the legal framework for AI[Act] regulatory sandboxes, which the following report focuses on: 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. – Moreover, a ministry draft for a German federal law has existed since 12 September 2025 for which the consultation of federal states and associations has already been initiated. This earmarks the Bundesnetzagentur as the market surveillance authority responsible for AI[Act] regulatory sandboxes. Depending on the test product, the Federal Financial Supervisory Authority (among others) is also conceivable as a market surveillance authority.

Unlike other types of (regulatory) sandbox, regulatory sandboxes within the meaning of the AI Act ("AI regulatory sandboxes") can only be established by competent authorities (notifying authorities and market surveillance authorities, see Article 3(48) of the AI Act). Alongside the **fostering of innovation**, the primary purpose of this regulatory instrument is **regulatory learning** by the supervisory authorities involved, especially the market surveillance authorities, as well as improved dissemination and early incorporation of AI risk knowledge in the sectors regulated. In addition, AI[Act] regulatory sandboxes are intended to enhance legal certainty and initiate the transfer of insights back to the legislator allowing for timely adjustments to the regulations. The added value in terms of legal policy thus lies in **gaining generalisable solutions** for identifying and overcoming existing legal obstacles to innovation and less in expediting case-by-case decisions for promoting specific AI undertakings.

The EU AI Act prescribes the establishment of at least one official AI[Act] regulatory sandbox at the national level. This is primarily intended to assist SMEs (including start-ups) in steering their product towards the planned risk category in the development of the AI system before being placed on the market in order to be compliant with the requirements of the AI Act. Article 57(5) of the AI Act sets out the tasks of AI[Act] regulatory sandboxes.

A central task is coordination by the competent authority by drawing up a **sandbox plan.** This takes place in consultation with the companies and may vary in terms of the extent to which technical data processing environments or regulatory support are primarily provided. Legal advice is provided at the most indirectly by way of "guidelines" or "guidance on regulatory expectations". In other words, the aim is to promote the development of the product in terms of its market suitability by means of accompanying preparation for the requirements to be expected in the approval process. This includes the provision of information on legal requirements to be observed for market approval. A key concern is the timeliness of information in order to enable new products to incorporate regulatory requirements at an early stage and enter the market more quickly. There are two directions of feedback in this respect [see Figure 2]: information is sent on the one hand to companies concerning the statutory requirements they need to meet and on the other hand to the authorities concerning how the supervised market is developing and the legal challenges arising from innovations.

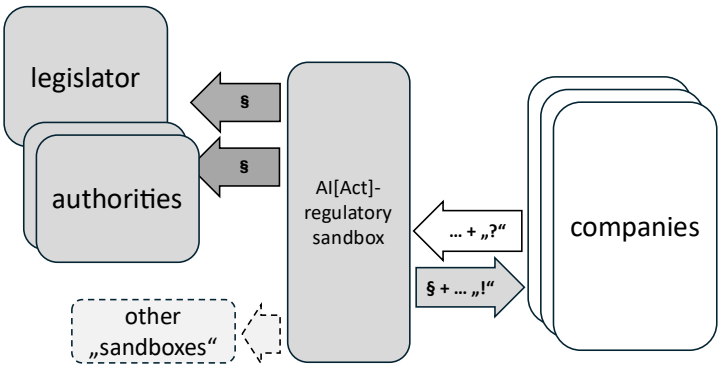

Fig. 2: Directions of feedback in an AI[Act] regulatory sandbox

Following successful conclusion of the regulatory sandbox procedure, the company is provided with an **exit report** by the competent authority and, upon request, documentary evidence of the activities carried out in the regulatory sandbox. These confirm that the company has already dealt extensively with the subset of regulatory requirements considered in the AI regulatory sandbox. AI regulatory sandboxes are intended to foster innovation but are also themselves an innovative

instrument. Digital policymakers are therefore well advised **to view the "AI regulatory sandbox" format itself as a learning task and ground for experimentation**. Against this backdrop, the following report aims to support the launch of the AI[Act] regulatory sandbox as a new "learning" instrument under real world experimental conditions.

3. About the pilot project

In May 2025, the **Bundesnetzagentur**, together with the **Hessian Ministry for Digitalisation and Innovation** and **the Federal Commissioner for Data Protection and Freedom of Information**, jointly initiated a seven-month **pilot project** to simulate an AI regulatory sandbox in accordance with the European AI Act. The project was supported by the **Hessian Ministry of Justice**, the Hessian Center for Artificial Intelligence **hessian.AI** research centre, the **AI Innovationlab** and the **AI Quality & Testing Hub (AIQ)**. The **Centre Responsible Digitality (ZEVEDI)** of the State of Hesse was consulted in a scientific supporting role and for preparation of the final report.

The objective of the pilot project was to gain practical insights at an early stage, prior to the institutionalised operation of a national AI[Act] regulatory sandbox that all EU Member States are required to establish (alone or in collaboration) by August 2026, regarding the key requirements and processes of AI[Act] regulatory sandboxes and the challenges posed by implementation of the Act's provisions.

The pilot project was conducted on the basis of **two use cases**. Two companies from the medical device sector agreed to participate for this purpose. The regulatory sandbox period lasted around five months in total. A schedule (the equivalent of a **sandbox plan**) was drawn up and executed for each use case. Alongside this, the project managers met regularly to reflect on their experiences. In addition, one-to-one discussions took place with regulatory sandbox experts and an exchange format (round table) with other German (regulatory) sandbox projects was set up. The participants refined key topics on several occasions in the course of the project and incorporated specialist expertise from professional associations, other authorities at national and federal state level and from science and technology in a targeted manner.

Both use cases were at an early stage of product development and had no legally compliant test data available. For this reason, no **technical testing** took place during the pilot project. Overlaps between the AI Act, the EU Medical Device Regulation (MDR), and the GDPR were identified as central issues.

The **exit reports for the companies** illustrate the tasks and summarise the recommendations (including a roadmap) by the authorities. The simulated AI[Act] regulatory sandbox has proven interesting and fruitful in all its dimensions (legal implementation issues, organisation, communication, pragmatism). It has established a broad **knowledge base** for future use and business cases. Other valuable benefits include **successful cooperation across authorities**, nationwide **networking benefits** and potential **scientific insights**. The initiators therefore wish to thank all those involved in the pilot project, in particular the two companies.

4. Project results

The results of the pilot project that have immediate practical implications can be divided into three dimensions:

(1) requirements applicable to (and also selection criteria for) companies as the target group and users of an AI[Act] regulatory sandbox;

(2) services provided as part of the AI[Act] regulatory sandbox – also for the companies involved;

(3) organisational and procedural recommendations to assist the implementing authorities with the successful development and implementation of a regulatory sandbox.

A particular challenge is posed in all three dimensions by **widely interpretable wording** in the AI Act and the **dynamics of the legal framework**. Many requirements concerning the operation of an AI regulatory sandbox had not yet been specifically defined by the EU at the time the pilot project took place, while the deadline for initial establishment is tight. The pilot project successfully derived requirements for operationalisation for the AI Act, identified solutions, and established a structured procedure based on the specific use cases. The European Commission published an initial draft implementing act for the AI Act[2] for consultation that was not yet finalised in December 2025.

The bodies managing regulatory sandboxes should generally bear in mind the heterogeneous objectives of AI[Act] regulatory sandboxes: regulatory learning, fostering of innovation, testing, and regulatory support/coordination. It is conceivable that between these objectives, **political prioritisations may also** have to be defined, within the general legal framework, by individual authorities.

4.1. Who may use an AI[Act] regulatory sandbox?

AI[Act] regulatory sandboxes are **not primarily about technical feasibility checks**, but are aimed first and foremost at finding a solution for **dealing with relevant legal issues** concerning AI product development. In addition, problems submitted by companies need to be suitable for gaining generalisable solutions that are also helpful for other cases. It is therefore necessary to conduct a **selection** of the companies and use cases suitable for a regulatory sandbox process. This in turn presupposes clear **selection and approval criteria** that are tailored to the respective priorities/objectives of the regulatory sandbox and also communicated publicly. The selection may implement industrial policy priorities but must avoid unjustified competitive advantages for the companies involved.

(a) AI[Act] regulatory sandboxes particularly address (according to the law and the draft implementing act) SMEs, including start-ups, that are headquartered or have branches in the EU. Access for such companies must be free of charge. AI[Act] regulatory sandboxes need to ensure a **suitable mix of user groups** (size, sector etc.). Many objectives of AI[Act] regulatory sandboxes,

[2] https://digital-strategy.ec.europa.eu/en/consultations/commission-seeks-feedback-draft-implementing-act-establish-ai-regulatory-sandboxes-under-ai-act.

especially the valuable example of regulatory learning, may also require the testing of AI projects of larger, experienced market participants.

(b) An important criterion of approval is that there must be broad interest also among other market participants in the legal uncertainty to be resolved through regulatory sandbox testing. This legal uncertainty should pose an obstacle to innovation of substantial character and relevance. Furthermore, the uncertainty must be of a nature that the company cannot simply eliminate by consulting a lawyer. AI[Act] regulatory sandboxes should therefore only select companies that are able to put forward a well-justified **need for clarification of a sufficiently fundamental nature**. A general need for advice does not suffice (this is covered, among others, by the innovation portal of the Federal Ministry for Economic Affairs and Energy). Support in the AI[Act] regulatory sandbox therefore ends with a summary of the results in the exit report that may also be **published** with the consent of the company. As well as internal learning and the associated improvement of supervisory practice under the AI Act, it must be possible to make the generalisable **knowledge usable for all market participants**. The case to be approved should therefore be capable of improving the overall guidance of market participants.

(c) The AI system undergoing product development requires a **suitable degree of maturity**, meaning that comprehensive planning documents, technical documentation, and software with AI components that can be tested must be provided by the sandboxing participant. The company must also still be able to make adjustments to the product. If technical implementation of the entire AI product is already completed in full, this will prejudice the 'learning process' envisaged in an AI[Act] regulatory sandbox. The availability of data suitable for testing should at all events already be ascertained when selecting and approving projects and safeguarded via appropriate instruments if necessary. It would also be conceivable to offer companies the use of an AI[Act] regulatory sandbox for **different development phases** of an AI system with a different focus for each phase (e.g. theoretical and regulatory feasibility study or final technical check immediately prior to the product's application maturity).

(d) As well as the project outline, companies should if necessary also be able to submit a clearly worded **business plan including a business model**. This serves to assess both the market relevance and the political and social relevance, as well as to determine the legal classification of the need for clarification put forward.

(e) The points of contact at the company must bear responsibility for all relevant processes of the project, have comprehensive skills and be able to communicate with the AI[Act] regulatory sandbox provider also with regard to cross-cutting issues. Only if the company provides **competent staff** with sufficient time capacities can a regulatory sandbox plan including resource planning be drawn up in cooperation with the parties involved within the AI[Act] regulatory sandbox.

4.2. What does an AI[Act] regulatory sandbox offer for the companies involved?

(a) AI[Act] regulatory sandboxes help with assessing the **nature and extent** of the risks posed by an AI system (including classification into risk categories pursuant to the AI Act) and with **restructuring** the project if a different risk category or containment of specific risks is targeted. The interplay of different regulatory requirements specifically entailed by an AI project must be taken

into consideration here. The offices managing regulatory sandboxes are to this extent obliged to draw attention to the existing regulatory requirements in force (guidance on regulatory expectations). However, they do not provide legal counsel. As companies frequently have more far-reaching expectations and ideas, **the guiding nature of the dialogue** should be **clearly communicated** when initiating regulatory sandbox projects.

(b) An AI[Act] regulatory sandbox can and should facilitate **compliance by design**, i.e. it should enable companies to address regulatory requirements proactively as early as the development stage of their products. This speaks in favour of constructing an AI[Act] regulatory sandbox in such a way that it can cater to earlier phases of product development. The regulatory sandbox should ideally be capable of managing different phases of an AI development project. If it is prepared to place the focus, depending on requirements and with the involvement of the relevant authorities and specialists, on other specific issues, the **steering effect** of its recommendations will be enhanced. An AI[Act] regulatory sandbox can then also deal more easily with possible tensions between the regulatory and the innovation-related mandate: on the one hand it can bring about an early restructuring of the project in order to avoid legal problems and on the other hand it can notify the legislator and regulatory benchmark planners and law enforcement bodies in good time of legal uncertainties and new challenges arising due to technical innovations.

(c) The AI[Act] regulatory sandbox and its institutionalised network facilitate exchange processes between persons with expertise from authorities at municipal, federal state, national and EU level. Participating companies can, if an AI[Act] regulatory sandbox makes use of these exchange processes, benefit from the **expertise of a network** and obtain guidance about regulatory responsibilities. An important practical added value was derived from this in the pilot project for the use cases involved.

(d) As market surveillance authorities (and potentially also conformity assessment bodies and notifying authorities) are involved in the process and already gain an insight into the technical development and provide expertise at an early stage, the participation in and results of the regulatory sandbox testing can be positively taken into account when assessing the conformity of the finished product. This can potentially accelerate product development and the requisite certification of conformity of the AI system with other regulatory requirements. The **swift submission of a substantive exit report** in this respect and proof that the activities have been successfully carried out is one of the key services provided by an AI[Act] regulatory sandbox.

(e) If companies only have vague expectations and ideas concerning the functional operation and procedure of a regulatory sandbox while trust is simultaneously expected from them, the AI[Act] regulatory sandbox bears **responsibility for communication** and is particularly responsible for clearly communicating the step-by-step approach during the procedure. This also includes public communication (such as FAQs) and publication of the exit reports.

(f) As well as clearly defining what the AI[Act] regulatory sandbox has to offer, it should also be the competent authority's job to draw attention to alternatives that may be more suitable for companies than the AI[Act] regulatory sandbox itself. The latter serves as an element in an EU-wide "AI ecosystem" that also comprises other information, testing and advisory products and services (such as other AI regulatory sandboxes, TEFs, AI factories, EDIHs). Synergy potential lies in the interest of all parties involved.

4.3. What must a competent authority pay attention to when operating an AI[Act] regulatory sandbox?

(a) **Confidentiality** is a particularly important concern for companies. This was also shown by the pilot test. If company secrets are disclosed in the AI[Act] regulatory sandbox, questions of confidentiality must be resolved very precisely in advance and if necessary also put into writing in order to ensure trustworthy collaboration.

(b) Communication is crucial for the success of a project in the AI[Act] regulatory sandbox. The requirements, criteria and available options must be clearly communicated by the AI[Act] regulatory sandbox, as must a comprehensive project outline by the companies, via media (e.g. website and FAQs) and in an initial low-threshold discussion if necessary. The preparation of a joint regulatory sandbox plan with clearly defined objectives for the collaboration in the AI regulatory sandbox is also dependent on the linguistic quality of the dialogue. The coordinative management of the AI[Act] regulatory sandbox must work towards **mutually comprehensible communication**. Further explanations must if necessary be offered for technical and legal matters so that the company is able to engage in productive dialogue.

(c) Effectively supporting a project requires an up-to-date overview of the responsibilities of the various authorities, of other AI [Act] regulatory sandboxes (and other sandboxes), and of the relevant expert landscape. This also serves to facilitate potential cooperation. Corresponding **transdisciplinary orientational knowledge** must be built up and institutionalised in a targeted manner at the body managing regulatory sandboxes. This also raises issues regarding the selection and training of staff at the body managing regulatory sandboxes. Specific technical AI expertise depending on the layout of the AI[Act] regulatory sandbox is essential. This AI expertise is necessary in order to understand operational matters adequately. At the same time, the aforementioned orientational knowledge serves as the core resource for a successful AI[Act] regulatory sandbox.

(d) The insights gained in an AI[Act] regulatory sandbox should be published in a generalised form and with due respect for confidentiality in order to ensure their subsequent usability for other companies. Attaching an appropriate **publishable summary** to the exit report is recommended. The insights should also be incorporated into best practices, guidelines and FAQs (if applicable also of other offices or providers).

(e) Ensuring the comparability of regulatory sandbox procedures should be an objective of the work of an AI[Act] regulatory sandbox. However, strictly **uniform workflows** for conducting regulatory sandbox projects are not recommended. In a situation in which companies participate voluntarily, they should not be confronted with a rigid pattern of bureaucratic requirements not suited to the specific case at hand. The authorities involved should therefore fundamentally enter into dialogue pragmatically and develop a “routine of flexibility”.

(f) Particularly in the initial years, an AI[Act] regulatory sandbox should **actively steer the way it is used through PR work**. The competent authority should communicate publicly and clearly not only the specific product and the benefits of using its AI[Act] regulatory sandbox, but also any limitations and expenses entailed by participation. Particularly suitable companies should be encouraged to apply for a project in an AI[Act] regulatory sandbox as collective and mutually beneficial learning is only possible with lively and intensive participation.

5. Further questions

Further questions that remain unanswered arose during the pilot project regarding the AI Act. While the practical testing was unable to answer them, they are to be investigated further:

> (1) How can market distortion be avoided and how should competitive situations be handled, for example regarding insights gained in a specific case when providing subsequent regulatory support to other companies?
>
> (2) How can opportunities for cooperation with other AI (regulatory) sandboxes be configured, particularly about the provision of test environments?
>
> (3) How is contact with policymakers specifically facilitated to ensure a backflow of information and accelerated implementation of changes to guidelines and laws?

(1) The question of how an AI[Act] regulatory sandbox can **treat competition neutrally** and avoid market distortion already arises when selecting the companies. For capacity reasons and considering the focus on generalisable solutions, not all interested projects can receive access to an AI[Act] regulatory sandbox, at least following an establishment phase of the instrument of the AI[Act] regulatory sandboxes. Conflict situations are conceivable. Regulatory sandboxes must display prudence here. Constant monitoring of new market developments (market screening) and legal protection are needed. In order to receive helpful regulatory support, the companies involved frequently need to disclose large amounts of technical data and other product information. How can this proprietary information be used without distorting competition? AI[Act] regulatory sandboxes will have to address this question – especially if they wish or are required to produce generalisable, public information.

(2) The second topic concerns the cooperation of AI[Act] regulatory sandboxes with each other and with other national and federal state authorities. Potential cooperation is also conceivable between AI[Act] regulatory sandboxes and other AI (regulatory) sandboxes that are specifically geared (exclusively) to technology, economic development or administrative modernisation [see Figure 3]. Are policymakers aiming for highly integrated networking with a functional division of labour across Germany and Europe or a hierarchy of the different types of regulatory sandbox or geographical/federal segmentation? The answer to this question not least affects the range of services of each individual sandbox: to what extent must it provide its own technical test environment or can it cooperate with other partners in this regard? When should a company be sent on to another AI[Act] regulatory sandbox, how broadly should a national AI[Act] regulatory sandbox specialise and which respon-

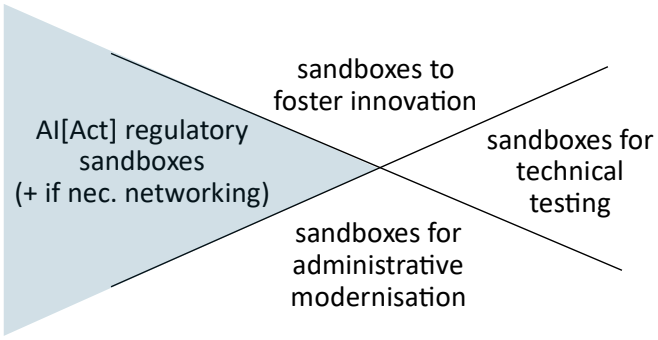

Fig. 3: Possible fields of application and cooperation of AI[Act] regulatory sandboxes with “other” (AI) sandboxes

sibilities is it unable to cede under any circumstances? The European and national **AI[Act] regulatory sandbox landscape** is still only in its infancy. Participants need to discuss a target vision for this, initiate joint projects and create continuous exchange opportunities.

(3) The regulatory learning mandate raises the question of how an office managing regulatory sandboxes can generalise, consolidate and **return to the legislator** specific insights – or at any rate return them to participants who have the possibility of updating and substantiating the AI-related regulatory programme. This also concerns the market surveillance and certification authorities implementing and substantiating the regulatory programme. Various information channels and mechanisms are already predetermined in this respect in the AI Act. However, at present the relationship of the different information channels with each other and their respective degree of institutionalisation and effectiveness for the purposes of regulatory learning cannot yet be reliably assessed. It is in any event crucial for the success of a regulatory feedback process that the offices managing regulatory sandboxes are well connected to the legislator and market surveillance authorities. This poses a challenge as market surveillance authorities are frequently located at lower federal levels than the legislator (in this case the EU and the Federal Government).

6. Conclusion

The pilot project has established insights with regard to selection criteria, services and organisational recommendations for AI regulatory sandboxes pursuant to Articles 57 to 59 of the AI Act and highlighted the necessity of a balance between regulatory learning and the fostering of innovation. It has shown that AI[Act] regulatory sandboxes are effective if they prudently select use cases suitable for running the procedure and are operated as process-driven learning and guiding infrastructure rather than as general advisory services.

The administrative participants involved therefore need to prioritise five tasks in the run-up to the regulatory sandbox becoming operational (2 August 2026 at the latest for the national AI[Act] regulatory sandbox): (1) competence and network development, (2) communication with the market – identify needs and convey added value, (3) access control, (4) processes and templates – to be designed in a standardised manner while upholding flexibility in workflows, (5) safeguarding of regulatory and institutional learning.

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The ZEVEDI research and expertise Network combines the academic expertise of universities in Hesse in order to analyse the ethical and legal dimensions of digital transformation, thus contributing to shaping this transformation.

ZEVEDI identifies and discusses responsibility as a crucial yet uncertain aspect of technological development and aims at making responsible digitality conceivable as well as practically feasible.

ZEVEDI engages in research projects, promotes the transfer of scientific knowledge into society and the economy and provides research-based policy advice on the topic – for a digital transformation guided by a democratic and humane orientation.

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