

## **Position Paper – ‘Regulatory Sandboxes: Testing and Learning’**

### *1. Introduction: The first EU sandbox framework*

Regulatory sandboxes (hereafter: sandboxes) are not a new concept. They are ‘schemes that enable organisations to test innovations in a controlled real-world environment, under a specific plan developed and monitored by a competent authority.’<sup>1</sup>

Up until now, sandboxes have been a national phenomenon. The proposed Artificial Intelligence Act (hereafter: AI Act) creates a European legal framework for sandboxes in Articles 53-54b.<sup>2</sup>

NL is pleased that the framework in its current wording already provides a strong level of support for developers that participate in sandboxes, especially for small and medium enterprises. NL thinks that even more value can be gained from sandboxes by further utilizing the knowledge they generate on a European level to improve regulatory practices and future legislation, i.e. through **regulatory learning**.

### *2. The need for regulatory learning*

Compliance with legislation for a quickly developing field of technology is challenging for both developers and competent authorities. Regulatory learning can help them both.

In a sandbox, developers have the opportunity to receive compliance assistance by a competent authority during their product development process. This results in better understanding of the applicable rules for the developer, a reduction of development costs and a ‘safe space’ due to supervisory flexibility in order to boost innovation. In turn, competent authorities can increase their understanding of the legislation as well so that they can improve their future supervisory practices.

So why should we ensure that their lessons learnt are utilized to the best extent possible?

- **Improved supervisory practices.** National Competent Authorities (NCAs) can learn from each other’s sandbox experiences. Sharing technical and procedural knowledge between NCA’s helps improve supervisory practices throughout the EU. This is especially prudent since it will be necessary to quickly build the required knowledge about and experience with supervision on AI in a quickly growing EU market.
- **Clarity about the law.** If interpretations of the law are shared between NCAs and communicated to the wider public, developers have better knowledge about what is expected from them throughout the whole European Union. This strengthens the EU AI-market and facilitates cross-border trade in the EU.
- **Evidence-based policy making.** Various aspects of the AI Act can be amended through delegated acts such as the areas of AI that are classified as high-risk. Practical experience in sandboxes can provide insight into the current working of the AI Act. A coordinated learning approach ensures a continuous feedback-loop between developers, NCAs and the Commission. The soft law instruments of the AI Act, such as guidance, can also be informed by the lessons learnt of sandboxes.
- **A level playing field.** Sandboxes are scarce resources and therefore bear the risk to disrupt the level playing field for market participants. Developers with access to a sandbox will reap the benefits from their participation while other market-players are left empty-handed. To justify this distinction between developers, the knowledge generated in sandboxes needs to flow back into the market through information-sharing and utilizing obligations so that the whole market benefits from improved supervisory practices, clarity about the law and better future regulation.

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<sup>1</sup> Commission’s Better Regulation Toolbox (November 2021), p. 597.

<sup>2</sup> Building on earlier reflections on a European framework for sandboxes in the Commission’s Better Regulation Toolbox (November 2021 edition) and the Council Conclusions on regulatory sandboxes (12683/1/20 REV1).

### 3. How do we achieve regulatory learning?

Textual changes to the AI Act are possible to facilitate regulatory learning in addition to the current set-up that already benefits participating AI-developers. Below we explain the main changes to the text and why these are necessary, also listed in Annex I.

- **Explicitly name regulatory learning as a goal of sandboxes.** In the latest draft text (June 2022), three objectives were removed from art. 53 (1b). These objectives specifically addressed 'improved supervision' and 'evidence-based policy making' and should therefore be returned because these goals reflect the above-mentioned aspects that will make sandboxes even more beneficial for the EU's AI-market. Furthermore, we propose that the implementing acts of art. 53(6) also support, amongst other things, regulatory learning to the best extent possible.
- **Ensure that knowledge is documented.** The lessons from sandboxes are only comparable if there is a common framework for the learning aspect. We propose to lay down harmonized rules in the AIA for the documentation inside sandboxes; strengthening the plan of participation and introducing an exit report. These documents ensure that learning goals are set and evaluated, without compromising on the flexibility of NCAs on how they want to engage with participants. We value this flexibility in the design of sandboxes themselves, since this design should also be amendable based on new insights. The Spanish AI Sandbox pilot, launched on 27 June, is a good start of this learning-cycle. This timely pilot will be the first to define the needs of developers and competent authorities alike in the design of AI regulatory sandboxes. These lessons can serve as a solid basis for the modalities and conditions of the first EU sandbox.
- **Ensure that knowledge is utilized.** In order to establish a feedback-loop and concretise learning from a sandboxes, we propose to explicitly include the following obligations for the Commission, the AI Board and the European Standardisation Organisations. If an expert pool is included in a future text of the AIA, we suggest to lay a similar explicit (feedback-)link between sandboxes and this pool.
  - o the Commission should consider annual reports and exit reports of NCAs when amending Annex I, II, IV and when drafting guidance or common specifications;
  - o the AI Board should consider annual reports and exit reports of NCAs when carrying out its tasks.
  - o the ESO's should take these reports into account when developing harmonised standards.
- **Prevent sandbox-shopping while ensuring flexibility for NCAs.** In line with the recent Czech compromise proposal, we recognise the importance for NCAs to adjust their procedures to the national context. To further stress the importance of this flexibility for NCAs, we propose to add that the modalities and conditions that will be laid down in implementing acts '*shall to the best extent possible support flexibility for national competent authorities...*'. Nonetheless, we propose to lay down harmonized *rules* (instead of principles) for criteria for participation and the terms and conditions applicable to participants. This prevents 'sandbox-shopping' between different Member States and a consequential competition between NCAs to attract participants.

### 4. Testing in real world conditions

We see real world testing as an important tool for the development of high-quality AI-systems for developers that are dependent on testing AI-systems outside a lab environment. We expect a high demand for testing in real world conditions and are glad that there is flexibility to decide whether it takes place inside or outside a regulatory sandbox.

In order to ensure the necessary level of protection, we propose to change Article 53(7) to apply the relevant safeguards of Articles 54a and 54b to testing in real world conditions inside sandboxes as well.

**Annex I – text suggestions**

<b>Current AIA text (June 2022) and proposed changes</b>	<b>Comments</b>
<p><i>Article 53</i> <i>AI regulatory sandboxes</i></p>	
<p><b>-1c</b> <b>Regulatory sandboxes that consider AI-systems and that are established under national law before the entry into force of this Regulation shall be exempt from the obligations concerned of paragraphs 2a, 2b, 4a, 5 and 5a of this Article and from the general common rules that are adopted through implementing acts under paragraph 6 of this Article.</b></p> <p><b>This exemption lasts for a maximum period of two years after the entry into force of this Regulation.</b></p> <p><b>Member States shall endeavor to implement the obligations of this Article into those already existing sandboxes to the best extent possible.</b></p>	<p>There have been signals that harmonized rules may interfere with already existing AI regulatory sandboxes that have been established under national law.</p> <p>With this paragraph, we aim to give Member States some leeway when implementing this Regulation. During the first two years of this Regulation, they are encouraged to implement the requirements of this Article as much as possible into already existing sandboxes but have no obligation to do so.</p> <p>The obligations that those already existing sandboxes are exempt from concern mostly the design and rules of the sandbox. Consequently, NCAs are also exempt from paragraph 5 (annual reports) since these already existing sandboxes cannot be compared with the harmonized sandboxes established under this Article.</p>
<p><b>-1a. National competent authorities may establish AI regulatory sandboxes for the development, training, testing and validation of innovative AI systems under the direct supervision, guidance and support by the national competent authority, before their placement on the market or putting into service. Such regulatory sandboxes may include testing in real world conditions supervised by the national competent authorities.</b></p>	<p>Add “under the direct supervision, guidance [...] by the national competent authority”.</p> <p>The key element of supervision and guidance by the national competent authority was deleted by deleting the whole article 53 (1) and should be returned.</p> <p>Add “support”: Especially for start-ups it is very important that competent authorities – within their legal possibilities – act as supporters in ensuring compliance, e.g. through mentoring, personal exchange or customized guidance. The impressive examples of data regulatory sandboxes by the French CNIL and the British ICO also explicitly “support” the projects. The term “support” is also used in EU Commission’s Better Regulation Toolbox Tool #69 on regulatory sandboxes (page 597).</p>
<p><b>1b</b> <b>The establishment of AI regulatory sandboxes under this Regulation as defined in paragraph 1 shall aim</b></p>	<p>Although the additional objectives of AI regulatory sandboxes have also to some extent been listed in Recital 72, we propose to return these into the Article itself.</p>

<p>to contribute to one or more <u>of</u> the following objectives:</p> <ul style="list-style-type: none"> <li>a) foster innovation and competitiveness and facilitate the development of an AI ecosystem;</li> <li>b) facilitate and accelerate access to the Union market for AI systems, <del>including in particular when provided by small and medium enterprises (SMEs), including and start-ups;</del></li> <li>c) improve legal certainty and contribute to the shareing of best practices through cooperation with the authorities involved in the AI regulatory sandbox with a view to ensuring future compliance with this Regulation and, where appropriate, with other Union and Member States legislation;</li> <li><del>d) enhance authorities’ understanding of the opportunities and risks of AI systems as well as of the suitability and effectiveness of the measures for preventing and mitigating those risks;</del></li> <li><del>e) contribute to the uniform and effective implementation of this Regulation and, where appropriate, its swift adaptation, notably as regards the techniques in Annex I, the high-risk AI systems in Annex III, the technical documentation in Annex IV;</del></li> <li><del>f) contribute to the development or update of harmonised standards and common specifications referred to in Articles 40 and 41 and their uptake by providers.</del></li> <li><b>d) enhance authorities’ understanding of the opportunities and risks of AI systems as well as of the suitability and effectiveness of the measures for preventing and mitigating those risks;</b></li> <li><b>e) contribute to the uniform and effective implementation of this Regulation and, where appropriate, its evidence based swift adaptation, notably as regards the techniques in Annex I, the high-risk AI systems in Annex III, the technical documentation in Annex IV;</b></li> <li><b>f) contribute to the development or update of harmonised standards and common specifications referred to in Articles 40 and 41 and their uptake by providers.</b></li> <li><b>g) Contribute to the possible future evidence-based advancement of this Regulation and, where appropriate, of other Union and Member States legislation.</b></li> </ul>	<p>This underscores the importance of regulatory learning in sandboxes. To further underscore this, we propose to add another objective to this list. Regulatory sandboxes should contribute to resilient and relevant legislation through facilitating regulatory learning.</p>
<p>2a</p>	<p>First, we think it is important to limit the participation to sandboxes to providers</p>

~~Access to the AI regulatory sandboxes and supervision and guidance by the relevant authorities shall be free of charge, without prejudice to exceptional costs that national competent authorities may recover in a fair and proportionate manner. It~~ Access to the AI regulatory sandboxes shall be open to any provider or prospective provider of an AI system who **is established in the Union or has appointed a legal representative who is established in the Union and** fulfils the eligibility and selection criteria referred to in paragraph 6(a) and who has been selected by the national competent authorities or, where applicable, by the European Data Protection Supervisor following the selection procedure referred to in paragraph 6(b). Providers or prospective providers may also submit applications in partnership with users or any other relevant third parties.

Participation in the AI regulatory sandbox shall be limited to a period that is appropriate to the complexity and scale of the project ~~in any case not longer than a maximum period of 2 years, starting upon the notification of the selection decision. The participation may be extended for up to 1 more year.~~ This period may be extended by the national competent authority.

Participation in the AI regulatory sandbox shall be based on a specific plan referred to in paragraph 6 of this Article that shall be agreed between the participant(s) and the national competent authority(ies) or the European Data Protection Supervisor, as applicable. **The plan shall contain as a minimum the following:**

- ~~a) description of the participant(s) involved and their roles, the envisaged AI system and its intended purpose, and relevant development, testing and validation process;~~
- ~~b) the specific regulatory issues at stake and the guidance that is expected from the authorities supervising the AI regulatory sandbox;~~
- ~~e) the specific modalities of the collaboration between the participant(s) and the authority(ies), as well as any other actor involved in the AI regulatory sandbox;~~

established in the Union or has a legal representative in the Union, similar to the requirement to testing in real world condition 54a(4)(d).

But more importantly, we want to return the requirements to the specific plan in this Article.

When NCAs and participants have to think about the included elements before they start their cooperation within a sandbox, they will know exactly what the added value of participation is. This is true for both the participant and the national competent authority.

The participant can check whether it is necessary to enter into a time-consuming process or whether the questions that they have can be answered through readily available information.

The NCA can help the participant with this process and can also assess whether the questions of the participants justify the resource-heavy process of a sandbox.

Harmonizing the rules concerning this specific plan of participation helps regulatory learning as well.

- It is important to have a clear objective in mind when operating a regulatory sandbox.
- If the context of participation is documented well, it is easier to compare the results of the sandbox with sandboxes that have taken place under the supervision of other NCAs.

Additionally we propose a new provision 2a(bb). Note that this does not require participants to have a novel regulatory issue in order to participate in the sandbox. Whether a regulatory issue is novel can also become clear during the sandbox.

Furthermore, we also propose a new provision 2a(f). It is important to think about the information that has to be shared before

<p><del>d) a risk management and monitoring mechanism to identify, prevent and mitigate any risk referred to in Article 9(2)(a);</del></p> <p>e) <del>the key milestones to be completed by the participant(s) for the AI system to be considered ready to exit from the regulatory sandbox.</del></p> <p>a) <b>description of the participant(s) involved and their roles, the envisaged AI system and its intended purpose, and relevant development, testing and validation process;</b></p> <p>b) <b>the specific regulatory issues at stake, and the guidance that is expected from the authorities supervising the AI regulatory sandbox;</b></p> <p>bb) <b>the novelty of the specific regulatory issue, compared to the annual reports referred to in Article 53(5), and whether analyzing this regulatory issue in the regulatory sandbox contributes to the objectives of Article 53(1b)(c) and (d);</b></p> <p>c) <b>the specific modalities of the collaboration between the participant(s) and the authority(ies), as well as any other actor involved in the AI regulatory sandbox;</b></p> <p>d) <b>a risk management and monitoring mechanism to identify, prevent and mitigate any risk referred to in Article 9(2)(a);</b></p> <p>e) <b>the key milestones to be completed by the participant(s) for the AI system to be considered ready to exit from the regulatory sandbox;</b></p> <p>f) <b>the information that has to be shared between the participant(s) and the authority(ies) to allow proper evaluation of the project.</b></p>	<p>the project takes off. This is important for both the participant (who then knows what they have to share) as well as the supervisory authority (to ensure that the necessary information for evaluation is collected during the sandbox).</p> <p>It merely requires the participant and NCA to think about whether this is the case. This helps to assess whether the sandbox has value for guidance or other lessons learnt after the sandboxes has ended.</p>
<p><b>2b</b></p> <p><b>After an AI regulatory sandbox has ended, the participant(s) and the national competent authority(ies) or the European Data Protection Supervisor, as applicable, shall draw up an exit report. This exit report shall contain as a minimum the following:</b></p> <p>a) <b>The plan referred to in paragraph 2a of this Article;</b></p> <p>b) <b>An evaluation of the specific regulatory issues that were at stake during the AI regulatory sandbox, including a problem definition and proposed solutions;</b></p> <p>c) <b>Whether the key milestones referred to in paragraph 2a(e) of this Article have been completed;</b></p> <p>d) <b>A conclusion on the lessons learnt, specified in the following categories of use:</b></p>	<p>In various national regulatory sandboxes, it is common practice to issue an exit report after the sandbox has concluded. We propose to include this practice in the AI Act as well. The exit reports focus more specifically on the case at hand, instead of the more vaguely drafted ‘annual reports’ (which also focus on the <u>implementation of sandboxes</u>).</p> <p>In order to truly utilize lessons learnt, they must first be defined. The national competent authorities are in the best position to do this, right after a sandbox has ended.</p> <p>Under paragraph 5a, the exit reports will then be used by the AI Board and Commission to improve interpretation,</p>

<p>a. <b>An improved understanding on the implementation of the AI regulatory sandboxes;</b>  b. <b>Improved methods of supervision by national competent authorities;</b>  c. <b>A revised or novel interpretation of this Regulation.</b></p>	<p>guidance, communication and amendments regarding this Regulation.</p>
<p>4a.  Upon request of the provider or prospective provider of the AI system, the national competent authority shall provide, where applicable, a written proof of the activities successfully carried out in the sandbox. <del>The national competent authority may also provide an exit report detailing the activities carried out in the sandbox and the related outcomes.</del> Such written proof <del>and exit report</del> could be taken into account by market surveillance authorities or notified bodies, as applicable, in the context of conformity assessment procedures or market surveillance checks.</p>	<p>Although we are glad that the ‘exit report’ is mentioned in the latest compromise text, the addition to art. 53(4a) does unfortunately not support regulatory learning. It seems almost identical to the already existing written proof, and only relevant in the context of conformity assessment procedures or market surveillance checks.</p> <p>We therefore propose to delete this new addition and include the exit report as proposed in our paragraphs 53(2b) (contents of the exit report) and 53(5a) (utilization of the exit report).</p>
<p>5.  <del>Member States’ National competent authorities that have established AI regulatory sandboxes and the European Data Protection Supervisor shall coordinate their activities and cooperate within the framework of the European Artificial Intelligence Board.</del> They National competent authorities shall make publicly available <del>publish on their websites</del> submit annual reports <del>on to the Board and the Commission on the results from the implementation of those</del> the AI regulatory sandboxes, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox. <b>Those annual reports shall be submitted to the AI Board which shall annually make publicly available publish on its website a summary of all good practices, lessons learnt and recommendations. This obligation to make annual reports publicly available shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities. The Commission and the AI Board shall, where appropriate, take the annual reports into account when exercising their tasks under this Regulation.</b></p>	<p>Small addition to ensure regular feedback from the AIB.</p> <p>We welcome the last sentence of this paragraph, which was added in the latest compromise proposal. Nevertheless, we still propose to introduce an exit report that ensures that lessons are actually documented and further utilized. This is also necessary to draw up useful annual reports.</p>

<p><b>5a.</b></p> <ol style="list-style-type: none"> <li><b>1. The exit report shall not be made accessible to the public, unless both the participant and the national competent authority have explicitly agreed with this.</b></li> <li><b>2. After an AI regulatory sandbox has ended, the national competent authority shall share the exit report referred to in Article 53(2b) with the AI Board and the Commission, unless the participant explicitly objects to this.</b></li> <li><b>3. The exit reports shall be shared on a confidential basis and in accordance with Article 70.</b></li> <li><b>4. The AI Board shall use the annual reports of paragraph 5 of this Article and the exit reports it receives according to paragraph 1 in the exercise of its tasks as listed in Article 58.</b></li> <li><b>5. The Commission shall use the annual reports of paragraph 5 of this Article and the exit reports it receives according to paragraph 1 in the exercise of its tasks in Articles 4, 7, 11(3) and 58a.</b></li> </ol>	<p>To ensure that sandboxes will deliver more than vaguely defined annual reports, this paragraph requires the AI Board and Commission to utilize the exit reports that have been drawn by the national competent authorities.</p> <p>As these exit reports may contain sensitive information that should be kept confidential, an explicit reference to Article 70 has been made. If a participant still feels uncomfortable with sharing this exit report with the AIB and the Commission, it may object to this.</p> <p>Also, the exit report will only be made public if both the concerning participant and the national competent authority have given consent to this.</p> <p>This also prevents a situation in which participants may be reluctant to participate in sandboxes because they are afraid that their trade secrets or other sensitive information will be made public.</p>
<p>6. The <del>detailed</del> modalities and the conditions <b>for the establishment and</b> of the operation of the AI regulatory sandboxes <b>under this Regulation</b>, <del>including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants shall be set out in implementing acts. Those implementing acts shall be adopted</del> <b>through implementing acts</b> in accordance with the examination procedure referred to in Article 74(2). <b>These modalities and conditions shall to the best extent possible support flexibility for national competent authorities to establish and operate their regulatory sandboxes, foster innovation and regulatory learning and shall take into account particularly the special circumstances of participating SMEs .</b></p> <p>Those implementing acts shall include <b>general common rules</b> <del>common main principles</del> <b>general common rules</b> on the following issues:</p> <ol style="list-style-type: none"> <li>a) <del>the eligibility and selection criteria</del> <b>criteria</b> for participation in the <b>AI</b> regulatory sandbox;</li> <li>b) <del>the procedure for the application, selection participation, monitoring, and exiting from and</del></li> </ol>	<p>We propose to return to the previous text. The lessons from sandboxes are only comparable if there is a common framework for the learning aspect. ‘Common main principles’ may result in differently organised sandboxes throughout Europe.</p> <p>We included an additional sentence to ensure the objective to ensure flexibility for national competent authorities, foster AI innovation (recital 71) and regulatory learning. In order to promote innovation, it is important that the interests of small-scale providers are taken into particular accounts (recital 73). This is must be reflected in the regulatory sandboxes’ modalities and conditions.</p> <p>The more procedural aspects of sandboxes regarding the application, participation, monitoring, exiting from and termination can be laid down in common main principles in order to ensure flexibility for national competent authorities.</p>



<p><del>termination of the AI regulatory sandbox, including templates of all relevant documents;</del></p> <p>c) <del>the terms and conditions applicable to the participants, including in relation to their collaboration with the authorities supervising the sandbox, as well as the conditions for suspension and termination of the participation in the sandbox;</del></p> <p><del>Those implementing acts shall also include common main principles on the following issues:</del></p> <p>d) <del>procedure for the application, participation, monitoring, evaluation, exiting from and termination of the AI regulatory sandbox.</del></p> <p>e) <del>the modalities for the involvement in the AI regulatory sandbox of other national authorities and other actors within the AI ecosystem;</del></p> <p>f) <del>the modalities and procedures for cross-border cooperation, including the establishment and operation by two or more Member States of cross-border AI regulatory sandboxes.</del></p>	
<p>7</p> <p>1. <del>Testing in real world conditions supervised within the framework of an AI regulatory sandbox established under this article may be authorised by the national competent authority.</del></p> <p>2. <del>When authorised, providers may conduct testing in accordance with Articles 54a(2), 54a(3), 54a(4)(c), 54a(4)(e-l), 54a(5), 54a(6), 54a(7), 54a(8) and other terms and conditions of such testing agreed between the participant and the national competent authority.</del></p> <p><del>When national competent authorities consider authorising testing in real world conditions supervised within the framework of an AI regulatory sandbox established under this Article, they shall specifically agree with the participants on the terms and conditions of such testing and in particular on the appropriate safeguards, with the view to protect fundamental rights, health and safety. Where appropriate, they shall cooperate with other national competent authorities with a view to ensure consistent practices across the Union.</del></p>	<p>We propose to use the relevant requirements of Article 54a when allowing testing in real world conditions in an AI regulatory sandbox.</p> <p>We feel like these are reasonable safeguards that ensure that the rights of the persons involved are respected.</p> <p>Allowing national competent authorities and participants to draw up their own terms and conditions carries the risk of ‘unsafe testing’. This risk is increased to the undefined term of an AI regulatory sandbox, potentially carrying on indefinitely.</p> <p>An undefined term for an AI regulatory sandbox is acceptable, since the goal will always be to end up with a product that is compliant with the AI Act. On the contrary, indefinite testing can be a loophole to use an AI-system without complying with the AIA.</p>