



Field Guide: Regulatory Sandbox

The What, Why and How

August 2020

Contents

HOW TO USE THIS FIELD GUIDE	3
1 WHAT IS A REGULATORY SANDBOX?	4
2 WHEN IS A REGULATORY SANDBOX USED?	6
3 LAUNCHING A REGULATORY SANDBOX	8
(A) SET UP THE SANDBOX	8
(B) SELECT SANDBOX ENTITIES	11
(C) MONITOR TESTING	13
(D) EVALUATE AND/OR AMEND REGULATIONS	13
4 CHALLENGES OF SETTING UP A SANDBOX	14
5 EXAMPLES OF SANDBOX VARIATIONS	16
6 CONCLUSION	24
REFERENCES	25
ACKNOWLEDGEMENTS	28

HOW TO USE THIS FIELD GUIDE

More regulatory bodies around the world are using sandboxes and setting them up in variety of ways. Yet, there are similarities across these sandbox variations. This guide was put together using online information published by regulators, reports from governmental and non-governmental bodies, and academic literature on regulatory sandboxes. We have also included insights from local government representatives to keep this guide applicable to regulators in Singapore.

The focus of this guide is to provide some clarity on the sandbox concept by covering the what, why and how of setting up a sandbox. It is not meant to provide a comprehensive listing of all sandbox variations and/or steps to launching a sandbox. Instead, it covers the key steps that a regulator needs to carry out pre-sandbox, during testing and post-sandbox.

At the end of the guide, local examples are used to illustrate how sandboxes can be set up differently to support various objectives and context. These examples were selected from a range of different sectors and written after interviewing officers of regulatory agencies involved in setting up a sandbox.

For those who are setting up a sandbox for the first time or refining your sandbox, we hope you will find this guide a useful resource to your work!

1 WHAT IS A REGULATORY SANDBOX?

A regulatory sandbox is a “safe space” where eligible firms are allowed to test their innovative products or services in a live but controlled environment agreed between the regulator and sandbox entity (Baker McKenzie 2018, 3). For the duration of the regulatory sandbox, certain legal and regulatory requirements may be waived temporarily until the end of testing (Baker McKenzie 2018, 3). Safeguards are also put in place to manage the risks and ensure that failures are contained in the sandbox environment (Monetary Authority of Singapore 2016a, 4). Sandboxes can be mistaken as “pilots”, but they are not always the same (see **Box 1**).

Box 1: Pilots Versus Regulatory Sandboxes

The terms ‘regulatory sandbox’ and ‘pilots’ are sometimes used interchangeably. Yet, there is a key difference. While both involve small-scale testing in a live environment, a regulatory sandbox is an altered regulatory environment where certain legal and regulatory requirements are waived. Small-scale trials, which are pilot testing, do not always involve regulatory waivers.

Knowing the distinction between a regulatory sandbox and pilot is crucial because not all innovations need to be tested in a regulatory sandbox. If the testing and/or introduction of the new product or service already complies with existing regulations and there are no new risks, there is no need for regulators to set up a sandbox. Otherwise, going through a sandbox could slow down the firm’s innovation progress because the firm will be required to comply with the sandbox conditions. Furthermore, operating and maintaining regulatory sandboxes require more resources, so regulators need to prioritise the testing of new products or services that require and can benefit from a sandbox.

Regulatory sandboxes used across different domains and jurisdictions vary in how they are set up and operated. There are different objectives of setting up a sandbox, but many share a common objective of encouraging and supporting innovation (Financial Conduct Authority 2015; Monetary Authority of Singapore 2020a.; National Environment Agency 2019; Canadian Securities Administrators n.d.; Reserve Bank of India 2019). Regulatory sandboxes first gained traction in the financial industry, and it is now also used to test non-financial products or services such as Autonomous Vehicles (AVs), telemedicine, and drones.

Broadly, the benefits of using a regulatory sandbox are:

- (i) **Provides opportunities for companies to experiment and develop innovative products or services for consumers and/or industry** (Financial Conduct Authority 2017, 3): With the rapid developments of technology and business models in many sectors, companies increasingly need to experiment with new products and/or services to stay ahead. Firms sometimes hold back innovating if they are unsure about the legal and regulatory requirements. Regulatory sandboxes can help capture some of these missed opportunities because it provides a controlled environment for testing, which reduces regulatory uncertainty.

- (ii) **Reduces time-to-market** (Armstrong, Bárd and Engström 2020, 30): Where there is regulatory uncertainty, it can be difficult for firms to obtain funding from investors and to introduce their products to the market. Regulatory sandboxes provide the opportunity for firms to test and fine-tune their product or service based on market feedback. This helps to increase their credibility with investors and enables firms to make quicker progress towards a wider market launch (Armstrong, Bárd and Engström 2020, 31).
- (iii) **Keeps pace with new developments** (Financial Conduct Authority 2017, 3): While the sandbox provides space for companies to experiment, regulators need to do their part by reviewing regulations and ensuring that they are relevant for the current environment and context. Running a sandbox helps regulators keep pace with new developments as they need to work closely with sandbox entities on their regulatory obligations, challenges and progress. This enables regulators to adopt a more anticipatory approach to market developments, so that regulations remain conducive to innovation (Armstrong and Rae 2017, 8).¹
- (iv) **Signals regulators' support for innovation and willingness to update regulations** (Armstrong, Bárd and Engström 2020, 30): Dedicating time and resources towards supporting innovation signals a regulator's pro-innovation stance to the market. It shows the regulator's willingness and openness to experimentation and the possibility of updating its regulations, which ensures that the sector is sustainable in the long run.

¹ Sandboxing is an example of anticipatory regulatory approach. This approach was coined by Nesta to encourage regulators to be pro-active, iterative and collaborative, so that regulatory frameworks can be more forward-facing.

2 WHEN IS A REGULATORY SANDBOX USED?

Regulators should determine if the new product or service requires setting up a sandbox. Supporting innovation may be a common motivation for setting up sandboxes, but it should not be the only criterion as outlined in the last section of this guide, which showcases sandbox variations. Other ways to support innovation include innovation hubs, accelerators, incubators and financial grant schemes (Buckley et al. 2020).² From the range of possible regulatory tools, regulators need to choose the tool that can achieve the objective in the most effective and efficient way.³

Broadly, regulatory sandboxes are set up for the following purposes (see [Figure 1](#)).⁴

- (i) **Product-Testing:** When firms test their new products or services before they are formally registered or licensed (Armstrong, Bárd and Engström 2020, 24). This allows firms to assess the uptake and viability of their product or service, and address regulatory feedback (UNSGSA and CCAF 2019, 27).
- (ii) **Policy-Testing:** When regulators need to identify existing regulations that may hinder innovation (e.g. new business models or technologies) and evaluate whether a new regulatory framework needs to be developed (Armstrong, Bárd and Engström 2020, 24). This approach is commonly used when the new product or service does not comply with existing legal and regulatory requirements or there are no existing legal and regulatory requirements for the new product or service, which will be launched in a regulated market or industry.

To date, these are the two most common sandbox models. However, these are not mutually exclusive (UNSGSA and CCAF 2019, 27). For example, firms participating in policy-testing sandboxes will usually include product-testing, and regulators may evaluate existing regulations in a product-testing sandbox if there is regulatory uncertainty (UNSGSA and CCAF 2019, 27).

² Buckley et al. concluded that regulatory sandboxes do not work effectively as a stand-alone approach to develop the fintech ecosystem. They concluded that many advantages of a sandbox can also be achieved through an effective innovation hub, which could include a regulatory sandbox among other regulatory tools.

³ When choosing a suitable regulatory tool, regulators should consider factors such as objectives, market conditions and feasibility, legal and regulatory framework, stakeholder ecosystem, and risks (World Bank 2020, 34).

⁴ These are the common situations identified from various regulators' approaches to sandboxing (Financial Conduct Authority 2020a; Monetary Authority of Singapore n.d.; National Environment Agency 2019; Ministry of Health Singapore n.d.).

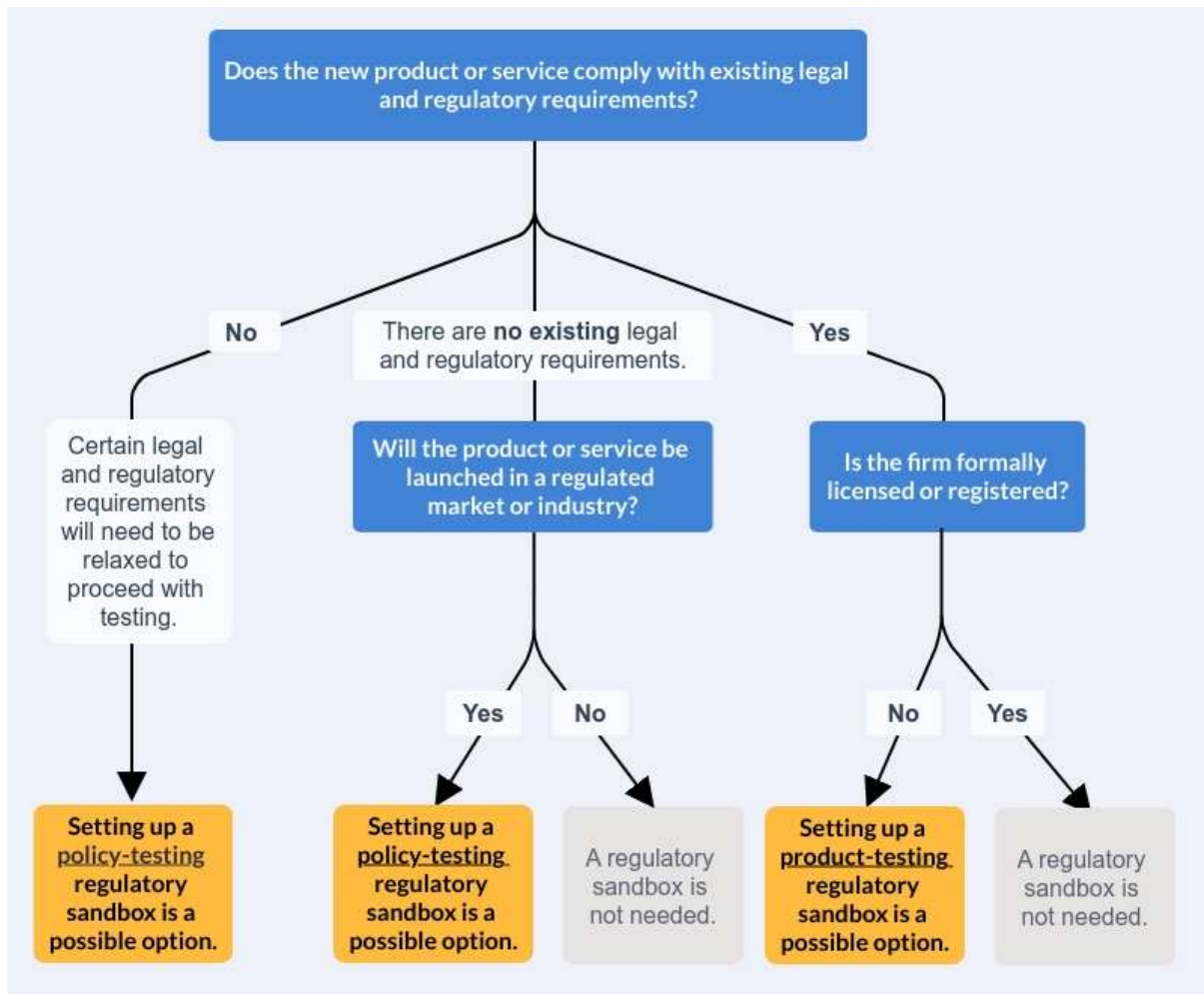


Figure 1: When are Regulatory Sandboxes Generally Used?

3 LAUNCHING A REGULATORY SANDBOX

The next steps cover tasks that a regulator needs to carry out pre-sandbox, during experimentation, and post-sandbox (see **Figure 2**).

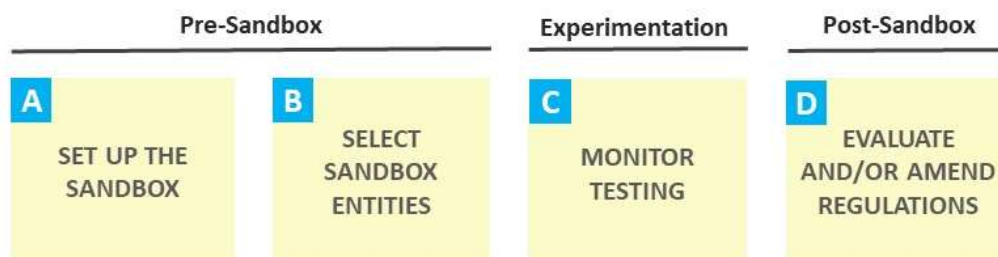


Figure 2: Steps to Launching a Regulatory Sandbox

(A) SET UP THE SANDBOX

A useful starting point when setting up a sandbox is thinking about whether it should be bespoke or pre-defined. Under a bespoke approach, the regulator customises the sandbox construct according to the risks of the product or service, whereas a pre-defined sandbox comes with a fixed construct for all its sandbox entities (read more these approaches in [Box 3](#)). Regardless of the approach, the following are the common elements of constructing sandboxes.

SANDBOX DURATION

There is no fixed duration for a regulatory sandbox. For example, a sandbox could last as short as 3 months (e.g. UK's Financial Conduct Authority (FCA)) or as long as 3 years (e.g. Singapore's Energy Market Authority (EMA)). Regulators decide on the duration depending on the level of risk and uncertainty, and time needed by the regulator and sandbox entity to gather meaningful data. For example, regulators may decide on a shorter testing duration if the data can be collected quickly, and the level of risk is low and well-understood.

Some regulators like Singapore's National Environmental Agency (NEA) and EMA allow firms to propose the duration, which is subject to the regulator's approval. In most cases, firms have the option of applying for an extension. The application to extend their testing must be submitted before the end of the sandbox and they are required to provide a reason. However, some regulators limit the number of extensions and entire duration of testing including the extended testing period.

**PROBLEM
STATEMENT**

Most regulatory sandboxes allow the testing of new products or services of any problem statement for their own sector. The alternative is to set up thematic sandboxes, where the regulator puts out problem statements to attract solutions that meet the sector's priorities and needs (e.g. EMA).

**SANDBOX
ENTITIES**

Regulators may choose to restrict the sandbox to certain sectors or firms depending on their regulatory responsibilities and approach to managing risks.

- MAS Sandbox Express is only available for insurance broking, and recognised market operators.
- Hong Kong's Monetary Authority Fintech Supervisory Sandbox is only for banks and its partnering technology firms.

In contrast, the FCA and the Monetary Authority of Singapore (MAS) Fintech Regulatory Sandbox are examples of agencies with sandboxes open to any interested players including unlicensed or unregulated firms.

**TARGET
CUSTOMERS**

Regulators might also limit the number and type of customers in the sandbox often to manage the risks better. However, they differ in how they decide on the target customers.

- MAS allows sandbox entities to choose their limit on the number and type of customers (e.g. retail customers), but this is still subject to their agreement.
- Singapore's Land Transport Authority (LTA) limited the number of customers by restricting the testing of AVs to one-north in Singapore.
- Other regulators accept firms according to their customer base profile. Under the Australian Securities and Investments Commission (ASIC) Fintech Licensing Exemption, only businesses with no more than 100 retail clients and a total client exposure of not more than \$5 million are permitted to operate in the sandbox.

**REGULATORY
RELIEFS**

Most regulators will decide which legal and regulatory requirement to suspend on a case-by-case basis. In the MAS Fintech Regulatory Sandbox, MAS lists examples of regulatory requirements that can be relaxed and those they would like to maintain.

Where risks are low and certain, some sandboxes have their regulatory exemptions predefined. For example, the MAS Sandbox Express specifies the regulatory reliefs (see [Box 3](#)). Besides suspending certain regulatory requirements, some regulators like the FCA also issue no enforcement action letters, which allows no disciplinary action to be meted out to sandbox entities if something goes wrong – as long as the entity has complied with the sandbox conditions and has taken steps to protect consumers. This tool might only be suitable when the risks are complex and not well-understood.

These regulatory exemptions only last for the duration of the sandbox and firms are still expected to comply with the full legal and regulatory requirements after exiting the sandbox. If testing shows that existing regulations cannot manage the risks of the new product or service and there is value in allowing these new products and services into the market, regulators might consider updating their regulations.

**RISK
DISCLOSURE**

Regulators might require sandbox entities to inform consumers that it is operating in a sandbox, and the risks involved, especially if there are substantial and complex risks. In some cases, they are also required to seek consumers' consent and bear a regulatory sandbox logo or identification (e.g. Singapore's Ministry of Health (MOH) regulatory sandbox for telemedicine, AVs in Singapore can be identified by a decal) A more common approach is to list the sandbox entities on their website (e.g. EMA, MAS, FCA, ASIC).

As failure and iterations are integral to outcomes of experimentation, it is crucial for regulators to consider the above elements when constructing sandboxes, to manage responses to potential failures and any risks.

(B) SELECT SANDBOX ENTITIES

Next, firms interested to test in the sandbox are required to submit an application. Regulators usually use the following eligibility criteria to assess whether a firm qualifies to test in a sandbox (Financial Conduct Authority 2020b; Monetary Authority of Singapore 2020a.; Ministry of Health Singapore n.d.; National Environment Agency 2019).

Does it require a sandbox?

This question helps regulators identify products and services that do not need to be tested in a sandbox (see **Figure 1**). Applicants are required to know their legal and regulatory requirements (e.g. which regulations need to be waived during the sandbox).

Is it a genuine innovation?

Some regulators provide these guidelines to provide clarity on what is considered innovative:

- No similar products or services existing in the local market.
- Show how the proposed product or service uses a different technology.
- Show how it uses the same technology differently.

Is it beneficial?

Besides managing risks, regulators also need to ensure that the proposed product or service brings benefits to consumers and/or industry. Firms need to show how their product or service can address a problem or gap in the market. Evidence of the product or service benefit could come from the firm's past consumer or industry research, as well as operations in other countries.

Is the firm ready for testing?

Firms are required to prepare the following information, so regulators can assess whether they are ready for testing.

- Test scenarios;
- Outcomes;
- Test parameters;
- Risk assessment;
- Safeguards;
- Monitoring plans; and
- Evaluation plans.

What is the firm's exit strategy?

If a firm fails to comply with the sandbox conditions or achieve its intended outcomes, testing should be discontinued. This might pose risks to consumers and/or industry, so regulators will need to know the firm's exit strategy (e.g. how they plan to fulfil existing obligations to consumers before exiting the sandbox).

What is the firm's transition strategy?

To assess the benefits and risks, regulators need to know the applicant's plan for the actual market launch after graduating from the sandbox.

In addition to the above eligibility criteria, some regulators require firms to provide details on their organisation. Specifically, the background of the company, profile of its key personnel, financial standing and authorised regulatory status.

To help firms assess their eligibility criteria properly, regulators like the FCA also provide examples of positive (e.g. "The full authorisation process would be too costly/difficult for a short viability test") and negative indicators (e.g. "There are numerous examples of similar offerings already established on the market") of each criterion.

Whether firms apply to the sandbox depends on how these criteria are written. Firms might be discouraged from applying if they also perceive the criteria to be overly stringent, complex and/or unclear. Hence, regulators might find it useful to obtain feedback from firms before confirming the sandbox eligibility criteria.⁵

Operational Considerations

Having determined the eligibility criteria, it is important to ensure that the 'last mile' to participating in the sandbox is well-designed when operationalising it. These critical operational considerations are as outlined below.

- Intake of Applicants: Some regulators choose to run cohort-based sandboxes (e.g. UK's FCA). Under this sandbox model, firms enter and exit the sandbox at the same time. The alternative is to not standardise the start of testing for the sandbox entities, which is what many regulators choose to do.
- Application Forms and Process: The application process should not be too daunting for applicants. Regulators can provide an application form to streamline the application process. However, these application forms should not be too long or complicated. Smaller firms with insufficient resources will be deterred from applying if the application process is too onerous.

In addition, firms find it useful if they can clarify their concerns and regulatory requirements with regulators before submitting their application. Hence, regulators need to ensure that communication channels are kept open for firms to reach out for regulatory guidance.

- Processing Time: The time taken to notify the applicant about their application outcome varies across sandboxes because regulators need to work with firms to revise their proposals. Depending on the complexity of the proposed product or service, some regulators could take as long as a few months to process an application. It would be useful to set such expectations upfront to facilitate the process.
- Approval from Regulator: Most regulators only allow firms to start testing after approving the firm's application. However, applicants under the ASIC's Fintech Licensing Exemption are only required to notify the regulator that they will be experimenting in the sandbox. If they are eligible for the specified regulatory exemption and they adhere to the sandbox requirements, no approvals are required. Upon completing the notification process, these firms can begin testing.

⁵ MAS held a public consultation on the proposed guidelines for their Fintech Regulatory Sandbox and Sandbox Express. Besides consolidating feedback from firms, MAS also released its responses to the feedback received (Monetary Authority of Singapore 2016b; Monetary Authority of Singapore 2019).

(C) MONITOR TESTING

When testing in the sandbox commences, regulators need to monitor the sandbox entities' progress and performance. They do this by requiring their sandbox entities to submit progress reports periodically. The frequency of reporting is often determined based on the duration of testing, and severity and complexity of risk involved. If the testing period is short, there should be adequate progress reporting before the end of testing. For example, the MAS requires Sandbox Express entities to submit a progress report form every two months. The sandbox entity would have agreed to this requirement before the start of the sandbox.

The basic fields in a progress report form are (Monetary Authority of Singapore 2020b):

- Declaration by the sandbox entity that it continues to meet the conditions imposed;
- Sandbox boundaries and test results (e.g. indicators including quantitative and qualitative outcomes);
- Problems and feedback (e.g. complaints from consumers);
- Action taken in response to the problems; and
- Enhancements to product or service (if any).

Ongoing engagements with stakeholders, and surprise visits to companies are other ways regulators can monitor testing. The latter is sometimes used if there are warning signs of potential misconduct (e.g. false reporting of test results). In situations of high and severe risks, regulators have used CCTVs and set up their own data platform to closely monitor the test outcomes and any unintended consequences (e.g. monitoring of AV testing in Singapore).⁶

(D) EVALUATE AND/OR AMEND REGULATIONS

During the sandbox period, regulators assess if existing regulations need to be amended and review the progress to check if the intended test outcomes have been achieved. At the end of testing, regulatory reliefs expire, and sandbox entities are required to submit a final report on the test outcomes. Entities with unsuccessful test results will proceed with their exit strategy, which would have been planned and agreed on at the point of application (see [Step B](#)).

For sandbox entities with successful results, they can transit and scale for the broader market but only after complying with the relevant legal and regulatory requirements (e.g. obtaining licence). To help these firms transit as smoothly as possible into the market, some regulators work closely with them to prepare for their wider market launch in the weeks leading up to the end of the sandbox (e.g. measures to manage new problems and/or risks surfaced during testing).

⁶ LTA installed CCTVs at identified locations to monitor the testing of AVs and real-time footages were integrated with data to evaluate whether AVs were ready for public use.

4 CHALLENGES OF SETTING UP A SANDBOX

Some regulators have been running their sandbox function for a few years while others are still just starting out. Here are challenges commonly faced by regulators regardless of their level of experience.

(i) Operational Challenges

Regulatory resources: Regulators need to consider the cost, manpower and relevant set of capabilities required to set up and run a sandbox (Armstrong, Bárd and Engström 2020, 31; World Bank 2020, 32). The process of setting up and running a sandbox is not straightforward because each application requires extensive reviews and discussions with the firm to fine-tune the product or service, and to establish the sandbox conditions like regulatory waivers. If there is insufficient manpower (e.g. case officers), lack of legislature knowledge and/or funds to run the sandbox efficiently, this will hinder the process substantially (World Bank 2020, 38).⁷

Organisation structure: Sandbox entities might find it challenging to work with officers belonging to different departments. This could slow down the progress of experimentation because firms might have to provide repeat updates to officers belonging to different teams or receive unclear regulatory guidance. As technological disruptions have blurred the distinction of roles and responsibilities between departments, regulators need to decide how their organisation can be structured to support their sandbox function.⁸

(ii) Fair Treatment to Market Players

The sandbox should not be perceived as a platform for regulators to endorse the product or service. Yet, in an interview conducted by Deloitte with the FCA's sandbox entities, majority of them agreed that operating in a sandbox was a "badge of honour" for them (Deloitte 2018, 3). This is because a sandbox provides firms with a measure of credibility. A product or service tested in a sandbox would be fine-tuned to address the regulator's concerns and comply with regulatory requirements. Consumers and investors prefer products or services that have been tried-and-tested. This advantage could also extend to overseas jurisdictions. For instance, regulators overseas might be more willing to extend a full licence to those with sandbox experience. This creates the unintended consequence of an uneven playing field between those in a sandbox and those that are not.

This problem is further complicated when firms perceive regulators to be picking winners at their own discretion (World Bank 2020, 38). Regulators should take measures to ensure that sandbox entities are selected fairly. Firms need to see that regulators are fair and transparent. Thus, the eligibility and assessment criteria should be made known and clear with little room for ambiguity.

⁷ In an interview of the FCA's sandbox entities by Deloitte, the firms highlighted the importance of case officers whose responsibility is to support the firms in a timely manner and gather information from other teams (Deloitte 2018, 4).

⁸ For example, the Singapore's EMA Corporate Planning team is the sandbox secretariat in charge of liaising with the sandbox applicant on administrative processes. If necessary and depending on the type of expertise required, the team facilitates discussions between the applicant and other departments in EMA.

(iii) **Aligning Intent with Impact**

Because sandbox entities experiment in a controlled environment, there is a risk that the impact might turn out differently when the product or service is launched into the market after the sandbox (Kelly 2018). Hence, regulators need to ensure that the sandbox construct and environment are not too different from reality, so that risks can be accurately assessed.

(iv) **Evaluating the Effectiveness of Sandboxes**

In general, regulators use these indicators to evaluate their sandboxes:

- Number of applications
- Number of sandbox entities
- Spread of sandbox firms by sectors
- Size and type of firms
- Percentage of firms that graduated from the sandbox

However, these indicators focus on the “output” of the sandbox rather than the “outcomes”. A high number of sandbox applications does not necessarily indicate an increase in innovation. For example, many applications received by MAS eventually did not require testing through a sandbox (UNSGSA and CCAF 2019, 32). This could indicate that the existing regulatory ecosystem is performing well in terms of encouraging innovation. The ambiguity of this shows that we still need a greater understanding of whether a sandbox can bring about better outcomes vis-à-vis other regulatory approaches (e.g. innovation hubs, wait-and-see approach). The more clarity regulators have on this, the better they will be at knowing when to channel effort and resources to the sandbox function.

5 EXAMPLES OF SANDBOX VARIATIONS

This field guide concludes by sharing a collection of local sandbox examples highlighting the different journeys and challenges experienced by regulators. These examples are selected to show when and how different types of sandboxes are used (see [Box 2](#) and [Box 3](#)), and how a sandbox can be set up to support innovation involving multiple regulators (see [Box 4](#)).

Box 2: A Sandbox for Telemedicine Service Providers Without Regulatory Waivers

Telemedicine is set to become a key feature of Singapore's healthcare landscape as Singaporeans become more digitalised with high mobile penetration rates and more involved in their healthcare. For those who are unable to attend their hospital or clinic appointments, telemedicine enables continued accessibility to care for the patients. However, while the technology is in place, the adoption of telemedicine by healthcare providers had been generally limited. Doctors have been hesitant to use telemedicine in their practice, due to the lack of clarity relating to the standards of practice expected with the use of this new modality and concerns over medico-legal issues. This was despite that guidelines on the use of telemedicine are widely available both locally and internationally, such as the National Telemedicine Guidelines, codes of conduct and practice set by the various professional entities (e.g. Singapore Medical Council (SMC) in Singapore, American Telemedicine Association in USA and Care Quality Commission in UK).

Recognising that telemedicine would grow and that the service would carry similar, if not greater risks, as the traditional in-person consultation, the Ministry of Health decided to regulate the service under the upcoming Healthcare Services Act (HCSA) in 2022. These regulations would mirror existing rules around the provision of other healthcare services, such as clinics and hospitals, and set governance features and out-of-bounds markers to ensure the safe provision of telemedicine services.

When the ministry started to look into regulating telemedicine, it quickly realised that there was a need to 'demystify' telemedicine by separating the real and perceived risks. To do this, the ministry worked closely with the telemedicine practitioners and providers to co-create effective, efficient and fit-for-purpose regulations. While there were many ways to achieve this, the ministry chose to use the regulatory sandbox approach to signal an openness to work with the sector to explore new and innovative services.

Inside the Sandbox: More Stringent Regulatory Requirements

However, unlike other sandboxes which allowed for regulatory exclusions, this sandbox had higher and more stringent clinical and organisational requirements. These requirements reflected (i) the higher-risk nature of healthcare where single failure could result in patient harm; and (ii) the need to give assurance that telemedicine would be piloted safely.

What Is in It for the Sandbox Entities?

So why would sandbox entities subject themselves to these higher requirements? Providers wanted to participate in the sandbox because they saw value in being first movers and growing the telemedicine sector; and recognised the need to co-create future regulations with the ministry. Having early insights and clarity on this regulatory future, and the opportunity to shape it was critical for these telemedicine providers in achieving business continuity and long-term viability.

Telemedicine Regulatory Sandbox

Given that each telemedicine model could be different, the ministry’s sandbox for telemedicine was based on a bespoke model in consideration of the different risks and mitigation measures. **Table 1** below summarises the key elements of this sandbox.

Table 1: Key Elements of the Telemedicine Regulatory Sandbox

PRE-SANDBOX	
Eligibility	Sandbox applicants were required to submit their organisational, clinical, financial and data security information to the ministry. This was an iterative process because applicants may be at different stages of implementation.
Duration	Telemedicine providers participating in this sandbox will continue until the new HCSA comes into effect or earlier if the ministry deems necessary.
Safeguards	Examples of the safeguards put in place to manage the risks: <ul style="list-style-type: none"> • Compliance with all applicable laws. • SMC-registered clinical lead required to ensure clinical safety and audit. • Requirements for onboarding and training of doctors to provide telemedicine. • Patients must be informed about the limitations of telemedicine (e.g. telemedicine should not be used for chest pains or breathing problems). • Clear escalation protocols for conditions unsuitable for telemedicine. • Medication delivery in-line with Singapore Standards (SS SDM 644).
Regulatory Reliefs	No regulatory waivers. Instead, sandboxed providers are required to adhere to additional regulatory requirements (i.e. requirement to comply with the Private Hospitals and Medical Clinics Act and relevant legislation and guidelines).
EXPERIMENTATION	
Monitoring	Sandbox entities are required to submit quarterly (e.g. consultation frequency, common medical diagnosis, system downtime) and ad-hoc data (e.g. serious reportable events like death, clinical complaints like misdiagnosis, cybersecurity breaches). The ministry also schedules regular meetings for sandbox entities to share updates (e.g. new developments) and provide feedback on certain issues.
POST-SANDBOX	
Evaluate and/or Amend Regulation	Outcomes of the sandbox are evaluated quantitatively using the quarterly and ad-hoc data collected, and qualitatively via interviews with doctors, patients and administrators. Most importantly, there should be no public harm and the sandbox should achieve its main objective of establishing fit-for-purpose and effective regulations for telemedicine.
Exit Plans	In-line with existing requirements for healthcare institutions, the sandbox entity must have provisions to transfer the patient to another medical provider if there is a need to close the business or if the ministry determines that there is a need to do so.

Tips for a Successful Regulatory Sandbox

- 1) Be clear on why a sandbox is needed. There are various reasons for a sandbox (e.g. growing the sector, understanding the risks and collecting data for new service) and there might be other ways to achieve the aim without a sandbox.
- 2) Be clear on what needs to be sandboxed. If there is no clarity on this, the sandboxing team could be inundated with multiple requests from variety of providers to be part of the sandbox.
- 3) Be clear on how to sandbox (e.g. contract or letter of acceptance). Consider the risks of each method, available levers, and the strength of each lever to effectively mitigate risks.
- 4) Recognise that sandboxing attracts attention. In order to manage the number of sandbox applications, decide early if the sandbox should be inclusive (i.e. allowing all business models) or exclusive by restricting entry to only new models that are also representative of the sector. There are trade-offs for each approach. If it is exclusive, it may become a quality mark, which is an unintended consequence. If it is inclusive, you will need resources to assess and manage new applicants within a reasonable time frame.
- 5) Understand the limitations of a sandbox. A sandbox is an artificial environment and sandbox entities may behave differently when operating within a sandbox compared to outside of it. Thus, other risks may only surface after the sandbox ends.

Box 3: Bespoke Versus Pre-Defined Sandbox Models: Managing Risks with Different Set-ups

The Monetary Authority of Singapore (MAS) has two types of sandboxes. The Fintech Regulatory Sandbox (“Sandbox”) was launched in 2016 and Sandbox Express was recently set up in August 2019 to enhance the overall sandbox approach. Both were set up to facilitate the experimentation of innovative products or services through use of technology. Sandbox Express is the faster option for firms conducting certain regulated activities to test their product or service, by relying on standard disclosures and pre-defined rules.

What Is the Difference?

The Sandbox is based on a bespoke model, so that MAS can customise the sandbox construct according to the risks of each product or service. Decisions on regulatory reliefs and testing parameters are only made after an extensive review of the firms’ applications. In comparison, Sandbox Express has pre-defined regulatory reliefs and only allows certain types of products or services to be tested.

Given that Sandbox Express speeds up the approval process, it is only suitable for products or services with low and well-understood risks that can be properly managed and contained within the pre-defined sandbox boundaries. In contrast, the Sandbox supports more complex products and services through customisation of sandbox constructs on a case-by-case basis.

These two sandboxes illustrate MAS’ risk-based approach where resources are allocated according to different risk levels. For example, more resources can be channelled to the Sandbox which deals with more complex and high-risk products and services. This approach not only enables MAS to prioritise their resources accordingly, but it also removes the need for ‘low-risk’ innovation to go through an extensive review.

It is still too early to conclude if these two types of sandboxes are sufficient to meet the changing demands of the industry. But MAS will continue to monitor the progress and evaluate its effectiveness (e.g. whether the Sandbox Express boundaries are too narrowly defined).

Box 4: Four Agencies, One Regulatory Sandbox: Paving the Way for a New Business Idea

Eating and drinking used to be prohibited activities on reservoirs in Singapore. This changed in 2018 when a regulatory sandbox was set up for The Floating Donut Company Pte. Ltd to test their business idea of offering refreshments on-board its donut-shaped boat in Marina Bay. When the company first introduced this idea to several government agencies, the agencies had their concerns because it flouted existing regulations. Even if the regulations were waived to permit the operation of this business idea, there were ongoing risks to contend with like water pollution, public disorder and disamenities arising from drunken behaviour, and water safety issues as there are larger vessels plying the area. The fact that the regulations came under multiple agencies complicated the problem further. These challenges hindered the company from making any headway for 3 years (Heng 2019).

Crystallising the Opportunity

The company finally made progress when they approached the Singapore Tourism Board (STB). STB saw that it could offer a different experience for tourists. However, it also recognised that cross-cutting regulatory issues needed to be resolved. When this idea was brought to the Pro-Enterprise Panel's (PEP) attention, they convened a meeting with the company, then Ministry of Environment and Water Resources (MEWR), Urban Redevelopment Authority (URA), Maritime and Port Authority of Singapore (MPA) and Singapore's national water agency (PUB).⁹ This was an opportunity for all stakeholders to discuss their views, which ensured that any decision would not be made based on the interest and regulatory mandate of one agency.

It was decided that testing the business idea in a regulatory sandbox could advance the matter. The company could test their business idea instead of being rejected from the outset, and agencies could assess the probability and magnitude of the risks before deciding whether the idea could be implemented in the long term. If there were incidents of non-compliance, the agencies could choose to discontinue the sandbox. Without a regulatory sandbox, the decision to either reject or permit the new business idea could have resulted in a missed opportunity or a misguided regulatory decision respectively.

Co-Creating a Regulatory Sandbox

The sandbox conditions were not pre-determined by a single agency, and this proved to be advantageous in this situation because this gave the agencies a sense of control over the testing parameters, sandbox duration, safeguards and regulatory reliefs. Given that several agencies were involved, the sandbox boundaries had to address each agency's concerns. As each agency negotiated and defined the sandbox boundaries according to their own risk assessment, this eased their initial hesitation about setting up a regulatory sandbox. This was a learning experience for the agencies as they learnt that it is possible to take on more risk, within reasonable limits, by putting safeguards in place.

To properly manage the risks involved during testing, the agencies also worked closely with the company to revise their proposal. For example, the firm removed their barbeque services to reduce the risks of water pollution and safety. This process required regulators to shift their mindset from eliminating risks to managing and reducing risks, and also co-creating possible solutions with the company. If the agencies only focused on eliminating risks, the company would have had to forgo many of their original ideas (e.g. consumption of alcohol onboard).

While the agencies agreed to share responsibility of this sandbox, there needed to be clarity on which agency would be responsible if something went wrong. The agencies managed this issue of accountability by establishing their own roles and responsibilities based on their regulatory mandate.

Regulatory Sandbox: The Floating Donut

Table 1 below summarises the key elements of this regulatory sandbox.

Table 1: Regulatory Sandbox for The Floating Donut Company

PRE-SANDBOX	
Duration	The regulatory sandbox duration was 6 months.
Safeguards	These were examples of safeguards put in place to manage the risks: <ul style="list-style-type: none"> • Restricted operating area; • Only cooked food is allowed; and • No cooking and washing activities are allowed on-board.
Regulatory Reliefs	The exemption allowed for the sale of alcoholic beverages on the Marina Reservoir.
POST-SANDBOX	
Evaluate and/or Amend Regulation	Throughout the period of the sandbox, no incidents or disamenities were reported. When the sandbox ended, the company's activities were reviewed by the agencies concerned, and it was allowed to continue operating its services (with food and alcoholic beverages) on Marina Bay.

What Made the Sandbox Work?

- 1) Keep an open mind about new ideas and adopt a pro-enterprise mindset by communicating with businesses. Focusing solely on an agency's given regulatory mandate might sometimes result in valuable missed opportunities.
- 2) Preserve space for collaboration and co-creation of solutions between agencies and businesses. This provides an opportunity to address each stakeholder's concerns and co-create solutions.
- 3) Rather than reject the idea from the outset, explore alternative options with the stakeholders and company. Even if an idea is eventually rejected, regulators should explain the reasons to the firm, so that they understand and are guided towards feasible steps.
- 4) Regulators should reframe how they approach regulating innovative products or services by including an industry development perspective where possible. Society could benefit more if regulators give more consideration to helping a new product or service enter the market. Regulation should not be an afterthought, but it should neither be the only and first consideration for regulators.

⁹ PEP is a private-public panel chaired by the Head, Civil Service. The Ministry of Trade and Industry's (MTI) Pro-Enterprise Division is the secretariat for the PEP, which works with public agencies to address regulatory concerns faced by businesses. Information on PEP's initiatives can be found on MTI's website: www.mti.gov.sg/PEP/About

OFFICIAL (OPEN)

Note: The Floating Donut Company Pte. Ltd ceased operations around mid-December 2019 for commercial reasons. Agencies are working with the company to explore possible solutions to keep alive its concept of operating a leisure cruise service using a donut-shaped vessel on Marina Bay.

6 CONCLUSION

In this field guide, we focused on the key steps and considerations of setting up and maintaining a regulatory sandbox. Despite the growing use of sandboxes, it is still very much an emerging field, especially in the non-financial sector. There is no clear winning model for now, but there are useful lessons to be gleaned from regulatory sandbox experiences across sectors, usually distinguished by context and regulatory requirements.

We hope this guide has been useful in establishing the purpose and basic steps of setting up and operationalising a regulatory sandbox.

REFERENCES

Armstrong H., I. Bárd, and E. Engström. 2020. "Regulator Approaches to Facilitate, Support and Enable Innovation." Accessed 28 August, 2020. <https://www.gov.uk/government/publications/regulator-approaches-to-facilitate-support-and-enable-innovation>.

Armstrong, H., and J. Rae. 2017. "A Working Model for Anticipatory Regulation." Working Paper. Accessed 28 August, 2020. <https://www.nesta.org.uk/report/a-working-model-for-anticipatory-regulation-a-working-paper/>.

Baker McKenzie. 2018. "International Guide to Regulatory Fintech Sandboxes." Accessed 28 August, 2020. <https://www.bakermckenzie.com/en/insight/publications/2018/01/guide-regulatory-fintech>.

Buckley, R. P., D. W. Arner, R. Veidt, and D. A. Zetsche. 2020. "Building Fintech Ecosystems: Regulatory Sandboxes, Innovation Hubs and Beyond." *Washington University Journal of Law & Policy* 55-98. <http://dx.doi.org/10.2139/ssrn.3455872>.

Canadian Securities Administrators. n.d. *CSA Regulatory Sandbox*. Accessed 28 August, 2020. https://www.securities-administrators.ca/industry_resources.aspx?id=1588.

Deloitte. 2018. "A Journey Through the FCA Regulatory Sandbox: The Benefits, Challenges, and Next Steps." Accessed 28 August, 2020. <https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/financial-services/deloitte-uk-fca-regulatory-sandbox-project-innovate-finance-journey.pdf>.

Financial Conduct Authority. 2020a. *Sandbox Tools*. Accessed 28 August, 2020. <https://www.fca.org.uk/firms/innovation/regulatory-sandbox-tools>.

—. 2020b. *Applying to the Regulatory Sandbox*. 23 July. Accessed 9 September, 2020. <https://www.fca.org.uk/firms/innovation/regulatory-sandbox-prepare-application>.

—. 2017. "Regulatory Sandbox Lessons Learned Report." Accessed 28 August, 2020. <https://www.fca.org.uk/publications/research/regulatory-sandbox-lessons-learned-report>.

—. 2015. *Regulatory Sandbox*. Accessed 28 August, 2020. <https://www.fca.org.uk/firms/innovation/regulatory-sandbox>.

Kelly, J. 2018. A "fintech sandbox" might sound like a harmless idea. It's not. 5 December. Accessed 29 August, 2020. <https://ftalphaville.ft.com/2018/12/05/1543986004000/A--fintech-sandbox--might-sound-like-a-harmless-idea--It-s-not/#:~:text=Instead%2C%20it%20is%20essentially%20a,in%20practice%2C%20it's%20not.>

Ministry of Health Singapore. n.d. *Licensing Experimentation and Adaptation Programme (LEAP) – A MOH Regulatory Sandbox*. Accessed 28 August, 2020. [https://www.moh.gov.sg/home/our-healthcare-system/licensing-experimentation-and-adaptation-programme-\(leap\)--a-moh-regulatory-sandbox#:~:text=Launched%20in%202018%20by%20Senior,by%20partnering%20early%20with%20industry.](https://www.moh.gov.sg/home/our-healthcare-system/licensing-experimentation-and-adaptation-programme-(leap)--a-moh-regulatory-sandbox#:~:text=Launched%20in%202018%20by%20Senior,by%20partnering%20early%20with%20industry.)

Monetary Authority of Singapore. 2020a. *Overview of Regulatory Sandbox*. Accessed 28 August, 2020. <https://www.mas.gov.sg/development/fintech/regulatory-sandbox.>

—. 2020b. *Sandbox Express*. Accessed 28 August, 2020. <https://www.mas.gov.sg/development/fintech/sandbox-express.>

—. 2019. "Response to Feedback Received - Sandbox Express." Accessed 28 August, 2020. <https://www.mas.gov.sg/-/media/MAS/Smart-Financial-Centre/Sandbox-Express/Response-to-Feedback-Received-7-Aug.pdf?la=en&hash=E681A2F72DD5BEB66A4A3C5FEA8E8F6804173796.>

—. 2016a. *Fintech Regulatory Sandbox Guidelines*. Accessed 28 August, 2020. <https://www.mas.gov.sg/-/media/MAS/Smart-Financial-Centre/Sandbox/FinTech-Regulatory-Sandbox-Guidelines-19Feb2018.pdf?la=en&hash=B1D36C055AA641F580058339009448CC19A014F7.>

—. 2016b. "Response to Feedback Received - FinTech Regulatory Sandbox Guidelines." November. Accessed 28 August, 2020. <https://www.mas.gov.sg/-/media/MAS/Smart-Financial-Centre/Sandbox/Response-to-Feedback-Received.pdf?la=en&hash=3F35F4C5F1CF0C7EE85D22E62C4C0B28114BF97E.>

National Environment Agency. 2019. *Regulatory Sandbox*. Accessed 28 August, 2020. <https://www.nea.gov.sg/industry-transformation-map/guide-on-uniforms-for-environmental-services-industry/regulatory-sandbox.>

Reserve Bank of India. 2019. *Enabling Framework for Regulatory Sandbox*. Accessed 28 August, 2020. <https://www.rbi.org.in/Scripts/PublicationReportDetails.aspx?UrlPage=&ID=938.>

United Nations Secretary-General's Special Advocate for Inclusive Finance for Development (UNSGSA) FinTech Working Group and Cambridge Centre for Alternative Finance (CCAF). 2019. *Early Lessons on Regulatory Innovations to Enable Inclusive FinTech: Innovation Offices, Regulatory Sandboxes, and RegTech*. New York, NY and Cambridge, UK: Office of the UNSGSA and CCAF.

World Bank. 2020. *How Regulators Respond to Fintech – Evaluating the Different Approaches – Sandboxes and Beyond*. Accessed 28 August, 2020. <https://elibrary.worldbank.org/doi/abs/10.1596/33698>.

ACKNOWLEDGEMENTS

The author would like to express her appreciation to:

- Praveen Raj Kumar, Jasmine Koh and Jessie Tan from Singapore's Ministry of Health for sharing their insights for Box 2;
- Ken Chua from the Monetary Authority of Singapore for providing inputs to the field guide and sharing his insights for Box 3;
- Alvin Sim and Tessa Goh from Singapore's Ministry of Trade and Industry for sharing their insights for Box 4;
- Lee Seng Wai, Dave Lew and Law Gee Yong from Singapore's Energy Market Authority for providing their inputs to the field guide.

ABOUT THE INSTITUTE

The Institute of Governance and Policy (IGP) researches into major policy issues that Singapore faces. IGP aims to bring new insights to Singapore's public policies and governance model.

ABOUT THE AUTHOR

Charmaine Lim is a Senior Researcher at the Institute of Governance and Policy, Civil Service College.

OFFICIAL (OPEN)

EQUIP • **CONNECT** • **EXPLORE** • **CREATE**



Civil Service College, Singapore
31 North Buona Vista Road Singapore 275983
www.ccollege.gov.sg
www.facebook.com/CivilServiceCollegeSingapore

© 2020 Civil Service College, Singapore. All rights reserved. No part of this paper may be reproduced, modified, stored in a retrieval system, or transmitted in any form by any means, electronic, mechanical, photocopying, recording or otherwise, without the prior written permission of the Civil Service College, Singapore.