Prospective Study on Regulatory Sandbox as a Conceptual Innovation in Processed Food Control in Indonesia

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ARTICLE INFO

Article history
Received:
October 30, 2023

Revised:
December 9, 2024

Accepted:
December 31, 2024

DOI:
https://doi.org/10.54384/eruditio.v5i1.172

ABSTRACT

The enhancement of innovation in processed food products in Indonesia faces regulatory challenges that often limit the speed and flexibility of development, particularly for high-risk products. The recent implementation of the Omnibus Law has brought significant changes to the food oversight framework, including the exemption of criminal sanctions for low to medium-risk business activities and the transition of distribution permits into business licenses. However, these regulations have not fully addressed the barriers to innovation in processed food development. The concept of a regulatory sandbox has been identified as a promising prospective approach to overcoming these challenges, providing a controlled testing environment for businesses to develop innovative products within a more adaptive ecosystem. This article explores the potential of a regulatory sandbox as a creative tool for overseeing high-risk processed food products through a qualitative literature review method. The study indicates that the success of implementing a sandbox depends on several key factors: collecting robust experimental data to assess product safety and efficacy, developing adaptive procedures responsive to industry feedback, and granting limited yet flexible authorization for testing new technologies. Other factors, such as limitations on the duration, scope, and use of the sandbox, must be established to avoid consumer safety risks. As a recommendation, The Indonesian Food and Drug Authority (BPOM) may consider adopting a regulatory sandbox as a strategic framework to support the oversight of processed food products with a dynamic approach, accelerating innovation while maintaining a balance between consumer safety and industry growth.

Peningkatan inovasi dalam produk pangan olahan di Indonesia dihadapkan pada tantangan regulasi yang sering membatasi kecepatan dan fleksibilitas pengembangan, terutama pada produk berisiko tinggi. Penerapan Undang-Undang Cipta Kerja baru-baru ini membawa perubahan signifikan dalam kerangka pengawasan pangan, termasuk pengecualian sanksi pidana bagi kegiatan usaha berisiko rendah hingga menengah dan transisi izin edar menjadi perizinan berusaha. Namun, peraturan ini belum sepenuhnya memberikan solusi terhadap kendala pengembangan inovasi pangan olahan. Regulatory sandbox diidentifikasi sebagai pendekatan konseptual prospektif yang potensial untuk mengatasi hambatan ini, memungkinkan lingkungan uji coba yang terkendali bagi pelaku usaha untuk mengembangkan produk inovatif dalam ekosistem yang lebih adaptif. Artikel ini mengeksplorasi potensi regulatory sandbox sebagai alat inovatif dalam pengawasan pangan olahan berisiko tinggi melalui metode kualitatif berbasis kajian pustaka. Kajian menunjukkan bahwa keberhasilan implementasi sandbox bergantung pada beberapa faktor utama: pengumpulan data eksperimental yang kuat untuk menilai keamanan dan efektivitas produk, pembentukan prosedur adaptif yang responsif terhadap masukan industri, serta pemberian otorisasi terbatas namun fleksibel untuk pengujian teknologi baru. Di samping itu, faktor-faktor lain, seperti batasan dalam durasi, ruang lingkup, dan penggunaan sandbox, juga perlu ditetapkan untuk menghindari risiko keamanan konsumen. Sebagai rekomendasi, Badan Pengawas Obat

dan Makanan (BPOM) dapat mempertimbangkan regulatory sandbox sebagai kerangka kerja strategis yang mendukung pengawasan produk pangan olahan dengan pendekatan dinamis, mempercepat inovasi sambil tetap menjaga keseimbangan antara keamanan konsumen dan pertumbuhan industri.

Keywords: Regulatory Sandbox, Control, Processed Food
Kata Kunci: *Regulatory Sandbox, Pengawasan, Pangan Olahan*

1. Introduction

Innovation in processed food control is vital for national food security and public health amid accelerating technology and diversification of food products. In Indonesia, the urgency to develop a flexible and responsive food control system is increasingly prominent, particularly in high-risk processed foods with unique nutritional products. While Indonesia's *pre-market approval* system ensures product safety before marketing, the procedure is often perceived as stifling innovation, especially among resource-constrained small and medium-sized enterprises (SMEs). (Eggers & Turley, 2018). Establishing uniform regulations for all businesses often does not align with dynamic market needs and rapidly evolving product innovations. This leads to violations, such as circulating processed food products without distribution permits.

To overcome this obstacle, the Indonesian government, through the Job Creation Law Number 6 Year 2023, has introduced additional flexibilities in the formal regulatory perspective, including exemptions from criminal sanctions for low- to medium-risk businesses. While these measures are expected to support economic growth and innovation, these regulatory changes have not fully addressed the key challenges in controlling high-risk processed food, especially for processed food for special nutritional needs (PKGK) products, which are one of the focuses in mitigating *stunting* in Indonesia. (Presidential Regulation of the Republic of Indonesia, 2021). Based on data from the Food and Drug Administration (BPOM), processed food products without a distribution permit (TIE) dominate regulatory violations from year to year, namely 60% of 158 cases in 2018, 47% of 306 cases in 2019, 56% of 333 cases in 2020, 63% of 388 cases in 2021, 66% of 442 cases in 2022, and 62% of 173 cases in 2023. This condition shows that conventional *pre-market approval-based* control faces limitations in supporting the development of innovative yet safe food products.

In the face of these limitations, the *regulatory sandbox* approach is considered an innovative and prospective solution that can assist regulators in creating a more adaptive supervisory ecosystem. According to Brown and Piroska (2022), the *regulatory sandbox* is defined as a framework created by regulators that allows innovators to conduct hands-on experiments in a controlled environment under the supervision of regulators. The *regulatory sandbox* framework will enable innovators to experiment and innovate without significant risks, while regulators can understand the potential impact of new products or services before issuing formal regulations. This bridges the gap between strict regulation and unbridled innovation growth and creates a conducive environment for technological evolution while keeping in mind the limits of consumer protection. *Regulatory sandboxes* offer a controlled test bed for the food industry to develop and test new products in a flexible yet supervised environment. As a concept that has been applied successfully in the financial technology sector in various countries, *sandboxes* allow regulators to interact directly with innovators to understand risks and opportunities and shape a regulatory framework that is more in line with industry dynamics. (Sherkow, 2022). For the food sector, particularly in the case of PKGK food, the *regulatory sandbox* approach is projected to provide an experimental pathway that allows product innovations to be tested directly in the market under the close supervision of regulators, providing valuable empirical data for evidence-based policy decision-making.

This approach offers several relevant mechanisms to overcome the main obstacles in developing high-risk food products. First, the *sandbox* enables the collection of comprehensive

experimental data, providing a foundation for evaluating product safety and effectiveness more dynamically than rigid *pre-market* procedures. Second, establishing adaptive procedures responsive to industry input allows regulators to quickly adjust regulations based on market developments and technological innovations without compromising consumer safety. Third, the *regulatory sandbox* allows for limited but flexible authorizations for trials of new food technologies or products that do not yet have a definitive regulatory framework. (Burd, 2021). Thus, this approach can potentially reduce the circulation of illegal food products through a more constructive and innovative regulatory framework.

This article aims to assess the potential of implementing a *regulatory sandbox* in controlling high-risk processed food in Indonesia, focusing on the key elements that determine the successful implementation of this concept. As such, this study seeks to answer the main questions: What is the potential of the *regulatory sandbox* as an effective solution in controlling high-risk processed food in Indonesia, and what are the determinants of success that need to be considered in its implementation? This study is expected to contribute significantly to the collective crime prevention strategy in the processed food sector and offer recommendations for BPOM to develop a more innovative and adaptive supervisory policy that meets the needs of the growing food industry in Indonesia.

2. Methodology

This study adopts a qualitative approach based on *a literature review to assess the potential application of a regulatory sandbox* in controlling high-risk processed food in Indonesia, focusing on Processed Food for Special Nutritional Purposes (PKGK) products. This method was chosen to develop a comprehensive overview of the concept, best practices, and challenges and opportunities of implementing the *sandbox* as an innovative regulatory framework that can be adapted in the context of Indonesian food control. Secondary data were obtained through literature searches from significant databases, namely Scopus, PubMed, and Google Scholar, using keywords such as "regulatory sandbox," "high-risk food products," and "pre-market approval in the *food industry*." Additional keywords such as "high-risk processed food" and "food control in Indonesia" were also used to ensure relevance to the local context. The range of publication years reviewed was limited from 2018 to 2023 to ensure that the research only refers to the most recent and relevant literature.

Inclusion and exclusion criteria were applied to maintain the quality and focus of the analysis. The literature selected were publications relevant to the *regulatory sandbox* in the food, health, or financial sectors, emphasising high-risk food products such as PKGK, which directly impact public health. Literature inclusion also considers publications that provide empirical data or concept-based analysis to give depth to the research. Meanwhile, literature not directly related to food control or merely opinions without empirical basis is excluded. The review also includes studies in English and Indonesian to maximize the relevance and accessibility of the data.

The data collected was then analyzed using thematic methods, enabling the identification of key patterns such as the benefits and challenges of the *regulatory sandbox* framework, its potential application in food regulation, and its adaptability in the Indonesian context. Thematic analysis was chosen for its flexibility in grouping the data into meaningful categories, thus facilitating the drawing of conclusions and the formulation of recommendations. The limitations of this study, including reliance on secondary data and limited access to contextual literature, were managed by selecting diverse data sources with high validity and considering a variety of international perspectives to compensate for the limited local literature specific to the *regulatory sandbox* in the business process of Food and Drug Control.

3. Results and Discussion

3.1. New Approach to Processed Food Control

The current control of processed food in Indonesia focuses on the *pre-market approval* approach, where every food product must undergo strict evaluation before it can be marketed. This approach aims to ensure the safety of food products, especially high-risk products such as Processed Food for Special Nutritional Purposes (PKGK), which directly affect public health. (Eichler *et al*., 2012). PKGK is processed food that is specially processed or formulated to meet specific nutritional needs due to certain physical/physiological conditions and diseases/disorders. PKGK consists of Processed Food for Special Diets (PDK), such as infant formula, and Processed Food for Special Medical Purposes (PKMK), such as PKMK, for patients with chronic kidney disease.

While effective in maintaining safety standards, the *pre-market approval* system has significant limitations. High costs, lengthy processes, and administrative complexity can be barriers to innovation, especially for small businesses that do not have the resources to fulfil these requirements. As such, conventional *pre-market approval is* considered less adaptive to evolving market dynamics and the need to accelerate access to safe, innovative consumer products. These limitations create an urgency for regulators in Indonesia to explore more flexible methods that still meet stringent food safety standards.

Regulatory sandbox, as an alternative approach implemented in sectors such as finance and healthcare in many developed countries, offers an innovative solution to overcome the limitations of *pre-market approval*. In case studies from the UK and Singapore, the *sandbox* approach has created a controlled environment that allows businesses to test products with more flexible regulatory schemes while remaining under the watchful eye of regulators. (Allen *et al*., 2019; Tan & Taeihagh, 2021). The success of this model, particularly in driving accelerated innovation in the medical technology and financial sectors, suggests that *regulatory sandboxes* can provide a safe experimental space where innovation can flourish without putting consumers at risk. Another example is in the health sector of European countries, where *sandboxes* are used to accelerate the adoption of medical technologies such as artificial intelligence in medical devices, focusing on improving *post-market* surveillance to reduce the burden of complex *pre-market approval* and enable faster innovation in a safe environment. (Sherkow, 2022; Buocz *et al*., 2023).

As for Indonesia, adopting a *regulatory sandbox* in food control faces specific challenges that must be considered in the local economic and regulatory context. Uneven digital infrastructure, capability variation among stakeholders, and a low understanding of the benefits of the *sandbox* approach in the food sector may hinder its implementation. However, the successful implementation of a *regulatory sandbox* by the Ministry of Health through the *e-malaria* program shows the potential to be adapted to the food sector. This is illustrated by the *e-malaria regulatory sandbox* trial by the Ministry of Health on 4 (four) digital health service innovation clusters (ILKD), carried out from November 30, 2021, to June 30, 2022. The e-malaria regulatory sandbox implementation results are stated with the status of ILKD recommended, improved, or not recommended. (Malaria *Working Group*, 2021). This program, which involves testing innovations in a controlled environment, indicates that the *sandbox* model can accelerate innovation while maintaining oversight. Nonetheless, implementing sandboxes in the food sector will require more comprehensive policies, including integrating digital surveillance and stronger consumer data protection to ensure food safety (Fuad *et al*., 2023; Gromova & Ivanc, 2020). With close supervision from the Indonesian Food and Drug Authority (BPOM), *sandboxes* can enable innovative food products such as PKGK to be tested in the local market without going through the entire *pre-market* process, thus accelerating product access to consumers with holistically managed risks.

Globally, *regulatory sandboxes* have proven effective in balancing the need for innovation with strict safety standards, a balance that is much needed in Indonesia's processed food sector. In the UK, for example, *sandbox* implementation allows health technology companies to test innovations with

the support of regulators, who act as watchdogs and strategic partners (Eggers & Turley, 2018). A closer look at the theory described in Figure 1 shows that collaboration between the government and the private sector through the *regulatory sandbox* can create a more inclusive innovation ecosystem, thus encouraging the birth of safer and more innovative products at a higher speed. Implementation in other countries provides an essential perspective for Indonesia, which still focuses on rigid conventional control and requires reforms to support innovation acceleration without compromising safety.

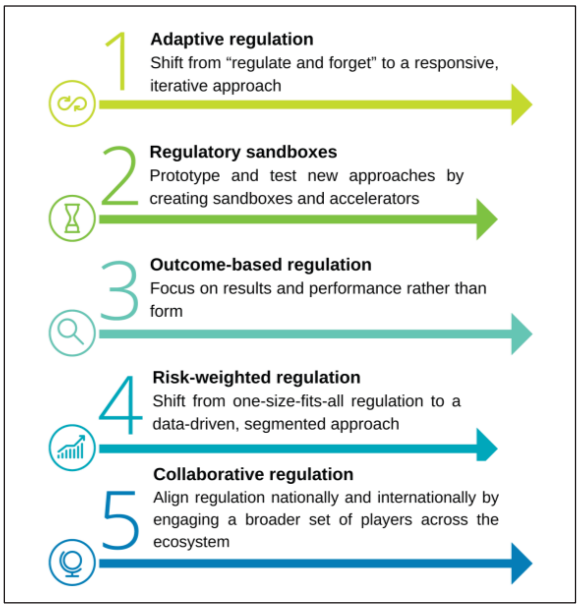

Figure 1: Regulatory Principles in Support of Innovation Ecosystems (Eggers & Turley, 2018)

The *regulatory sandbox* approach is predicted to be a solution for Indonesia to increase flexibility in food control without sacrificing safety aspects. With the implementation of the *sandbox*, high-risk processed food businesses can distribute products in a controlled environment without having to follow all applicable standards and regulations but still under the supervision of BPOM. This approach also allows for the collection of empirical data directly in the market, improving BPOM's understanding of the effectiveness and risks of innovative products. (Sherkow, 2022; Eichler *et al*., 2012). By strengthening *post-market* surveillance that emphasizes *real-time* risk detection, *the regulatory sandbox* can be an effective bridge between the needs of innovation and food safety, making Indonesia more responsive to developments in food technology.

3.2. History: The Pharmaceutical Sector that Inspired the *Regulatory Sandbox*

Regulatory sandboxes were first introduced in 2015 in the UK in response to the need for innovation in the financial sector. Originally developed based on the concept of clinical trials in pharmaceuticals, the *sandbox* provides a safe space for testing new technologies or products under the supervision of regulators but with more flexible regulatory constraints. Referring to the development of the *Regulatory Sandbox* in the financial sector, it is known that this approach accelerates innovation without compromising system stability. (Gromova & Ivanc, 2020). In this context, the health sector has also demonstrated the potential of the *regulatory sandbox* through the implementation of *Emergency Use Authorization* (EUA) by the US FDA during the COVID-19 pandemic. In the process, the EUA mechanism allows health products still in development to be used in emergencies as long as preliminary safety data are available. The EUA model inspires the implementation of a regulatory sandbox by BPOM in the processed food sector, especially for

products with high risks but the potential to provide significant benefits to the community. (Sherkow, 2022) as illustrated in Figure 2.

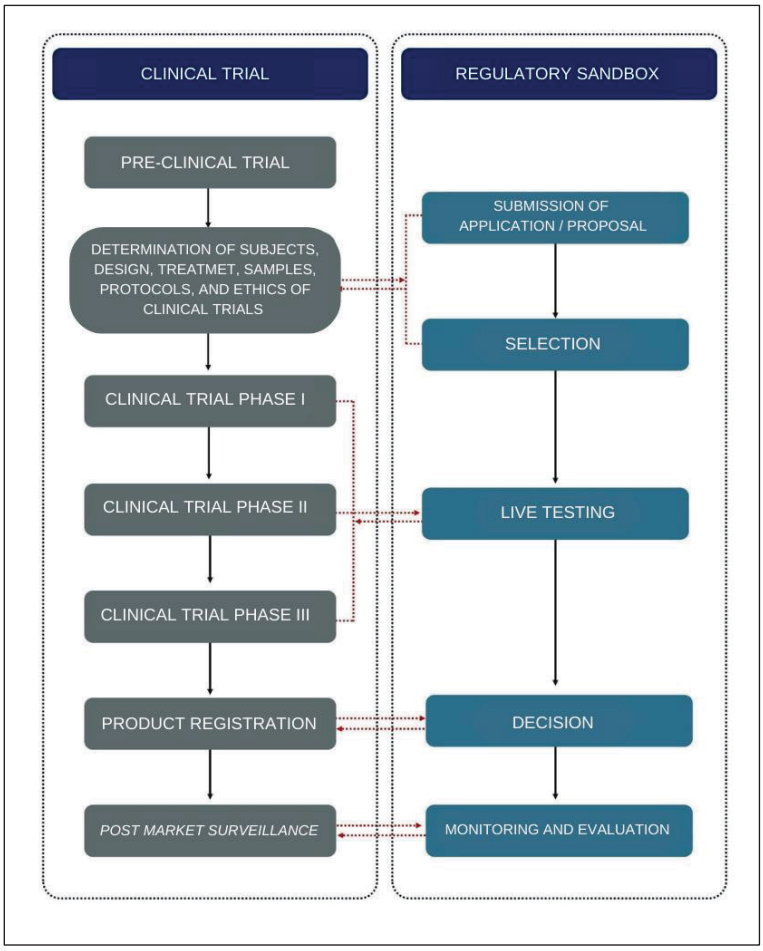

Figure 2: Comparison of Clinical Trial and *Regulatory Sandbox* Stages

In the Indonesian case study, the *regulatory sandbox* has great potential to support innovation in controlling processed food products without going through the time-consuming *pre-market approval* process. This is important as the existing *pre-market approval* system is often a significant obstacle in accelerating market access for innovative products containing certain active ingredients, such as functional drinks or probiotic products, which must be thoroughly tested before circulation. (Holle, 2018). Regarding potential implementation scenarios, the regulatory sandbox can be applied to processed food products with new health claims or innovative formulas. For example, manufacturers could conduct product testing with a limited scope of circulation to collect empirical data that would help BPOM conduct an evidence-based evaluation of the product's safety. This data collection includes direct monitoring of consumer response to the product in the market, providing more realistic and direct data on the impact of the product in a real-world setting. (Ranchordas, 2021).

Implementing a *sandbox* for these products will allow BPOM to monitor and collect data directly from consumers while still providing greater flexibility to manufacturers. The data collected may include consumer health responses, allowing for more accurate and evidence-based evaluations. However, significant challenges may arise regarding implementing adaptive regulations, especially given the uneven digital infrastructure in various regions and local supervision limitations. Looking at China, for example, the *sandbox* for the supervision of technology-based products has shown that flexible policy adaptation is necessary to deal with the complexity of local regulation. (Feng *et al*.,

2021). In addition, the *regulatory sandbox* also needs to be balanced with a strict consumer data protection framework to ensure that data collected during the testing phase is not misused or jeopardizes consumer privacy.

Overall, the *regulatory sandbox* bridges the need for innovation and consumer protection in Indonesia's processed food sector. By adopting elements from *regulatory sandbox* models in the global financial and healthcare industries, Indonesia can create an environment that encourages the development of new food products with controlled risks. The *sandbox* institution also allows BPOM to be a strategic partner in developing innovations rather than just a regulator overseeing compliance. To achieve this, the *sandbox* framework should include strong *post-market surveillance* policies and regular monitoring of product safety and effectiveness data. As implemented in the EUA by the FDA, this approach has proven to balance innovation with strict safety standards in emergencies, which provides essential inspiration for BPOM to apply the *sandbox* to the processed food sector in Indonesia. (Wallach *et al.,* 2018).

3.3. *Regulatory Sandbox* as an Approach to *Pre-Market* Control of Processed Food Products (PKGK Context)

Stunting in Indonesia remains a significant public health challenge, with the prevalence rate reaching 21.6% by 2022, according to the Indonesian Nutrition Status Survey (SSGI). This *stunting* reduction program is included in the national priorities, as stipulated in Presidential Regulation 72 of 2021, which encourages various parties at the central and regional levels to support nutritional interventions. In terms of *stunting* prevention, one of the roles of BPOM is to standardize food products, especially for the First 1000 Days of Life. The scope of standardization of food products, especially for 1000 HPK, includes products 1) Infant formula, advanced formula, and growth formula; 2) Complementary Food for Mother's Milk (MP-ASI); 3) Special Drinks for Pregnant Women and/or Breastfeeding Mothers; and 4) Processed Food for Special Medical Purposes for Infants and Children, of which the four types of products are included in PKGK products.

However, BPOM also faces challenges in regulating licensing, including distribution permits and clinical trials, often barriers to innovation. Nonetheless, interventions through PKGK have shown promising results. A study conducted by Devaera *et al.* (2018) using the *Randomized Control Trial* (RCT) method on children under five with inadequate nutrition in three villages in Central Jakarta (Manggarai, Kenari, and Paseban) showed that a specially formulated nutritional supplementation liquid milk product (Nutrinidrink multi FibeR) with calorie levels of 1.5 kcal/mL and 1.0 kcal/mL, was effective in increasing toddlers' weight over the 28-day study period. These results emphasize the importance of targeted nutritional interventions in Indonesia's stunting prevention efforts.

Regulatory sandboxes can potentially accelerate market access for PKGK products while ensuring safety through strict supervision. For example, a PMT biscuit product produced by PT Satoria Agro Industri obtained a BPOM distribution permit in 2018 and extended it in 2022, presented in Figure 3. This product has become part of the Supplementary Feeding Program (PMT) to support the nutrition of children under five. (Amarawardani *et al*., 2023).. However, the conventional licensing process is costly and often takes a long time. The licensing process of assessing the safety, quality, nutrition, and labelling of PKGK is carried out comprehensively on all documents filled in and uploaded to the system before a distribution permit is issued no later than 30 (thirty) days after the registration fee has been received and validated. However, suppose there are new nutrients, microorganisms, or types of PKGK that have not been regulated. In that case, they must be assessed first through the Directorate of Processed Food Standardization with a *timeline* of 85 (eighty-five) working days since the file is declared complete. (Directorate of Processed Food Registration of BPOM RI, 2024).. In the case of product registration for Food Category 13.0 (Processed Food for Special Nutritional Purposes), the non-tax state revenue (PNBP) fee rate is

regulated in Government Regulation (PP) No. 32/2017 on Types and Tariffs of Non-Tax State Revenues Applicable to the Food and Drug Supervisory Agency, which is IDR 3,000,000. The PNBP fee is Rp. 3,000,000 for new registration, Rp. 1,500,000 for data changes, and Rp. 2,500,000 for re-registration.

Figure 3: PMT biscuit products from PT Satoria Agro Industri that received a BPOM distribution license in 2018 and extended in 2022.

From a regulator's perspective, the *regulatory sandbox* offers an adaptive approach to respond to innovation needs without compromising safety standards. This approach allows BPOM to implement market trials with more flexible yet controlled requirements. In a *sandbox* environment, risks associated with PKGK products can be mitigated through close supervision and product circulation restrictions, allowing for rapid response to potential hazards. Meanwhile, from an industry perspective, the *regulatory sandbox* provides greater flexibility in the innovation process. Manufacturers can test new functional food or probiotic products without waiting for the entire complex licensing process, which often slows down product launches. The *sandbox* model allows companies to reduce costs and time through empirical data obtained during the limited testing phase, which can then strengthen the evidence base for a more thorough product evaluation. (Alaassar *et al*., 2020).

From a consumer perspective, the *regulatory sandbox* allows faster access to innovative food products. However, challenges related to risk perception and consumer protection need to be addressed. Studies show that while consumers favour access to food innovations, they still expect high safety assurance. (Zhu *et al*., 2021). Therefore, BPOM must ensure transparency in risk communication and consumer engagement through clear labelling and public communication strategies. A robust *post-market* surveillance system is essential to monitor risks and maintain public trust, especially for products with high health claims.

Overall, the *regulatory sandbox* offers a more dynamic and responsive framework to accommodate innovation while maintaining food safety in Indonesia. BPOM can serve as a strategic partner that supervises and supports product development by providing direct supervisory access during the trial period. This model allows BPOM to play an active role in ensuring that PKGK products are safe for consumption while collecting relevant empirical data to support a more holistic evaluation process. Through the *regulatory sandbox*, BPOM has the potential to create a more inclusive and adaptive innovation ecosystem, allowing Indonesia to respond more effectively to public health challenges.

3.4. *Best Practice Regulatory Sandbox* in the Healthcare Sector

Regulatory sandboxes were initially implemented in the financial sector in response to fast-growing innovations requiring close control to maintain market stability. While more and more sectors are adopting this concept, *sandbox* implementation in the healthcare sector is still limited in

several countries. The complexity of the health sector, which is directly related to public safety and strict safety standards, makes its adoption a challenge. Only a few countries, such as Singapore, Japan, Canada, the United States, the United Kingdom, and Germany, have successfully implemented *regulatory sandboxes* in the health context with various approaches that enable a balance between innovation and public protection (Leckenby *et al*., 2021; Fuad *et al.,* 2023).

In Singapore, the *Licensing Experimentation and Adaptation Programme* (LEAP), launched in 2018, provides a platform for developing *telemedicine* and *mobile health* services in a controlled environment. The program demonstrates that *sandboxes* can accelerate digital health technology innovation while meeting safety standards. In Japan, the *regulatory sandbox* supports the development of artificial intelligence (AI)-based technologies and *the Internet of Things* (IoT) in healthcare. This initiative allows Japan to accelerate the adoption of the latest medical technologies, ensuring innovations are accessible to the public without neglecting safety aspects. (Tsai *et al*., 2019).

Canada uses *sandboxes* to test advanced therapeutic products, such as medical devices and innovative drugs. This approach allows companies to conduct limited testing before full launch, allowing for faster evaluation on a limited scale while maintaining public safety. (Leckenby *et al*., 2021).. In the United States, *the FDA's Emergency Use Authorization (EUA)* is a *sandbox-like* approach that accelerates public access to essential medical products during emergencies such as the COVID-19 pandemic. EUAs allow the use of innovative medical technologies under scrutiny, mirroring how *sandboxes* can accelerate access in times of need while maintaining safety standards. (Sherkow, 2022). Germany has also used *sandboxes* in the healthcare sector to support the development of AI-based digital medical devices. Through this approach, Germany creates a safe environment for health technology innovations that require further testing, facilitating rapid adaptation to disruptive technologies that are difficult to integrate into conventional regulatory systems. (Leckenby *et al*., 2021).

In Indonesia, the *regulatory sandbox* is beginning to be explored through the *e-malaria* program, which uses digital technology to support malaria surveillance. The program involves collaboration between the Ministry of Health and other stakeholders, providing a foundation for Indonesia to overcome regulatory barriers to disruptive health technologies. Despite challenges such as limited digital infrastructure and the need for stronger data protection, this step demonstrates Indonesia's commitment to adopting a *regulatory sandbox* approach to support health innovations with adequate oversight. (Fuad *et al*., 2023).

Regulatory sandboxes in the healthcare sector offer an interesting alternative approach and have great potential to accelerate innovation, especially for rapidly evolving health technologies. However, like all regulatory approaches, the *sandbox* has advantages and disadvantages that must be comprehensively considered from a technical, economic, social, and cultural perspective. The main advantages of the *regulatory sandbox* are known to lie in its flexibility and speed of adoption. Technically, the *sandbox* allows companies and healthcare institutions to test new technologies in a controlled environment, where oversight can be applied immediately without waiting for the time-consuming full regulatory approval. This supports faster iterative testing, allowing technology developers to make immediate adjustments based on findings in the field. This flexibility is significant in the healthcare sector, where medical technology constantly evolves with innovations such as artificial intelligence, IoT devices, and *telemedicine*. In an economic context, *sandboxes* allow companies to reduce regulatory costs, often a significant barrier for small- and medium-sized enterprises entering the market. With a *sandbox* setup, the cost and time for product testing can be reduced, providing substantial financial benefits to the company and encouraging innovation in the broader market.

However, despite its considerable economic potential, the *regulatory sandbox* has technical drawbacks that cannot be ignored. As the *sandbox* operates in a looser regulatory setting, there is a risk that the tested products may not fully meet the safety and effectiveness standards required in formal trials. This risk can directly impact consumer safety, which could result in decreased public

confidence in the health technologies resulting from the *sandbox* framework. The regulatory sandbox also poses potential challenges from a social and cultural perspective. People in different countries, especially countries with more conservative cultures regarding public health and safety, may feel uncomfortable with the idea of testing health products under looser regulatory conditions. Cultural sensitivity to safety and conservatism in the application of medical technology can be barriers to widespread acceptance of innovations developed through the *sandbox*, especially in countries with strict health systems.

Overall, *regulatory sandboxes* offer significant advantages in speed of adoption and economic efficiency, particularly valuable in fast-evolving health technologies. However, sandbox implementation must be balanced with adequate oversight mechanisms and precise transparency arrangements toward consumers to maximise these advantages. Ultimately, while the technical and economic potential of the *sandbox* is likely to be favourable, its success in the healthcare sector will depend on the balance between flexibility and accountability. If implemented carefully and tailored to each country's social and cultural context, *sandboxes* can effectively encourage healthcare innovation while protecting public safety.

3.5. Proposed Implementation of *Regulatory Sandbox* on the Registration of Food Products for Special Nutritional Purposes

In order to achieve a significant reduction in *stunting*, WHO, through World Health Assembly Resolution 65.6, set a reduction target of 40% by 2015, with baseline data in 2012. Despite efforts, the 2021 edition of the UNICEF/WHO/World *Bank Group* report states that Indonesia is still *off-track* in achieving this target. With *stunting* remaining high at 24.4% in 2021, the Indonesian government made reducing stunting a national priority in the 2020-2024 National Medium-Term Development Plan (RPJMN), with a target of reaching 14% by 2024. This challenge emphasizes the importance of quick access to Special Nutritional Needs Food (PKGK) products, especially those that support the nutritional needs of under-fives and pregnant women.

Implementing the *regulatory sandbox* offers a strategic opportunity to accelerate the market access to PKGK products. With a risk-based approach, the *sandbox* can support innovative programs such as Supplementary Feeding for Undernourished Toddlers and Pregnant Women with Chronic Energy, even though these products are not explicitly regulated in BPOM regulations. Based on a review of various international practices, such as the implementation of *sandboxes* for *telemedicine* in Singapore, therapeutic devices in Canada, and testing of emergent health products in the US, *regulatory sandboxes* have proven to be an effective tool to overcome the limitations of conventional regulation and accelerate product access to the market. (Leckenby *et al*., 2021; Sherkow, 2022).

Figure 4 shows the elements of the *regulatory sandbox* process that BPOM can adopt to ensure safe and effective sandbox implementation in PKGK. These elements include:

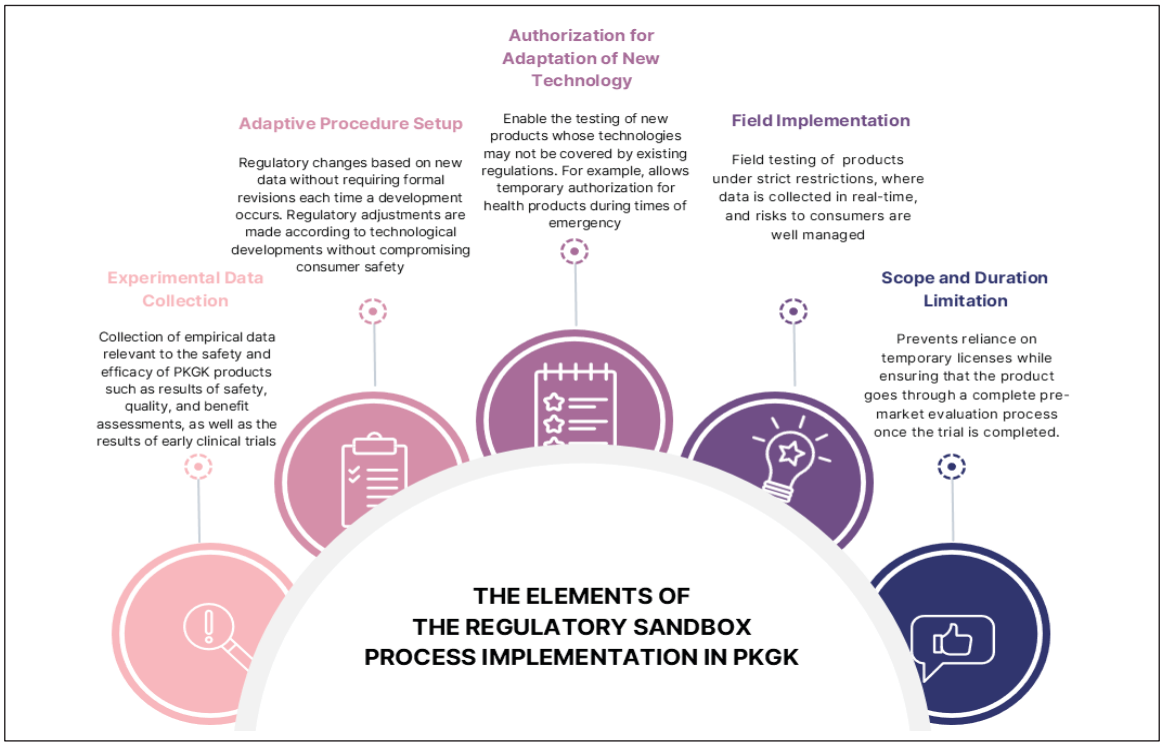

Figure 4: *Regulatory Sandbox* Process Elements for PKGK Product Regulation

a. Experimental Data Collection

The *regulatory sandbox* provides a controlled environment for collecting empirical data relevant to the safety and efficacy of PKGK products. This approach is used in the UK and Canada to collect comprehensive *post-market* data. In the context of PKGK in Indonesia, the data collected includes the results of safety, quality, and benefit assessments and early clinical trials. This process ensures that regulators have a sufficient evidence base to assess a product's appropriateness before allowing it to be widely circulated. (Gromova & Ivanc, 2020).

b. Adaptive Procedure Setup

Setting up adaptive procedures is essential to ensure the *sandbox* remains responsive to technological innovation and industry input. This approach allows for regulatory changes based on new data without requiring formal revisions each time a development occurs. In Japan, adaptive procedures in the *regulatory sandbox* have helped facilitate the application of AI and IoT technologies in the healthcare sector, where regulatory adjustments are made according to technological developments without compromising consumer safety. (Tsai *et al*., 2019).

c. Authorization for Adaptation of New Technology

Adaptive authorization is essential to enable testing new products whose technologies may not be covered by existing regulations. In the US, for example, the *Emergency Use Authorization* (EUA) approach allows temporary authorization for health products during times of emergency. EUA inspired BPOM to provide flexible authorization for CCPs by leveraging consensus technical standards adapted to technological developments. This enables accelerated access to new products without compromising basic safety standards. (Sherkow, 2022).

d. Field Implementation

One of the advantages of a *regulatory sandbox* is the ability to test products under controlled market conditions. These tests are conducted in a supervised environment, essential for maintaining product safety. In the UK, for example, sandboxes allow field testing of new health

products under strict restrictions, where data is collected in *real time,* and risks to consumers are well managed. This approach can be adapted to the PMT program in Indonesia as part of the effort to prevent *stunting* through innovative PKGK products. (Ahern, 2019).

e. Scope and Duration Limitation

Limiting the scope and duration of *sandbox* implementation on the PKGK aims to ensure that only products directly relevant to the target population are tested in the *sandbox*. For MGT, the duration of testing can be limited to a specific period in the *stunting* prevention program cycle. At the same time, the scope is restricted to vulnerable groups such as high-risk children and pregnant women. This restriction prevents reliance on temporary licenses while ensuring the product goes through a complete *pre-market* evaluation process once the trial is completed. (Heymann *et al.,* 2021).

f. Economic Relevance and Impact of *Regulatory Sandbox* Implementation

Experience from other countries shows that the *regulatory sandbox* serves as a tool to accelerate innovation and provides significant economic impact. According to a study by Leckenby *et al.* (2021), *regulatory sandboxes* in the healthcare sector can lower administrative costs usually imposed on companies and reduce the waiting time for products to enter the market. Another study by Maci & Marešová (2022) also shows that effective *sandbox* implementation can improve the efficiency of product time to market, which is relevant for maintaining the competitiveness of the PKGK industry in local and global markets. This indicates the enormous economic potential of *sandboxes* for the food and health sector if implemented with a pro-innovation approach in Indonesia. (Frazier & Walter, 2020). Adapting this model in the context of PKGK not only helps lower costs for businesses but also improves BPOM's responsiveness to the evolving nutritional needs of the public.

By adapting the elements of a structured *regulatory sandbox*, BPOM has the potential to establish a more flexible and adaptive supervisory environment for PKGK. This process will allow BPOM to obtain empirical data essential in evaluating innovative products without compromising safety. If effectively implemented, the regulatory sandbox will support the faster launch of PKGK products, enable Indonesia to better respond to the stunting challenge, and create new economic opportunities for the food and health sectors.

3.6. Impact of *Regulatory Sandbox* Implementation on Food and Drug Crime Control and Prevention

a. Public Trust

Applying a *regulatory sandbox* in the Food and Drug control context, especially in the *pre-market approval* process, can impact public trust, depending on how it is implemented. Public trust has the potential to increase, especially towards innovation, because it provides space to develop innovative product solutions without having to be trapped in bureaucracy and regulations that tend to be rigid. Conversely, implementing a *regulatory sandbox* that is considered flexible and loose will erode public confidence in the safety of the food products produced.

Sherkow (2022)warns regulators to act cautiously in implementing regulatory sandboxes. However, if the good intentions are to cut bureaucracy and accelerate innovation, the public may misinterpret them. To avoid eroding public trust in implementing the *regulatory sandbox*, transparency is needed, which means being open and explicit that implementing the *regulatory sandbox* is inherently risky and experimental.

b. Political Tools

The *Regulatory Sandbox* is a form of recognition that there are other mechanisms to obtain *pre-market approval* from regulators. The existence of this mechanism can be an opportunity to be utilized as a political tool and purpose. In the United States, at least for products

used in handling COVID-19 (*Emergency Use Authorization* / EUA), it is used as a subject for political purposes by the Government, including hydroxychloroquine products, convalescent plasma, *neutralizing antibody therapy*, and vaccines. Even BPOM, as a regulator, has also experienced political pressure, especially for the availability of COVID-19 vaccines in Indonesia, such as the archipelago vaccine and similar new technologies.

To protect regulators from such political interference, the first thing that is needed is the formalization of *regulatory sandbox* procedures, especially to meet the needs of the public regarding processed food products for special needs such as *stunting.* In addition, transparency of data related to the *regulatory sandbox* is needed as a bulwark against political interference. Transparency can provide opportunities for the public and/or academics to take part in monitoring policies related to product innovation; they can undoubtedly assess whether the policy is *scientifically based* or whether there is political pressure/interference. (Sherkow, 2022).

c. Relaxation of Standards/Regulations

Implementing the *regulatory sandbox* is a form of relaxing the standards or regulations. Still, some things that must be emphasized are that the approval given is temporary and can be cancelled, and in parallel, the pre-market approval process continues to run with the same methods. Despite the relaxation of standards, innovators must prioritize food safety aspects.

d. Accelerating Innovation

The application of a *regulatory sandbox,* although limited and temporary, provides convenience and/or simplification to experimentation. In addition, it can give tremendous acceleration to innovation, increase effectiveness and efficiency, and even provide significant cost reductions before products enter the market.

e. Optimizing Food and Drug Crime Prevention

The relaxation of distribution permits due to implementing the *regulatory sandbox* can motivate the public and/or business actors to register their products legally. This is one of the positive effects of the *regulatory sandbox* approach in promoting compliance and product registration with the competent authority. However, it is essential to note that the relaxation of distribution permits must be balanced with strict supervision by regulators. Tested products must still meet food safety standards to protect consumers. With the right approach, the relaxation of distribution permits in the *regulatory sandbox* can be an essential motivator for businesses to operate within a legitimate legal framework.

4. Conclusions and Recommendations

Regulatory sandboxes can be a practical strategic framework for accelerating innovation in health and food products, particularly Special Nutritional Needs Food (PKGK), which is critical in supporting Indonesia's *stunting* reduction targets. Through a flexible and risk-based approach, the *sandbox* enables PKGK product trials in a controlled environment that accelerates innovation without compromising safety. This makes the *regulatory sandbox* an approach that can support BPOM in accelerating *the pre-market approval* process, reducing administrative barriers, and opening up more excellent space for industry innovation while maintaining safety and consumer health standards.

However, the success of *regulatory sandbox* implementation will depend on BPOM's readiness to adopt adaptive procedures, an integrative supervisory system, and collaboration with other sectors. *A regulatory sandbox implemented with the support of regular and empirical evidence-based evaluations can strengthen BPOM's position as a facilitator of innovation with integrity and* a consistent supervisor in protecting public health.

4.1 Implementation Recommendation

To ensure that the *regulatory sandbox* can function optimally and is aligned with national health policies and international standards, the following are recommendations that BPOM can implement:

a. Development of Integrated National Policy

BPOM can align the *regulatory sandbox* policy with national health programs related to *stunting* and consider international standards from WHO and FDA as a reference. This is important so that the *regulatory sandbox* meets local innovation needs and global standards in food and health product control.

b. Periodic and Dynamic Evaluation of *Regulatory Sandbox* Effectiveness
BPOM needs to implement periodic evaluations to assess the effectiveness of the *regulatory sandbox*, covering aspects of product safety, innovation, and consumer satisfaction. These evaluations allow BPOM to dynamically adjust and improve the sandbox framework based on market *feedback* and empirical data collected from field trials.

c. Provision of Digital Infrastructure and Resources for *Real-Time* Data Collection
BPOM should prioritize digital infrastructure for real-time data reporting and monitoring. This system will enable BPOM to monitor trials more effectively, accelerate the evidence-based decision-making process, and ensure safety during PKGK product trials.

d. Collaboration with Academia and Industry for Procedural Adjustment
BPOM needs to build strategic collaborations with academia and industry to improve the quality of experimental data and research in the *sandbox*. This collaboration can also accelerate the adjustment of risk-based licensing procedures, including applying *risk-benefit analysis* that prioritizes product safety and benefits.

e. Strengthening Public Education and Transparency
Regulatory sandboxing requires greater public involvement to maintain consumer confidence in PKGK products. BPOM needs to ensure that the public understands the trial process and the benefits of PKGK products through optimal education and transparency so that consumers can understand the potential benefits and risks of the products being tested.

4.2 Challenges and Mitigation Strategies

The implementation of the *regulatory sandbox* in Indonesia will face several challenges that require special attention, namely:

a. Limited Supervisory Resources and Infrastructure
Limited human resources and uneven supervisory infrastructure may hinder the implementation of the *sandbox*. BPOM is advised to increase investment in the training of supervisory personnel and develop a digital surveillance system that allows *real-time* remote monitoring.

b. High Consumer Safety Risk
As the *sandbox* accelerates innovative products' access to the market, potential risks to consumer safety need to be mitigated through restrictions on the use, scope, and duration of product trials. In addition, BPOM should conduct close monitoring during and after trials to ensure that risks are identified and managed effectively.

c. Complexity in Regulatory Adjustments and Updates
Regulatory change is a complex and time-consuming process. BPOM can simplify this process by implementing an adaptive policy that allows changes to *sandbox* procedures without formal regulatory revisions by developing flexible technical standards that can be adjusted dynamically based on the results of periodic evaluations.

By implementing a *regulatory sandbox* that is structured, adaptive, and integrated with national frameworks and international standards, BPOM can accelerate the development of innovative PKGK products, accelerate the achievement of *stunting* reduction targets, and improve industry competitiveness. The *regulatory sandbox* not only accelerates the innovation process in the food and health sector but also enhances the role of BPOM as an adaptive facilitator and reliable supervisor. Implementation accompanied by flexible policies, digital infrastructure support, and cross-sector

collaboration will make BPOM more responsive and able to accommodate innovation while maintaining public health.

References

Ahern, D. (2019). "Regulators Nurturing Fintech Innovation: Global Evolution of the Regulatory Sandbox as Opportunity-Based Regulation." *Indian Journal of Law and Technology*, *15*(2). https://doi.org/10.55496/snpi2967.

Alaassar, A., Mention, A. L., & Aas, T. H. (2020). Exploring how social interactions influence regulators and innovators: The case of regulatory sandboxes. *Technological Forecasting and Social Change*, *160*. https://doi.org/10.1016/j.techfore.2020.120257.

Allen, H. J., Awrey, D., Ford, C., Gevurtz, F., Oei, S.-Y., & Pollman, E. (2019). *Regulatory Sandboxes* (Vol. 87, Issue 3).

Amarawardani, N., Qolbi, L., Ramadhan, H. R., & Saputra, I. K. (2023). Analisis Kadar Lemak Menggunakan Uji Fat Gerber pada Biskuit Varian Makanan Tambahan (MT) Ibu Hamil di PT Satoria Agro Industri. *Proceedings of Life and Applied Sciences*.

Brown, E., & Piroska, D. (2022). Governing Fintech and Fintech as Governance: The Regulatory Sandbox, Riskwashing, and Disruptive Social Classification. *New Political Economy*, *27*(1), 19–32.

Buocz, T., Pfotenhauer, S., & Eisenberger, I. (2023). Regulatory sandboxes in the AI Act: Reconciling innovation and safety? *Law, Innovation and Technology*, *15*(2), 357–389. https://doi.org/10.1080/17579961.2023.2245678.

Burd, J. T. J. (2021). Regulatory Sandboxes for Safety Assurance of Autonomous Vehicles. In *UNIVERSITY of PENNSYLVANIA JOURNAL of LAW & PUBLIC AFFAIRS* (Vol. 7, Issue 1). https://www.

Devaera, Y., Syaharutsa, D. M., Jatmiko, H. K., & Sjarif, D. R. (2018). Comparing Compliance and Efficacy of Isocaloric Oral Nutritional Supplementation Using 1.5 kcal/mL or 1 kcal/mL Sip Feeds in Mildly to Moderately Malnourished Indonesian Children: A Randomized Controlled Trial. *Pediatric Gastroenterology, Hepatology and Nutrition*, *21*(4), 315–320. https://doi.org/10.5223/pghn.2018.21.4.315.

Direktorat Cegah Tangkal BPOM RI. (2023). *Data Kerawanan Kejahatan Obat dan Makanan Tahun 2023* .

Direktorat Registrasi Pangan Olahan BPOM RI. (2024). *Registration Officer Pangan Olahan*.

Eggers, W. D., & Turley, M. (2018). *The future of regulation Principles for regulating emerging technologies*.

Eichler, H. G., Oye, K., Baird, L. G., Abadie, E., Brown, J., L Drum, C., Ferguson, J., Garner, S., Honig, P., Hukkelhoven, M., Lim, J. C. W., Lim, R., Lumpkin, M. M., Neil, G., O'Rourke, B., Pezalla, E., Shoda, D., Seyfert-Margolis, V., Sigal, E. V., … Hirsch, G. (2012). Adaptive licensing: Taking the next step in the evolution of drug approval. *Clinical Pharmacology and Therapeutics*, *91*(3), 426–437. https://doi.org/10.1038/clpt.2011.345.

Feng, Y., Liu, L., & Li, W. (2021). Research on the Construction of Regulatory Sandbox for Safety Supervision on Intelligent Connected Products. *E3S Web of Conferences*, *235*. https://doi.org/10.1051/e3sconf/202123503043.

Frazier, G., & Walter, N. (2020). *Regulatory Sandboxes: How Federal Agencies Can Take Part in Cooperative Federalism and Catalyze Innovation and Economic Growth by Exercising Their Exemptive Authority*. https://www.mercatus.org/system/files/Baugus-Sunset-Legislation.pdf

Fuad, A., Tiara, A., Kusumasari, R. A., Rimawati, R., & Murhandarwati, E. E. H. (2023). Introducing a Regulatory Sandbox Into the Indonesian Health System Using e-Malaria as a Use Case: Participatory Action Study. *Journal of Medical Internet Research*, *25*, e47706. https://doi.org/10.2196/47706.

Gromova, E., & Ivanc, T. (2020). Regulatory sandboxes (Experimental legal regimes) for digital innovations in brics. *BRICS Law Journal*, *7*(2), 10–36. https://doi.org/10.21684/2412-2343-2020-7-2-10-36.

Heymann, F., Schmid, J., Vazquez, M., & Galus, M. (2021). Regulatory Sandboxes in The Energy Sector - Review and Learnings for The Case of Switzerland. *IET Conference Proceedings*, *2021*(6), 3229–3233. https://doi.org/10.1049/icp.2021.1730.

Holle, M. (2018). Pre-Market Approval and Its Impact on Food Innovation: The Novel Foods Example. In *Regulating and Managing Food Safety in the EU* (pp. 291–330). Springer International Publishing. https://doi.org/10.1007/978-3-319-77045-1_14.

Leckenby, E., Dawoud, D., Bouvy, J., & Jónsson, P. (2021). The Sandbox Approach and its Potential for Use in Health Technology Assessment: A Literature Review. In *Applied Health Economics and Health Policy* (Vol. 19, Issue 6, pp. 857–869). Adis. https://doi.org/10.1007/s40258-021-00665-1.

Maci, J., & Marešová, P. (2022). Critical Factors and Economic Methods for Regulatory Impact Assessment in the Medical Device Industry. *Risk Management and Healthcare Policy*, *Volume 15*, 71–91. https://doi.org/10.2147/RMHP.S346928.

Malaria Working Group. (2021). *Panduan Uji Coba Regulatory Sandbox untuk e-Malaria Edisi Kedua Malaria Working Group*.

Peraturan Pemerintah (PP) Nomor 32 Tahun 2017 Tentang Jenis Dan Tarif Atas Jenis Penerimaan Negara Bukan Pajak Yang Berlaku Pada Badan Pengawas Obat Dan Makanan (2017).

Peraturan Presiden RI. (2021). *Peraturan Presiden Nomor 72 Tahun 2021 tentang Percepatan Penurunan Stunting*.

Ranchordas, S. (2021). Experimental Regulations for AI: Sandboxes for Morals and Mores. *Morals & Machines*, *1*(1), 86–100. https://doi.org/10.5771/2747-5174-2021-1-86.

Sherkow, J. S. (2022). Regulatory Sandboxes and The Public Health. *University of Illinois Law Review*, *2022*(1), 357–410. https://perma.cc/7DMQ-JN38].

Tan, S. Y., & Taeihagh, A. (2021). Adaptive governance of autonomous vehicles: Accelerating the adoption of disruptive technologies in Singapore. *Government Information Quarterly*, *38*(2), 101546. https://doi.org/10.1016/j.giq.2020.101546.

Tsai, C., Lin, C.-F., & Liu, H.-W. (2019). The Diffusion of the Sandbox Approach to Disruptive Innovation and Its Limitations. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.3487175.

Undang-Undang Republik Indonesia. (2023). *Undang-Undang Republik Indonesia Nomor 6 Tahun 2023 tentang Penetapan Peraturan Pemerintah Pengganti Undang-Undang Nomor 2 Tahun 2022 tentang Cipta Kerja menjadi Undang-Undang*.

Wallach, J. D., Ross, J. S., & Naci, H. (2018). The US Food and Drug Administration's expedited approval programs: Evidentiary standards, regulatory trade-offs, and potential improvements. *Clinical Trials*, *15*(3), 219–229. https://doi.org/10.1177/1740774518770648.

Zhu, Y., Chu, M., Wen, X., & Wang, Y. (2021). Food Safety Risk Communication between the Food Regulator and Consumer in China: An Evolutionary Game Perspective. *Complexity*, *2021*(1). https://doi.org/10.1155/2021/9933796.