

# REGULATORY SANDBOXES AND EXPERIMENTATION CLAUSES: AN ATTEMPT TO MAKE THE (CROATIAN) LEGAL SYSTEM MORE ENTREPRENEURIAL

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## **ABSTRACT**

*There is a growing need to develop a suitable regulatory framework for innovative business models. Entrepreneurs who seek to explore new opportunities, test out new technologies and offer new services or products are constrained by the existing legal framework, which in most cases does not allow any experimentation and requires the implementation of strict rules. The EU Council Conclusions 13026/20 of 16 November 2020 on Regulatory Sandboxes and Experimentation Clauses highlight that better regulation is one of the key drivers of sustainable, inclusive growth, fosters innovation, digitalisation, and job creation, increases transparency and ensures public support for EU legislation. This paper explores the design of regulatory sandboxes and the distinctions of experimentation clauses. The starting hypothesis is that innovative business is often unrecognised by the legal system. The second hypothesis is that legal requirements and public interest in diligent entrepreneurial behaviour and customer protection should not be compromised. The research and analysis have reinforced and proved that both hypotheses are reasonable. The findings impact on the raising of the regulators', entrepreneurs', customers' and any other stakeholders' awareness of the need for proper application and creation of the law in accordance with current social needs, while preserving the fundamental social values achieved.*

**Keywords:** entrepreneurs, experimentation clauses, innovative business, opportunity, regulatory framework, regulatory sandbox, social system

## **1. INTRODUCTION**

Both law and entrepreneurship are facing a complex world. The relation between law and entrepreneurship is an emerging field of study. Law is often understood as a restriction of behavioural choices. However, the law can be understood as

support for the behaviour which would not be possible without the law.<sup>1</sup> In some instances, legal rules and practices are tailored to the entrepreneurial context, and in some other cases, rules of law find novel expression in the entrepreneurial context. As a result, studying the ties between law and entrepreneurship offers unique insights into both of them.<sup>2</sup>

Entrepreneurship is seen as the process through which new economic activities and organisations come into existence.<sup>3</sup> Global Entrepreneurship Monitor (GEM)<sup>4</sup> Global Report 2021/2022 sustains entrepreneurship as a key driver of economic development and a vital source of new jobs and income, so policymakers will increasingly consider entrepreneurship a crucial component of the repair solution for national economies in the post-pandemic era.<sup>5</sup>

Already Drucker asserted that innovation is an economic or social rather than a technical term.<sup>6</sup> The EU Regulation 2021/819 on the European Institute of Innovation and Technology (EIT)<sup>7</sup> provides for The EIT's mission to contribute to sustainable Union economic growth and competitiveness by reinforcing the innovation capacity of the Union and Member States to address significant challenges faced by society. It shall do this by promoting synergies, integration and cooperation among higher education, research, and innovation of the highest standards, including by fostering entrepreneurship, thereby strengthening the innovation ecosystems across the Union.<sup>8</sup> The EU Regulation 2021/819 sees innovation as the process, including its outcome, by which new ideas respond to societal, economic or environmental needs and demand and generate new products, processes, services, or business, organisational and social models that are successfully intro-

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<sup>1</sup> Luhmann, N., *Law as a Social System*, Oxford University Press, 2004, p. 151

<sup>2</sup> Ibrahim, D. M.; Smith, G. D., *Entrepreneurs on Horseback: Reflections on the Organization of Law*, Arizona Law Review, Vol. 50, pp. 71 – 89, 2008, p. 85, [<https://ssrn.com/abstract=1030503>], Accessed 10 March 2022

<sup>3</sup> Davidsson P., *Entrepreneurial opportunities and the entrepreneurship nexus: A re-conceptualization*, Journal of Business Venturing, Vol. 30, No. 5, 2015, pp. 674 – 695, p. 675 [<https://www.sciencedirect.com/science/article/abs/pii/S0883902615000130>], Accessed 7 January 2022

<sup>4</sup> Global Entrepreneurship Monitor (GEM) is the most comprehensive longitudinal global research of entrepreneurship since 1999. For more visit: [<https://www.gemconsortium.org/>], Accessed 15 January 2022

<sup>5</sup> *GEM 2021/2022 Global Report: Opportunity Amid Disruption*, London, 2022 (GEM 2021/2022 Global Report), p. 29, [<https://www.gemconsortium.org/report/gem-20212022-global-report-opportunity-amid-disruption>], Accessed 15 January 2022

<sup>6</sup> Drucker, P. F., *Innovation and Entrepreneurship*, Harper & Row Publishers Inc. 1985, p. 33

<sup>7</sup> Regulation (EU) 2021/819 of the European parliament and of the Council of 20 May 2021 on the European Institute of Innovation and Technology, OJ L 189, 2021, pp. 61–90 (Regulation (EU) 2021/819)

<sup>8</sup> *Ibid.*, Art. 3

duced into an existing market or that are able to create new markets and that provide value to society.

Artificial intelligence (AI)-based applications and information technologies (IT) often require a normative regulation that allows for innovation and upholds high standards of protection. In that context, the legal system is challenged to create the necessary infrastructure to facilitate the testing of innovations. Another great challenge is to keep legal framework constantly updated in a responsible and targeted manner.

This paper explores the phenomenon of regulatory sandboxes<sup>9</sup> as testing environments created by regulatory authorities for new business ventures. Legal instruments for regulatory sandboxes embodiment are experimentation clauses, as legal provisions that enable the exercise, on a case-by-case basis, of a degree of flexibility in the testing of innovative entrepreneurial models.

## 2. RESEARCH DESIGN

### 2.1. Hypotheses

Our starting hypothesis is that innovative business is often unrecognised by the legal system. Legal systems are often seen as lagging behind the evolution of society and technology,<sup>10</sup> while business is looking for quick changes. The slowness of law is due to complex legislative procedures and regulatory authorities' decision making. Furthermore, new business models face significant regulatory issues.

The second hypothesis is that there are legal requirements and public interest in diligent entrepreneurial behaviour and customer protection that should not be compromised. Even if the necessity of constant and rapid change is accepted as inherent to modern society, it is also true that the same society has achieved a high degree of civil rights and liberties and the high quality of relations that it wants to preserve.

Thus, the assertions from our hypotheses may be somehow opposed. In this paper, we are checking whether they can exist simultaneously and whether regulatory

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<sup>9</sup> The word 'sandbox' originally refers to the box filled with sand where children play. Occasionally the term has acquired new meanings. In the computer science, a sandbox stands for a closed testing environment designed for safe experimenting with web or software projects

<sup>10</sup> Ranchordas, S., *Sunset Cluses and Experimental Regulations: Blessing or Curse for Legal Certainty?*, *Statute Law Review*, Vol. 36, 2015, No. 1, pp. 28 – 45, p. 28; Parenti, R., *Regulatory Sandboxes and Innovation Hubs for FinTech*, *Study for the Committee on Economic and Monetary Affairs*, Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament, Luxembourg, 2020, p. 16

sandboxes and experimentation clauses are suitable solutions to the mentioned conflict.

## 2.2. Methodology, methods, and theoretical background

Instead of dealing with law based on legal principles alone, the methodological approach taken in this work consists of dealing with the law as a social system that exists in a complex setting (ecosystem). We are interested in understanding how the legal framework works in a given environment, examining its efficiency, advocating changes, helping with finding solutions to problems (normative analysis vs empirical analysis). Our methods focus on trying to describe, understand, and discover the meaning of the phenomenon by interpreting its characteristics and features (qualitative research). The data were found primarily in European Union (EU) legislation, regulators' webpages, agencies' webpages, and publications. We analyse relevant EU legislation and implement a multidisciplinary approach to the use of literature and research (law, economy, and social systems theories). The analysis of legal sources relies mainly on the objective teleological (target) method of interpretation of law and the appropriate additional use of normative economic analysis of law.

When we use the term “legal framework” or “legal system” in this paper, we primarily think of it as a formal and written expression (text) recognised and defined by the legal system, made by a legislator, authorised governmental institutions, even contracting parties. However, the initial motivation for empirical research did not arise from the desire to explain the content of the law itself, but rather from the desire to show that legal rules are embedded in social relations. Thus, we are not predominantly interested in the doctrinal content of the law, nor are we interested in pure economic analysis of law. We will instead pay more attention to behavioural and social dynamics of entrepreneurial and legal actions that will help us understand how entrepreneurs and the law deal with innovativeness and contingency – future uncertainty, and the limits of the legal system in this regard.

## 2.3. Social systems theory

System theories recognise the legal system as a separate social system (a sub-system of the social system).<sup>11</sup> The same applies to the economic system.<sup>12</sup> Each of the systems represents the environment (ecosystem) of the other system. We could get lost by defining the parts of an enormous social system network, e.g., culture,

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<sup>11</sup> Luhmann, N., *Law as ... op. cit.*, note 1, p. 89

<sup>12</sup> *Ibid.*, p. 391

art, political system etc. Nevertheless, for our discussion in this paper, it is worth noticing that each system has its structure, distinguishing elements, and internal functioning programs (processes).

Luhmann finds that social systems are operatively closed, meaning that each social system can regenerate only by applying its distinguishing elements regardless of its environment. That is the autopoiesis of a system – system self-creation.<sup>13</sup> However, this does not exclude the relations between different social systems provided through structural couplings, meaning that one system presupposes certain features of its environment and relies on them structurally.<sup>14</sup> Understanding how various social systems function and the possibilities of their mutual communication<sup>15</sup> lights up the complexity of contemporary ecosystem as a whole.

### 3. ENTREPRENEURIAL UNCERTAINTY AND LEGAL CERTAINTY

A new product or service environment is unclear and unknown because there is no market experience. Uncertainty arises mainly because the future is not bound or determined to emerge from the present in a stochastically predictable way.<sup>16</sup> Moreover, today's actions are themselves sources of the changes that render the future uncertain. Uncertainty is a part of real-world economies.<sup>17</sup> As part of such an environment, the legal system cannot predict nor respond to all the challenges of innovative entrepreneurship. But, let us suppose the legal framework is not structured to respond adequately to new factual circumstances. In that case, the result of a legal operation, i.e., deciding whether an endeavour is illegal, will disappoint the stakeholders.

A too strict legal framework can merely decide not to deal with the uncertainty: it will not recognise innovation or will declare illegal an idea. Case-closed! However,

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<sup>13</sup> *Ibid.*, p. 381; We rely here to the theory of social systems and organizations that reproduce themselves through their own operations irrespective of the environment, as described and named by Niklas Luhmann as *Autopoietic systems*. For more about defining the Autopoiesis of social systems please see e.g., Luhmann, N., *Organization and decision*, Cambridge University Press, 2018, pp. 29 – 36; Luhmann N., *Introduction to Systems Theory*, Polity Press Cambridge, 2013, pp. 70 – 83 or Lauc, A.: *Metodologija društvenih znanosti*, Sveučilište J. J. Strossmayera, Pravni fakultet, 2000, pp. 483 – 489

<sup>14</sup> Luhmann, N., *Law as ... op. cit.*, note 1, p. 382

<sup>15</sup> Geyer F., *Autopoiesis and Social Systems*, International Journal of General Systems, Vol. 21, No. 2, pp. 175 – 183, p. 180, [<http://dx.doi.org/10.1080/03081079208945068>], Accessed 15 January 2022

<sup>16</sup> Boudreau D.J.; Holcombe, R.G., *The Coasian and Knightian theories of the firm*, in: Sarasvathy S.D.; Dew N.; Venkataraman S. (eds.), *Shaping Entrepreneurship Research Made, as Well as Found*, Routledge, 2020, pp. 221 – 236, p. 229

<sup>17</sup> *Ibid.*, p. 230

by applying the legal coding "legal – illegal," the legal system will absorb even future uncertainty, but will not effectively resolve the issue.

We presume two main features of entrepreneurship and law. The first is that each business event has a factual ground, meaning that it is based on a real deal of the involved parties. The second is that the legal system tells an abstract story of imagined future behaviour, providing what is expected from the actors – their mutual commitments – and how each of the actors will be sanctioned if these expectations are not met – the parties' liabilities.

When a legislator creates a law, i.e., parliamentary acts, and when the authorised institutions apply it or even when they develop a second-level law, i.e., ordinances, all lawmakers expect reduced uncertainty in future events. Also, parties to a contract have the same motive to avoid or manage possible unwanted side effects. Nevertheless, legal professionals, especially attorneys supporting their clients, try to predict future events and provide solutions for possible problems by drafting statements, contracts and other documents. In that sense, legal framework is also a tool for dealing with future uncertainty.

Legal certainty can be defined as the possibility of knowing in advance what legal consequences will follow from one's conduct.<sup>18</sup> Dimensions of legal certainty are stability and predictability. Stability of law stands for an expectation that the law will not be arbitrarily changed. Predictability tells it is possible to foresee the legal consequences of one's behaviour.<sup>19</sup> However, the principle of legal certainty should not be interpreted as a request for the immutability of legal rules. Instead, a certain degree of gradual or temporary uncertainty may be necessary to ensure that laws continue to mirror society and grant sufficient certainty.<sup>20</sup>

On the other hand, it would be wrong to think that certainty is an unwanted feature of entrepreneurial endeavours. It is simply that in real life, it is accepted that things do not last forever and are not unchangeable. In entrepreneurial science, it is known as the Strong Premise of Entrepreneurship. This premise holds that even if some markets approach a state of equilibrium and stability for some time, the human condition of the enterprise, combined with the temptation of profits and advancing knowledge and technology, will in due course destroy the equi-

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<sup>18</sup> Ranchordás, S., *Sunset Clauses and Experimental Regulations: Blessing or Curse for Legal Certainty*, *Statute Law Review*, Vol. 36, No. 1, 2015, pp. 28 – 45, p. 36  
[<https://academic.oup.com/slr/article-abstract/36/1/28/1614369?redirectedFrom=fulltext>], Accessed 10 February 2022

<sup>19</sup> *Ibid.*, p. 37

<sup>20</sup> *Ibid.*, p. 38

librium.<sup>21</sup> In simple words, entrepreneurial endowers need some lasting stability while inevitably being disposed to constant change. Therefore, legal rules as formal expressions of commitments and social artefacts can never be completed and immutable but should nonetheless reflect both equilibrium and ability to change.

## 4. THE DESIGN OF REGULATORY SANDBOXES

### 4.1. Innovation Principle

The European Commission has recognised the importance of a more innovation-oriented European Union (EU) acquis, exploring how EU rules can support innovation. It is the result of increasing awareness among policymakers of the importance of well-designed regulations to promote innovation. The Directorate-General for Research and Innovation of the European Commission has given an articulate and consistent role to the Innovation Principle to ensure that the impact on innovation is fully assessed whenever a policy is developed.<sup>22</sup>

The Innovation Principle encompasses three essential components.<sup>23</sup> The first is The Research and Innovation Tool, which provides activities to assess the impacts of EU legislation on all forms of innovation, including consultations with stakeholders, evaluating the potential effects of EU initiatives on research and innovation, considering the impact of legislative design on research and innovation, and improving the design of EU initiatives to make them more innovation-friendly. The second component are the Innovation Deals which aim to remove the perceived barriers to innovation arising from the implementation of existing EU legislation by clarifying current rules and using the existing flexibility in the EU legislative framework. The third component of the Innovation Principle is Foresight and Horizon Scanning, a technique for detecting early signs of potentially significant developments through a systematic examination of potential threats and opportunities, with an emphasis on new technology and its effects on the issues at hand.

All the aforementioned components of the Innovation Principle are non-legislative tools. They represent an approach achieved through cooperation among the

<sup>21</sup> Venkataraman S., *The Distinctive Domain of Entrepreneurship Research*, Advances in Entrepreneurship, Firm Emergence and Growth, Vol. 3, 1997, pp. 119-138, p. 121, [[https://www.researchgate.net/publication/228316384\\_The\\_Distinctive\\_Domain\\_of\\_Entrepreneurship\\_Research](https://www.researchgate.net/publication/228316384_The_Distinctive_Domain_of_Entrepreneurship_Research)], Accessed 12 February 2022

<sup>22</sup> Simonelli, F.; Renda, A., *Study supporting the interim evaluation of the innovation principle: final report*, European Commission, Directorate-General for Research and Innovation, Publications Office, 2019, p. 8, [<https://data.europa.eu/doi/10.2777/620609>], Accessed 10 March 2022

<sup>23</sup> *Ibid.*, p. 9

European Commission, the relevant Member State authorities and businesses.<sup>24</sup> In any case, understanding the notion of innovation and its significance is vital for understanding the concept of regulatory sandboxes, which is shown in our further discussion.

## 4.2. Regulatory Sandboxes

There is still no broadly accepted definition of a regulatory sandbox. That is not surprising when bearing in mind that it goes for a relatively new phenomenon.<sup>25</sup> There are even different terms that are often used as synonyms: regulatory sandboxes, living labs, innovation spaces, regulatory testbeds, real-life experiments and similar.<sup>26</sup> The social sciences frequently look at regulatory sandboxes as experimental spaces at the interface of innovation, science and society. Solutions are primarily sought for societal challenges and transformation processes.<sup>27</sup>

Regulatory experiments can be defined as means to deliberately deviate from the current regulatory framework to try out new or different rules in a real-world setting.<sup>28</sup> Entrepreneurs experiment with new technologies to create new products and services, and regulatory authorities should do the same with legal rules and regulations. Regulatory sandboxes are frameworks for testing innovation and allowing to try new technologies, business models, products, and services in real life. They are intentionally established instruments of economic and innovation policy.

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<sup>24</sup> The European Commission's regulatory fitness and performance programme (REFIT) [[https://ec.europa.eu/info/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-less-costly-and-future-proof\\_en#documents](https://ec.europa.eu/info/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-less-costly-and-future-proof_en#documents)], Accessed 5 March 2022

<sup>25</sup> The concept of regulatory sandbox emerged firstly in the financial sector of developed countries shortly after the Global Financial Crisis of 2007. Please see: Wechsler, M.; Perlman, L.; Gurung, N., *The State of Regulatory Sandboxes in Developing Countries*, SSRN 2018, p. 8, [<http://dx.doi.org/10.2139/ssrn.3285938>]; Pop, F.; Adomavicius L., *Sandboxes for Responsible Artificial Intelligence*, EIPA Briefing 2021/6, p. 1, [[https://www.eipa.eu/wp-content/uploads/2022/03/EIPA-Briefing\\_Sandboxes-for-Responsible-Artificial-Intelligence.pdf](https://www.eipa.eu/wp-content/uploads/2022/03/EIPA-Briefing_Sandboxes-for-Responsible-Artificial-Intelligence.pdf)]; Leimüller G.; Wasserbacher, S., *Regulatory Sandboxes - Analytical paper for BusinessEurope*, Winnovation consulting gmbh Vienna, 2020, p. 4, [[https://www.business-europe.eu/sites/buseur/files/media/other\\_docs/regulatory\\_sandboxes\\_-\\_winnovation\\_analytical\\_paper\\_may\\_2020.pdf](https://www.business-europe.eu/sites/buseur/files/media/other_docs/regulatory_sandboxes_-_winnovation_analytical_paper_may_2020.pdf)], all Accessed 23 January 2022

<sup>26</sup> *Making space for innovation - The handbook for regulatory sandboxes*, Federal Ministry for Economic Affairs and Energy of Germany (BMWi) 2019, (Making space for innovation) p. 9, , [<https://www.bmwk.de/Redaktion/EN/Publikationen/Digitale-Welt/handbook-regulatory-sandboxes.html>] Accessed 24 January 2022

<sup>27</sup> *Ibid.*

<sup>28</sup> Bauknecht D. *et al.*, *How to design and evaluate a Regulatory Experiment? A Guide for Public Administrations*, Öko-Institut e.V., Freiburg, 2021, p. 4, [[https://www.oeko.de/fileadmin/oekodoc/Regulatory-Experiments-Guide\\_for\\_Public-Administrations.pdf](https://www.oeko.de/fileadmin/oekodoc/Regulatory-Experiments-Guide_for_Public-Administrations.pdf)], Accessed 13 April 2022



A regulatory sandbox can come to life only if interactions are established between various stakeholders, from governments and public administration to business, science, and other fields, e.g., customer protection associations. Regulatory authorities grant permissions for running a novel business model. The stakeholders enter into a cooperation agreement establishing the parameters of the cooperation and ensuring that the support they need is in place. In addition, principles guiding action and rules and hierarchies for decision-making can be clarified and stipulated amongst the partners with different instruments such as statements, certifications, or other forms.<sup>29</sup>

We found in Germany an example of a structured approach to the construction of a regulatory sandbox frame in the EU. The German Federal Ministry for Economic Affairs and Energy adopted the Regulatory Sandboxes Strategy in December 2018, intending to bring together public policymaking experts and authorities, entrepreneurs, associations, research establishments, civil society, and other participants on regulatory sandboxes. The Strategy was intended to improve the degree of expertise relating to regulatory sandboxes, investigate the variety of ways in which regulatory sandboxes were used, and provide recommendations and practical examples. Very soon, in spring 2019, the Ministry set up the Regulatory Sandboxes Coordinating Office to implement the Strategy and follow its progress. A few months after the establishment, the Coordinating Office counted around 400 members.<sup>30</sup>

### 4.3. EU Council's Regulatory Sandbox Initiative

In November 2020, during German Presidency, the EU Council issued its premier Conclusions on Regulatory Sandboxes and Experimentation Clauses (EU Council Conclusions).<sup>31</sup> It was a clear and straight message to all Member States' delegations. The EU Council recognised regulatory sandboxes as instruments to create an innovation-friendly and future-proof legal framework.<sup>32</sup> The EU Council Conclusions highlight that better regulation is one of the crucial drivers of

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<sup>29</sup> *Making space for innovation, op. cit.*, note 26, p. 29

<sup>30</sup> *Ibid.*, pp. 2-3 and 14-17

<sup>31</sup> EU Council Conclusions 13026/20 of 16 November 2020 on Regulatory Sandboxes and Experimentation Clauses (EU Council Conclusions), [<https://www.consilium.europa.eu/en/press/press-releases/2020/11/16/regulatory-sandboxes-and-experimentation-clauses-as-tools-for-better-regulation-council-adopts-conclusions/>], Accessed 5 March 2022

<sup>32</sup> *New flexibility for innovation – Guide for formulating experimentation clauses*, Federal Ministry for Economic Affairs and Energy of German (BMWi) 2020, (New flexibility for innovation), p. 7, [[https://www.bmwk.de/Redaktion/EN/Publikationen/Digitale-Welt/guide-new-flexibility-for-innovation-en-web-bf.pdf?\\_\\_blob=publicationFile&v=2](https://www.bmwk.de/Redaktion/EN/Publikationen/Digitale-Welt/guide-new-flexibility-for-innovation-en-web-bf.pdf?__blob=publicationFile&v=2) ], Accessed 24 January 2022

sustainable, inclusive growth. The legal system can be used to foster competitiveness, innovation, digitalisation, and job creation. The EU Council emphasised the need to ensure that EU regulation is transparent and straightforward while always considering a high level of consumer and employees protection, health, climate and the environment.<sup>33</sup> The EU Council advocates a regulatory framework that is competitive, effective, efficient, coherent, predictable, innovation-friendly, future-proof, sustainable and resilient as possible.<sup>34</sup>

The intended regulatory framework may be developed by applying the Innovation Principle, which entails taking into account the impact on research and innovation in developing and reviewing regulation in all policy domains. The Member States are called to include the perspective of innovation-friendly and future-proof regulation as part of their discussions on existing national regulations.<sup>35</sup> The EU Council sees regulatory sandboxes as concrete frameworks that, by providing a structured context for experimentation, allow, where appropriate in a real-world environment, the testing of innovative technologies, products or services for a limited time and in a narrow part of a sector or area under regulatory supervision ensuring that appropriate safeguards are in place.<sup>36</sup> Regulatory sandboxes can offer significant opportunities to innovate and grow for all businesses, especially small and medium enterprises (SMEs), including micro-enterprises and start-ups in the industry, services, and other sectors.<sup>37</sup>

Regulatory sandboxes are currently being increasingly used, particularly in the context of digitalisation in a range of sectors. So far, they have been used in finance, health, legal services, aviation, transport and logistics, as well as energy sectors, where there is need or room for the use of new, emerging technologies – such as artificial intelligence and blockchain/distributed ledger technologies (DLT) – or for innovative use of the existing technologies. Regulatory sandboxes are seen as tools for making regulatory progress and proactive regulatory learning. They enable regulators to gain better regulatory knowledge and find the best means to regulate innovations based on real-world evidence, especially at a very early stage, which can be particularly important in the face of high uncertainty and disruptive challenges and when preparing new policies.<sup>38</sup>

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<sup>33</sup> EU Council Conclusions, *op. cit.*, note 32, Point 1

<sup>34</sup> *Ibid.*, Point 2

<sup>35</sup> *Ibid.*, Point 3

<sup>36</sup> *Ibid.*, Point 8

<sup>37</sup> *Ibid.*, Point 11

<sup>38</sup> *Ibid.*, Points 5 and 10

The EU Council places regulatory boxes in the ecosystems of Member States and at the Single Market level.<sup>39</sup> The exchange of information and good practices regarding regulatory sandboxes between the Member States is encouraged to analyse how learning from regulatory sandboxes at the national level can contribute to evidence-based policymaking at the EU level.

## 5. EXPERIMENTATION CLAUSES AS DRIVERS OF INNOVATION

### 5.1. Dealing with legal obstacles

In the narrow sense, legal consideration starts with the question whether an innovation can be allowed for launch on the market under the existing legal framework. If there are doubts about the positive answer to this question, it is necessary to determine the legal barriers that stand in the way. Designing efficient legal rules from scratch or adapting them to new factual circumstances has always been challenging. Legislators typically use *ex-ante* impact assessments, which rely on past experiences and many assumptions about future which is uncertain. The actual effects of a regulatory framework often differ from the expected ones because the legal *status quo* simply cannot anticipate all current developments and reactions of individuals or groups whom the regulation addressed. Furthermore, today's digital technologies have increased the gap between the quick emergence of business innovations and regulatory timeframes. As Elster noted, 'history is the result of human action, not human plans.'<sup>40</sup>

The solution to this problem was found by creating experimentation clauses and inserting them in the existing legal framework. The experimentation clauses are temporary exemptions from current legal rules. The exemptions or adaptations remove direct legal barriers for a part of the entire innovation that otherwise is not allowed. The exemptions refer to economic obstacles, i.e., the experiment is not economically viable under the current regulatory framework.<sup>41</sup>

Experimentation clauses serve two primary purposes:<sup>42</sup> firstly, where the existing legal framework does not permit specific innovations, they create the opportunity for entrepreneurs and public authorities to test innovations in a controlled manner in a regulatory sandbox, and, secondly, experimentation clauses allow legisla-

<sup>39</sup> *Ibid.*, Point 14

<sup>40</sup> Elster, J., *Uvod u društvene znanosti, Matice i vijci za objašnjenje složenih društvenih pojava*, Croatian edition: Jesenski i Turk, 2010, p. 195

<sup>41</sup> Bauknecht D., *et al.*, *op. cit.* p. 7

<sup>42</sup> *New flexibility for innovation, op. cit.*, note 32, p. 5

tors and public authorities to learn at an early stage about innovations, their effects under real conditions and about the appropriate legal framework for innovations, and to develop further the general legal framework based on the information obtained from the regulatory box life.

Experimentation clauses are an attempt to deal with the challenges mentioned above. They can be part of responsive governance that adequately addresses new developments. By using experimentation clauses, regulatory authorities can advance regulation through proactive regulatory learning, enabling regulators to gain better regulatory knowledge and find the best means to regulate innovations based on real-world evidence. That is significant, especially for a business project at a very early stage, which can be particularly relevant in the face of high uncertainty.

It is, however, correct that the law serves to protect citizens and social values. Therefore, experimentation clauses must also consider legal provisions and principles outside the experimental scope. That certainly applies to the fundamental principle of equality, which may become relevant when people are confronted with different legal regulations due to the experimentation clauses with time-limited validity for selected stakeholders, allowed to test the innovation, and maybe due to the limited location. Also, conflicts with other national legislative acts, e.g., consumer protection regulation, social laws, or EU legislation, are possible. High-risk innovations should be subject to additional risk-related requirements, especially liability issues.<sup>43</sup> Here, the authorised regulator should make an assessment of public interest and individual rights for granting exceptions. A significant legal issue is the regulation of liability during experimentation in regulatory sandboxes. The legal framework will have to provide a solution based on an appropriate balance between applying a strict type of liability based on risk and fault liability based on negligence.<sup>44</sup>

The knowledge about how the experimental clauses work and about their effectiveness is essential for their review, improvement, and, as the case may be, transfer into “regular operation.”<sup>45</sup>

## 5.2. The design of experimental clauses

Experimentation causes mainly relate to:

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<sup>43</sup> *Ibid.*, pp. 12 – 14

<sup>44</sup> Truby, J. *et al.*, *A Sandbox Approach to Regulating High-Risk Artificial Intelligence Applications*, Cambridge University Press, 2021, p. 28, [<https://doi.org/10.1017/err.2021.52>] Accessed 20 March 2022

<sup>45</sup> *Ibid.*, p. 10

- Exemptions, by a predefined degree, from the existing legal requirements aimed at conducting a specific commercial activity;
- Exemptions from particular approvals or documentation requirements, technical standards or rules;
- Exemptions from taxes or fees;
- Funding or compensation of costs that would be incurred under current regulatory framework;
- Limited period duration of the exception.

Such clauses explicitly authorise governmental institutions or other authorities with decision-making powers to deviate from the existing law.<sup>46</sup> That means the ability of discretionary deciding: “can”, “may”, “is entitled to” and the like. The authority may determine whether to apply the clause and how.

An experimentation clause cannot be designed as a ‘general’ clause applicable to all innovations. Such a clause would not be even efficient as innovative projects defer in their characteristics and require different actors’ conditions. The phrasing of the experimentation clause should meet an appropriate balance between specificity and flexibility. The specificity of the norm ensures legal certainty and transparency. Flexibility ensures sufficient openness for innovation. In order to achieve the right balance between specificity and flexibility, it is preferable to describe what is to be tested rather than to provide a detailed definition.<sup>47</sup>

Experimentation clauses provide for exceptions, and therefore their duration in time is limited, making them sunset clauses. The period of validity needs to be long enough to permit sufficient testing of the innovative model and to allow the achievement of meaningful findings.<sup>48</sup> The duration of experimentation clauses and regulatory sandboxes generally ranges between six and 24 months.<sup>49</sup>

Here are some examples of experimentation clauses. We have chosen experimentation clauses applied in the German legal system.

<sup>46</sup> Bischoff, T. S. *et al.*, *Regulatory experimentation as a tool to generate learning processes and govern innovation – An analysis of 26 international cases*, Sofia-Diskussionsbeiträge, Vol. 20-7, Darmstadt, 2020, [https://www.sofia-darmstadt.de/fileadmin/Dokumente/Diskussion/2020/Netzversion\_Portmann-Regulatory.pdf], Accessed 17 February 2022, p. 11

<sup>47</sup> *New flexibility for innovation, op. cit.*, note 32, p. 14

<sup>48</sup> Feser, D. *et al.*, *Institutional conditions for the up-take of governance experiments – A comparative case study*, IFH - Universität Göttingen Working Papers No. 28202, p. 10, [https://www.ifh.wiwi.uni-goettingen.de/upload/veroeffentlichungen/WP/ifh\_wp-28\_2021.pdf], Accessed 17 February 2022

<sup>49</sup> Wechsler, M.; Perlman, L.; Gurung, N., *The State of Regulatory Sandboxes in Developing Countries*, SSRN 2018, p. 12, [http://dx.doi.org/10.2139/ssrn.3285938], Accessed 23 January 2022

Based on a general experimentation clause in the German Public Transport Act, exemptions have been approved, for example, for testing autonomous driving and delivery, as well as new forms and business models of car/ride-sharing. The wording of the clause is:<sup>50</sup>

“(§ 2 Abs. 7) For the purpose of practically testing new types or means of transport, the authorising authority may, upon application in individual cases, approve deviations from provisions of this Act or from provisions issued on the basis of this Act for a period not exceeding four years, provided that public transport interests are not opposed thereto).”

The Media Act of North Rhine-Westphalia (Germany), Section 10b, the clause states:<sup>51</sup>

(1) The implementation of temporary pilot trials is permissible for the purpose of the introduction and development of digital terrestrial transmission technologies. The duration should not normally exceed three years. These pilot trials serve the preparation of decisions on the future use of digital terrestrial transmission technologies.

(2) The Minister-President shall announce the transmission capacities available for the purpose of the trial and shall work to ensure that the participants agree on an objective allocation. If an agreement is reached, the Minister-President shall allocate the transmission capacities and shall inform the relevant committee of the Landtag about this.’

The Trust Services Act (Germany) Section 11 subsection 3, the wording of the clause is:<sup>52</sup>

“[...] 3) Innovative identification methods which are not yet recognised by an order in the official journal can be provisionally recognised by the Federal Network Agency in consensus with the Federal Office for Information Security and following a hearing of the Federal Commissioner for Data Protection and Freedom of Information for a period of up to two years as long as a conformity assessment body has confirmed the equivalent security of the identification method within the meaning of Article 24(1)(2)(d) of Regulation (EU) No 910/2014. The Federal Network Agency shall publish the provisionally recognised identification methods on its website. The Federal Network Agency and the Federal Office for Information Security shall supervise the suitability of the provisionally recognised

<sup>50</sup> *New flexibility for innovation, op. cit.*, note 32, p. 7

<sup>51</sup> *Making space for innovation*, p. 80

<sup>52</sup> *Ibid.*, p. 85

identification methods during the entire period of the provisional recognition. If the supervision identifies security-relevant risks in the provisionally recognised identification method, the supervisory body can in consensus with the Federal Office for Information Security instruct the qualified trust service provider to take additional measures to remedy these risks where this makes sense in terms of security. If additional measures cannot ensure sufficient security of the provisionally recognised identification method, the supervisory body shall prohibit the qualified trust service provider from using this identification method.”

We can summarise the main issues to be considered when drafting an experimentation clause and present them in a table.

**Table 1.** Creation and life of experimental clause

Preparation	Drafting	Implementation	Evaluation
Determine a factual need – innovation	Choose the appropriate type of clause	Monitor the implementation	Evaluate clause application in order to learn
Determine a legal barrier – obstructive norm or legal gap	Define clause duration – per experiment	Adapt clause design, if needed	Assess clause impact on the legal framework
Define the objective of the experiment	Define the powers of competent authorities – discretion degree	Involve the stakeholders – activity audit	Recommendations: <ul style="list-style-type: none"> <li>• Clause termination</li> <li>• Clause modification</li> <li>• Keeping the clause after the experiment</li> </ul>
Clarify possible legal issues – risks			Adapt the existing law based on evaluation results
Prepare evaluation and learning			

### 5.3. EU approach to experimentation clauses

We have already examined the EU Council Conclusions of 16 November 2020, where the 27 EU Member States called on the European Commission to make greater use of experimentation clauses and regulatory sandboxes.

The EU Council understands experimentation clauses as:

” ...legal provisions which enable the authorities tasked with implementing and enforcing the legislation to exercise on a case-by-case basis a degree of flexibility in

relation to testing innovative technologies, products, services or approaches, [...] experimentation clauses are often the legal basis for regulatory sandboxes [...].”<sup>53</sup>

However, the application of experimentation clauses should be cautious. It is underlined that experimentation clauses always need to respect the fundamental values of the EU legislation and Member States. They must be designed to foster the application of the principles of subsidiarity and proportionality, as well as the precautionary principle. A high level of protection of citizens, consumers, employees, health, climate and the environment, legal certainty, financial stability, and fair competition always need to be ensured, and the existing levels of protection need to be respected.<sup>54</sup>

Finally, the EU Council encourages the EU Commission to continue considering the use of experimentation clauses on a case-by-case basis when drafting and reviewing legislation and evaluating the use of experimentation clauses in ex-post evaluations and fitness checks.<sup>55</sup> We can presume that there would be changes in the way the EU legislation is drafted, which certainly poses a challenge to legal professionals who have an important role in law designing.

## 6. POSSIBLE IMPACTS ON THE (CROATIAN) REGULATORY FRAMEWORK

New businesses bring new jobs, increased income and added value, often by introducing new ideas, technologies and products to society. Successful new business accelerates social structural changes.<sup>56</sup> A recent research of the Global Entrepreneurship Monitor on the social, cultural and economic context of a business shows that policymakers can make better-informed decisions to help entrepreneurs. Such help will be essential in the post-pandemic era but has proven to be highly relevant even in the throes of the economic chaos and volatility currently being experienced across the globe.<sup>57</sup> In the GEM study, two groups of government policies towards entrepreneurship have been examined: the policies that identify priorities and support for entrepreneurship and tax and regulatory framework policies. The ratings of both groups of government policies in Croatia during the reference period of ten years are lower than the EU Member States’ average. In 2020, Croatia had the lowest-rated regulatory framework policies of all EU countries. Of the ten lowest-rated statements related to the components of

<sup>53</sup> EU Council Conclusions, *op. cit.*, note 31, Point 9

<sup>54</sup> *Ibid.*, Point 12

<sup>55</sup> *Ibid.*, Point 13

<sup>56</sup> *GEM 2021/2022 Global Report, op. cit.*, note 5, p. 22

<sup>57</sup> *Ibid.*, p. 30



entrepreneurial environment, five are related to government policies: it is difficult for new and growing businesses to deal with bureaucracy, legal and regulatory requirements; inability to obtain all the necessary permits and certificates within reasonable time; the regulatory framework is still complicated and the administration is slow.<sup>58</sup> That should be taken into account when seeking investments. The limiting nature of these components of the business environment is probably the reason for some lost business opportunities that could have been realised through domestic and foreign investments. The regulatory framework of any country can either support or hamper entrepreneurial initiatives. As a component of entrepreneurial environment, the effect of the Croatian legal system on entrepreneurial activity is more restrictive than stimulating.

We believe our paper has succeeded in pointing out the strength of changes in modern society and the need for the legal system to follow these changes. There are fears of change and ignorance about how to carry out a change. Regulatory sandboxes are a recent phenomenon. However, numerous economies, including the Croatian, already have significant experience with business incubators like entrepreneurship hubs and technology parks.<sup>59</sup> The complexity of modern society often requires complex solutions to challenges. Such solutions arise from the synergistic work of all segments of society. Regulators, public institutions and business sector need to communicate. Through communication they exchange knowledge and experience and learn. Communication also builds trust. Science should not be left out in the participation either. The same applies to legal science and legal professionals. Scholars from different fields are called to strengthen multidisciplinary approaches.

We have noticed a significant development of e-government services in Croatia. Today, Croatian citizens and entrepreneurs can use more than 100 public services through the e-Citizens Information and Services Portal (e-Citizens).<sup>60</sup> The COVID-19 epidemic influenced a rapid development of e-Citizens. Although legally equivalent to standard administrative systems, this e-service portal is still an alternative. E-Citizens is a valuable project, but it does not satisfy many needs.

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<sup>58</sup> Singer, S. et. al., *What makes Croatia a (non)entrepreneurial country? 2019 – 2020*, GEM Croatia - CEPOR – SMEs and Entrepreneurship Policy Center Zagreb, 2021, pp. 68 – 98

<sup>59</sup> Examples of business incubators in Croatia: Tehnološki park Zagreb (TPZ), established 1994 [<https://investcroatia.gov.hr/wp-content/uploads/2016/12/67-Tehnoloski-park-Zagreb-ZAGREB.pdf>]; BIOS – Poduzetnički inkubator Osijek, established 1996 [[https://inkubator.hr/o\\_biosu](https://inkubator.hr/o_biosu)]; TechPark Varaždin – poduzetnički kampus, established 2007 [<https://www.techpark.hr/home/>]; STeP Ri – Science and Technology Park of the University of Rijeka, established 2008, [<https://www.step.uniri.hr/>]; TCS – Tehnološki centar Split, established 1997 [<http://tcs.hr/>], all accessed 10 April 2022

<sup>60</sup> e-Citizen Information and Services Portal / e-Građani, is available in Croatian and English language, see: <https://gov.hr/en>, Accessed 10 April 2022

Unfortunately, the progress of the e-Citizens was not the result of regulatory experimentation and synergy of various stakeholders, especially final users. Croatia has not yet developed regulatory sandboxes. One of the reasons is the insufficiently developed communication culture between public institutions, business sector, and citizens. Social and political consensus is needed to change the legal system. Furthermore, there is still not sufficiently reliable infrastructure to implement innovative solutions in Croatia. The Croatian legal system and the legal systems of other countries have the opportunity to become stimulators of innovative entrepreneurial activities and market growth by introducing experimentation clauses in the system. At the same time, due to the social values, about which they care, legal systems can influence the elimination of destructive and undesirable forms of entrepreneurial behaviour. Of course, regulatory sandboxes do not eliminate the risk of business failure.<sup>61</sup> But a well-established legal framework can reduce the unwanted consequences of the testing on consumers and reduce risks.

A modern legal framework should be flexible, enable innovation and uphold high standards of protection. In this context, experimentation clauses are a valid legal instrument that provides the necessary space to test innovations in the controlled environment of regulatory sandboxes. They also allow the legal framework to be updated in a responsible and targeted manner.<sup>62</sup> Experimentation clauses are placed in an 'area of conflict'<sup>63</sup> between various legally protected interests and the promotion of innovation. The need for the legal system to be predictable and reliable is not lost with the application of experimentation clauses. Their objective is also to make legal effects predictable for those affected – innovators, competitors, customers, and similar third parties. The main parameters around which the experimentation clauses should be formulated to ensure legal compliance are openness to innovation, responsibility for innovation and efficacy, as already shown.

We have to change the concept of validity of law from static, with relative invariance, to dynamic.<sup>64</sup> It is broadly accepted in various legal systems that the change of law happens through court decisions tailored for specific cases. Already here, judges as case-law makers during the decision-making process, consider significant risk of future uncertainty. This shows that introducing experimental clauses and allowing certain discretionary space for the regulators' decisions is not unknown to the legal system, especially when such conduct comes hand in hand with ac-

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<sup>61</sup> Alaassar, A.; Mention A.L.; Aas. T.H., *Exploring a new incubation model for FinTechs: Regulatory sandboxes*, Elsevier Technovation, 2021, p. 3, [<https://doi.org/10.1016/j.technovation.2021.102237>], Accessed 10 January 2022

<sup>62</sup> *New flexibility for innovation*, *op. cit.*, note 32, p. 3

<sup>63</sup> *Ibid.*, p. 9

<sup>64</sup> Luhmann, N., *Law as ... op. cit.*, note 1, p. 473

countability and transparency. Furthermore, the notion of rationality as understood in the legal framework also changes. Traditionally, legal rationality was seen as the will of the legislator,<sup>65</sup> whereas now, it is more and more perceived as the rational decision-making of various authorised decision-makers.

Today, there is high time-related instability of the structures of legal norms. The law cannot guarantee security if a society sees its future as a risk contingent on decision-making. Should there ever be socially adequate legal concepts, they will have to be found by testing and re-testing solutions to establish possible eigenvalues of the legal system in modern society.<sup>66</sup> A legal system that does not change lacks risk awareness.

## 7. CONCLUSION

This paper provides the most significant characteristics of regulatory sandboxes and experimentation clauses. We were primarily interested in understanding the reasons why regulatory sandboxes occur. They result from dynamic changes in a modern society that require quick reaction, quality communication among stakeholders, and the ability to quickly adapt.

A regulatory sandbox should not be seen just as a legal institution or a ‘legal creature.’ It is a phenomenon that includes elements of economic, legal, social, and even cultural matters. Honestly, no big plan can satisfy all the challenges a society faces in the constant pursuit of welfare and safety. Regulatory sandboxes are about learning by acting. This research raises the awareness about why and how a legal system should be made to support entrepreneurial action. The law aims to protect the stakeholders involved. Nevertheless, it should also embrace the opportunity and give room for future events by allowing changes in the legal framework. We believe that in this process legal professionals are essential, since they closely participate in entrepreneurial endeavours when drafting legal acts, programs, contracts, and other documents.

Our first hypothesis is that innovative business is often unrecognised by the legal system. We find that the legal system changes best by learning: constant interpretation of rules, accompanied by the recognition of social dynamics. By putting in effort to understand social dynamics and applying suitable law interpretation methods, the legal system can use experimentation clauses as building blocks to create a flexible and reliable legal framework with regulatory sandboxes as limited testing environments. The EU Member States have already expressed their will-

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<sup>65</sup> *Ibid.*, p. 474

<sup>66</sup> *Ibid.*, p. 473

ingness and readiness in that direction. The second hypothesis is that there are legal requirements and public interest in diligent entrepreneurial behaviour and customer protection that should not be compromised. Experimentation clauses lie in a zone of conflict between a wide variety of legally protected interests and the promotion of innovation. The requirement for the legal system to be reliable is not lost with the application of experimentation clauses. Their objective is to make the legal effects predictable for those affected – innovators, competitors, customers, and similar third parties. The legal system has developed control and check mechanisms, primarily by employing the judiciary system. The proper functioning of the latter is a separate, demanding, topic of another research. We find that the research and the analysis have proven the validity of both hypotheses, and that our work contributes to the raising of regulators', entrepreneurs' and all other stakeholders' awareness of the need for proper interpretation and creation of laws, which keep pace with accelerated changes in the ecosystem, especially in conditions of constant IT and AI growth, while preserving the achieved fundamental social values. We believe that Croatia could be an excellent place for the development of regulatory sandboxes once that the communication between regulatory authorities, business sector and citizens is strengthened.

There is still plenty of room for further research on regulatory sandboxes and experimentation clauses. Currently, there are no significant works of legal scholars on these issues. Economics science literature shows that efforts are being made to gather and analyse samples of sandboxes in different countries and their influence on economic growth. Further legal research could focus on specific models of regulatory sandboxes and types of experimentation clauses, as well as on a comparative analysis of statutory solutions in various legal systems. There will undoubtedly be abundant opportunities for future research on completed regulatory sandboxing projects and the influence of experimentation clauses on the change(s) in legal framework change.

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