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SMART REGULATION FOR ENTREPRENEURSHIP IN THE DIGITAL ECONOMY: THE EU EXPERIENCE

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Abstract. *Purpose of the article.* The aim of this research is to conceptualize the theoretical, methodological, and practical foundations of smart regulation of business development within the context of the digital transformation of the economy, drawing on the advanced experiences of the European Union. The study seeks to substantiate the transition from rigid, reactive regulatory frameworks to adaptive, data-centric, and platform-driven mechanisms capable of stimulating entrepreneurial initiative, fostering digital innovation, and ensuring market safety and digital fairness across various EU member states. *Research methodology.* The methodology is grounded in a systemic, comparative, and institutional analytical approach. The theoretical framework synthesizes mission-oriented governance, agile regulatory approaches, and digital governance theories. Comparative analysis was employed to examine the institutional models of smart regulation across four representative EU nations (Estonia, Germany, Denmark, and Spain). The study uses qualitative synthesis, institutional mapping, and empirical categorization of regulatory tools, including Regulatory Sandboxes, RegTech/SupTech implementations, and digital platform integration, to extract strategic implications for emerging market economies. *Results.* The study demonstrates that smart regulation in the EU represents an evolutionary paradigm shift rather than mere deregulation. It balances economic efficiency with digital fairness through landmark frameworks such as the Digital Markets Act, Digital Services Act, and AI Act. Four distinct national models of smart regulation were identified and systematized: Estonia's integrated "Digital-First" model based on automated governance and zero bureaucracy; Germany's structured framework focusing on industrial IoT (Mittelstand 4.0) and stringent data protection; Denmark's Scandinavian model combining green twin transitions with open-data transparency; and Spain's experimental model leveraging AI regulatory sandboxes and startup-support legislation. The findings confirm that effective regulatory environment relies on data interoperability, real-time compliance monitoring, and safe experimental regimes. *Practical implications.* The practical significance lies in providing actionable policy recommendations for developing and transition economies, particularly those aiming for EU integration. The study outlines specific pathways for institutional adaptation: expanding AI and fintech regulatory sandboxes, implementing the "Once-Only Principle" via national interoperability platforms (similar to Estonia's X-Road or Ukraine's Trembita), and adopting Digital Regulatory Impact Assessments (Digital RIA) to prevent bureaucratic barriers for small and medium-sized enterprises (SMEs). *Value/Originality*. The paper contributes to the academic discourse by offering a comprehensive comparative taxonomy of smart regulation strategies within the EU. It bridges the theoretical gap between innovation economics and digital regulatory design, offering a novel synthesis of how adaptive state mechanisms, RegTech solutions, and experimental legal regimes can co-exist to maximize entrepreneurial resilience in the era of artificial intelligence and platform economics.

Keywords: agile governance, digital economy, entrepreneurship development, European Union, digital transformation, RegTech, regulatory sandboxes, smart regulation, SupTech, twin transition.

JEL Classification: L26, O38, K23

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1. Introduction

The rapid development of digital technologies, the institutionalization of artificial intelligence, the spread of the platform economy and big data are transforming the fundamental principles of the functioning of modern economic systems. In the context of the formation of a digital global space, traditional instruments of state regulation of business are losing their effectiveness due to high bureaucracy, slow adaptability and frequent inconsistency with the dynamics of innovative business models. This creates an acute dilemma for state administration bodies: on the one hand, the need to protect public interests, competition and personal data; on the other – ensuring a favorable environment for entrepreneurial initiative, scaling startups and digital investments.

A key response to this challenge has been the deployment of the concept of smart regulation, which involves a transition from rigid directive methods of influence to flexible, adaptive, data-centric and digital regulatory mechanisms. The European Union acts as a global testing ground for the implementation of institutional and legal experiments in this area. By integrating the strategic guidelines of the "Digital Decade 2030" with new generation regulatory acts (in particular, the Digital Markets Act, the Digital Services Act, the Data Act and the AI Act), the EU is forming a unique model of smart regulation aimed at combining digital sovereignty, technological development and the protection of fundamental rights.

At the same time, within the European Union itself, there is a significant heterogeneity of institutional models and practices for the application of smart regulation. EU member states demonstrate different approaches: from the total digitalization of public services for business in Estonia to balanced legal regulation and the concepts of "Mittelstand 4.0" in Germany or the proactive deployment of regulatory sandboxes in Denmark and Spain. Researching and systematizing this diversity is an extremely urgent task for developing effective mechanisms for transforming the business environment in countries on the path of European integration.

The purpose of the article is to theoretically generalize the conceptual foundations of smart regulation of entrepreneurship in the context of digitalization of the economy and conduct a comparative analysis of the practical experience of its implementation in leading EU countries to determine the imperatives for increasing the competitiveness of business ecosystems.

2. Key Theoretical Approaches

The concept of smart regulation in modern economic thought has evolved from the classical understanding of "better regulation" (Better Regulation) to a complex paradigm of digital and adaptive governance (Agile & Digital Governance). In the context of digitization, smart regulation is defined as a system of regulatory influences based on the use of digital tools (RegTech, SupTech), real-time data analytics, flexible legal regimes, and stakeholder involvement through co-regulation.

In the works of European researchers (Galindo-Martín, Castaño-Martínez, Méndez-Picazo, 2023), the conceptualization of smart regulation is carried out in several key areas:

1. The Regulation-Innovation Nexus. European scholars (Autio, Nambisan, Thomas, Wright, 2018), in their research on digital transformation, emphasize that state regulation should not be a restrictive barrier to innovation. According to their conclusions, smart regulation acts as a "mission-oriented governance" that shapes new markets and stimulates the private sector to invest in digital and green technologies. At the same time, (Bogers, Chesbrough, Moedas, 2018) points to a fundamental dilemma of the European approach: balancing economic efficiency (increasing the total productivity of production factors through digitalization) and digital fairness (data security, AI ethics, and anti-monopoly).

2. Agile Regulation & Sandboxing. Researchers (Buiten, 2021), analyze institutional mechanisms for adapting legislation to disruptive technologies. They emphasize that classic ex-ante regulation lags behind the pace of technological progress (the so-called "Collingridge problem"). An alternative is the introduction of regulatory sandboxes – isolated legal regimes where companies can test new digital products or business models without the risk of immediate sanctions for non-compliance with outdated norms under the supervision of the regulator.

3. The Concept of "Digital-by-Default Governance". Scientists (Kuzior, Pakhnenko, 2023) consider smart regulation through the prism of digital transformation of state institutions. According to their approaches,

the regulatory environment becomes "smart" when administrative procedures for business (registration, licensing, reporting, taxation) are fully algorithmized and integrated into digital platforms, minimizing the human factor and bureaucratic burden.

Thus, modern European discourse (Nambisan, 2017; Nambisan, 2018; Nambisan2019) shapes the understanding of smart regulation not as a simple reduction of regulations (deregulation), but as an optimization of the regulatory burden through the digital transformation of the very tools of control and interaction between the state and business entities.

3. Comparative Analysis of the Experience of EU Countries

The countries of the European Union apply variable models of smart regulation of entrepreneurship, which is due to differences in the institutional structure, levels of development of digital infrastructure and traditions of public administration. For comparative analysis, four countries were selected that represent different conceptual models: Estonia (the model of total institutional "Digital-First"), Germany (the model of high regulatory standards and support for industrial innovations), Denmark (the Scandinavian model of flexible governance and ecosystem trust) and Spain (the Southern European model of active deployment of regulatory sandboxes and digital vouchers).

Let us first consider the experience of Estonia, which uses the Integrated Digital Governance Model. Estonia is recognized by the European Commission as a world leader in building a digital state and a smart environment for entrepreneurship. The key tools of the model are: the use of the e-Residency system, which allows entrepreneurs from all over the world to establish and manage a company in the EU completely remotely; the use of the X-Road database interoperability platform; the Once-Only Principle, which prohibits state authorities from requesting information from businesses that is already in state registers. The main regulatory results are: company registration is carried out online in 15 minutes; 99% of public services for businesses are available around the clock; tax reporting is fully automated thanks to the direct integration of companies' accounting software with the tax service (e-Tax). The main specific feature of smart regulation is the minimal bureaucratic burden combined with a high level of cybersecurity and automatic compliance with the law thanks to the algorithmization of norms (Steininger, Brohman, Block, 2022).

Next, we will consider the experience of Germany, which uses a structured model and support for "Mittelstand 4.0". Germany demonstrates an approach aimed at systemic data protection, transparency and deep digitalization of traditional small and medium-sized businesses (SMEs – Mittelstand). Key tools of the model are: the Federal Strategy "Digital Agenda", the Electronic Government Act (EGovG), the deployment of a network of Mittelstand-Digital support centers; strict compliance with GDPR regulations and the adaptation of German competition law to digital platforms (through amendments to the Competition Act – GWB). Regulatory results have been: the formation of high consumer and business trust in digital transactions; the creation of standardized security protocols for the Industrial Internet of Things (IIoT). At the same time, the country faces a significant bureaucratic burden and a slower implementation of completely paperless procedures compared to the Nordic EU countries. A specific feature of smart regulation in this country is the emphasis on data security, preventing the dominance of big tech giants (Big Tech), and encouraging traditional manufacturing enterprises

Table 1
Conceptual Foundations of Smart Regulation of Entrepreneurship

Theoretical Approach	Main Tenets and Regulatory Focus
Mission-Oriented Governance	The state shapes the digital architecture and creates incentives for scaling private innovation
Digital Platform Economy & RegTech	Combining real-time data analytics with self-regulation of platform ecosystems
Agile Governance & Sandboxing	Experimental law enforcement and testing of innovations within safe legal frameworks
Digital Governance Institutional Model	Automation of public services, Zero Bureaucracy, and data interoperability

to implement Industry 4.0 solutions (Verhoef, Broekhuizen, Bart, 2021).

Next, we will consider the experience of Denmark, which uses the Scandinavian model of "Centralized Mission and High Trust" and consistently occupies leading positions in the European Union's Digital Economy and Society Index (DESI). The key tools of the model are: National Digitalization Strategy, focused on the "twin transition" (Twin Transition – a combination of digitalization and green growth); a single digital business identification platform MitID Erhverv; an extensive system of regulatory consultations in real time. Regulatory results were: almost complete abandonment of paper document flow between the state and SMEs; high level of integration of digital technologies into circular economy processes; rapid coordination of regulatory requirements due to digitalization of the dialogue between business and regulatory authorities. A specific feature of smart regulation was high flexibility, openness of state data (Open Data) for the development of private digital services, and the priority of green digital innovations (Autio, Szerb, Komlósi, Tiszberger, 2019).

The experience of Spain, which uses an innovative and experimental regulatory sandbox model, is also interesting. Spain has chosen the path of actively developing an infrastructure to support digital startup entrepreneurship. The key tools of the model are: the adoption of a specialized Law on Startups (Ley de Startups), the deployment of the National Regulatory Sandbox for Artificial Intelligence (Spanish AI Sandbox) – the first such initiative in the EU before the entry into force of the AI Act; the large-scale Kit Digital program (digital vouchers for SMEs). The regulatory results were: ensuring the testing of High-Risk AI technologies in a safe environment; simplifying the tax and migration regime for digital nomads and technology founders; accelerating the digitalization of traditional micro-enterprises. A specific feature of smart regulation in this country is the use of legal experiments for the proactive adaptation of national legislation to European requirements and stimulating technological entrepreneurship (Galindo-Martín, Castaño-Martínez, Méndez-Picazo, 2023; Santos, Bogers, Norn, Mendonça, 2021).

The analysis confirms that effective smart regulation does not have a universal template. However, the common vector for all considered EU countries is the transition from the inspection and punishment model of control to the service-platform support of enterprises, where technologies serve as a guarantor of public interests without creating unnecessary barriers for business.

4. Conclusions

Smart regulation of entrepreneurship development in the context of digitalization of the economy is a holistic paradigm of public administration that combines flexible legal instruments, algorithmization of public services, data-centric control, and experimental legal regimes (regulatory sandboxes).

The analysis conducted allows us to draw the following general conclusions:

1. There has been an evolution of conceptual approaches, i.e. European experience indicates a shift in emphasis from classical deregulation to the formation of a digital environment of trust and efficiency. Smart regulation in the EU is based on a balance between stimulating innovative activity of enterprises and ensuring digital justice, which

Table 2

Comparative Analysis of Smart Regulation Models in Selected EU Countries

Comparison Criteria	Estonia	Germany	Denmark	Spain
Dominant Institutional Type	Integrated Digital-First	Normative-Legal Regulatory	Centralized Mission-Specific	Experimental-Innovative
Key Technological Driver	X-Road, e-Residency, e-Tax	IIoT (Industry 4.0), Mittelstand-Digital	MitID Erhverv, Open Data Platforms	AI Sandboxes, Kit Digital Vouchers
Bureaucratic Burden Level	Minimal (Zero Bureaucracy)	Medium / High (due to compliance rules)	Very Low	Medium (trending downwards)
Regulatory Policy Focus	Cross-border business freedom, automation	Data security, competition protection	Twin (green and digital) transition	Startup attraction, AI piloting
Primary Advantage for Business	Speed and elimination of paper procedures	High legal certainty and reliability	High trust and environmental sustainability	Flexible conditions for testing disruptive technologies

is recorded in the latest EU regulatory framework (Digital Markets Act, Digital Services Act, AI Act) (Autio, Szerb, Komlósi, Tiszberger, 2019).

2. It can be argued about the diversification of European practices, that is, the comparative study demonstrates the presence of clearly expressed national models: Estonia ensures maximum speed and paperlessness through the "Digital-First" architecture; Denmark effectively combines digitalization with the tasks of the green transition; Germany guarantees a high level of legal protection and standardization of the industrial Internet of Things; Spain forms an advanced experience in adapting business to artificial intelligence solutions through regulatory sandboxes.

3. Certain key success factors can be identified, i.e. common elements of successful smart regulation models in the EU are the implementation of the Once-Only Principle, end-to-end interoperability of state registers, proactive provision of real-time business advice, and the creation of safe conditions for testing disruptive technologies.

4. The experience of the countries considered allows us to formulate the following recommendations for Ukraine (Shaposhnykov, Filyppova, Bilousov, Seleznova, Lozychenko, 2024):

– institutionalization of regulatory sandboxes – it is advisable to expand the practice of creating special legal regimes (following the example of Spain) not only for the financial sector, but also for the areas of artificial intelligence, agrotechnology and digital logistics;

– deepening system interoperability: Having seen the success of the Estonian X-Road system, Ukraine should continue to expand the functionality of the Trembita platform and the Diya.Business ecosystem, automating tax and administrative reporting of enterprises "by default";

– implementing Digital Regulatory Impact Assessment (Digital RIA) – it is necessary to ensure that any new regulatory act is tested for its digital suitability (Digital-ready legislation), preventing the emergence of outdated paper requirements for small and medium-sized businesses.

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