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QUALITY MANAGEMENT SYSTEM ISO 9001 AND INNOVATION SUSTAINABILITY IN 27 EU COUNTRIES

Abstract: *The increasingly uncertain business environment and the growing rate of changes require organizations to improve their competitiveness, sustainable development and innovation. To achieve these objectives, organizations are, among other things, implementing quality management system ISO 9001. The primary purpose of our research was to obtain the answer to our research problem of whether there is any correlation between the number of ISO 9001:2015 certificates, the innovation index and the sustainable development index in 27 EU member states. The empirical analysis was conducted based on data from ISO, the International Organization for Standardization, the Eurostat statistical office of the European Union and the Europe Sustainable Development Report 2020. The main finding of the research is that the number of ISO 9001:2015 certificates in EU member states neither impacts the innovation index nor the SDG index. The findings presented here are relevant and useful for organizations to help them implement in their operations those systems and tools that will directly increase innovation. Also, based on our findings, national governments can examine the effectiveness of their mechanisms aimed at increasing innovation.*

Keywords: *quality management, ISO 9001 certification, innovation standards, national economy, sustainable development goals, innovation index*

1. Introduction

Today, organizations are faced with an increasing demand for operational excellence and performance, requiring them to implement continuous improvement and innovation. Those that wish to survive long-term in the ever more demanding global market need to be efficient as well as adaptive and innovative. However, it has been questioned whether quality management system concepts and practices enable tackling these challenges (Lilja, Hansen, Fredrikson, & Richardsson, 2017).

In today's socio-economic context, organizations face serious challenges and are therefore seeking better and innovative methods, helping them remain competitive, improve their profits and performance. But to meet these objectives, innovation is key. In addition to business requirements, organizations also have a responsibility to the environment and society. In order for them to adequately respond to these responsibilities, they also need to focus on the importance of sustainable products and innovations (Maier, Maier, Așchilean, Anastasiu, & Gavriș, 2020).

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The emergence of new global competitors, the convergence of high-technology industries and the increasing speed and cost of technological development promise an increasingly uncertain environment for organizations (Ruiz-Moreno, Tamayo-Torres, & García-Morales, 2015). Moreover, the increasing complexity of products and services, rapidly changing market demands, shorter life cycles, or growing pressure from various societal groups require new or different management practices to successfully develop innovations and sustain a company's competitive advantage (Rauter, Globocnik, Perl-Vorbach, & Baumgartner, 2018). Thus, organizations are constantly adapting to changes in the economy, and those that adapt best are the ones that have the best chance of surviving in the market, whereby innovation is the key factor of their success. To gain a competitive advantage and facilitate innovation, organizations implement different management practices, such as the implementation of the ISO 9001 quality management system (Bernardo, 2014) which brings internal and external benefits for the organization (Başaran, 2016).

In today's aggressive global competition, organizations are obliged to improve quality and promote innovation to create and safeguard their sustainable competitive advantage (El Manzani, Sidmou, & Cegarra, 2019). Implementation of a systems approach and development and investment in innovativeness are a prerequisite for competitiveness, development of organizational performance and survival on the market (Vujović, Jovanović, Krivokapić, Peković, Soković, & Kramar, 2017). Quality and innovation play a crucial role in ensuring organizations' competitive advantage in an increasingly competitive global market (Zeng, Anh Phan, & Matsui, 2015), whereby the implementation of product innovations is a necessary strategy for organizations that wish to face the aggressive competition (El Manzani, Sidmou, & Cegarra, 2019).

One of the consequences of globalization is the increasing competitiveness in the global market, while quality is one of the prerequisites for an organization to succeed in this market. In terms of competitiveness and quality, the product or service provided by an organization needs to be innovative and it needs to meet the customers' needs better than those offered by competitors. One of the ways in which customers can make sure that organizations meet the high-quality standards is the implementation of the ISO 9001 quality management system. Quality management and innovation can be considered as two elements or rather two fields of organizations' operations that strive to simultaneously achieve good results in both fields. In addition to studying the overall impact of quality management activities on innovation, the focus should also be placed on individual relationships between different aspects of the two (Damic, Naletina, & Buntic, 2021).

Due to the growing competitive pressure generated by increasing customer demands, rapidly changing technology and shorter product life cycles, innovation is key to the survival of organizations and is currently one of the most recognizable strategies of sustainable development. However, greater efforts to implement innovations are made in quality management system certified organizations as opposed to non-certified companies, but innovations are largely focused on organizational innovation rather than on products and process innovations (Daoud Ben Arab, 2021).

Adaptation to changes in the environment thus poses a growing challenge to organizations, while the implementation of quality management system is one of the alternatives through which organizations may be able to respond to this challenge (Ruiz-Moreno, Tamayo-Torres, & García-Morales, 2015). The main impact of innovation on organizations is the fact that it enables them to respond quickly to changes in the environment in which they operate (Martínez-Costa & Martínez-Lorente, 2008).

Also, one of the management system advantages is that organization gains flexibility and speed for change (Başaran, 2017).

However, quality management alone is not enough to achieve competitiveness and survive. Today, quality could be defined as a prerequisite for procuring customer orders, while innovation guarantees that customers will stay with an organization in the long run. Therefore, organizations aim to simultaneously achieve high levels of quality and innovation (Manders, de Vries, & Blind, 2016). At a time when organizations are facing a turbulent and rapidly changing environment, innovation has become a strategic tool for management (Martínez-Costa & Martínez-Lorente, 2008). If organizations wish to be successful in the long run, they need to innovate, transform the existing products and develop new ones, as well as invest in research and development (Lazaretti, Giotto, Sehnem, & Bencke, 2019).

Organizations tend to set a number of different objectives; lately, a lot of focus has been placed on competitiveness, high profit and long-term survival. Sustainability has become a diligent act of business organizations because it moves them toward superior performance; and greater sustainability and performance are achieved through innovation (Zhang, Khan, Lee, Salik, 2019). Organizations that truly aim to become sustainable will need to change ways in which they operate. Those that lack the capacity for innovation will probably never become sustainable, regardless of their size (Lazaretti, Giotto, Sehnem, & Bencke, 2019).

2. Theoretical framework

2.1. Quality management system ISO 9001 and other innovation standards

Improving organizational performance is the primary objective of every successful

organization that wishes to improve its competitiveness and financial stability. One of the models contributing to better performance is the ISO 9001 quality management system (Zhang, Khan, Lee, Salik, 2019).

The ISO 9000 family of standards has been in existence for more than 30 years. Throughout the years, these standards have become an integral part of the quality movement and have been classified among the most important international standards (Rogala & Wawak, 2021). The first version of the ISO 9001 standard published in 1987 was formulated based on the concept of quality assurance (Wilson & Campbell, 2016). The second edition of the standard published in 1994 was improved based on the concept of preventive action. The third version, published in 2000, was formulated based on the concept of quality management. The fourth version was published in 2008 and it underwent minor changes from the previous version with the objective to gain better understanding of the given requirements. The latest version of the quality management standard was published in 2015. The changes include a new dimension focused mainly on the organizational context and risk-based thinking (Sari, Wibisono, Wahyudi, & Lio, 2017). The ISO 9001:2015 standard titled Quality management systems - Requirements (ISO, 2015) is widely applied throughout the world. In 2020, there were 916,842 organizations all over the world that had the ISO 9001:2015 (ISO, 2022) quality management system standard in place, while there was an estimation made for G20 countries till year 2026 (Başaran, 2021).

The latest version of the ISO 9001 quality management system published in 2015 includes and promotes the awareness of organizational knowledge and activities aimed at preserving it. Organizations need to be capable of retaining and storing knowledge and experience, and then implementing systemic measures to transfer and share this very knowledge and

experience. Thus, they can perform activities that contribute to organizations' sustainable development (Demir, Budur, Omer, & Heshmati, 2021).

A detailed review of the contents of the ISO 9001:2015 standard revealed that term »innovation« was used twice. First, in section 0.1 General where it is indicated that in order for an organization to be able to address the needs and expectations of the interested parties and to meet their demands, it can implement processes of continuous improvement, corrective measures as well as disruptive changes, innovation and reorganization. The second mention of the term can be found in section 10.1. Improvement - General where the examples of improvement include disruptive changes, innovation and reorganization. In addition to term 'innovation', the text of the ISO 9001:2015 standard was analyzed for term »sustainability«, which was only mentioned once, i.e. in section 0.1 General where it is specified that the adoption of quality management system is a strategic decision of an organization that may improve its performance and provide a solid basis for sustainable development initiatives. On the other hand, the term 'sustainability' is much more emphasized in the ISO 9004:2018 standard titled Quality management - Quality of an organization - Guidance to achieve sustained success (ISO, 2018a) which the ISO 9001:2015 standard refers to in section 0.4 Relationship with other management system standards. ISO 9004:2018 provides guidance for organizations looking to develop beyond the requirements of the ISO 9001:2015 standard. While ISO 9001:2015 is focused on ensuring confidence in an organization's products and services, ISO 9004:2018 concentrates on ensuring confidence in an organization's ability to achieve a lasting success.

ISO 9004:2018 can be implemented in any organization, regardless of its size, type and business activity. This standard provides organizations with guidelines helping them achieve a lasting success based on the

principles of quality management in a complex, challenging and constantly changing environment. At the same time, the standard facilitates self-assessment and provides tools for the verification of an organization's performance as regards the implementation of quality management principles.

The focus of an organization's top management on the organization's ability to meet the needs and expectations of customers and other interested parties brings confidence in the ability to achieve a lasting success. Factors affecting an organization's performance keep appearing, evolving, increasing or decreasing over the years, and an organization's ability to adapt to all changes is key to a lasting success. An organization's success is also dependent on improvement and innovation. Thus, ISO (International Organization for Standardization) has published the ISO 56002:2019 standard titled Innovation management - Innovation management system - Guidance (ISO, 2018b). The standard does not prescribe any requirements or specific tools or methods for innovation activities, but rather provides guidance for the establishment, implementation, maintenance, and continual improvement of an innovation management system for use in all established organizations. All the guidance within the document is generic and intended to be applicable to all types of organizations and innovations, such as product, service, process, model, and method.

The innovation management system described in ISO 56002:2019 is based on the following principles:

- realization of value;
- future-focused leaders;
- strategic direction;
- culture;
- exploiting insights;
- managing uncertainty;
- adaptability;
- systems approach.

Prior to publishing the last revision of the ISO 9001 quality management system standard in 2015, technical committee ISO/TC 176 had discussed the relationship between quality management system and innovation management. There were strong arguments for including innovation management in the new edition of the ISO 9001 standard based on the belief that it was not enough to simply continue with improvements and operational excellence but that another aspect needs to be considered, i.e. that the likelihood of an organization's survival does not depend so much on its ability to manage quality as on its ability to manage innovation. There were also counterarguments that highlighted the fact that everything that is put into the new ISO 9001 will become a requirement, a compulsory commitment, and thereby affect all certified organizations. The second counterargument concerned the very nature of quality management versus innovation management. It was questioned whether it is even possible for a quality management system to be complemented by the innovation management elements. As a result, it was agreed that it would be wise to clarify the management of innovation in a separate global standard for innovation management. Thus, the recently released standard ISO 9001 published in 2015 came to exclude innovation management. However, the discussion itself was a clear sign of the need to merge quality management system and innovation management (Lilja, Hansen, Fredrikson, & Richardsson, 2017).

Although quality is typically associated with the quality of products and services, it is in fact a multidimensional concept, while quality management system is a holistic philosophy of management, including a variety of principles (El Manzani, Sidmou, & Cegarra, 2019). Quality management system facilitates the creative process in organizations and contributes to the development of an innovative organizational structure (Shi, Lin, Chen, & Su, 2019); it

also serves as the basis for gaining competitive advantage in terms of innovation (Zeng, Anh Phan, & Matsui, 2015). Moreover, quality management is considered to be suitable as support for the integration of sustainability considerations in areas such as product development (Siva, Gremyr, Bergquist, Garvare, Zobel, & Isaksson, 2016). By addressing the risks and opportunities, ISO 9001-certified organizations strive for sustainability of their operations (Suriseti, Kulkarni, & Naveen, 2021). For complex economic entities, the implementation of the ISO 9001 quality management system is a challenge in itself and, as such, can be considered as separate organizational innovation (Troshkova & Levshina, 2016).

At a time when Industry 4.0 is gaining momentum and digitalization is radically transforming organizations' operations, there is a need to adapt quality management system to these changes or rather predict and consider their impact, facilitating sustainable results and organizations' sustainable success. Both Industry 4.0 and quality management system have a common objective – to improve organizational performance (Fonseca, Cardoso, Pereira, Ávila, 2021). Quality management according to ISO 9001 has established itself in almost all organizational activities, while the implementation of quality management methodologies and tools positively affects an organization's performance. Therefore, it can be said that quality management system is an innovation in itself, and the functioning of quality management system in an organization generally goes hand in hand with significant organizational innovations. However, it should be taken into consideration that the ISO 9001 standard is based on systematization and formalization, which could actually hinder innovation because of its tendency to increase bureaucracy (Castillo-Rojas, Casadesús, Karapetrovic, Coromina, Heras, & Martín, 2012).

The overall organizational system of management as well as organization strategy as essential components must implement sub-systems of planning, development and innovation management. It is precisely the quality management system that represents the base for stimulating innovative development and creative thinking, especially based on the promotion of small incremental improvements and measuring of the level of achievement of particular objectives at process level (Vujović, Jovanović, Krivokapić, Peković, Soković, & Kramar, 2017). Quality and innovation are often regarded as two separate processes or fields; however, they both have a similar purpose and meaning in an organization's business results, while their interaction may affect an organization's performance and its development. Therefore, opportunities and incentives for innovation brought by quality management system are highly appreciated in organizations, whereby special focus is placed on critical factors for the improvement of innovation performance or rather on internal and external aspects of an organization. That said, it should be pointed out that the latest version of the ISO 9001 quality management system standard published in 2015 gives special attention to the organizational context as well as internal and external issues (Camisón & Puig-Denia, 2015).

There is, however, a risk that if an organization takes a classic approach to the use of quality management system, it can quickly become too focused on formalization and systematization, resulting in linear thinking and creating a comfort zone, which inevitably leads to avoiding changes and creativity that are the fundamental generators of product and process innovation. In such cases, an organization's management only facilitates organizational improvements, while innovation is only promoted to a certain degree. Being focused only on quality improvement and provision of human resources is far from sufficient when it comes to facilitating technical innovation.

On the other hand, proper implementation of quality management system according to the ISO 9001 standard, requiring the definition of measurable goals and periodic measuring of the achievement of these goals, results in improved organizational capacities that lead to innovation (Daoud Ben Arab, 2021).

Organizations certifying their quality management system according to ISO 9001 believe that the system can improve processes, effectiveness and performance as well as the quality of research activities (Kasperavičiūtė-Černiauskienė & Serafinas, 2016). Over the past half century, the results of quality management system have shown that the system is an important factor for facilitating competitiveness of organizations and economy as a whole. Due to increased global competition, the question of whether the implementation of quality management system in organizations still makes sense has become highly relevant. ISO 9001 quality management system is one of the most popular quality management systems in the world and is recognized as one of the most effective tools for increasing organizations' competitiveness (Priede, 2012). Organizations operating in environments where continuous innovation is a necessity should not only see quality management system as a tool for improving quality but also as a tool for facilitating and systematizing the innovation process (Martínez-Costa & Martínez-Lorente, 2008).

2.2. Innovation and sustainability

As regards the application, innovation can be product innovation, process innovation, marketing innovation or organizational innovation (El Manzani, Sidmou, & Cegarra, 2019). Product innovation can be a new product or service, and it can mean the introduction of a product or service that is new or significantly improved with respect to its characteristics or intended uses. This includes, among other things, significant improvements in technical specifications, components and materials, incorporated

software, user friendliness or other functional characteristics developed with the purpose of meeting the needs and expectations of customers (El Manzani, Sidmou, & Cegarra, 2019). The latest version of the Oslo Manual 2018 defines innovation as a new or improved product or process (or combination thereof) that differs significantly from the unit's previous products or processes (OECD, 2019), but it could also be interpreted as a practical implementation of knowledge, ideas and discoveries that result in the introduction of new products, production methods, changes in organizational processes and opening up of new markets or sources (Lazaretti, Giotto, Sehnem, & Bencke, 2019).

Innovation can be divided into incremental innovation which is based on current technical capabilities of an organization and is distinguished by minor changes, and radical innovation bringing about sudden and significant changes (Manders, de Vries, & Blind, 2016). The term innovation includes radical or incremental changes in an organization's products, processes and strategies. Changes can be associated with the improvement of individual elements of an organization and its environment, with new implementation of known elements in a manner different from what was known in the past, and with the development of completely new elements. Thus, innovation does not only mean the development and implementation of completely new elements, such as products, technologies and business processes, but also the adoption of the existing elements. Innovative development should be seen as a process of qualitative change in an organization implemented through the introduction of innovation (Troshkova & Levshina, 2016). Innovation process differs from one organization to another, resulting in different performance levels (Latan, Chiappetta Jabbour, Lopes de Sousa Jabbour, de Camargo Fiorini, & Foropon, 2019).

From a wider perspective, innovation can be seen as the implementation of a new or

significantly improved product, process, marketing method, organizational method in business practices, workplace organization or external relations. This definition entails different types of innovation that can be found in literature and organizations. Further, organizational innovation can be defined as an organization's ability to generate innovation through continuous learning, knowledge transformation, creativity and exploitation of internal and external resources. Thus, innovation is a result of an organization's capabilities based on organizational innovativeness, which is positively affected by successful implementation of the ISO 9001 quality management system. Higher degree of internal motivation for the implementation of the ISO 9001 quality management system ensures a more consistent implementation, generating a positive relationship with organizational innovativeness. Quality management system principles can have a positive effect on organizational innovativeness if they are adopted in the right way. One of the quality management system seven principles is namely continuous improvement which may serve as a good basis for organizations to transform their continuous improvement process into the innovation process (Damic, Naletina, & Buntic, 2021). Implementation of organizational innovation usually correlates with a higher level of quality management, especially in organizations with a higher number of employees and a higher turnover (Llach, Casadesus, & Marimon, 2010).

Due to rapid changes in all aspects of business, organizations are putting more emphasis on the adoption of measures aimed at improving innovation processes. The process of continuous innovation can be defined as a sustainable effort in building organizations' ability to innovate continuously in terms of products, processes, marketing and organizations themselves. Efforts for continuous innovation are thus becoming a priority of many organizations. While innovation may emerge occasionally

and randomly, the process of continuous innovation creates conditions for their constant generation and thus transforms the innovation capabilities of an organization into an organization's sustainable innovation performance. Dynamic changes in the market environment require organizations to constantly adapt their structure and strategy. In this context, continuous innovation is an important factor of competitive advantage, helping organizations face turbulent market environments (Latan, Chiappetta Jabbour, Lopes de Sousa Jabbour, de Camargo Fiorini, & Foropon, 2019).

Of course, when addressing innovation, the impact that may be generated by collaboration between the academia and the industry must not be neglected. Therefore, the primary objective of collaboration between universities and the industry, and the resulting innovation strategy, is to support the economic growth of the country and facilitate more social interaction that is innovative and likely to create employment opportunities. The primary purpose of any economy is to generate knowledge and innovation. However, innovation is a multidimensional concept that in many ways goes beyond the production of new products. When universities and industry collaborate in research and development, innovations increase. Collaboration between universities and industry as regards research and development and innovation is stronger in high-income countries compared to that in middle- and low-income countries. Therefore, the same level of improvement of such collaboration may lead to higher levels of innovation in high-income countries, as opposed to middle- and low-income countries. Thus, incentives that facilitate collaboration between the academia and the industry in research and development in fact foster innovation in industry and improve the level of quality management in private and public sector. It is in this way that high-income countries are given an opportunity to invest more in technological progress and R&D projects that will eventually lead to

innovation. Organizations in these countries are therefore motivated to standardize their products, services and processes through the certification of their quality management system according to the ISO 9001:2015 standard. When it comes to quality management, ISO 9001:2015 is recognized as the most popular and prevalent quality management system (Aldabbas, Pinnington, & Lahrech, 2020).

The traditional approach to innovation assessment has mainly focused on the economic outcomes and failed to capture the ecological and social dimensions of sustainability. However, the sustainability orientation in the assessment of innovation performance is becoming increasingly important. This poses a unique challenge to organizations that need to discover and establish the conditions under which innovation will lead to sustainability. This is essential for developing novel systems approaches, methods and tools that will facilitate innovation (Degato, 2017). With that in mind, it is very important to adopt and correctly interpret the concept of innovation i.e. to deviate from the earlier understanding of innovation as a technical solution. In line with the new understanding of the concept of innovation, it can be concluded that besides the concept of an entirely new solution, innovation also implies implementation of some well-known solution from the global level in the local environment in which it is an absolute novelty that brings benefits, even those of financial nature (Vujović, Jovanović, Krivokapić, Peković, Soković, & Kramar, 2017).

To achieve innovativeness, organizations may engage their internal resources, but involving external resources to resolve sustainability-related issues is becoming increasingly popular. Many organizations have come to realize that an individual approach and internal resources alone cannot result in the same level of innovation as the one obtained through involvement in innovation systems based on external

resources and collaboration with other innovative organizations. Recognizing the importance of involvement in systems that facilitate innovation is primarily a responsibility of an organization's top management, because this is how they are able to better understand sustainability challenges they are faced with (Greco, Eikelenboom, & Long, 2021).

The potential of sustainable innovation is also reflected in the transformation of technologies, and organizations may utilize sustainable technologies to support their efforts to foster social and environmental preservation. However, sustainable innovation may be construed as a method of changing business and society. It is evident that external stakeholder pressure on organizations to become sustainable is growing. However, sustainable development is also based on the process of continuous innovation which leads to periodic, if not continuous assessment of innovations and technological changes (Lazaretti, Giotto, Sehnem, & Bencke, 2019).

Sustainability orientation of an organization increases the likelihood of generating both product and process innovations. While product innovations mainly result from an organization's internal capabilities, process innovations require external knowledge outside the organization (Loredo, Lopez-Mielgo, Pineiro-Villaverde, García-Álvarez, 2019). Sustainability is in fact a multidimensional phenomenon. It is often merged with environmental and economic performance and described as a measure of an organization's capability to accomplish its mission and serve its stockholders over a longer period (Zhang, Khan, Lee, Salik, 2019).

The fields of innovation and sustainability have a lot of similarities in their evolution; therefore, the main aspects of both concepts can be combined in a single concept, such as sustainable innovation (Maier, Maier, Aşchilean, Anastasiu, & Gavriş, 2020). Sustainability innovation performance is

related to economic innovation performance enabling organizations to meet their economic and sustainability innovation goals simultaneously (Rauter, Globocnik, Perl-Vorbach, & Baumgartner, 2018). Social innovation should also be mentioned here. It is the type of innovation that is concerned with social mobilization and impact and is increasingly seen as an option to address sustainability challenges (Repo & Matschoss, 2019).

Although quality management and innovation management remain two separate disciplines when it comes to synergies between the two, it is also clear that the two fields share a wide number of common practices and methodologies (Ruiz-Moreno, Tamayo-Torres, & García-Morales, 2015). From the future perspective, it seems that the relationship between quality management system and innovation management will soon reach a new level of mutual acknowledgment because both systems will have a vital role to play in most organizations of the future (Lilja, Hansen, Fredrikson, & Richardsson, 2017).

2.3. Hypothesis development

Quality and innovation are two strategies that complement each other and enable organizations to face aggressive competition and sustain a solid competitive advantage. Although there is a large body of literature dealing with quality and innovation, the relationship between the two strategies has not yet been sufficiently explored, while the available studies do not bring an in-depth answer regarding the issue of the relationship between quality management system practices and innovation (El Manzani, Sidmou, & Cegarra, 2019). However, it should be pointed out that studies do not reject the potential impact of quality management system on the development of innovation. In this context and based on continuous improvement principle, quality management system may have a minor significant short-term impact

on radical product innovation before producing long-term benefits (El Manzani, Sidmou, & Cegarra, 2019).

Quality management facilitates innovation in organizations. There is evidence that companies that apply quality management system and develop organizational innovation get more benefits than companies that do not do so. One of the key elements of quality management system is continuous improvement, which usually causes companies to change, and this change is then reflected in the development of new products, services and processes (Martínez-Costa & Martínez-Lorente, 2008).

Implementation of quality management system creates a productive environment for innovation because it includes principles that are congruent with innovation (Vujović, Jovanović, Krivokapić, Peković, Soković, & Kramar, 2017); what's more, implementation of quality management system and innovation may improve an organization's performance (Martínez-Costa & Martínez-Lorente, 2008). Among the quality management system elements, leadership and employee engagement have a positive impact on innovation in terms of product and process innovation (Urban & Toga, 2017). Moreover, financial indicators only provide an improvement in the financial results of the organization, benefiting innovation strategies related to processes, while non-financial indicators primarily improve operational performance and enable implementation of innovation strategies related to products and processes (Antunes, Quirós, & Justino, 2018).

On the contrary, some studies have shown that a direct correlation between the ISO 9001-certified quality management system and innovation has no significant impact, but that increased implementation of quality management system practices and its certification facilitate the culture of continuous improvement, which provides a good starting point for the development of innovation (Daoud Ben Arab, 2021). As

regards the performance of technical innovations in practice, there are no significant differences between organizations that implement quality management system and those that do not (Ruiz-Moreno, Tamayo-Torres, & García-Morales, 2015). Moreover, there is a weak and even negative relationship between the ISO 9001 quality management system and product innovation (El Manzani, Sidmou, & Cegarra, 2019).

Empirical studies about the link between the ISO 9001 quality management system and innovations present conflicting results. While some empirical studies prove a positive influence of ISO 9001 on innovation, others prove the opposite (Vujović, Jovanović, Krivokapić, Peković, Soković, & Kramar, 2017).

Our main research problem was formulated in view of the fact that the relationship between quality management system and innovation has not been sufficiently explored and in consideration of the findings of the examined studies which present conflicting results. We wanted to find out whether there is a positive correlation between the number of ISO 9001:2015 certificates, the innovation index and the sustainable development goals (SDG) index in 27 EU member states (hereinafter: EU). So, is the quality management system ISO 9001 giving a solid base and offers efficient tools to support innovation processes in the organizations.

Innovation index is an indicator of the ability of an individual country to operate successfully in the field of innovation (Eurostat, 2022). The 2030 Agenda and the Sustainable Development Goals (SDGs) were adopted by all member states of the United Nations in 2015. The SDG index is an indicator of the success of each country in achieving the 17 goals of sustainable development. The maximum possible score or target value of each goal is 100 points. The results achieved both indicate whether the activities carried out by the individual country are effective, and at the same time help to determine priorities for further

improvement (Sustainable Development Report, 2020).

Based on the research problem, the following hypotheses were defined:

Hypothesis 1 (H1): »The number of ISO 9001:2015 certified quality management systems is positively contributing to the Innovation index in the 27 EU member states.«

Hypothesis 2 (H2): »The number of ISO 9001:2015 certified quality management systems is positively contributing to the Sustainable Development Goals or SDG index in the 27 EU member states.«

Since quality management ensures processes that helps developing innovations in organizations (Shi, Lin, Chen, & Su, 2019) and both quality management and innovation processes are based on continuous

improvement philosophy, the interaction between quality management systems and innovation (Camisón & Puig-Denia, 2015), is to be explored. Therefore, these two hypotheses are providing an answer, if higher number of certified quality management systems is a contributing factor to have a higher innovation and SDG index.

At the same time, our study examined a potential correlation between the number of ISO 9001:2015 certificates, the innovation index and the SDG index on one hand, and gross domestic product, business enterprise expenditure on R&D, government support of business R&D index, patent application index and human resources in science & technology index on the other.

Figure 1 illustrates the research model and the set hypotheses.

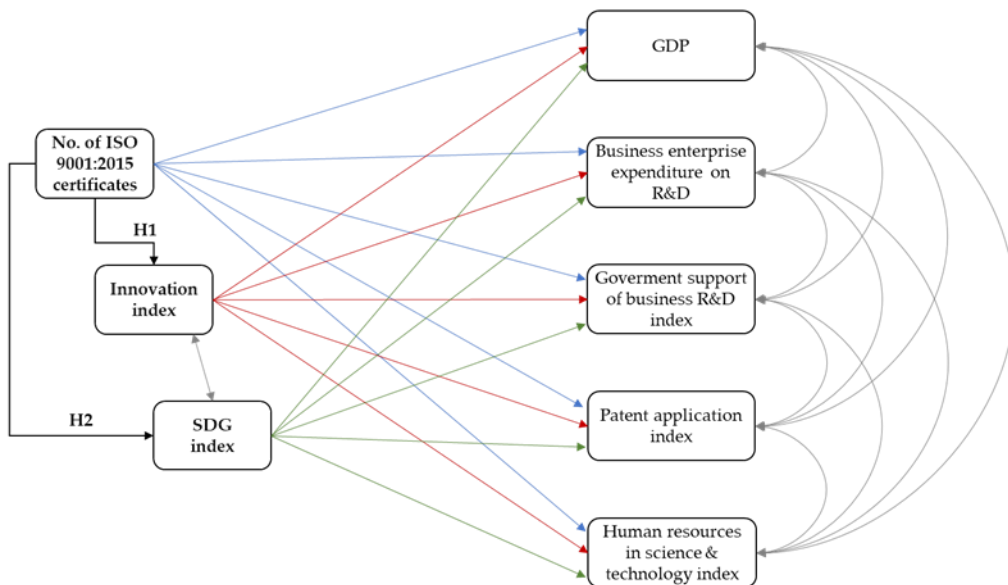


Figure 1. Construction model with set hypothesis.

3. Method

Our research included publicly available data. The empirical analysis was conducted using the data on the number of ISO 9001:2015 certificates in 2020 published by

ISO, the International Organization for Standardization, (ISO Survey 2020, 2022), and data on the SDG index value presented in the Europe Sustainable Development Report 2020 (Sustainable Development Report, 2020). Data on the innovation index, gross domestic product (hereinafter: GDP),

business enterprise expenditure on R&D, government support of business R&D index, patent application index and human resources in science & technology index for 2020 was obtained from the Eurostat statistical office of the European Union (Eurostat, 2022).

Data made publicly available by the EU statistical office, the Sustainable Development Report and the International Organization for Standardization was obtained and calculated with their standard and verified methods. By making the data publicly available, they guarantee their reliability and credibility.

The sample in our research consisted of the following 27 EU member states in 2020: Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

The number and trend of growth of ISO 9001 certificates in EU between 1993 and 2020, the number of certificates by individual EU member states in 2020 and the number of certificates in relation to gross domestic product in 2020 are shown by distribution or bar charts. The oldest data on the number of ISO 9001 certificates, published by ISO, are available for 1993 (ISO Survey 2020, 2022) and that's why our research starts with this year.

The correlation between individual factors considered and the degree of interaction between them were analyzed using the Spearman's rank correlation coefficient r_s . Statistical processing of numerical data used in the analysis was done by means of the Minitab software.

4. Results

4.1. EU member states and ISO 9001

The number of ISO 9001 certificates in EU member states between 1993 and 2020 is shown in Figure 2.

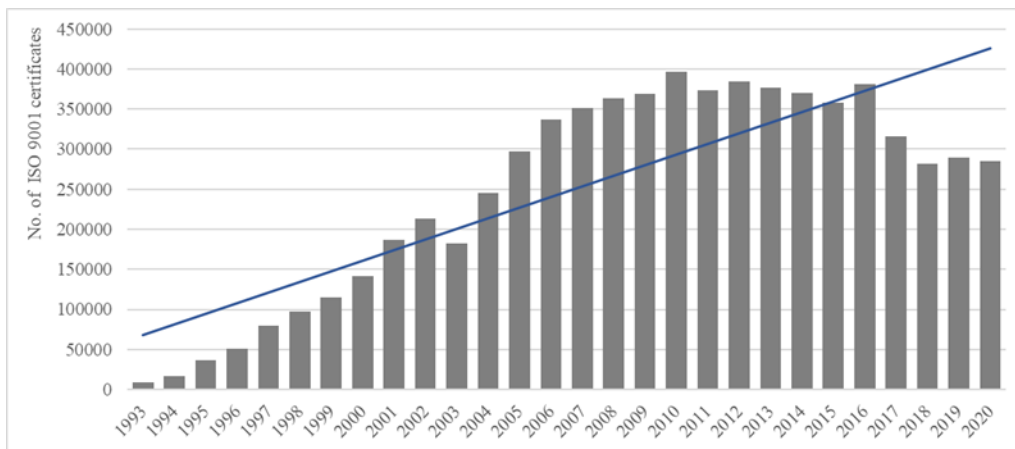


Figure 2. The number of ISO 9001-certified organizations in EU between 1993 and 2020.

There was a constant increase in the number of issued ISO 9001 certificates in the period between 1993 and 2002. In 2003, there was a minor decline, followed by another increase in the number of certificates until 2010.

Following a minor stagnation, the number of issued certificates grew in 2016. In 2017, there was a drop in the number of certificates. From 2018 to 2020, there was a steady number of issued ISO 9001

certificates. The blue line in the chart in Figure 2 illustrates a positive trend in the number of ISO 9001 certificates in EU.

In 2020, there were 285,230 organizations in EU member states that held the quality management system ISO 9001: 2015

certificate (ISO Survey 2020, 2022). The number of ISO 9001-certified organizations by individual EU member states is shown in Figure 3.

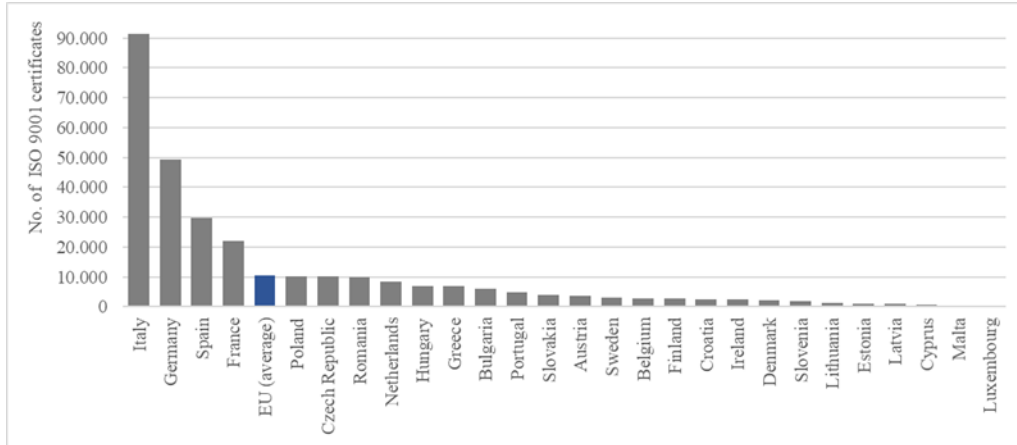


Figure 3. The number of ISO 9001-certified organizations in EU member states in 2020.

The greatest number of ISO 9001:2015 certificates in 2020 was held by Italian organizations, followed by those from Germany, Spain and France.

The number of ISO 9001:2015 certificates by EU member states (see Figure 3) is shown regardless of their GDP, which differs

between countries. To make the representation of the number of ISO 9001:2015 certificates more realistic, a common denominator was used, i.e. one billion EUR of GDP. Using this criterion, the number of ISO 9001:2015 certificates in EU member states is illustrated in Figure 4.

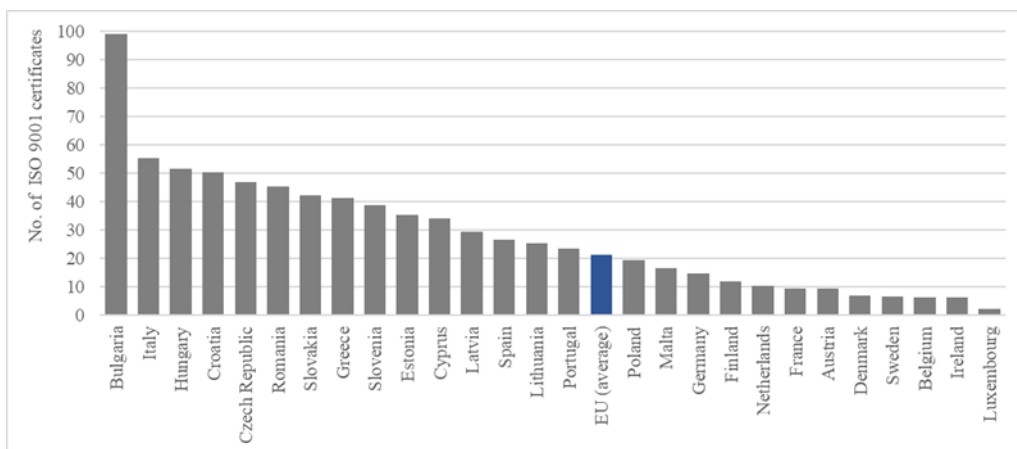


Figure 4. The number of ISO 9001-certified organizations per 1 billion EUR of GDP in EU member states in 2020.

Considering this same criterion, i.e. one billion EUR of GDP, the greatest number of certified organizations was found in Bulgaria, followed by Italy, Hungary, Croatia and the Czech Republic.

4.2. Correlation study between discussed factors

The impact of the number of ISO 9001:2015 certificates in EU member states on the innovation index and the SDG index explored in the hypotheses, the interaction

between them and other selected innovation indicators, as well as the interaction between other innovation indicators were analyzed using the Spearman's rank correlation coefficient »r_s«. Our research included a survey of 27 EU member states (N = 27). With regard to the sample size in our research, the confidence level of 95% and significance level α at 0.05, the critical value of the Spearman's rank correlation coefficient »r_s« was at **0.382**. This critical value was taken into consideration in the study of correlations illustrated in Table 1.

Table 1. The Spearman's coefficient values for correlation between number of certificates ISO 9001 and chosen factors.

	No. of ISO 9001:2015 certificates	Innovation index	SDG index	GDP	Business enterprise expenditure on R&D	Gov. support of business R&D index	Patent application index
Innovation index	r _s = - 0.137 p < 0.494						
SDG index	r _s = 0.118 p < 0.556	r _s = 0.638 p < 0.001					
GDP	r _s = 0.769 p < 0.001	r _s = 0.415 p < 0.031	r _s = 0.453 p < 0.018				
Business enterprise expenditure on R&D	r _s = 0.635 p < 0.001	r _s = 0.608 p < 0.001	r _s = 0.657 p < 0.001	r _s = 0.912 p < 0.001			
Gov. support of business R&D index	r _s = 0.433 p < 0.024	r _s = 0.502 p < 0.008	r _s = 0.520 p < 0.005	r _s = 0.661 p < 0.001	r _s = 0.734 p < 0.001		
Patent application index	r _s = 0.054 p < 0.788	r _s = 0.912 p < 0.001	r _s = 0.740 p < 0.001	r _s = 0.536 p < 0.004	r _s = 0.707 p < 0.001	r _s = 0.603 p < 0.001	
Human resources in science & technology index	r _s = - 0.203 p < 0.309	r _s = 0.855 p < 0.001	r _s = 0.744 p < 0.001	r _s = 0.317 p < 0.107	r _s = 0.491 p < 0.009	r _s = 0.473 p < 0.013	r _s = 0.820 p < 0.001

Since the value of the Spearman's rank correlation coefficient between the number of ISO 9001:2015 certificates and the innovation index is at - 0.137, it was discovered that there is a very weak negative

correlation between the two factors.

The Spearman's rank correlation coefficient between the number of ISO 9001:2015 certificates and the SDG index is at 0.118,

indicating a very weak positive correlation between the two.

On the contrary, the correlation between the innovation index and the SDG index is strong, whereby the calculated value of the Spearman’s rank correlation coefficient is at 0.638.

In addition to the already discussed correlations, we also examined correlations

between the number of ISO 9001:2015 certificates, the innovation index and the SDG index on one hand, and GDP, business enterprise expenditure on R&D, government support of business R&D index, patent application index and human resources in science & technology index on the other. Correlations between the listed factors are illustrated in Figure 5.

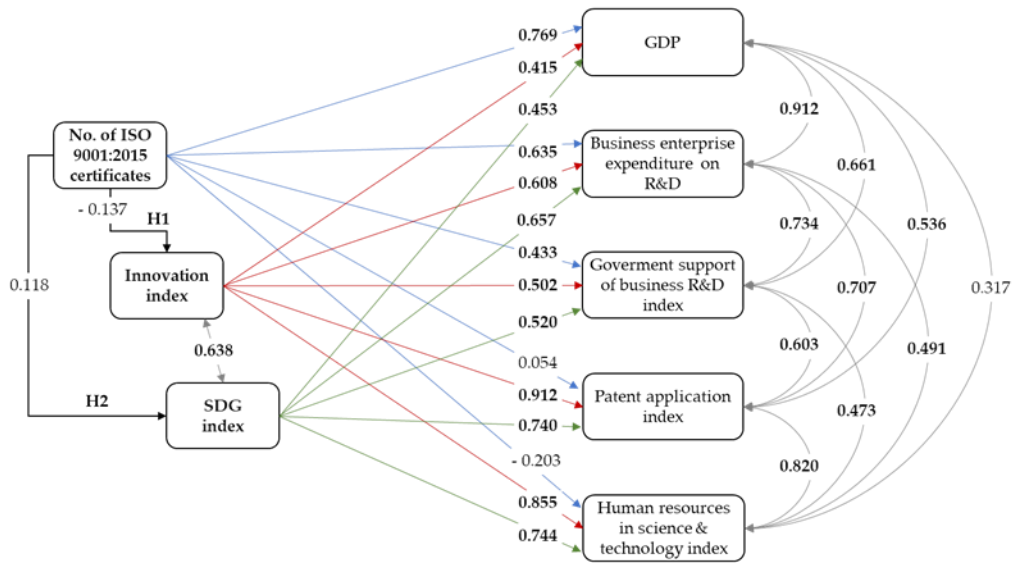


Figure 5. Structural model of correlations between discussed factors.

5. Discussion

The number of certificated organizations had been constantly increasing from 1993 until 2002, followed by a 14-percent decline in 2003 and then with a noticeable upward trend until 2010. From 2010 to 2015, the number of certified organizations slightly stagnated, while in 2016, there was another increase in the number of organizations with a certified quality management system. In 2017, there was a 17-percent drop in the number of certificates, resulting from a change in the method of recording the issued certificates in Italy. Thus, the recorded number of ISO 9001 certificates in 2016 in Italy was 150,143; in 2017, the number dropped to 97,646 (ISO Survey 2020, 2022).

Between 2018 and 2020, the number of certificates was rather steady. It seems that the decline of the number of ISO 9001-certified organizations stopped. However, when compared with 2010 when there was a record number of organizations with the ISO 9001-certified quality management system, the share of such companies in 2020 dropped by 28%. This is something that should not be overlooked. The decrease could also be attributed to the saturation effect resulting from the process of certification as the distinguishing factor. When the number of certified organizations reaches a certain limit, certification loses its connotation and becomes less attractive for the remaining non-certified companies (Sampaio, Saraiva, & Guimarães, 2011). Moreover,

organizations are deciding to withdraw from ISO 9001. The most important reasons for decertification are financial problems within the organizations, a perceived lack of added value from certification, high certifications costs, and organizational changes, such as internal restructuring (Simon & Kafel, 2018). Nevertheless, the trend in the growth of the number of ISO 9001 certificates between 1993 and 2002 was positive. Simon and Kafel (2018) also find that there has been a huge growth in the implementation of management systems and the corresponding certification of standards in the management arena in the past few decades.

The country with the highest number of issued ISO 9001:2015 certificates in 2020 was Italy (91,493 certificates), followed by Germany (49,139), Spain (29,814) and France (21,880) (Figure 3). The EU average number of organizations with ISO 9001:2015 certificates in 2020 was 10,564. The remaining 23 EU member states were below the EU average.

EU member states vary in size and economic indicators; therefore, a comparison of absolute numbers of ISO 9001 certificates in individual countries (Figure 3) is not the most optimal. The comparison was thus made in view of the number of certificates issued per GDP in individual countries. Rodriguez-Arnaldo and Martínez-Lorente (2020) claim that economic development is the ability of countries to create wealth in order to promote or maintain the prosperity and economic and social wellbeing of all their inhabitants. There are many economic indicators, but the most commonly used one is gross domestic product (GDP). The authors further claim that economic development could have significant influence on the level of the ISO 9001 quality management system implementation, since the greater is the development, the higher is the number of enterprises and therefore potentially more certifications. They also point out that organizations in poorer countries tend to be more interested in the ISO 9001 quality management system

certification. It can be said that the positive relationship between economic development and ISO 9001 implementation is valid for countries with low GDP, while for countries with high GDP the relationship is reversed.

Comparison of the number of ISO 9001 certificates in view of GDP of an EU member state showed that the greatest number of ISO 9001:2015-certified organizations was in Bulgaria (99 certificates per 1 billion EUR of GDP), followed by Italy (55), Hungary (51), Croatia (50), and the Czech Republic (47 certificates) (Figure 4). In 2020, the EU average number of organizations with ISO 9001:2015 certificates per 1 billion EUR of GDP was 21. 15 EU member states were above the average, while the remaining 12 were below it.

For every factor examined in our study, we wanted to discover in which country the values of a specific factor were at the maximum and minimum level in 2020. Moreover, Table 2 also shows the average EU value of a specific factor.

Table 2 illustrates that there are significant differences between countries with minimum levels of individual values and indexes.

The two hypotheses formulated in our research (see Chapter 2.3) were examined on the basis of the calculated Spearman's rank correlation coefficients (Table 1, Figure 5).

Hypothesis 1 (H1): »The number of ISO 9001:2015 certified quality management systems is positively contributing to the innovation index in 27 EU member states.«

The calculated Spearman's rank correlation coefficient between the number of ISO 9001:2015 certificates and the innovation index in EU member states in 2020 ($r_s = -0.137$) indicates a very weak negative correlation between these two discussed factors (Table 1, Figure 5), as it is below the critical value of 0.382. Vujović, Jovanović, Krivokapić, Peković, Soković, & Kramar (2017) claim that empirical studies about the link between the ISO 9001 quality management system and innovations present

conflicting results. While some empirical studies prove a positive influence of ISO 9001 on innovation, others prove the opposite. Rodriguez-Arnaldo and Martínez-Lorente (2020), for example, state that the most innovative countries use the ISO 9001 standard more, because, according to Damic, Naletina, and Buntic (2021), a higher level of the ISO 9001 quality management system implementation positively affects the organizational innovativeness. Aldabbas, Pinnington, and Lahrech (2020) point out that there is a significant positive relationship between the ISO 9001 quality management system and innovation.

In contrast, Camisón and Puig-Denia (2015) found in their study that the implementation level of the ISO 9001 quality management system is not directly related to organizational innovation performance. Daoud Ben Arab (2021) agrees, stating that a direct correlation between the ISO 9001-certified quality management system and innovation has no significant impact or that the impact is rather negligible. Our findings are in compliance with the last two mentioned authors. On the basis of our calculations, Hypothesis 1 was therefore rejected.

Table 2. Maximum and minimum values of chosen factors and average for EU.

	Max value	Min value	EU average
No. of ISO 9001:2015 certificates	Italy 91,493	Luxembourg 157	10,564
Innovation index	Sweden 148.07	Romania 33.14	101.26
SDG index	Finland 81.10	Romania 58.31	69.35
GDP [in million €]	Germany 3,367,560	Malta 13,060	496,285
Business enterprise expenditure on R&D [in million €]	Germany 71,032	Malta 56	7,674
Government support of business R&D index	France 213.38	Cyprus 2.66	72.08
Patent application index	Sweden 225.24	Romania 6.93	71.09
Human resources in science & technology index	Luxembourg 54.8	Romania 20.9	34.4

Hypothesis 2 (H2): »The number of ISO 9001:2015 certified quality management systems is positively contributing to the sustainable development goals or SDG index in 27 EU member states.«

As regards Hypothesis 2, the calculated Spearman’s rank correlation coefficient (0.118) is below the critical value of 0.382. It was therefore concluded that there is a very weak positive correlation between the number of ISO 9001:2015 certificates and the SDG index.

Sustainability indicators were defined to measure the sustainability development progress and thus facilitate decision-making

processes. These indicators combine national information about the three dimensions of sustainability that are essential for a long-term comparison of performance between different countries. Thus, the 17 sustainable development goals are related to social, economic and environmental issues (Diaz-Sarachaga, Jato-Espino, & Castro-Fresno, 2018). Although Aldabbas, Pinnington, and Lahrech (2020) claim that governments in numerous developed and developing economies promote innovation to achieve economic growth, we rejected our Hypothesis 2 based on the calculated Spearman’s rank correlation coefficient.

The Spearman's rank correlation coefficient was not only calculated to test the hypotheses but also to establish whether there is a correlation between the innovation index and the SDG index. In view of the value of the correlation coefficient, which was at 0.638, it was established that there is a strong correlation between the two factors.

Moreover, the Spearman's rank correlation coefficient was also calculated to find out if there is a correlation between the number of ISO 9001:2015 certificates, the innovation index and the SDG index on one hand, and GDP, business enterprise expenditure on R&D, government support of business R&D index, patent application index and human resources in science & technology index on the other. Mutual correlations between the five listed factors were also explored and are shown in Table 1 and Figure 5.

6. Conclusion

Drawing on the analysis of the quantity of quality management systems certified according to ISO 9001 in 27 EU member states, there were 285,230 ISO 9001:2015-certified organizations in EU member states in 2020 (Figure 3). In absolute numbers of certificates, Italy was in the first place, followed by Germany, Spain and France. On the other hand, the country with the highest number of ISO 9001:2015 certificates per one billion EUR of GDP was Bulgaria, followed by Italy, Hungary, Croatia and the Czech Republic (Figure 4).

ISO 9001:2015 quality management system serves as a foundation for gaining a competitive advantage in terms of innovation (Zeng, Anh Phan, & Matsui, 2015) and provides an optimum environment for the development of innovations in a company (Martínez-Costa & Martínez-Lorente, 2008). One of the key principles of ISO 9001:2015 is continuous improvement (Damic, Naletina, & Buntic, 2021), which, however, encourages incremental innovation but hinders radical innovation (Aldabbas,

Pinnington, & Lahrech, 2020). It should be pointed out that the better the integration of quality management system, the higher is the rate of integration of the innovation process and, consequently, also the innovation performance (Bernardo, 2014). Although certification of organizations according to ISO 9001:2015 is useful for the adoption of quality management system principles and culture of continuous improvement, it does not have any direct impact on innovation (Daoud Ben Arab, 2021). Establishment of a quality management system does not only create an environment for an organization's effective innovative development, but it represents a separate organizational innovation that can facilitate organizational changes and innovation (Troshkova & Levshina, 2016). Innovation is namely a multidimensional concept extending in many ways beyond producing new products and providing new services (Aldabbas, Pinnington, & Lahrech, 2020). From the future perspective, it seems that the relationship between quality management system and innovation management will soon reach a new level of mutual acknowledgment (Lilja, Hansen, Fredrikson, & Richardsson, 2017).

Based on the calculated Spearman's rank correlation coefficient »r_s« (Table 1, Figure 5) in our research, both suggested hypotheses were rejected. It was established that there was a very weak negative correlation between the number of ISO 9001:2015 certificates and the innovation index in 27 EU member states in 2020, while there was a very weak positive correlation between the number of ISO 9001:2015 certificates and the SDG index.

Damic, Naletina, and Buntic (2021) conclude that the relationship between the ISO 9001 quality management system and organizational innovativeness is still ambiguous. Vujović, Jovanović, Krivokapić, Peković, Soković, and Kramar (2017) find that some results of empirical studies regarding interactions between the ISO 9001 quality management system and innovation

prove a positive influence of ISO 9001 on innovation, while others prove a negative one or say that there is no correlation between the two. Based on their own research, authors establish that there is a positive relationship between ISO 9001 certification and innovation performance, with which Aldabbas, Pinnington, and Lahrech (2020) also agree; however, El Manzani, Sidmou, and Cegarra (2019) claim that there is no significant relationship between quality management system practices and incremental or radical product innovation, or rather that quality management system has no direct impact on innovation performance. In compliance therewith, Camisón and Puig-Denia (2015) find in their study that the level of integration of the ISO 9001 quality management system is not directly related to innovation performance, while Daoud Ben Arab (2021) establishes that the interaction between quality management system and innovation is not significant.

Notwithstanding the arguments of the above mentioned authors who claim that the ISO 9001 quality management system has a positive, negative or no impact on innovation, and regardless of the claims of Manders, de Vries, and Blind (2016) that the impact of quality management system on innovation is in general still not clear, the finding of our research is that the number of ISO 9001:2015 certificates in 2020 in 27 EU member states does not have any positive impact on the innovation index. Neither does it affect the SDG index.

Considering the set of factors discussed and especially the study of the impact of the number of quality management system certificates on the innovation and the SDG index in 27 EU member states, we believe that our research is unique in this field.

The results of our research provide information on the number of issued certificates for the ISO 9001 quality management system by individual EU member states and for EU as a whole. This

data is available to organizations, and what is more important, organizations can see that the trend in the growth of the number of awarded ISO 9001 certificates is still positive. This piece of information could stimulate non-certified organizations to obtain certification. It should not be overlooked that the continuous improvement principle being one of the seven principles of the ISO 9001 quality management system lays the foundation and stimulates organizations to work towards innovation. However, the finding that the number of issued certificates for the ISO 9001 quality management system does not have a positive impact on innovation may be a signal for organizations that wish to increase their innovation and thus also their competitive advantage to implement in their operations other systems and tools that are known to directly facilitate and increase innovation.

Based on our findings, national governments can examine the effectiveness of their mechanisms aimed at increasing innovation, and by considering the examined factors (Table 1) they can also allocate the designated resources more effectively.

The research was narrowed down to 27 EU member states, while the set hypotheses were tested using the latest publicly available data on the number of issued ISO 9001 certificates in 2020 (ISO Survey 2020, 2022) and other discussed factors (Table 1).

The methodology of our research enables the research to be conducted in any EU member state, whereby it should involve the factors or innovation indexes specific to that country. Thus, national governments can examine the effectiveness of their mechanisms aimed at increasing innovation.

It would also make sense to conduct reverse research to determine which systems and tools are used by organization in their innovation processes. These results would generate a list of effective systems and tools that could be used by organizations still struggling to implement effective innovation processes.

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