REGULATION OF PRODUCT CERTIFICATION AND STANDARDIZATION PROCESSES IN THE EUROPEAN UNION

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Abstract. Research is aimed at investigation of current state of technical regulation system in European Union. Special attention is paid to peculiarities of standardization and certification in certain countries of EU in order to implement foreign experience in Ukraine. Despite the wide academic coverage of technical regulation issue, a range of issues remain unsolved, especially the problem of historical retrospective and possibility of positive experience implementation. *Subject of study.* Theoretical and methodological approaches to the regulation of certification and standardization of processes in the EU, as well as comparative analysis of the systems in the past and the present. *Methodology.* The survey is based on research of available publications on the topic, comparative analysis, induction and deduction. Issues of standardization and certification were widely discovered by numerous researchers: F.D. Duyvis (1960), W. Hesser and A. Inklaar (1998), C. Shapiro (1999), A. Richen and A. Steinhorst (2005). But in spite of the deep theoretical background of scientific works, it is obvious that the most important documents for technical regulations are ISO standards (especially ISO/IEC 17021:2006 «Conformity assessment – Requirements for bodies providing audit and certification of management systems»). *Results.* The article discovers relationship between main standardization bodies in EU, studies main legislative documents, reveals its historical retrospective and provides in-depth study of technical regulation system in Germany and the UK. Information from the article can be used for general understanding of main processes of technical regulation in EU; practical discovery of marking signs on the products and comparative analysis of standardization systems in different countries. *Practical implications.* It is important to mention practical demonstration of technical requirements in the EU: the signs marking Certificate IN, Certificate VS, Certificate ONORM, Certificate LVS, which mean compliance with national standards of the community. For example, Certificate DIN means compliance with the German Standards Institute (Deutsches Institut für Normung), Certificate BS – requirements for producers in the UK, Certificate ONORM – sign labeling in Austria and Certificate LVS has French origins. *Value/originality.* The study provides complex overview of product certification and standardization processes in the European Union, taking into account legislative basis and executive authorities on the European as well as on the local markets.

Key words: standardization and compatibility, technical requirements, international trade policy.

JEL Classification: L15, D63, F13

1. Introduction

At the present stage of economic development efficiency of production depends mainly on the implementation of standards. States with well-developed technical regulation system have the appropriate level of competitiveness on the world market. According to the European Committee for Standardization, all products produced at the enterprises of the EU (regardless of the size of enterprises) meet the standards. Such policy ensures free trade policies in the EU and protects consumers.

2. Certification and standardization in the EU

Currently, the processes of standardization and certification in the European Union are governed in accordance with international requirements of ISO (International Organization for Standardization). It should be noted that ISO influence is extended to all areas of economic activity, except for electronics and electrical engineering. Regulation of electronics and electrical engineering is entrusted to the International Electrotechnical Commission (IEC – International Electrotechnical Commission).

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As it is mentioned in ISO/IEC 17021:2006 «Conformity assessment – Requirements for bodies providing audit and certification of management systems», the overall aim of standardization is declared as "an assurance to all stakeholders that the management system meets specific requirements. The value of certification is reflected in the degree of public trust and confidence, which are provided by an impartial and competent assessment by a third party".
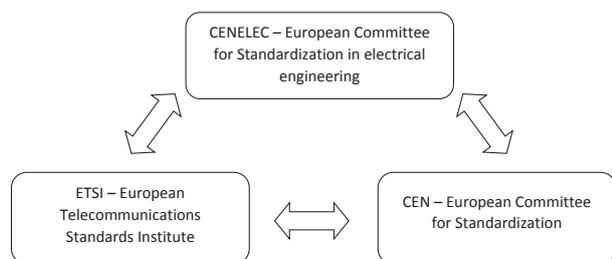
Fig. 1. Major standardization bodies in The European Union

Source: developed by author

The European Committee for Standardization was established in March 1961, although in fact it began the development of standards only in 1970. Currently, CEN members are all Member States of the European Union, three are the members of the European Free Trade Association (Iceland, Norway and Switzerland are assigned to the Central Secretariat – scientific and technical non-profit organization based in Brussels).

European Committee for Standardization in electrical engineering, which was established in 1972, is not an institution of the European Union, although it is directly involved in the formation of the technical adjustment for EU Member States. Under Belgian law The Committee is a nonprofit organization headquartered in Brussels. Members of the European Committee for Standardization in electrical engineering are the national standards bodies of electrical products in European countries.

The European Telecommunications Standards Institute, formed in 1988, bases its activities in the technological park of Sophia Antipolis, France. Each year European Telecommunications Standards Institute publishes two thousand European standards for information and communication technologies (ICT), including fixed, mobile, radio communication and Internet technologies.

3. Principles of standardization and certification

An important aspect of the study of standardization and certification are the principles of their implementation in EU member states.

The analysis allows establishing the basic principle of certification and standardization for the European Union – liberalization of relations concerning certification and standardization. We mean the fact that the product

which has all necessary documents valid on the territory of one country of the community can be implemented in other EU countries.

In our opinion, the second essential principle of certification and standardization of products in the EU is harmonization of technical regulation procedures. The essence of harmonization is to create single unified product requirements affecting the health and safety of humans and the environment. Features of harmonization are being discussed in detail by the EU Directives, approved by the EU Commission.

For instance, Directive 98/34 / EU «Laying down a procedure for the provision of information in the field of technical standards and regulations» regulates the exchange of information on technical regulations between Member States; Directive № 2001/95 / EU "On general product safety" declares the purpose and means of placing safe products on the market. Responsibility for the harmonization of standards is entrusted to CEN and CENELEC as well as implementation of standards at the national level is done by certification authorities of each of Member State.

In the above-mentioned ISO 17021:2006 certification and standardization principles underlying the activities of technical regulation in the European Union are classified in a different way.
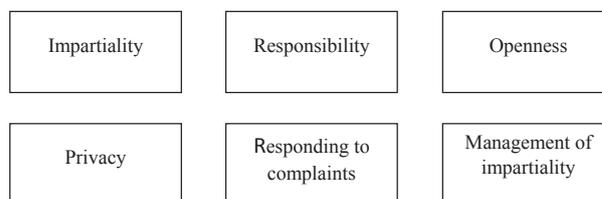
Fig. 2. Principles of certification and standardization in The European Union

Source: developed by author
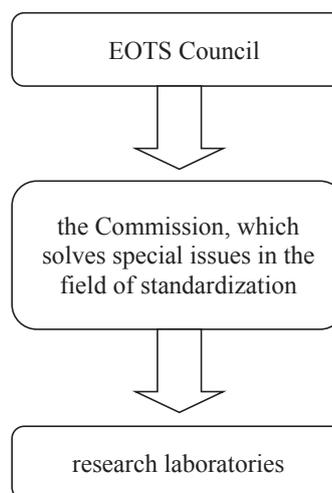
Fig. 3. Structure of The European Organization for Testing and Certification

Source: developed by author

For the successful implementation of its duties certification bodies in each country must be accredited (accreditation means formal recognition of competence to perform relevant types of certification).

According to Global concept for certification and testing of industrial products, adopted in 1989, certification bodies and research laboratories that are accredited in one of the countries automatically receive accreditation for all countries of the European Community. The only requirement is timely notification of EU Commission's authority.

Undoubtedly, there is a clear need for coordination and control over the activities of certification at European level. These functions are performed by the European Organization for Testing and Certification (EOTC), which was established by the EU Commission, the Secretariat of the European Free Trade Area (EFTA) and the European Committee for Standardization (CEN, CENELEC).

4. Local technical regulation systems

In our opinion, Germany can be accepted as a country with the most prominent example of successful organization of the national standardization system. Since January 2010 there is a single national accreditation body DAkkS (Deutsche Akkreditierungs Stelle GmbH). So, all certification bodies and testing laboratories are tested in this institution, with the possibility of getting comprehensive information on the desired subject.

The system of technical regulation of products in the UK is very similar to the German and is considered as one of the oldest in Europe. The main body for certification and standardization is the British Organization for Standardization, which was established back in 1910. As s part of Organization operates Testing center for serial production and Quality Assurance Council, which is responsible for certification and labeling. Undoubtedly, British standards organization represents the country in ISO, CEN and CENELEC.

In fact, accession to the European Union means accepting the rules of technical regulation and providing a representative (usually the national authority certification and standardization) to the three main EU standardization bodies: CEN (European Committee for Standardization); CENELEC (European Committee for Standardization in electrical engineering) and ETSI (European Telecommunications Standards Institute).

An important feature of standardization and certification of products in the EU is sequence of reforms and transformations. According to the resolution of the European Council from 21 December 1989 law dynamics in the chosen field depends on the development of individual modules for each stage of the assessment. In other words, this provision makes it impossible to develop the legal framework for technical regulation without considering each element of the system in practice.

5. Conclusions

Summarizing the above information, we can conclude the existence of a powerful system of technical regulation in the EU, which ensures high quality of products (thus defending the interests of consumers), facilitates the exchange of information between manufacturers in Europe and is able to dynamically respond to changing needs of the international market. Consequently, the successful implementation of certification and standardization of industrial products in the EU for a long period indicates the feasibility of the relevant case law in Ukraine.

References

Clayton, C., Michael, R. (2003). The Innovator's Solution: Creating and Sustaining Successful Growth, Boston: Harvard Business School Press.

Different types of ETSI standards. – Retrieved from: www.etsi.org

Duyvis, F.D. (1960). Standardization as a Tool of Scientific Management. – Retrieved from: https://www.ideals.illinois.edu/bitstream/handle/2142/5530/librarytrendsv2i3g_opt.pdf?sequence=1

Hesser, W., Inklaar, A. (1998). An Introduction to Standarts And Standartization, Beuth Verlag GmbH.

List of CEN Members. – Retrieved from: // www.cen.eu/go/members/

RAPEX alert system. – Retrieved from: ec.europa.eu

Richen, A., Steinhorst, A. (2005). Standardization or Harmonization, BPTrends.

Shapiro Carl (1999). Information Rules: A Strategic Guide to the Network Economy, Boston: Harvard Business School Press.

Людмила ШАБЕЛЬНИК

РЕГУЛИРОВАНИЕ ПРОЦЕССОВ СЕРТИФИКАЦИИ И СТАНДАРТИЗАЦИИ ПРОДУКЦИИ В СТРАНАХ ЕВРОПЕЙСКОГО СОЮЗА

Аннотация. Исследование направлено на изучение текущего состояния системы технического регулирования в Европейском Союзе. Особое внимание уделяется особенностям стандартизации и сертификации в некоторых странах ЕС в целях реализации зарубежного опыта в Украине. Несмотря на широкий охват исследования проблемы технического регулирования, ряд вопросов остаются нерешенными, особенно проблема

исторической ретроспективы и возможности реализации положительного опыта. Предмет исследования. Теоретические и методологические подходы к регулированию сертификации и стандартизации процессов в ЕС, а также сравнительный анализ систем в прошлом и настоящем. *Методология*. Работа основана на исследовании имеющихся публикаций по теме, сравнительном анализе, индукции и дедукции. Проблемы стандартизации и сертификации были досконально изучены многочисленными исследователями: F.D. Duyvis (1960), W. Hesser и A. Inklaar (1998), C. Shapiro (1999), A. Richen и A. Steinhorst (2005). Но, несмотря на глубокие теоретические основы научных работ очевидно, что наиболее важными документами в области технического регулирования являются стандарты ISO (в частности, ISO / IEC 17021: 2006 «Оценка соответствия – Требования к органам, проводящим аудит и сертификацию систем менеджмента»). *Результаты*. В статье обнаруживается взаимосвязь между основными органами по стандартизации в ЕС, изучаются основные законодательные документы, раскрывается историческая ретроспектива и обеспечивается углубленное изучение системы технического регулирования в Германии и Великобритании. Информация из статьи может быть использована для общего понимания основных процессов технического регулирования в ЕС; практического исследования маркировочных знаков на продуктах и сравнительного анализа систем стандартизации в разных странах. *Практическое значение*. Важно отметить практическую демонстрацию технических требований в ЕС: знаки маркировки Сертификат IN, Сертификат VS, Сертификат ONORM, Сертификат LVS означают соответствие национальным стандартам сообщества. Например, сертификат DIN означает соблюдение требований Института стандартов Германии (Deutsches Institut für Normung), сертификат BS – требований для производителей в Великобритании, сертификат ÖNORM – знак маркировки в Австрии, сертификат LVS имеет французские корни. *Значение/оригинальность*. В исследовании содержится комплексный обзор по процессам сертификации и и стандартизации продукции в Европейском Союзе, с учетом законодательной базы и исполнительной власти на как на общеевропейском, так и на местных рынках.