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STRUCTURE AND FUNCTIONING OF THE EUROPEAN CONFORMITY ASSESSMENT SYSTEM OF PRODUCTS

8.1 INTRODUCTION

The Union is a term for a community, a community of people which is focused on a common goal, ideas, and interests. The European Union is based on 4 fundamental principles. One of them is the principle of free movement of goods and services, reflected in the liquidation of traditional customs controls between the countries of the community. No customs controls cause a complete lack of control over the "imported" products. In the case of some products being potentially dangerous, they could pose a threat to the health and life of citizens of the community. Therefore, it was necessary to develop a single solution – the conformity assessment system. This system consists of many elements constituting its structure. The European authorities and institutions, national authorities and institutions, credible assessment bodies as well as producers. This system is regulated by a number of laws, regulations, standards, and its abundance causes difficulties in navigating this complex structure. The aim of the article is to describe in an accessible, cross-sectional, and also consistent manner the currently functioning European conformity assessment system products. Consistency description of the system was achieved through a common description of these institutions at European and national level – in Poland. In particular, polish entrepreneurs so that they can develop better understanding of the current rules for the European conformity assessment system, including the principle of marking (CE) devices, which are part of the rules of that system.

8.2 ORIGINS OF THE EUROPEAN CONFORMITY ASSESSMENT SYSTEM

Name of the European Union was introduced in 1993, under the Treaty on European Union. Earlier, by means of expansion and developing of the concept of cooperation has repeatedly changed its name and structure. The beginning of the emergence of the EU dates back to the year 1952, when the European Coal and Steel Community was formed. The EU now has 28 full members. One of the fundamental aims of European integration was the creation of a single European market for goods and services and the gradual establishment of a common economic policy.

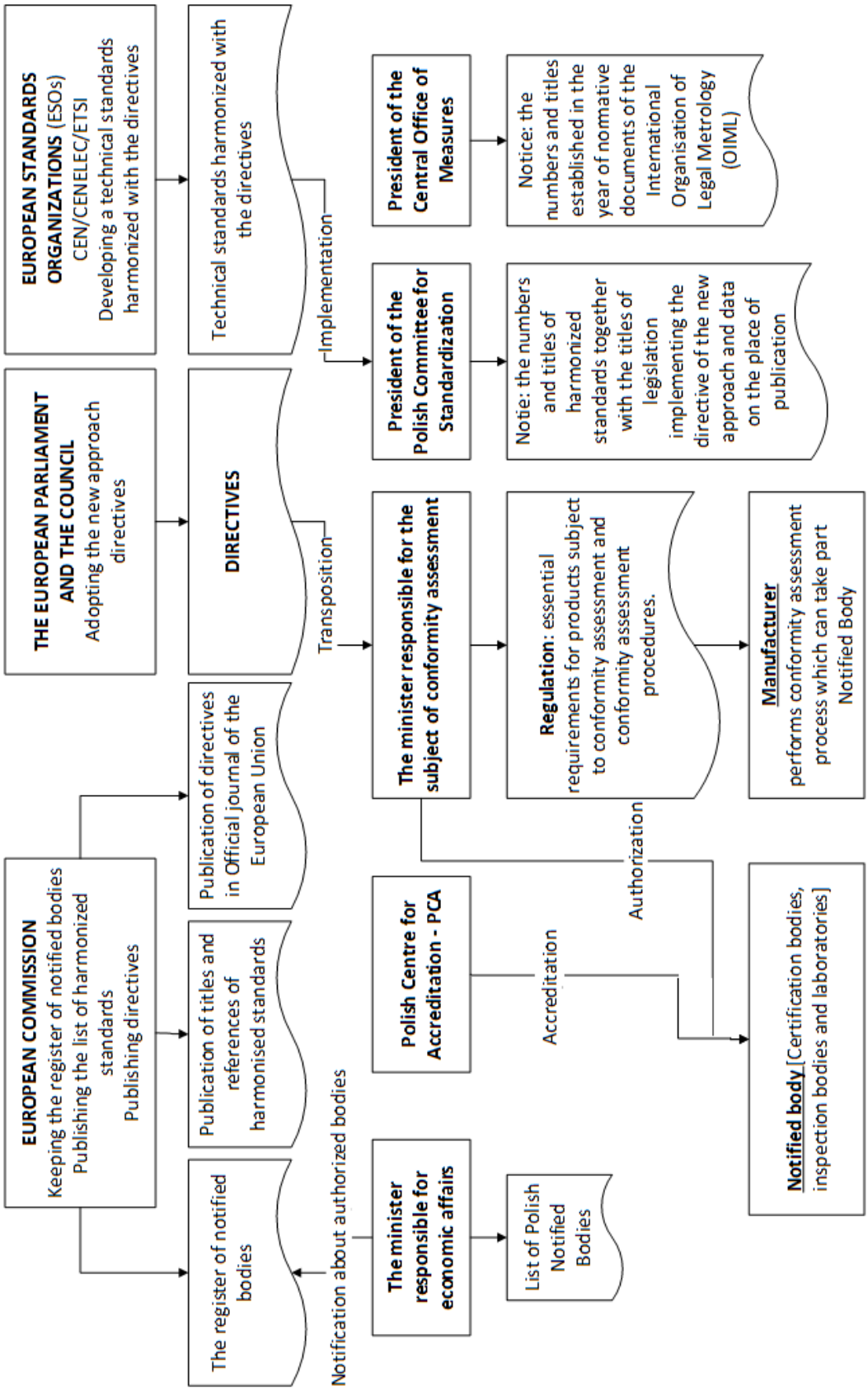

Fig 8.1 Model of The European Conformity Assessment System of Products

Source: Own elaboration

The basic condition for, and also the problem of economic integration, has become part of the community aiming to remove the technical barriers that prevented, or hindered the free movement of goods. It is not difficult to imagine how both technical development of products, their amount, type, combined with various technical norms and standards in individual countries limited the free movement of goods between the countries concerned. In order to establish an uniform technical standards for many products in all EU countries posed as a real challenge for the authorities of the community.

Harmonization of laws in the European Union so approximation of laws, has become the most basic method of removal of technical barriers. For this purpose, the directives addressed to the authorities of the Member States were forwarded. The directive is an act of European Union law, under which the legislator Union Member States are obliged to introduce specific legislation, aimed at achieving the desired state of affairs specified in the directive. However, the directive leaves member states a considerable flexibility during the implementation into national law ie. Transpose.

Up until 1985 the law harmonization process has been named "the Old Approach to standardization". Old Approach Directives contain concrete products, and applied only to them, as they described the requirements for technical compatibility. The advantage of such a solution was the ease to identify the product and to assess compliance. The main drawback of this solution was slow course of the enactment and amendment of this type of specific directives. As a result, such solutions remained difficult to research and develop, and as a result have become an obstacle to technological progress. It was necessary to introduce a new solution, which was named – the New Approach. The illustrative model of structures and relations based on the New Approach are contained in Fig. 8.1.

8.3 THE EUROPEAN CONFORMITY ASSESSMENT SYSTEM OF PRODUCTS – THE EUROPEAN LEVEL

The New Approach to standardization is also based on the directives. New Approach directives were developed and implemented in the European Union, following a European Council resolution of 7 May 1985, initially called the New Approach to technical harmonization and standards [2], [8]. The New Approach has introduced the following principles [6]:

- legal harmonization is limited to essential safety requirements (or other requirements of a social nature) which need to be met by products marketed and covered in connection with the free movement within the European Union.
- the development of technical specifications of production is entrusted to competent institutions in the field of industrial standards that take into account the state of technology,
- technical specifications are not mandatory, they retain their status of voluntary standards,

- authorities are obliged to grant presumptions of conformity to products prepared according to harmonized standards with the essential requirements laid down by the directive, if the manufacturer does not produce according to these standards, it is obliged to comply with the essential requirements of products.

The illustrative model of structures and relations of the European level of the ECASP are contained in Fig. 8.2.

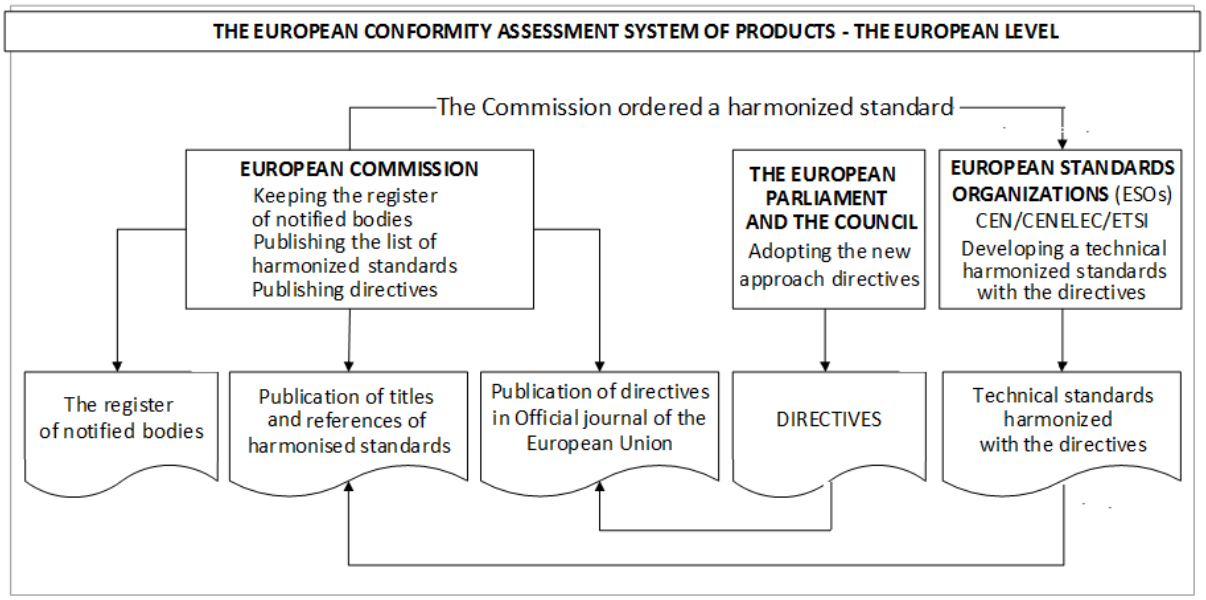

Fig 8.2 Model of the European conformity assessment system of products - the European Level

Source: Own elaboration

8.4 THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION

New Approach directives are adopted by the European Parliament and the Council of the European Union. New Approach directives include regulations of the Member States of the European Union in the field of product liability [8]. Each directive specifies in detail the range of products which are subject to it. This range includes the features of the products and/or type of risk that the product may pose. New Approach directives apply to new products, as well as to new and used products imported into the European Union from third countries. The same product can simultaneously be obliged by a few directives, which is to be decided by manufacturer [7]. Each of the directives has attachments along with requirements that aim to ensure a high level of product safety. This forces manufacturers to perform risk analysis and transcribe its inclusion into the technical documentation.

Under the new approach, the directives contain the essential requirements relevant as to what is to be achieved – the safety of the product. The technical requirements have been transferred to the level of European standardization. In contrast, the process of assessing demands compliance with the essential requirements needed for further regulation. Therefore, it was necessary to define criteria for a reliable assessment of the conformity of products with essential requirements, namely, the creation of conformity

assessment mode. The first step in this direction is the Council Resolution of 21 December 1989 on a global approach to certification and testing (90/C10/01) [3]. The resolution was replaced and supplemented by Council Decision of 22 July 1993. Concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are to be used in the technical harmonization directives (93/465/EEC) [4], [1]. Currently, conformity assessment procedures regulate the Decision of the European Parliament and of the Council No 768/2008/EC of 9 July 2008 on a common framework for the marketing of products (...) [5].

The conformity assessment procedures described in those decisions, and referred to in the New Approach Directives, are based on a system with eight basic modules. These modules help manufacturers to choose the most appropriate way during the establishment and refinement of products, with particular emphasis on hazards of the product [9].

8.5 EUROPEAN COMMISSION AND EUROPEAN STANDARDS ORGANIZATIONS

Some conformity assessment procedures require participation of independent bodies in assessing the conformity assessment, such as laboratories. In order to authenticate such bodies, the concept of the notified body was introduced [2], [7]. A notified body is an institution independent from both the producer and the consumer, operating in an objective manner, meeting certain requirements implemented in the directives. For an institution to function as a notified body, it must be notified by the authorities of the country, which is further notified to the European Commission. With the notification process is closely related to the accreditation process already taking place at national level. The accreditation process is regulated by the Regulation of the European Parliament and Council Regulation (EC) No 765/2008 (EC) of 9 July 2008. Establishing requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 [10].

After receiving the notification, the European Commission puts the notified body in the list of notified bodies for precise directives. The list is published by the European Commission in the official EU journal, C series. The product conformity assessment system plays a key role for standardization bodies and standards harmonized with the directives. The main standardization organizations in Europe dealing with technical standards include CEN (European Committee for Standardization), CENELEC (European Committee for Electrotechnical Standardization), ETSI (European Telecommunications Standards Institute). These are entities that develop, each in their respective areas of competence, standards harmonized with the directives. The harmonized standards are European standards, which are developed in a special mode. They are being developed for the European Commission by one of the 3 aforementioned European standardization organizations, based on the requirements approved by the European Commission. Harmonized standards must remain upheld in accordance with the rules of the CEN/CENELEC/ETSI and officially submitted to the European Commission after

their approval. The European Commission, as part of their duties shall publish in the form of messages a list of harmonized standards for individual directives. Fig. 8.3 contains an example publication.

16.1.2015 EN Official Journal of the European Union C 14/1

IV
(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Commission communication in the framework of the implementation of Directive 2004/108/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC

(Publication of titles and references of harmonised standards under Union harmonisation legislation)

(Text with EEA relevance)

(2015/C 014/01)

ESO (1)	Reference and title of the standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
(1)	(2)	(3)	(4)
CEN	EN 617:2001+A1:2010 Continuous handling equipment and systems — Safety and EMC requirements for the equipment for the storage of bulk materials in silos, bunkers, bins and hoppers	EN 617:2001 Note 2.1	Date expired (30.6.2011)
CEN	EN 618:2002+A1:2010 Continuous handling equipment and systems — Safety and EMC requirements for equipment for mechanical handling of bulk materials except fixed belt conveyors	EN 618:2002 Note 2.1	Date expired (30.6.2011)

Fig 8.3 A list of harmonized standards

Source: [10]

8.6 THE EUROPEAN CONFORMITY ASSESSMENT SYSTEM OF PRODUCTS POLISH LEVEL

Poland after joining the European Union was bound to approximate its national law to the requirements and solutions to the European Union. One of the many legal areas in which the EU law was transposed into Polish law is the conformity assessment system. Basic regulations forming the conformity assessment system in Poland include:

- Act of 30 August 2002. Conformity assessment system [11].
- Act of 12 December 2003, on general product safety. It is a transposed directive on General Product Safety Directive (2001/95/EC).
- Act of 2 March 2000, on protection of consumer rights and liability for damage caused by dangerous products. It is a transposition of the Directive on producer liability for damage caused by a defective product (85/374/EEC).

The basic legal act regulating the functioning of the European conformity assessment system in Poland is the Act on conformity assessment system, which aims to [11]:

- eliminate the risks posed by products for life or health of users and consumers and for property, as well as environmental risks;
- elimination of technical barriers to trade and facilitating international trade;
- to create conditions for a reliable assessment of products and processes for their preparation by competent and independent bodies.

Conformity assessment system consists of [11]:

- regulations defining the general and specific requirements for the products,
- regulations and standards for the operation of the bodies involved in the conformity assessment.

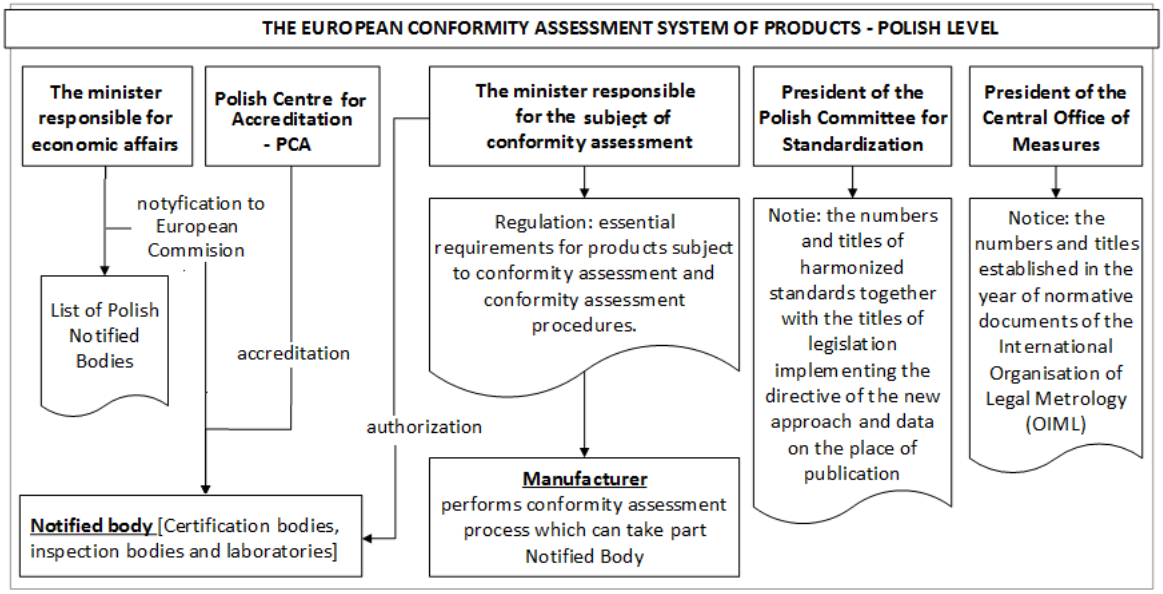

Fig 8.4. Model of the European conformity assessment system of products - the Polish Level

Source: Own elaboration

The illustrative model of structures and relations of the Polish level of the ECASP are contained in Fig. 8.4.

The Act imposes specific obligations on Polish executive authorities and state institutions, including their leadership. The law puts special role on the heads of ministries, who were assigned a responsibility for different groups of products. For example, the Minister of Economy is responsible for the Directive relating to the products used in the mining industry, and the health minister is responsible for the Directive containing the essential requirements for medical products.

8.6.1 The minister responsible for the subject of conformity assessment

The minister responsible for the subject of conformity assessment is required to determine, by means of regulations, the essential requirements for products subject to conformity assessment and conformity assessment procedures, taking into account the types of products and the degree of hazard posed by them, as well as other requirements contained in the directives of the new approach. The minister's responsibility is to transpose the Directive to polish law. In addition, the minister responsible, within its compe-

tence, determines the authorization of bodies involved in the conformity assessment. Decision for the authorization confirms the fulfillment of all criteria by an authorized body, which are found in the Act on conformity assessment system and issued on the basis of the regulations. In a broader context, it qualifies the authorization by the minister responsible (or manager of the central office, with jurisdiction over the subject matter of conformity assessment), submitting the bodies for the notification process.

8.6.2 President of the Polish Committee for Standardization

President of the Polish Committee for Standardization is obliged to publish twice a year, by a notice in the Official Journal of the Republic of Polish 'Monitor Polski':

- the numbers and titles of harmonized standards together with the titles of legislation implementing the directive of the new approach and data on the place of publication,
- the information announced by the European Commission during transition periods concerning the application of the presumption of conformity and warnings concerning the restriction of the presumption of conformity, both at 30 June and 31 December of each year.

8.6.3 President of the Central Office of Measures

President of the Central Office of Measures has an obligation to announce every 12 months, by a notice in the Official Journal of the Republic of Polish 'Monitor Polski', the numbers and titles established in the previous years documentation of the International Organization of Legal Metrology (OIML), together with an indication of the provisions which must be met to presume the conformity with the essential requirements of the product, as well as the titles of legislation implementing the Directive a new approach for measuring instruments along with data on the place of their publication.

8.6.4 The minister responsible for economic affairs

The minister responsible for economic affairs has an obligation to declare by way of a notice about notified certification bodies, inspection bodies and notified laboratories in the Official Journal of the Republic of Polish 'Monitor Polski', as well as to change the scope of the notification and its revocation.

8.6.5 Polish Centre for Accreditation – PCA

The institution which is the Polish Centre for Accreditation accredits upon request of the certification body, inspection body, laboratory or another entity conducting conformity assessment. Accreditation is the confirmation of the competence in a specified range.

8.6.6 Manufacturers and Notified Bodies

The conformity assessment procedures included in the directives, their transpositions and ministerial regulations are all implemented by manufacturers. This manufacturer is responsible for carrying out conformity assessment, and if required by regulation of product marking with the CE mark.

In many cases, product conformity assessment procedures require the intervention of notified bodies – the certification body, inspection body or a laboratory. In Poland, such bodies are notified by the Minister of Economy, after obtaining the accreditation of Polish Centre for Accreditation and an authorization by the minister responsible for the subject of the assessment of conformity or the relevant head of the central office. Tasks of the notified body are described in detail in conformity assessment procedures contained in the transposition of directives – ministerial regulation.

CONCLUSION

European conformity assessment system plays a very important role in the functioning of the EU. Because of this system it is possible to eliminate technical barriers and to implement the principle of free movement of goods within the community, without jeopardizing the European users of the products. These important functions gives rise to ECASP being based on bureaucratic rules and possessing a complex structure, which consists of the highest authorities, both at European and national level. At the European level, specific roles are played by the European Parliament and the Council of the European Union which are, responsible for the harmonization of laws and the establishment of New Approach directives. European Commission is an important institution ordering harmonized standards, which also oversees the authorities of the Member States relating to notified bodies. Of key importance is also the European standardization organizations, which are responsible for drawing up technical standards harmonized with the New Approach Directives. On a national level, such as Poland, the responsibility for the proper functioning of the system depends on the highest authorities at the level of heads of ministries and heads of the highest offices. The last participant in a system executing is the manufacturer's conformity assessment procedures contained in the Regulations transposing directives. Important elements of ECASP of the notified body are an additional element giving proof of the quality of the entire system.

The presentation of ECASP in a cross-cutting, yet consistent manner, guaranteeing the "friendliness" of content for the reader appears to be a difficult task. Achievement of the objective should be seen taking into consideration the structural complexity of this system, its bureaucratic and extensive character.

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3 Council Resolution of 21 December 1989 on a global approach to conformity assessment.

4 Council Decision of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives.

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11 Ustawa z dnia 30 sierpnia 2002 r. o systemie oceny zgodności.

STRUCTURE AND FUNCTIONING OF THE EUROPEAN CONFORMITY ASSESSMENT SYSTEM OF PRODUCTS

Abstract: *The article describes in a cross-sectional, yet consistent manner, the currently operating product conformity assessment system in Europe, called by author The European Conformity Assessment System of Products (ECASP). The article details the basic regulations currently in force, both at the level of European law, as well as polish domestic law that form the structure and operation of the system. The comprehension of the read shall be eased by comp model of the structure and the relationships between elements of the ECASP. The first part of the article is devoted to describe the origins of building a conformity assessment system in Europe. Another part of the study describes the European level of compliance system – a European framework and institutions that it constitutes. In the third section an overview of the system in Poland is presented. In particular, Polish entrepreneurs so that they can develop better understand the current rules for the European conformity assessment system, including the principle of marking (CE) devices, which elements are part of that system.*

Key words: *conformity assessment system, CE, new approach directives*

STRUKTURA I FUNKCJONOWANIE EUROPEJSKIEGO SYSTEMU OCENY ZGODNOŚCI WYROBÓW

Streszczenie: *W artykule opisano w sposób przekrojowy, a zarazem spójny aktualnie funkcjonujący w Europie system oceny zgodności wyrobów, nazwany europejskim systemem oceny zgodności wyrobów (ESOZW). W artykule wyszczególniono podstawowe regulacje prawne obowiązujące zarówno na poziomie prawa europejskiego, jak i krajowego – polskiego, które tworzą strukturę i zasady działania systemu. Lekturę artykułu ułatwi zawarty w nim poglądowy model struktury i relacji występujących pomiędzy elementami ESOZW. Pierwszą część artykułu poświęcono na opisanie genezy budowania systemu oceny zgodności w Europie. Kolejna część opracowania opisuje europejski poziomowi systemu zgodności – europejskie regulacje i instytucje, które go tworzą. W trzeciej części zawarto opis funkcjonowania systemu w Polsce. W szczególności polscy przedsiębiorcy dzięki temu opracowaniu będą mogli lepiej poznać aktualne zasady funkcjonowania europejskiego systemu oceny zgodności, w tym zasady oznakowywania (CE) wyrobów, które to zasady są elementem wspomnianego systemu.*

Słowa kluczowe: *system oceny zgodności, CE, dyrektywy nowego podejścia*

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