Improvement of Conformity Assessment System: Technical Harmonization Adjustment

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ABSTRACT

Nowadays technical harmonization is mainly used for ensuring unified functioning of the European Union internal market. In order to guarantee the functioning of it and mutual recognition as well as to promote international trade, the reliability of the activities carried out needs to be ensured by conformity assessment. The aim of the paper is to identify problems and offer new solutions thus improving the conformity assessment system and put forward proposals for technical harmonization improvement. The paper is focused on the product conformity assessment, as the limited scope of the research does not allow inspecting different kinds of conformity assessment. Research was done using qualitative and quantitative research methods. The research findings can be used by several interested parties in conformity assessment, and makes more clearly conformity assessment processes and ensure that safe products placed on the market. This reporting can be used as guidelines for improvement of conformity assessment system and technical harmonization in European Union.

Keywords: Conformity Assessment System, Technical Harmonization, European Union.

1. INTRODUCTION

Technical harmonization is mainly used for ensuring the functioning of the European Union (EU) internal market. Its aim is to develop a uniform approach for solving specific issues across the EU, thus ensuring that external technical barriers resulting from different national requirements have been eliminated. The influence of technical harmonization on the EU internal market is important because a lot of requirements for the EU products in circulation are uniform. In order to guarantee the functioning of the EU internal market and mutual recognition as well as to promote international trade, the reliability of the activities carried out needs to be ensured. For this purpose conformity assessment system has been formed. Conformity assessment system is applied very extensively; its object may be products and processes, as well as people, systems, etc. Thus, nowadays conformity assessment has become a prerequisite and guarantee for using safe products, receiving appropriate services, successful operation of the processes, competences of qualified persons etc. Uniform requirements are determined using a variety of technical harmonization approaches. Over time, introduction of new technical harmonization approaches does not sufficiently clearly show the set of different approaches and their consistency, the traceability of the changes is not obvious. This creates confusion for both the EU and national government institutions in the development of requirements, as well as for entrepreneurs in their execution, which can lead to a situation when uniform operation of the EU internal market cannot be achieved. Therefore, it is necessary to improve and structurally manage conformity assessment system, and review the existing technical harmonization approaches. The aim of the paper is to identify problems and offer new solutions thus improving the conformity assessment system and put forward proposals for technical harmonization improvement. The paper is focused on the product conformity assessment, as the limited scope of the research does not allow inspecting different kinds of conformity assessment. In addition, products are things that are purchased and used every day, so there is a greater risk that they may pose a hazard to human health, life or environment. Research was done using qualitative and quantitative research methods. On the basis of research and analysis, the authors developed the improved scheme of the conformity assessment system and proposed new methodology of requirements of the *Technical Harmonization Approach*. The research findings can be used by several interested parties in conformity assessment, and makes more clearly conformity assessment processes and ensure that safe products placed on the market. This reporting can be used as guidelines for improvement of conformity assessment system and technical harmonization in EU.

2. CONCEPTS RELATING TO CONFORMITY ASSESSMENT

Conformity assessment is carried out to ensure product compliance and safety to human health, life and the environment. It has an important role in the safety assurance of products, services, etc., but entrepreneurs and the society very rarely think about conformity assessment during everyday activities, knowledge and understanding of conformity assessment and its related issues is not sufficient.

After analysing the opinions about the concepts of ‘conformity’, expressed [1, 2, 3], as well the concept of ‘assessment’ expressed in literature (dictionaries, etc.) and by different authors [4, 5, 6] it was concluded that ‘conformity assessment’ compares the object with the requirements and finds its compliance or non-compliance to them. To adjust these definitions to the specific area of conformity assessment, improved definitions are offered: “Conformity is the fact that the object (product, process, etc.) fulfils the requirements” and “Assessment is the process of determining the object (product, process, etc.) compliance with the requirements”.

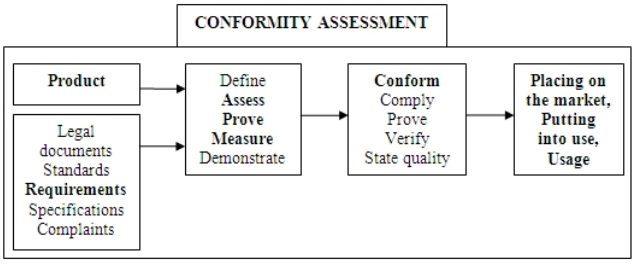

Figure 1. Interrelations of the terminology related to the concept of ‘conformity assessment’ [created by authors]

When the concept of 'conformity assessment' was evaluated, a scheme of interrelations of the related terminology was established (see Figure 1). It was concluded that conformity assessment is the process of comparing the product with the requirements and on the basis of the assessment taking decision of its compliance or non-compliance. The concept of 'conformity assessment' is defined by the EU and national legislation, standards, the documents of international and national organizations; also various authors have expressed their opinion about it [7, 8, 9]. During the evaluation of the definitions and opinions of the authors, it was seen that they are very general and partly compliant and do not specify the means of conformity assessment. Consequently, the authors propose to improve the definition of the concept of 'conformity assessment' as follows: "Conformity assessment is the process by which the conformity assessment procedures are carried out to evaluate the object (product, process, etc.) compliance with the requirements".

2.1. CONFORMITY ASSESSMENT PROCEDURES

Conformity assessment can be ensured by knowing its processes and activities, by understanding its elements and other aspects involved, by recognizing them as a whole (a uniform system).
In order to assess whether the product meets the requirements, conformity assessment is performed according to a specific conformity assessment process. Conformity assessment procedure is one of the important stages in conformity assessment. The concepts of 'conformity assessment process' and 'conformity assessment procedure' are widely used in conformity assessment field, but there are no precise definitions for them. The authors propose new definitions for these terms: "Conformity assessment process is a set of actions within the framework of which the object (product, process, etc.) conformity assessment is performed" and "Conformity assessment procedure is a way (action or module) in which the object (product, process, etc.) conformity assessment is performed and decision is made about issuing a certificate of conformity and/or marking". The differences of conformity assessment procedures depending on the applied approaches are shown in Figure 2.

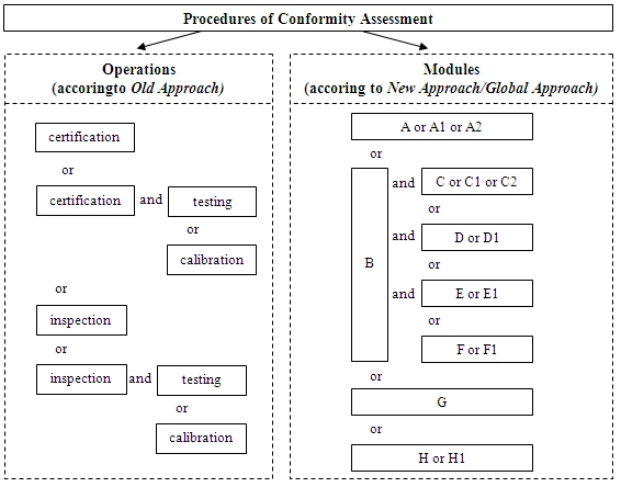

Figure 2. Conformity assessment procedures
[created by authors]

Performing of conformity assessment under the *Old Approach* and the *New Approach/Global Approach* is different. In the case of the *Old Approach*, certain conformity assessment activities (inspection or certification) or support activities (calibration or testing) are determined. In the *New Approach*/*Global Approach*, the manufacturer may choose which of the applicable conformity assessment modules or module combinations to use. The manufacturer must be sufficiently knowledgeable to be able to choose the most appropriate solution for a particular product and production process, and often prefers the more traditional solutions.
In the evaluation of conformity assessment activities – inspection, certification, calibration and testing, for each of them a scheme of interrelations of the terminology related to them has been made, and compared with the definitions and opinions of different authors found in literature. The authors have also developed the representation of relationships and interactions of these activities.
Conformity assessment modules are classified according to various criteria: at what stage – design and/or manufacturing – conformity assessment is carried out, who performs the conformity assessment activities, what kind of activities are carried out to ensure product compliance: internal control, verification or quality management system is introduced. After evaluating the information related to conformity assessment modules and modular nature of the *New Approach*, it is concluded that in order to understand the activities to be performed within each module, it is necessary to provide explanations and to develop guidelines for their practical application. The expression of the modular activities in the form of a definition will not solve the uncertainty for entrepreneurs about the choice of the module and its application.

2.2. CONFORMITY ASSESSMENT ELEMENTS

A prerequisite for successful business in the global market is the ability to recognize the importance of conformity assessment elements: accreditation, metrology, standardization, and to apply them.
Accreditation attests the competence of conformity assessment bodies to perform certain conformity assessment procedures in a particular area. It is significant for recognition of conformity assessment results and mutual recognition of products, as mentioned in several concepts of it [10, 11].
Essential and technical requirements, which are often standardized, are determined for products. Standardization has also contributed to the international trade. Further clarification of the definition of the concept of 'standardization' has been proposed: "Standardization is the process by which the parties involved determine the requirements and procedures that are the best to adjust the activity of a certain area" because the current definitions [12, 13, 14] are not sufficiently general and not focused on the development of standards. After evaluating the opinions expressed by different authors [15, 16, 17], and definitions of 'standard' included in literature resources, there is offered an improved definition as follows: "A standard is a document that includes terminology, requirements and operating conditions and which is approved by the responsible institution with the aim to facilitate the development of a certain area" which sets the objective of the standard and highlights the most important information contained in the standard (terminology, requirements, operating conditions).
Making measurements today is an integral part of manufacturing, conformity assessment, trade, etc. The term 'metrology' has several definitions expressed by various authors [18, 19, 20, 21]. The most common and most accurate definition is proposed by the International Bureau of Legal Metrology: "Metrology is the science of measurement". Measurements must have a uniform measurement system and standards: the measurement result is the value of an object with a certain uncertainty.
In the EU, there are uniform requirements for products and for conformity assessment during product design and manufacturing stages. At the same time, a uniform conformity

assessment system that would include all the processes, activities, elements etc. has not been created. Today, the conformity assessment system has become a complex and fragmented system, which is difficult to manage and is not fully comprehended. As a result, parties involved in conformity assessment are confused by the amount of requirements, they have difficulties ensuring a uniform interpretation of requirements and compliance with them, taking part in laying down the requirements and improvement of the conformity assessment system. Various elements, which contribute to decision making on compliance and ensure the reliability of the decisions, are not integrated into a single system and are not uniformly managed. This creates difficulties in performing conformity assessment. At the same time, the fact that parties involved in conformity assessment and the society have different understanding of the conformity assessment system, the requirements for the products, conformity assessment activities and the terms used in this field indicates problems in the system management. This confirms the need to structure the conformity assessment system and improve its management, meanwhile improving the conformity assessment terminology base.

3. TECHNICAL HARMONIZATION REGULATION

Technical harmonization is a process where uniform requirements are approved thus eliminating external technical barriers that could arise from different national requirements. [22, 23] Nowadays, technical barriers to trade are often subtly hidden in laws and regulations and technical specifications, focusing on protection of human health, life and environment, thus creating complications for entrepreneurship.

Technical harmonization is applied to specific products (toys, lifts, construction products, non-automatic weighings, etc.) and specific requirements related to these products (electromagnetic compliance, noise emissions, etc.), as well as requirements for specific activities and organization of elements (conformity assessment procedures, accreditation, market surveillance, etc.).

Over time, a number of technical harmonization approaches, i.e. solutions for the requirement regulatory organization, have been laid down. A common feature for technical harmonization approaches is setting definite requirements for products and their conformity assessment, without interference in the execution of requirements. Thus, the manufacturer is given some flexibility on how to ensure compliance and to demonstrate conformity, besides, entrepreneurs have access to a wider market, which also promotes competition among them.

After evaluating technical harmonization approaches and comparing them, it is concluded that the *New Approach* in comparison with the *Old Approach* is more general and flexible, while they both provide delivering compliant and reliable products for use. [24, 25] The *Global Approach* determines the requirements for conformity assessment and is considered as a complement to the *New Approach*. Nowadays they are integrated so well that the requirements of both approaches together are called the *New Approach.* The *New Legislative Framework* is a collection of solutions for improvement of the *New Approach* and the *Global Approach*, it contains provisions for development of market surveillance and promotes the transition from the *Old Approach* to the application of the principles of the *New Approach*. Adopting of the above technical harmonization approaches has not ensured the continuity and consistency of the changes, which has caused misunderstanding about their application in government institutions, businesses and society. The set of technical harmonisation approaches and the regulated requirements, as well authors' amendments can see in Figure 3.

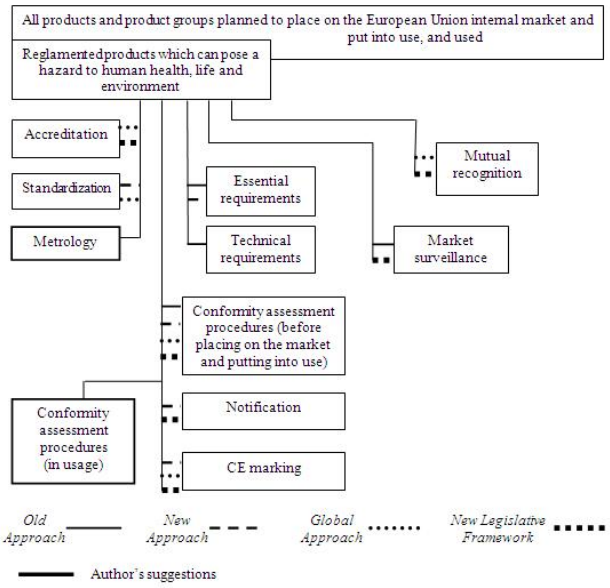

Figure 3. The set of technical harmonisation approaches and the regulated requirements [created by authors]

Over time, introduction of new technical harmonization approaches does not sufficiently clearly show the set of different approaches and their consistency, the traceability of the changes is not obvious. This creates confusion for both the EU and national government institutions in the development of requirements, as well as for entrepreneurs in their execution, which can lead to a situation when uniform operation of the EU internal market cannot be achieved. Therefore, it is necessary to review the existing technical harmonization approaches.

4. SURVEY ON CONFORITY ASSESSMENT AND TECHNICAL HARMONIZATION

Authors done survey between EU notified bodies to get approval of stated conclusions about conformity assessment system and technical harmonization. Research was done observing particular selection and its formation methods, as well as questionnaire formation and processing requirements. [26, 27] Overall respondent's statistical population of notified bodies surround all (1633) notified bodies, fully filled respond were from 56 notified bodies, which compile 3,4% of overall number of respondents. Statistical error of research is 4,7% (with 95% probability), that affirms credibility of results.

Authors gave several questions to respondents to get know more about conformity assessment system and its operation. Results of survey and respondents answers presented in Table 1.

The problems identified by authors and affirmed with the survey are summarized and grouped; their causes and possible consequences are defined. From the established interrelationships of the problems it is concluded that the conformity assessment system management problems can be grouped as follows:

- problems related to technical harmonization (the set of the requirements for the products, understanding of the requirements, availability of non-conforming products on the market etc.);
- problems related to the conformity assessment system management (activities of conformity assessment bodies, requirements for their competency etc.).

Table 1. Survey of notified bodies results [created by authors]

Question No	Answers
1. Do you consider it necessary to enhance application of all conformity assessment modules?	Yes – 19 (41%) No – 27 (59%)
2. Do you consider the notification procedure sufficiently fast and reliable?	Operative – 31 (55%) Non-operative – 4 (7%) Reliable – 43 (77%) Non-reliable – 4 (7%)
3. Do you take part in notified bodies networks, working groups etc. where you can exchange with topical issues?	Yes – 43 (80%) No – 11 (20%)
4. Do you support a view that accreditation should be a mandatory criterion for the notification?	Yes – 45 (83%) No – 9 (17%)
5. Does publication of the list of recommended harmonized standards facilitate your work?	Yes – 43 (81%) Partly – 10 (19%) No - 0
6. Do you consider it necessary to perform conformity assessment (re-verification, technical inspections, etc.) also during the period of use?	Yes – 38 (76%) No – 12 (24%)
. Do you consider that operation of the national conformity assessment system in your country complies with requirements of harmonized international regulatory framework?	Complies – 39 (72%) Partly – 14 (26%) Does not complies – 1 (2%)
8. Do you consider improvements of the *New Approach* and the *Global Approach* in line with adoption of the *New Legislative Framework* sufficient and compliant?	Sufficient – 22 (47%) Partly sufficient – 20 (43%) Non-sufficient – 5 (11%)

In order to eliminate the problems, authors concluded that the EU needs to improve the technical harmonization approaches, to concretize the scheme and management of the conformity assessment system and to improve the functioning of national conformity assessment system, thus ensuring that only conforming products are placed on the market.

5. PROPOSALS FOR CONFORMITY ASSESSMENT SYSTEM IMPROVEMENT

Through research authors find out that in order to ensure the system management, aspects to be identified and defined in each specific case are as follows:

- process to which the particular system relates (conformity assessment system);
- particular object (product) to which the process relates, when necessary;
- regulated requirements;
- harmonization level of the requirements;
- parties involved in the provision for the process activities, their functions and responsibilities;
- elements that would ensure functioning of the system and objectiveness;
- system surveillance provisions.

To ensure placement of conforming and safe products on the market and delivery for use as well as conformity to requirements of products in use, conformity assessment is carried out, thereby in the particular case the system is related to product conformity assessment. The product conformity assessment system is evaluated, structured and developed in accordance with the above mentioned aspects of system management (see Figure 4) in order to eliminate any inadequacies found in it.

Upon making changes in the conformity assessment system in relation to the product conformity assessment process, it is stated that in future during the product design and manufacturing stages conformity assessment is to be carried out only by making use of conformity assessment modules and uniform requirements laid down by the EU for carrying out conformity assessment of products during their use. In order to ensure reliability of conformity assessment and its results, specific conformity assessment elements related to particular stages are identified and defined.

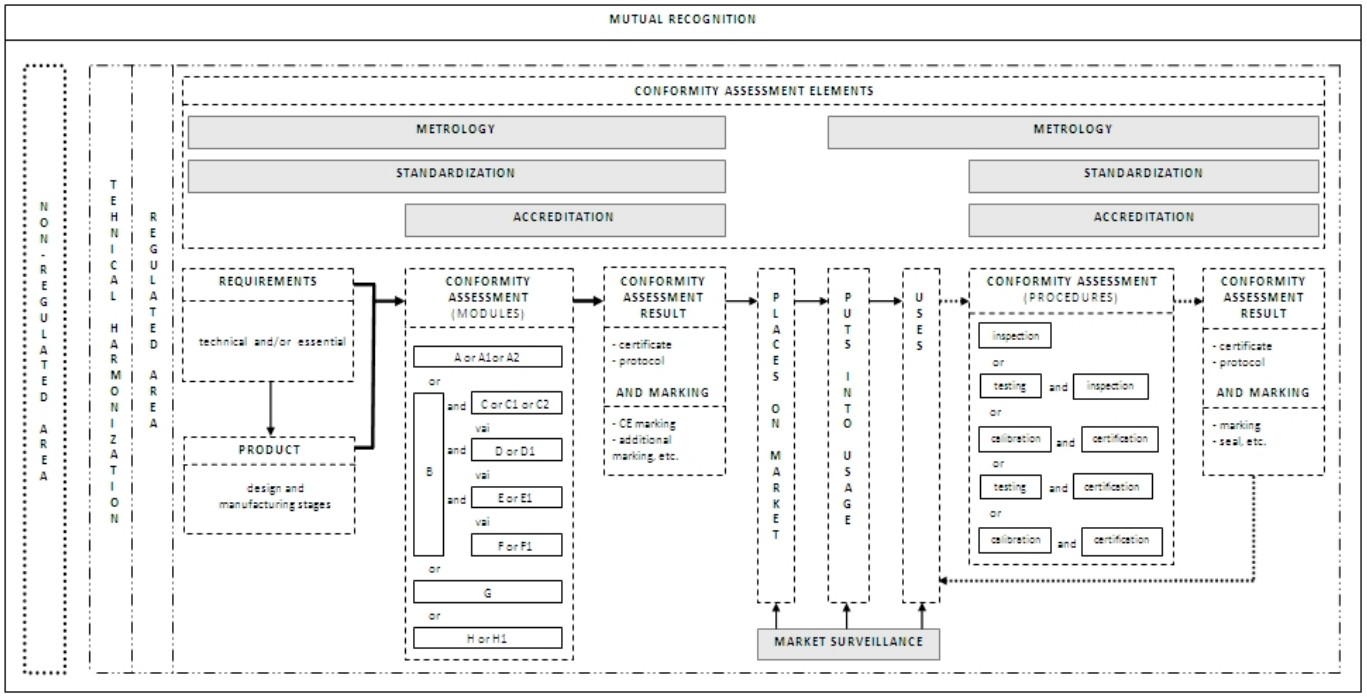

Figure 4. The scheme of the conformity assessment system [created by authors]

It is determined in which stages of the process the market surveillance is made to ensure that conforming and safe products are available on the market and are used. Requirements for conformity assessment and products, conformity assessment elements and market surveillance, which are harmonized at the EU level and allow applying mutual recognition to the products,

are to be improved. It is to be applied to the non-harmonized area as well.

6. PROPOSALS FOR TECHNICAL HARMONIZATION ADJUSTMENT

The new, uniform methodology proposed by the authors for laying down the requirements of technical harmonization to be applied in the EU from now is illustrated in Figure 5. The elaborated *Technical Harmonization Approach* is structured and within it alterations may be made consecutively and traceably.

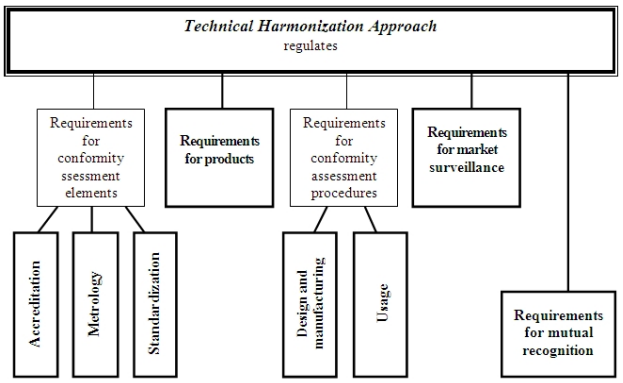

Figure 5. Methodology of requirements of the *Technical Harmonization Approach* [created by authors]

Also authors gave some proposals how to adjust each of eight *Technical Harmonization Approaches* groups.

Accreditation. To ensure equal conformity assessment of the products on the market, accreditation must be made a mandatory prerequisite for the activities of a conformity assessment body in the regulated area at the national level and their notification in order to obtain the status of a notified body. Furthermore, the EU needs to lay down uniform criteria for accreditation of conformity assessment bodies in order to be notified. So as to make the accreditation procedure more flexible and easy for the entrepreneurs, evaluation of the whole conformity assessment bodies' spheres is to be performed during one audit visit.

Metrology. Taking into account the importance of the field, it is necessary to ensure application of a uniform metrology scheme in all the EU Member States. For this purpose the EU needs to lay down a legislative act on requirements for organization of metrology at the national level. Simultaneously with adoption of such a legislative act, the bases of national standards of units of measurement are to be revised adjusting them to the actual needs of national economy and granting entrepreneurs the opportunity to reproduce their standards. The states need to cooperate and jointly evaluate, which of the national metrology bodies will offer particular calibration services of standard units of measurement; it is not necessary to offer all the services in all the states.

Standardization. In order to encourage development of new products and implementation of innovative ideas in the future, voluntary application of standards needs to be stimulated. Laying down compulsory standards is to be given up, and it is advised to recommend harmonized standards. In the field of metrology, the international standardization and metrology organizations have to cooperate closely to avoid contradictions in the requirements, which are included in the standards and documents of the International Organization of Legal Metrology.

Requirements for products. In the course of time the number of products and product groups, which are subject to regulation, is decreasing and currently the requirements are applied only for the products, which may pose hazard for human health, life and the environment. The author believes that this trend needs to be developed further, gradually decreasing the number of regulated areas. Upon making amendments in the legislative acts, the product requirements are to be uniform as far as possible depending on the specifics of the field, and conformity assessment modules are to be applied for carrying out conformity assessment. Different involved parties (including the experts, researchers etc.) are to be invited to find better and more comprehensive solutions. Work groups are to be organized for discussions about the requirements set for the products and their application, as well as guidelines are to be drawn up when necessary to eliminate discrepancies in the interpretation of the requirements.

Conformity assessment procedures during the stages of product design and manufacturing. A significant source of information is the Type Approval Register. It would be useful for the EU to maintain a uniform Type Approval Register. As well it is necessary to enhance the meaning of CE marking, so that customs institutions, entrepreneurs and the society would recognize improperly marked products, and on these grounds the products would not be placed on the market, or not submitted for use or purchased.

Conformity assessment procedures during product use. Until now conformity assessment procedures during product use were regulated only at the national level. In order to improve this area, subsequent verification in the EU needs to be carried out uniformly, with a prescribed periodicity for particular measuring instruments and performing verification. In respect to the fact of repairment or adjustment of the measuring instrument, the entrepreneur is issued a document, which is then presented to the conformity assessment body when submitting the measuring instrument for subsequent verification. Taking into account the possible instability of the measurements, the verification period for such measuring instruments needs to be shortened.

Market surveillance. In order to decrease the number of non-conforming products on the market, the customs institutions have to maximize the attention when inspecting the products that the EU imports from the third countries, and market surveillance organizations have to carry out informative campaigns to inform entrepreneurs and society regarding the meaning of CE marking. In order to improve market surveillance, the EU needs to elaborate guidelines for explanation of the requirements and make use of uniform document forms, as well as regularly update the knowledge of employees.

Mutual recognition. The current regulation of mutual recognition has been improved over time and may be considered adequate and sufficient. The name of the legislative act should be changed thus demonstrating unambiguously what requirements are regulated by the particular legislative act.

7. CONCLUSIONS

To ensure the reliability of conformity assessment and its results, the elements of conformity assessment (accreditation, metrology and standardization) are of utmost importance. In assessing the scope of conformity assessment, the author has identified that these elements are perceived and organized as separate systems, rather than integrated into the conformity assessment system; as a result of which the functioning of the conformity assessment system is not comprehensive.

To ensure organized management of the conformity assessment system and its covering all elements and activities involved in conformity assessment, a scheme for product conformity assessment system is created. The scheme depicts the sequence of activities within the product conformity assessment process and conformity assessment elements, thus facilitating the conduct of business.

Upon evaluation and comparison of technical harmonization approaches, it was found out that the changes in the technical harmonization approaches have not been structured, they do not cover all the relevant elements and in the EU there are no regulated uniform requirements for product conformity assessment during their use. Therefore, it is impossible to ensure the reliability of product conformity assessment. The solution to this problem is adoption of new uniform technical harmonization requirements (approach) to conformity assessment.

The EU internal market needs to follow the same requirements for products and their conformity assessment during the stages of design, manufacturing and use. On the basis of the evaluation of the current technical harmonization approaches and the conformity assessment system in the EU and Latvia and the identified problems, a new, uniform methodology for regulations – the *Technical Harmonization Approach* – is elaborated with the aim to replace the current technical harmonization approaches. The *Technical Harmonization Approach* is divided into several groups, so that it would be more understandable for entrepreneurs and facilitate the business. The new proposed approach has to be accepted by the EU regulatory bodies.

8. ACKNOWLEDGEMENTS

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