Product Conformity Assessment within the Integrated Management System: Manufacturing Compliance and Customer Safety

Svetlana MJAKUŠKINA and Inga LAPIŅA
Riga Technical University, Faculty of Engineering Economics and Management
Kalnciema iela 6, Rīga, LV-1048, Latvia

ABSTRACT

In the frame of the globalization economical operators who place the products on the market are facing new challenges in ensuring the compliance of the products. The aim of the research is to analyse the applicability of the integrated management system as a platform for development of possible solutions to improve business processes and ensure compliance of the non-food products made available on the market. The effectiveness of the existing conformity assessment system is evaluated through statistical analysis of unsafe product notifications in the Rapid Alert System and a case study of a compliance assessment for electrical appliances placed on the European Union market. The main findings are: (1) a correlation between the applicable conformity assessment procedure and non-compliant products; (2) the product compliance with essential requirements does not depend on whether the declaration of conformity has or has not been correctly drawn up and whether the product is covered by a test report.
Several research methods such as analysis of academic and professional publications, logical and comparative analysis of regulations and binding documents, statistics on product compliance, and survey analysis are applied in this research.

Keywords: product safety, conformity assessment, compliance evaluation, integrated management systems, RAPEX

1. INTRODUCTION

In the frame of market globalization and introduction of the concept of the global supply chains economic operators that place products on the market are facing new challenges in ensuring product safety and compliance with applicable regulations. The topic of product safety is not new and various authors have looked at this area mainly form manufacturers' point of view.
The Rapid Alert System is a data sharing platform used by the national authorities of 31 countries and the European Commission for a rapid exchange of information on unsafe non-food products identified on the European Union market. The data shows that since 2011 more than 20,000 measures have been taken against unsafe products reported in the Rapid Alert System [6]. The non-compliant products not only affect public health, but also have an impact on business environment creating an unfair competition on the market. The country of origin of the notified unsafe products clearly indicates the importers' role in ensuring the compliance of products entering the Community market. This also indicates the need to improve business processes from the importer's point of view. The aim of the research is to analyse the applicability of integrated management system as a platform for development of possible solutions to improve business processes and ensure compliance of products made available on the market. The concept of the integrated management system as a platform for the improvement of the business processes and ensuring the compliance of the products made available on the market is not scientifically explored. At the same time, different authors stressed the positive influence the system has on business processes. The elements of a conformity assessment procedure should be integrated and the evaluation criteria should be determined. The effectiveness of the existing conformity assessment system is evaluated through statistical analysis of unsafe product notifications in the Rapid Alert System and a case study of a compliance assessment for electrical appliances placed on the European Union market. The analysis of system effectiveness provides important information for the determination of criteria. The goal of the case study is to analyse if product compliance with essential requirements depends on conformity assessment documentation such as declaration of conformity and test reports.
The present paper provides a research on the role of process evaluation in ensuring the compliance and safety of products, and highlights the conformity assessment elements in the integrated management system.

2. THE EUROPEAN UNION AND ITS REGULATIONS

The European Union has achieved common market that ensures free circulation of products among its member states. The functionality of a single market is ensured by The New Approach and the European Standardization elements. The European Union Directives, also known as "New Approach Directives" define common requirements and methods for conformity assessment procedures to evaluate and ensure the compliance of the products [26]. This standardization provides technical solution and common technical language used to achieve and ensure product compliance.
The regulation clearly defines that a product placed on the Community market should be designed and manufactured in accordance with the essential requirements set by the applicable product-specific legislation and should be safe. The definition of a safe product is determined by the Directive 2001/95/EC of the European Parliament and of the Council on general product safety. Article 2(b) of the Directive 2001/95/EC on general product safety says that a safe product means any product which, under normal or reasonable foreseeable conditions of use, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of a person [5]. The base of the system is the trust between manufacturer and the importer. In cases where a manufacturer is located outside of the European Union, the product will only be placed on the market if it complies with the regulation, meaning that appropriate conformity assessment procedure is completed and the products meets essential requirements. The leading definition of conformity assessment is provided in the European Union regulations "Conformity assessment is the process demonstrating

whether specified requirements relating to a product, process, service, system, person or body have been fulfilled" [19].

3 PRODUCT CONFORMITY ASSESSMENT ELEMENTS

For time period 2011-2017, 15371 notifications of found unsafe non-food products on Community market have been submitted to the RAPEX system.

Different authors have identified various possible reasons that influence the compliance of the products: requirements, insufficient communication and cooperation, new technologies, lack of competence [2], [11].

The analysis of RAPEX notifications by product category (absolute values) for the time period between 2005 and 2016 clearly identifies 4 dominant product groups reported in the system – toys, electrical appliances, clothing/textile, motor vehicles (see Figure 1).

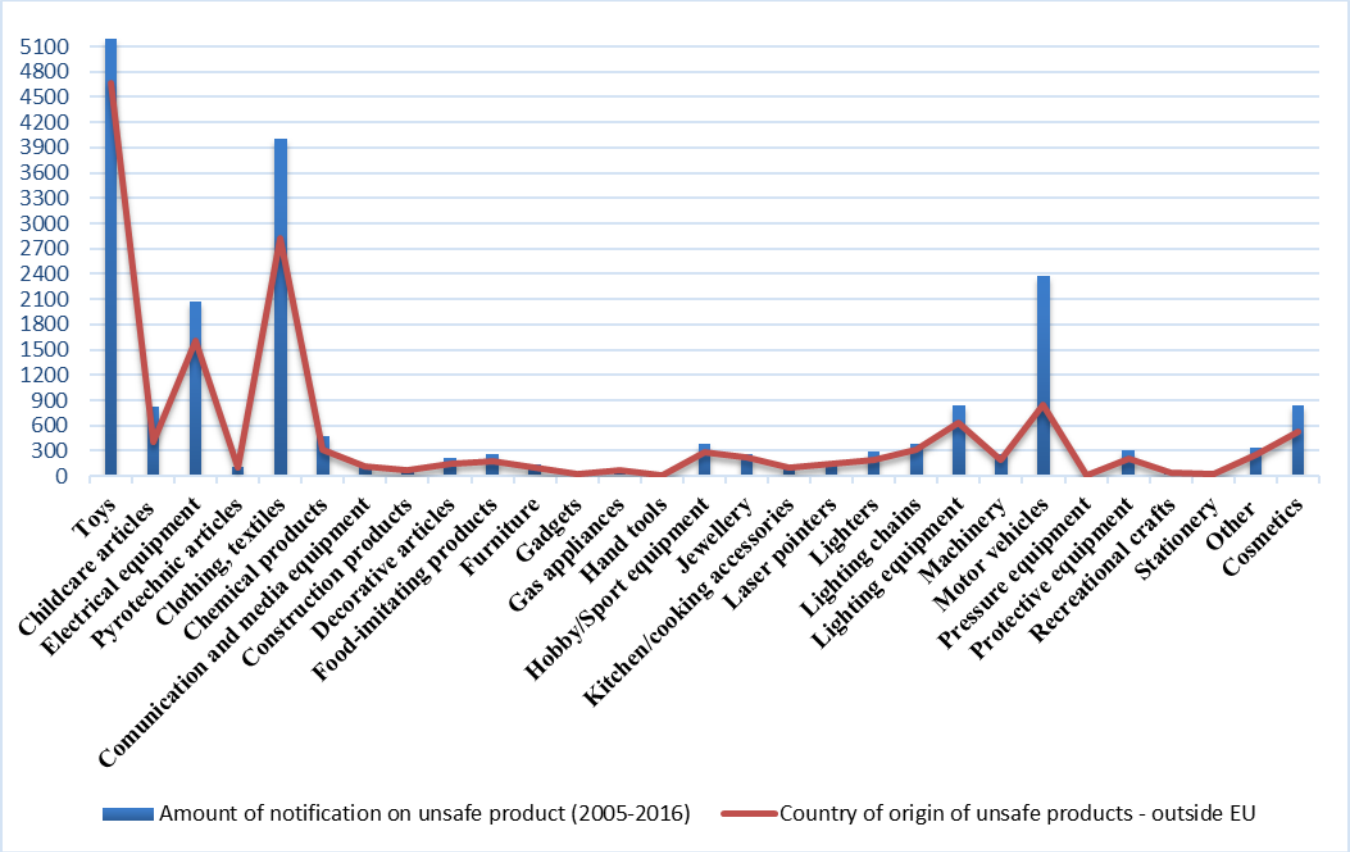

Figure 1. The number of RAPEX notifications by product category (absolute values), years 2005-2016 [created by authors]

The analysis of the conformity assessment procedures for the products most often notified through the RAPEX system do not require compliance evaluation by the third party i.e. the notified body (see Table 1).

Table 1. Applicable regulation for the types of the products most often notified through the RAPEX system [created by authors]

Product group	**Applicable regulation**	**Require third party evaluation**
Toys	Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys	No
Electrical equipment	Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limit Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electronical and electronic equipment	No
Clothing/ Textiles	Directive 2011/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety	No

This means that the key element for the presented conformity assessment procedures is the activities, fully organized and ensured by the manufacturer. The European Union regulations require manufacturer to establish technical documentation providing necessary information of the product to assess its conformity with the applicable regulation and to organize the manufacturing process and its monitoring to ensure compliance of the manufactured products with the technical documentation.

The detailed analysis of the RAPEX notifications on selected product groups identified that the country of origin of 14647 notified products of the total 20393 unsafe products for the period 2005-2016 is outside the European Union; it means that 72% of unsafe products entering the EU market originated outside of the EU. This identifies the need to draw more attention to the products entering the Community market. The Regulation (EC) 765/2008 of the European Parliament and of the Council determines the framework of controls for products entering the Community market. The control should ensure that products entering the Community market, as stated in article 27 paragraph 3 of Regulation 765/2008, are accompanied by the required documentation in accordance with the relevant regulations and demonstrate that the needed conformity assessment procedures have been performed and the product does not provide any risks to health, safety, the environment or any other public interests.

Taking into account that importers introduce products from the third countries to the Community market, they are the ones responsible for product compliance with the applicable regulation.

Liepiņa R., Mazais J. and Lapiņa I. [20] stressed that a prerequisite for successful business is the ability to recognize the importance of conformity assessment elements: accreditation, metrology, standardization, and to apply them.

Accreditation ensures recognition of the technical competence of bodies whose task is to ensure conformity with the applicable requirements [21]. Metrology ensures the correctness and reliability of the measurement results. The European Standardization places a significant emphasis on free circulation of products and defines it as a key element of the created system. The use of the harmonized European standards is voluntary. In order to stimulate the use of the standards the "presumption of conformity" is presented. The use of the standards published in the Official Journal of the European Union provides the presumption of conformity with the essential requirements set out in the applicable product regulations, but only so far as particular risks are covered by this standard [26]. The conformity assessment elements should be taken into account when determining the criteria for compliance evaluation.

4. CASE STUDY: COMPLIANCE ASSESSMENT OF ELECTRICAL APPLIANCES IN LATVIA

In the period of 2014-2016, Consumer Rights Protection Center, a market surveillance authority in Latvia responsible for control of non-food products made available on the market, implemented a project. The project entailed a compliance assessment of 117 electrical equipment models out of which 54 samples were taken at the border. The precondition for sampling was that the product should be ensured with a declaration of conformity. In cases where such documents were not available the importer was required to submit it with the product's test report. 47 samples were taken in shops. All samples were tested to ensure their compliance with the essential requirements set down in the Low Voltage Directive and the Electromagnetic Compatibility Directive. Both regulations do not require the involvement of a third party in the conformity assessment process. The testing results showed that 69 samples do not meet the requirements: 69% do not meet LVD and 58% EMC requirements.

When examining the data of samples taken at the border, all samples can be divided into two parts – those taken after the first request and those received upon repeated requests with the testing reports.

The products were not released for free circulation in 37% cases, but after a second request in 44% of cases. It is evident that the number of significant non-compliances does not change with the availability of documentation of conformity declaration upon first request.

However, it is significant that 58% of samples not released for free circulation were accompanied by test reports.

In 86% of cases with repeated requests for the release of goods for free circulation, submitted reports and product samples taken for testing, the products were not released for free circulation.

When the test report was submitted upon first request, only in 7% of the cases the products were not released for free circulation.

The analysis of the testing results in connection with the availability of the documents presumably ensuring the compliance of the products, leads to a conclusion that the test reports submitted for customs clearance after the second request do not ensure the compliance of the product with essential requirements. The product compliance with essential requirements does not depend on whether the declaration of conformity has or has not been correctly drawn up and whether the product is covered by a test report.

There is a need to determine the criteria that can be used by importers to ensure the compliance of the products they are placing on the market. The businesses understand the purpose of process effectiveness improvement and its positive influence on business performance.

5. INTEGRATED MANAGEMENT SYSTEMS (IMS)

Various internal and external factors place increasing pressure on the companies to adopt different standardised management systems. The last data of the ISO survey showed that in 2015 a total of 1,519,952 certificates were issued worldwide, compared to 1,476,504 in 2014, it means that the total number of certificates issued increased by 3 % [25]. The data provided by the International Organization for Standardization shows that the certification for ISO 9001 and 14001 makes 89% of the total number of the certificates issued in 2015. The certification of systems confirms that the system meets the criteria and the requirements identified in the applied standard. Various authors, [10], [14], [15], [22], have pointed out similarities between ISO 9001, ISO 14001 and OHSAS 18001 as applies to the management policy; planning; implementation and operation; performance evaluation; improvement and critical analysis.

The possibility of integrating elements into a common system creating an integrated management system that works as a whole organism was determined by several researchers. The standards have similarities in terms of their structure and philosophy as they are based on the Plan-Do-Check-Act cycle of continual improvement. The influence of standards integration into a single system was analysed by different authors, [1] defined the integration of management systems as "putting together different –function-specific management systems into a single and more effective integrated management system (IMS). The IMS is an approach that prevents duplication of tasks and that identifies common elements in separate systems that interflow, ensuring their holistic interoperability [1], [23]. Multiple benefits of the IMS were identified by many authors [3], [16], [10], [12]. The IMS was pointed out by many researchers as a way to improve the overall management system efficiency [23], [7], [3], [16], [9],

[12]. The case study performed by Nunhes et al. [24] as well as the research done by de Oliveira [16] and Abad et al. [9] showed that the IMS implementation increases the quality of goods and services produced and increases the reliability of products and processes.

The analysis of the IMS and the conformity assessment procedures identifies the processes that play an important role in ensuring the compliance of the products: personnel management, document management, procurement procedure, complaints-handling management, internal audit and communication (see Figure 2).

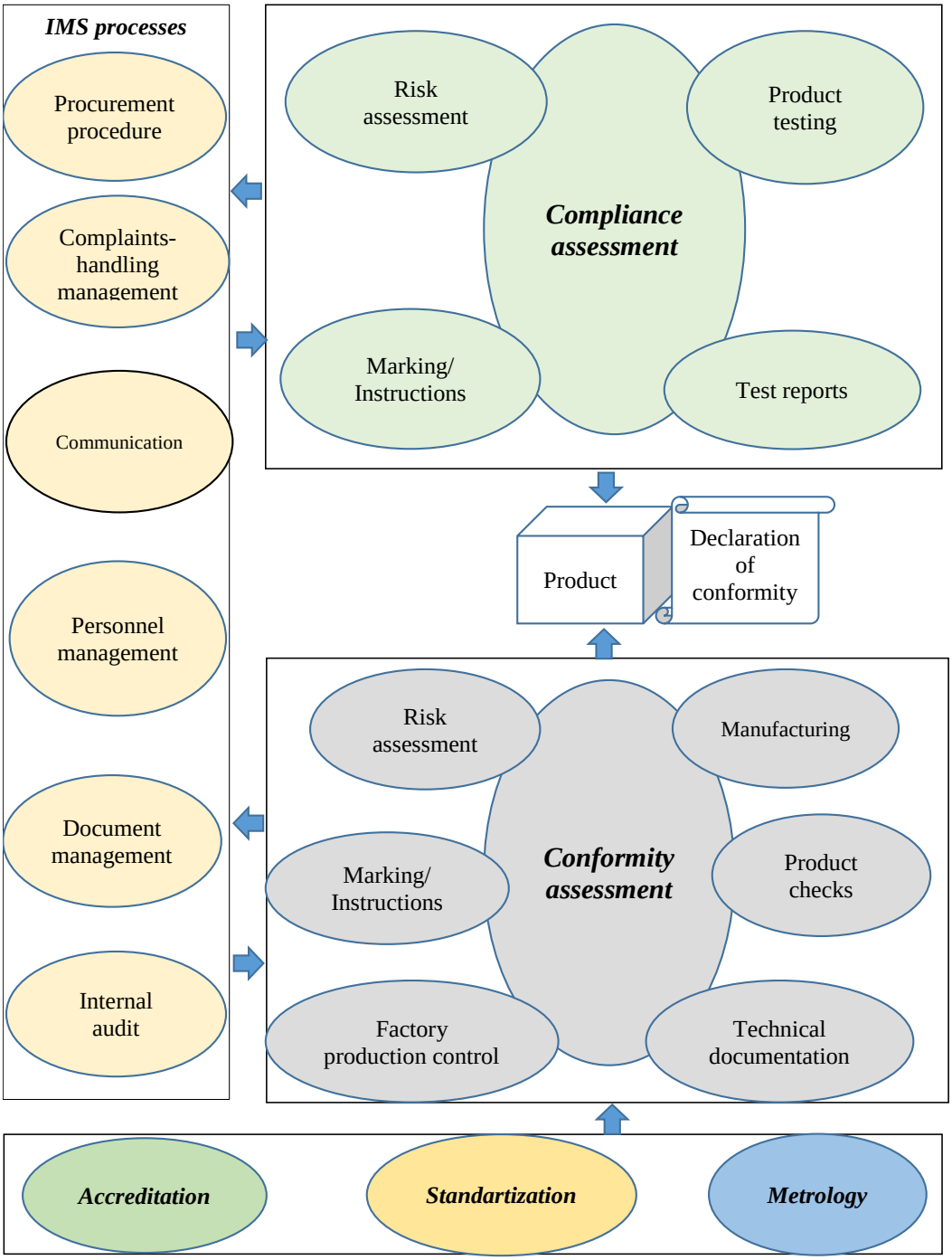

Figure 2. The interrelation of conformity assessment and the IMS processes [created by authors]

The right criteria for process evaluation can ensure a proper control system and as a result, the compliance of the final products that are placed on the Community market. A definition of such criteria is needed to execute the evaluation and as a result to improve internal procedures and the common management system.

Table 2. The criteria for process evaluation to ensure product compliance [created by authors]

Procurement procedure	*Criteria for product evaluation before making the purchase*
	✓ the procedure identifies the main criteria for potential supplier evaluation, such as certification of the management system, the status of the supplier – the manufacturer or distributor, third party evaluation ✓ the evaluation criteria for manufacturers to ensure their ability to produce compliant products (factory production control evaluation, product testing, certification, third party evaluation)
	✓ the procedure identifies criteria for ongoing evaluation of selected suppliers (testing frequency, production control certificates, third party evaluation)
	Criteria for product selection before purchasing
	✓ the applicable requirements are determined ✓ the product conformity assessment documents are evaluated ✓ the compliance of all applicable product markings and instructions is evaluated ✓ the availability of technical documentation is confirmed ✓ the product compliance with all the essential requirements is assessed
	Criteria for evaluation of the received products
	✓ administrative checks such as markings, conformity documentation and physical checks (i.e. sample testing)
Complaints-Handling management	✓ the traceability of products is ensured ✓ the compliance register is available ✓ the procedure to determine the cause of non-compliance is in place ✓ the procedure of corrective and preventive actions is available (risk assessment evaluation, withdrawal from the market/recall)
Document management	✓ the dates of available conformity assessment documentation are readily available ✓ procedures that ensure that the consumers received all the required product information and documentation ✓ producers ensure that consumers have access to the required product documentation in all official languages
Personnel management	✓ a training programme that helps to ensure competence development on product compliance matters ✓ record keeping of completed training responsibilities is clearly defined and documented
Communi-cation	✓ a clear and systematic information exchange between all parties on the found non-compliances and the corrective actions
Internal audit	✓ regular evaluation of the control system effectiveness

The IMS provides continuous improvement of quality, health and safety as well as environmental aspects. The development of the IMS by integrating criteria for evaluation of the processes to ensure the compliance and safety of the product can contribute to the organization [15]. The possibility of evaluating the internal processes and to ensure its effectiveness in preventing non-compliant products made available on the market provides different benefits for economical operators as well as improves the situation on the market.

6. CONCLUSIONS AND DISCUSSION

The analysis of non-compliant product notifications within the European Union clearly shows the need to draw more attention to the products entering the Community market. The primary focus should be made on the products that fall under the category of goods that do not require a third party compliance evaluation (i.e. notified body) as part of their conformity assessment procedures.

The outlined case study indicates that product compliance with essential requirements does not depend on whether the declaration of conformity has or has not been correctly drawn up and whether the product is covered by a test report.

There is a need to determine the criteria that can be used by importers to ensure the compliance of the products they are placing on the market. The businesses understand the purpose of process effectiveness improvement and its positive influence on business performance.

The existing regulations clearly state that it is the importers' responsibility to ensure the compliance and safety of the products entering the Community market. However, there is a lack of practical instruments and criteria available for the product evaluation.

The study showed a possibility of integrating elements of the product conformity assessment procedures into the IMS. This represents the current and future added value for businesses and a whole range of stakeholders. However, at this point these aspects have not been tested empirically. It is necessary to continue the research focusing on the identification of items for each of these aspects in order to construct reliable, valid measures for such a system.

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