Zeszyty Naukowe
Quality. Production. Improvement

No. 1(1)
2014
pp. 78-87

Joanna Rosak-Szyrocka[1], *Tomasz Hermaniuk*[2]

QUALITY IN THE PRODUCT CONFORMITY ASPECT

Abstract: The European system of ensuring safety of the product imposes on producers and importers of machines, equipment and elements of safety an obligation to provide the recipients with safe products. Characteristic of CE mark and its meaning for producers was present in the chapter.

Key words: CE mark, producer, quality.

1. Introduction

As safe products are considered those machines and elements of safety that meet the norms harmonized with directives 98/37/WE, 73/23/EWG (for electric equipment), 2000/14/WE (noise) and 89/336EWG (concerning electromagnetic compatibility). The assessment of conformity with fundamental requirements of safety and health protection included in the directive 98/37/WE can be carried out by a producer (or importer) himself or a competent external unit.

In Poland until 1.01.2003 every product introduced on the market by a producer that could pose any threat had to be given a document confirming that it meets suitable requirements defined by norms or legal regulations (by "product" are also meant parts, subassemblies, assemblies, raw materials, materials, fuels, products of agriculture etc.) (USTAWA Z DNIA 3 KWIETNIA 1993). Such a document was issued by an entitled unit independent of the producer as well as recipients (by the so

[1] Dr, The Czestochowa University of Technology, Faculty of Management, Institute of Production Engineering, e-mail: jrosak@zim.pcz.czest.pl.
[2] Dr, Tomasz Hermaniuk Katedra Marketingu i Przedsiębiorczości Wydział Ekonomii Uniwersytet Rzeszowski.

called third part) (USTAWA Z DNIA 22 LIPCA 1999). This document authorized the producer to put a product on the domestic market. It bore the name of a certificate. The so called B mark of safety is connected with certification of the product and it should be used for marking all the products that could pose threat to life, health and the environment. Mark B signifies that a given product, if used according to the conditions defined by the manufacturer (producer) does not pose hazard to life and health and is environmentally friendly. According to legal acts it stopped being in force on 1 January 2003, that is (WALCZAK M. 2004), before joining the European Union by Poland.

At present there is no obligation to obtain B mark which is optional. Yet, the products imported to Poland from the countries outside the European Union have to bear B mark. In countries belonging to the European Union (EU) the articles put on the market have to bear only CE marking which confirms conformity of the product with suitable directives, the so called "New and Global Approach" (WALCZAK M. 2004). The Institute of Certification IATM (Institute of Advanced Technologies Manufacture) carries out certification in the scope of optional B mark of safety for machines, devices and tools. That mark constitutes a guarantee recognizable in the whole country that purchased merchandise is safe in the highest degree. It is often a recipient's requirement, particularly in the industrial branch and it decides about competitive superiority at the time of the free market. Certification for obtaining a B mark in the Institute of Certification IATM is carried out through certification of conformity with the requirements of harmonized norms as well as national and international norms, normative documents, norms and directives of regional organizations. In the case of machines and devices such aspects, among others, are checked:

- Technical and traffic documentation (TTD), Conditions of technical acceptance (CTA).
- Design documentation.
- Manufacture of equipment with regard to TTD and CTA.

- Meeting the requirements for individual subassemblies and assemblies.
- Machine performance without load and with load.
- Functional features (e.g. fang diameter, weight).
- Works.

In the case of tools there are checked:

- Identifiability.
- Conditions of technical acceptance (CTA).
- Packaging.
- Instruction manual.
- External appearance.

The product marked with a B mark was regarded as safe, it sold more easily and the buyer was certain that there were not hazards to life and health. After Poland's joining the European Union new Union principles of putting products on the market came in the force. According to those principles, the producer is obliged to confirm the consistency of a manufactured product with the fundamental requirements of the directives of the new approach of the harmonized norms applying to that product.

2. CE mark characteristic

A declaration of conformity issued by the producer and placing CE marking on the product are evidence certifying that consistency. With Poland joining the EU, the domestic market has become part of a homogeneous EU market whose one of the basic principles is the principle of a free flow of commodities. The lack of customs barriers and border control caused that commodities are transported without bigger problems from the country of the producer to the states where there are markets for them. The consequence of that may be a situation in which consumers in the country of destination have problems with the interpretation of the markings binding in the country of origin, from which the commodities have been shipped. That problem has become an inspiration for the introduction of CE marking (European Conformity) (WIŚNIEWSKA M. 2005). CE marking is defined by the Union institutions themselves as a passport

that allows producers to introduce their products onto all markets of member states of the European Union and associate states within the so called European Economic Area (i.e. also Norway, Iceland and Liechtenstein), without formalities that prevail in the countries without harmonized legislation relating to the safety of products.

CE marking is applied in industry in such branches, as:

- household equipment,
- electronic equipment of general use,
- electronic components,
- heating, ventilation, air-conditioning,
- lighting,
- industrial steering equipment,
- wires and cables,
- electronic engines,
- information technology equipment,
- telecommunication equipment,
- cable fix-ups,
- medical equipment (active and not active),
- medical equipment (IVD products),
- medical equipment (laboratory equipment)

According to the directives of the New Approach the following products require placing CE marking:

- active medical implants,
- cranes,
- emission of noise in the environment by equipment designed for outdoor use,
- yachts,
- electromagnetic compatibility,
- machines,
- explosive materials for civil use,
- non - automatic weighing equipment,
- law voltage electric equipment,
- simple pressure reservoirs,

- watt - hour efficiency of refrigerators and freezers,
- watt - hour efficiency of water heaters,
- watt - hour efficiency of fluorescent lighting stabilizers,
- means of individual protection,
- equipment for use in explosive atmosphere,
- pressure equipment,
- gas equipment,
- medical equipment,
- diagnostic equipment in vitro,
- cable equipment for the transport of people,
- radio equipment and telecommunication terminals,
- construction products and building products,
- toys.

3. Procedure for obtaining the CE mark

The algorithm of the manufacturer's procedure leading to obtaining a CE marking has been shown on Fig. 1. The Directives of the New Approach include only fundamental requirements connected with safety, health, consumer protection and environmental protection, while the remaining technical details are included in appropriate harmonized European norms (EN). The directives of the New Approach are applied to the products that are introduced onto the market of the EU including the products brought from the area outside UE or the products that have been changed significantly.

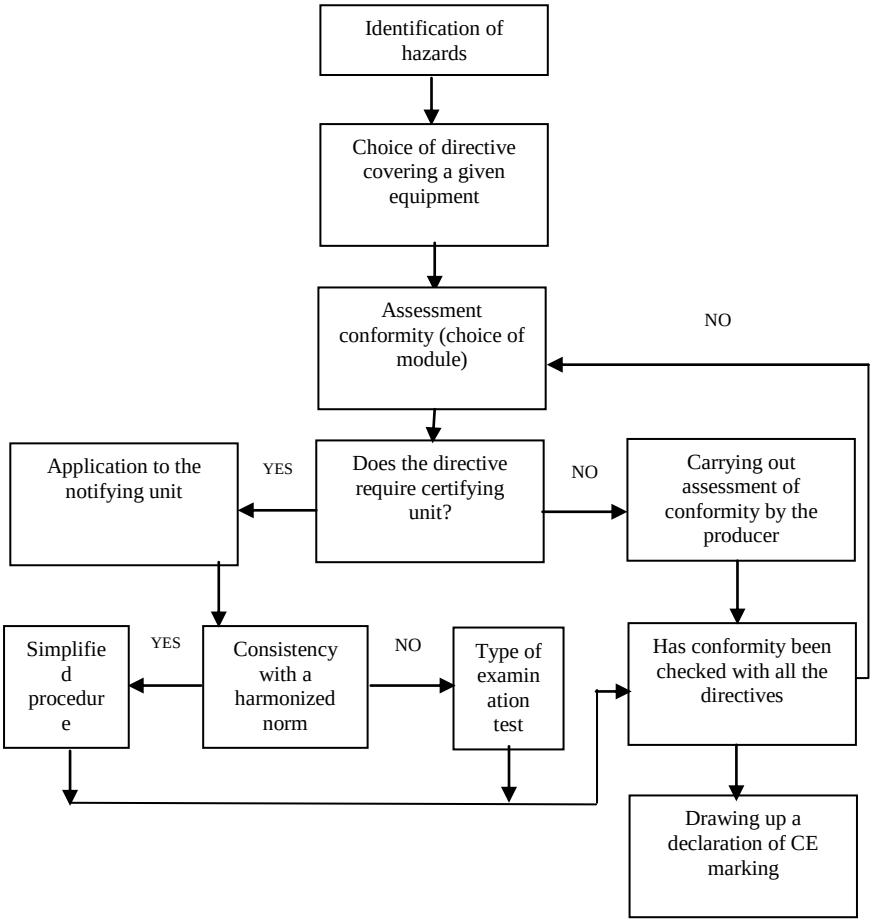

Fig. 1. The algorithm of producer's procedure procedure leading to obtaining a CE marking.

Source: WOSIŃSKI H. 2004

Each directive of the New Approach must include (GONDEK P. 2004):

– specification of the products which the directive applies to,
– kind of threats that should be eliminated by a given directive,

- guidelines concerning putting a given product on the market.(The responsibility for putting given products on the market rests on the government of the member state of the UE). The commodity that is covered by a directive of the new approach and does not meet it, cannot appear on the market. In the case of any failures to satisfy requirements, member countries have the right notto put a given product on the market, or to withdraw it once it has already been there.
- clause of a free flow of goods and services in the UE countries that satisfy the required directives without the necessity of secondary certification,
- procedures of conformity assessment which are based on the decisions of the UE Council regarding procedure modules of conformity assessment for the production line of a given product. The modules concern both the stage of design as well as the stage of production of a given product and they are indicated with letters A, B, C, D, E, F, G, H. Formulated in the directives of the new approach procedures of conformity assessment require participation of, the so called, notified unit. Notified units are organizations authorized by the state and registered at the European level but are not, in any way, treated as state organs; they are independent of the producer and the purchaser (they are "the third party"). Notified units must represent a high technical level, employ high-class specialists. Those units are subject to accreditation by an independent accreditation center. Notified units are employed by the producer, according to his needs, for the assessment of conformity procedure. The producer may use any notified unit from any EU country. It is worth emphasizing that the activity of the notified unit does not relieve the producer of full responsibility for the product put on the market.

4. Summary

The producer bears full responsibility for marking a product with CE. However, if a notified unit participated in the procedure of conformity assessment, then next to CE marking on the product there must be placed

its identification number, which along with other data in the official journal of the European Communities. Those units are subject to accreditation by an independent national accreditation center. The Polish Center of Accreditation has been such a notified unit in Poland since 1 January 2001. The CE is placed on the product, packaging of technical documentation by the producer, importer or authorized representative of the producer. According to the requirements of the new approach directive each producer id obliged to draw up technical documentation for a given product. Each directive defines what should be included in the documentation of the product. The producer is obliged to store technical documentation for 10 years since the introduction of the last batch of the product or service on the market. Directives of the new approach define which modules should be employed in the procedure of putting CE marking on definite products. A directive can specify even several modules which are applied for the products covered by it and there are also given the criteria that the producer should take into account when choosing a definite module.

As an example there can be given the directive referring to non-automatic weighing equipment. It results from it that the devices produced individually have to be tested according to module G while those produced serially are subject to the procedure B + D or B + F. Each directive of the new approach includes the following elements:

- range – indicates the area in which given articles can be used or, which they are assigned to,
- general decisions relating to the introduction of articles into turnover - the directives oblige the member countries to assure that in the turnover there may be exclusively the articles that do not pose hazards to health, life or the environment,
- basic requirements - concern the features of safety, they determine the aims the product has to fulfill,
- way of proving conformity with the basic requirements-providing by the manufacturer (supplier) conformity of the article with the basic requirements through consistency of the article with the European harmonized norm (published in the Official Journal of the European

Union). Thanks to showing by the manufacturer consistency with the basic requirements by means of conformity with the harmonized norm it is possible to avoid making reservations concerning the assessment of the product by the units supervising the market.

- required procedures of assessment conformity-every directive describes the procedure according to which the manufacturer or importer should proceed in order to prove appropriate authorities the conformity of the articles introduced to the market with the basic requirements. The procedures are based on the modules established by the Council of the European Communities and marked with letters A to H, including such elements as.: declaration of conformity, assurance of the production quality, assurance of the product quality, individual control of the article, full assurance of the quality.
- CE marking is addressed to the units supervising the market. CE mark is placed at the exclusive responsibility of the producer who is legally responsible for the consistency of the product with the directive.
- CE mark is a confirmation that all the proofs verifying the conformity of the product with the directive have been gathered.
- CE marking must be placed on product or its tag, it must be legible and irremovable. After Poland's joining the European Union industrial products are subject to a free flow on the common European market if they have a Union CE mark. Without CE marking the products of the Polish producers will not be sold on the Union markets as well as on the domestic market. In the case of the producer having its headquarters outside the UE his obligations and liabilities resulting from the directive and CE marking are taken over by the quthorized representative, but in the case of his lack – by the importer.

Bibliography

1. BORKOWSKI S., ROSAK-SZYROCKA J. 2009. *Procedury uzyskiwania znaków jakości*, Wydawnictwo Politechniki Częstochowskiej, Częstochowa.

2. GONDEK P. 2004. *Działania BBJ SEP na rzecz certyfikacji CE wyrobów elektrycznych*, Śląskie Wiadomości Elektryczne Rok I, 1/2004, s. 17-21.
3. Ustawa z dnia 22lipca 1999 o zmianie ustawy o badaniach i certyfikacji. Dz. U. Nr 70, poz. 776.
4. Ustawa z dnia 3 kwietnia 1993 o badaniach i certyfikacji. Dz.U. Nr 55, poz. 250.
5. WALCZAK M. 2004. *Ocena zgodności oraz certyfikacja wyrobów i usług: praktyczny poradnik dla producentów dystrybutorów*, stan prawny na dzień 01.01. 2004
6. WIŚNIEWSKA M. 2005. *ISO 22 000 – Nowy Standard zarządzania w przemyśle spożywczym*, Q Jakości 1/2005.
7. WOSIŃSKI H. 2004. *Wprowadzenie do obrotu sprzętu elektrycznego aspekcie europejskiego systemu oceny zgodności, Śląskie Wiadomości Elektryczne, Rok XI, 1/ 2004, s. 21-28*