

## **PRODUCT UNCONFORMABLE IN THE LIGHT OF LEGAL REGULATIONS AND THE ISO 9001: 2000 STANDARDS**

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**Abstract.** The supervision of unconformable product is a key problem in the era of globalization. In Poland the supervision of safety product has been entrusted to the President of the Office of Competition and Consumer Protection. The agency supporting its activities is the Trade Inspection. Growing popularity of the quality systems conformable with the ISO 9000 standard caused that they have been included in the EU regulations as criteria of assessment of conformability with requirements. The certificate of the quality management system is indispensable for companies for functioning in many market areas. One should remember that quality management system will help the company to supervise unconformable products only when it really functions and is not just on paper. Only then it will function efficiently.

**Key words:** unconformable products, ISO 9001:2000 standard, EU and Polish regulations, OCCP, supervision

### **INTRODUCTION**

The right to safe products and the right to complete information on products as well as the right to compensation for damages caused by dangerous product have been ones of the basic consumer rights on the American (since the 60's) and European (since the 70's) markets. In the era of tremendous market competition, businessmen have to make efforts to fulfil the consumers' expectations, who take into account not the price only, but first of all quality and safety of products. Producers have to be aware that they are responsible for their products. The appropriate regulations in the EU and Poland impose on producers a range of obligations related to product safety. Introduction of defective product is connected not with claim cost only, but first of all with loss of confidence,

which is very difficult to regain. Companies taking into account a long-term perspective, try to eliminate the occurrence of unconfirmable products. Implementation of the quality management systems in a company ensures consumers that the producer takes care of product quality and constantly improves it. The ISO 9000:2000 standard obliges organisations to create system dealing with unconfirmabilities, ensuring that product unconfirmable with requirements has been identified and is supervised to prevent from its unintentional use or delivery. Moreover, the company has to identify the reasons for unconfirmability and define corrective activities as well as preventive ones ensuring that the unconfirmability will not occur in future. Implementation of the quality management systems improves credibility and competitiveness of the company. Customers can be sure that the company cares about their needs and safety.

### **PRODUCT SAFETY IN THE LIGHT OF REGULATIONS**

In the article 76th of the Constitution of the Republic of Poland there is a record saying that public authorities protect consumers, users and hirers from activities threatening their health, privacy and safety as well as from fraudulent market practices. The range of the protection is defined by regulations.

Basing on European experiences, three acts connected with product safety were elaborated in Poland:

1. Act of 12th December 2003 on General Product Safety (with amendments) [Ustawa... 2003].
2. Act of 2nd March 2000 on Protection of Certain Consumer Rights and on the Liability for Damage Caused by Dangerous Product (with amendments) [Ustawa... 2000].
3. Act of 30th August 2002 on Conformity Assessment System [Ustawa... 2002].

The Act on General Product Safety [Ustawa... 2003] follows the example of European General Product Safety Directive No 2001/95/EC [Directive... 2002], which defines:

- general requirements concerning product safety,
- producer's and handler's obligations in the area of product safety,
- supervision procedures aiming at ensuring safety of products introduced to the market.

The Act does not violate regulations concerning safety of particular products. Producers are obliged to introduce only safe products.

According to the Act a producer is anyone who:

- conducts an activity in the EU or on the territory of the EFTA members countries consisting in goods' production and places on the product or encloses to it their own name, trade mark or other distinguishing indication,
- introduces a product to the market and this action may affect product properties related to product safety.

A handler (distributor) is considered separately. They are entrepreneurs who take part in trade but hardly affect product safety. The legislator specifies obligations of a producer and handler; however, more obligations are imposed on a producer (Table 1).

Table 1. Obligations of a producer and handler in the area of product safety  
Tabela 1. Obowiązki producenta i sprzedawcy w zakresie bezpieczeństwa produktów

Producent	Handler – Sprzedawca
<p>1. Providing complete information on a product (including cautions of possible danger and possibilities of counteracting against threats) 1. Dostarczenie pełnej informacji o produkcie (także ostrzeżenia o ewentualnym niebezpieczeństwie i możliwościach przeciwdziałania zagrożeniom).</p> <p>2. Undertaking activities reducing risk of defects (product testing, analysis of complaints, means enabling producer's identification). 2. Podejmowanie działań zmniejszających ryzyko wad (testowanie produktów, analiza skarg i reklamacji, środki umożliwiające identyfikację producenta).</p> <p>3. Observation of product on market and in usage (means enabling immediate withdrawal of a dangerous product) 3. Obserwowanie produktu na rynku i w użytkowaniu (środki umożliwiające natychmiastowe wycofanie produktu niebezpiecznego).</p> <p>4. Undertaking the activities connected to informing adequate authorities – central or local – on threats. 4. Podejmowanie działań związanych z informowaniem odpowiednich organów państwowych lub samorządowych o zagrożeniach.</p>	<p>1. Not selling products that are alleged to be dangerous 1. Niesprzedawanie produktów, co do których domniemywa się, że mogą stanowić zagrożenie.</p> <p>2. Gathering information on threats 2. Gromadzenie informacji o zagrożeniach.</p> <p>3. Cooperation with a producer 3. Współpraca z producentem.</p> <p>4. Storage and immediate access to documentation indispensable to establishing of product origins, on demand of supervisory body and Trade Inspection. 4. Przechowywanie i niezwłoczne udostępnianie na żądanie organu nadzoru i Inspekcji Handlowej dokumentacji niezbędnej do ustalenia pochodzenia produktu.</p>

Source: own elaboration on the basis of the Act on General Product Safety [Ustawa... 2003].

Źródło: opracowanie własne na podstawie Ustawy o ogólnym bezpieczeństwie produktów [Ustawa... 2003].

The Act specifies also such notions as product and safe product. A product is a movable thing, new or used (repaired or regenerated) destined for consumers' use. In turn, a safe product is a product, which in usual terms of utilization or in terms that may be reasonably predicted, does not create any threat for consumers or this threat may be insignificant.

In this case the regulations name four criteria of product safety assessment:

- 1) features and properties of a product (it concerns composition of a product, its construction, finish, packaging, installation manual and conservation),
- 2) the way the product affects other articles (joint usage),
- 3) information accompanying a product (appearance, indication, cautions, usage manual, etc.),
- 4) category of consumers exposed to increased danger (in particular children and the elder).

The right to safe products is strictly connected to the consumer right to complete information on a product. Information given by a producer is to enable a consumer the evaluation of threats related to the product use and it is helpful by undertaking adequate precautions in case of a danger.

Therefore lack of information is considered as a defect. A handler is obliged to strict cooperation with producer in the area of adequate flow of information concerning threats that the product may cause. They also have to participate in safety evaluation of

product introduced to market. The legislator underlines that the handlers activities should be undertaken —with appropriate care” [Ustawa... 2003].

The Act emphasizes the assumption that product is safe if it accomplishes the requirements resulting from the national regulations of the EU member countries being a transposition of the European regulations recognised by the EU Commission as conformable with the regulations concerning general product safety. Then product is safe in the requirements range framed by these norms.

The supervision of product safety is passed on to the President of the Office of Competition and Consumer Protection. The supporting agency is the Trade Inspection. The President of The OCCP has got many authorities, e.g. in case of ascertainment that the product is dangerous they order the producer to:

- eliminate threats,
- immediately withdraw the product,
- warn consumers,
- withdraw the product and destroy it.

The national system of informing on dangerous products and national system of consumers' incidents have been established. The details of their functioning are given in separate regulations.

The Regulation of Ministers' Board of 14th April 2004 on the manner of keeping the national information system on dangerous products defines the manner of keeping the national information system on dangerous products [Rozporządzenie Rady... 2004]. This system uses electronic techniques of data processing in such way to ensure immediate reading out and printing it as a whole or in parts. The authority supervising the information system is the President of the OCCP.

By managing the system the President of the OCCP inserts and removes information from the system. Information on products that do not accomplish general safety requirements as well as products unconfirmable with basic requirements is introduced by the President of the OCCP to the system immediately after including the products to the register of dangerous products or to the register of products unconfirmable with basic requirements.

The Regulation of Minister of Health of the 28th April 2004 on Manner of Functioning of the National Consumer Incidents' Monitoring System [Rozporządzenie Ministra... 2004] defines the detailed rules of organizing and functioning of the National Consumer Incidents' Monitoring System (NCIMS), managing this system as well as the obligations of people responsible in the area of transferring the collected data to the system. A consumer incident is considered as any incident occurring in relation to use of a product by consumers which is followed by death or injury requiring medical aid, in particular children's poisoning as a result of medicine or other chemicals ingestion.

National system of monitoring of consumers incidents consists of information that is essential to specify the product related to consumer incidents, circumstances, health effects, inferring about reasons dependent and independent from the injured, in particular:

- 1) age, gender, education of the injured,
- 2) time and place of the incident,
- 3) incident description including product features and behaviour of injured that could influenced the incident process,
- 4) information on the product involved in the incident enabling its identification,
- 5) injury description,
- 6) place of rendering the medical aid.

The Act on Protection of Certain Consumer Rights and on the Liability for Damages Caused by Dangerous Product established detailed regulations concerning agreements with consumer outside the company, local and remote agreements without simultaneous presence of both sides [Ustawa... 2000]. Chapter 3 of the Act introduces changes in law e.g. in the Judicial Code, through defining the range of responsibility for a damage caused by a dangerous product. According to the Article 449th of the Judicial Code anyone who in frames of their economic activity produces a dangerous product is accountable for a damage caused to anyone by this product (compensation is not entitled when a property damage does not exceed 500 € and the compensation for a damage does not cover the damage of the product itself and the benefits that could have been achieved while using the product). A dangerous product is considered as a product not ensuring the safety that could be expected while considering the ordinary product usage.

Growing popularity of systems conformable with the ISO 9000 standards caused that they have been included into the EU directives as the assessment criteria of conformability with requirements. The assessment area was divided into obligatory and voluntary [Zymonik 1999 b]. The activity without the certificate in the obligatory area is practically impossible, whereas in the voluntary area is very difficult [Wawak 2002]. In 2003 in Poland, the Act on Conformity Assessment System came into force. The text of the Act is harmonized with directives' requirements. Therefore, it is obligatory to have a quality system certificate to act in certain areas.

The aim of the Act on Conformity Assessment is to:

- eliminate threats for user and consumers' life or health and property as well as for the environment,
- remove technical barriers in trade and facilitate international trade,
- create conditions for reliable product and its production process assessment by competent and independent persons.

The Act of 30th August 2002 on Conformity Assessment System defines [Ustawa... 2002]:

- the rules of conformity assessment system with the basic and specific requirements concerning products,
- the rules and procedures of granting accreditation and authorization,
- the manner of announcing the authorized units and laboratories to the European Commission and member countries,
- the assignments of the Polish Accreditation Centre,
- the rules of functioning of controlling system of products introduced to trade.

The confirmation of the product or production system conformity with standards is important information for the client. It indicates that purchased product was designed or made in the manner that minimizes the risk of unconfirmability [Myszewski 2005].

## **SUPERVISION OF UNCONFORMABLE PRODUCT IN THE LIGHT OF THE ISO 9001:2000 STANDARDS REQUIREMENTS**

Even by well defined requirements and efficient systems or processes there occur situations in which products or services are not conformable with defined requirements [Lock 2002]. The ISO 9001 standard imposes on producer the obligation to create

a procedure of unconfirmable products management which would define responsibilities and authorization concerning proceedings with such products. When a product is unconfirmable with requirements the organisation should identify it (mark it) and supervise to prevent from unintentional use or delivery of the product. By proceedings with unconfirmable product it is possible to use one of the manners of behaviour [Górna and Matuszak-Flejszman 2007]:

- undertaking activity aiming to eliminate unconfirmabilities,
- admission to use, release or acceptance in frames of allowance granted by authorized person and client (when possible),
- undertaking the activity aiming to disable its originally intended use or application.

If the unconfirmable product has been improved, it should be re-verified. According to the standards' requirement, the records related to the unconfirmability should be prepared and maintained. Additionally the responsibilities and authorizations in the area of proceedings with unconfirmable products in documented procedure should be defined. In practice in such procedure the stages in which the unconfirmability identification may take place are defined during:

- verification of products and services from supplier,
- the process of product or service realization,
- controlling of finished products or services,
- use – by consumer, after delivery.

Then the activity and responsibility range is defined, which is essential to take control over the unconfirmability.

The implemented and certified quality management system should guarantee high quality of products, and first of all it obliges the organization to accomplish the law requirements. Producer introducing a product to trade, having quality management system will be able to prove that they did all their best not to allow the defect to occur again [Zymonik 1999 a].

The way the company decides about the manner of proceedings with unconfirmabilities demonstrates their attitude towards quality much more than any of their declarations in quality policy. Supervision of unconfirmable product is necessary to eliminate its incidental use or delivery. An organisation taking care of its good brand should always react to an unconfirmable product in appropriate way.

No matter where the unconfirmability was detected – after initial control, during the process or final trials and as client's turn – it should be examined to obtain a clear view on decision that is to make on the way of further procedures with the product and which activities to undertake, so that the situation would not repeat. After identifying the unconfirmable product it should be marked as "Unconfirmable Product". The text and manner of the mark can be arbitrary, although it should let the employees identify the product unambiguously. Very often there are used red labels or indicators in form of card put into mobile containers or bibbed tags, stickable tapes or specially separated rooms or zones, e.g. in a magazine or production hall.

The initial stage of the evaluation of separated products assures that they are in fact unconfirmable, defective or unconfirmable and defective. Therefore the work instructions should be checked to make sure if the defection has in fact taken place. Then the size of the defection and their amount should be defined. The next stage ought to ex-

plain the un conformity influence on product functioning and on that basis one should make a decision concerning further product disposal (e.g. modification, reparation, return to a supplier, reclassification, utilization). One cannot omit the identification of people responsible for un conformities to eliminate such occurrences in future and improve the system. To prove realization of activities connected to these stages one should make un conformity report/card (Table 2).

On the basis of the un conformity card/report the documents launching adequate activities (Table 3) are issued.

The drawn cards/reports of un conformity have to be kept by quality department (QMS Proxy) and evaluated if undertaken activities are effective in un conformables' amount reduction.

Table 2. Product un conformity card  
Tabela 2. Karta niezgodności wyrobu

Un conformity card Karta niezgodności		Date of invoicing: Data wystawienia karty: .....
Kind of product: Rodzaj wyrobu:	Product supplier: Dostawca wyrobu:	
Document identifying delivery: Dokumenty identyfikujące dostawę:		
Un conformity/damage object Przedmiot uszkodzenia/niezgodności	Type of damage Rodzaj uszkodzenia	Amount Ilości
Document filled by: ..... Dokument wypełnił: .....		
Dokument wypełnił: .....		
Decisions concerning further procedure: Decyzje odnośnie dalszego postępowania:		
Podpis osoby odpowiedzialnej za podjęcie decyzji: .....		
Data i podpis osoby podejmującej decyzje: .....		

Source: own elaboration.  
Źródło: opracowanie własne.

Table 3. Documentation of unconfirmable products management  
Tabela 3. Dokumentacja stosowana w zarządzaniu wyrobami niezgodnymi

Instruction Dyspozycja	Document Dokument	Document description Opis dokumentu
Use –as it is” Wykorzystać „taki, jak jest”	Agreement to a defection Zgoda na odstęp- stwo	Written authorization, given before release to further process defined number of unconfirmable product. Upoważnienie na piśmie, wydane przed zwolnieniem do dalszego procesu określonej liczby sztuk wyprodukowanych niezgodnie z ustalonymi wymaganiami.
Modify/repair Przerobić/ naprawić	Repair order card Karta zlecenia naprawy	Recommendation to repair or modification, alternatively other correcting activities, which exceed the level of work standards Polecenie naprawy lub przeróbki, względnie innych prac korygują- cych, które wykraczają poza poziom norm pracy.
Reject Zabrakować	Rejection card Karta braków	Authorization to dumping of material, which cannot be modified, repaired or used to set purpose Upoważnienie do złomowania materiału, który nie może być prze- robiony, naprawiony lub wykorzystany do zadanego celu.
Return to the supplier Zwrócić dostaw- cy	Return protocol Protokół zwrotu	Informing supplier on reason for return. Powiadomienie dostawcy o przyczynie zwrotu.
Procedures Działania	Document Dokument	
Correcting proce- dure Działania korygu- jące	Application for correcting proce- dure Wniosek o dzia- łania korygujące	Written instruction to a person or department responsible for uncon- formity, recommending defining reasons, preventive activities and means preserving from repeat. Instrukcja na piśmie, skierowana do osoby lub do komórki organiza- cyjnej odpowiedzialnej za niezgodność, polecająca określić przy- czyny, działania zaradcze i środki zabezpieczające przed powtórze- niem się zdarzenia.
	Tool order Zlecenie narzę- dziowe	Order to introduce new or modified tool. Polecenie wprowadzenia nowego lub zmodyfikowanego narzędzia.
	Operational instruction Instrukcja opera- cyjna	Written instruction defining in detail the output material, alteration method and tools needed to carry out the operation. Instrukcja na piśmie, określająca szczegółowo materiał wyjściowy, metodę przeróbki oraz narzędzia wymagane do wykonania operacji.
Requirement change Zmiana wymagań	Technical change card Karta zmiany technicznej	Authorization to implementing permanent changes to drawing or in technical conditions Upoważnienie do wprowadzenia na stałe zmiany w rysunku lub w warunkach technicznych.
	Admission to production Dopuszczenie do produkcji	Written authorization, given before production or service, for defec- tion from fixed requirement, concerning defined number of products or given for a fixed period. Upoważnienie na piśmie, wydane przed podjęciem produkcji lub usługi na odstępstwo od ustalonych wymagań, dotyczące określonej liczby wyrobów lub wydane na określony czas.

Source: own elaboration on basis of Lock [2002].

Źródło: opracowanie własne na podstawie Lock [2002].



## CONCLUSIONS

In the light of the events concerning introduction of the drug of completely different effect than the declared one, one can ask a question: are companies implementing the quality management systems capable of preventing unconformables? Are all the earlier settled procedures realized? And finally, is a client in time informed of threatening danger connected with the product use or consumption? It is necessary to remember that the established quality management system is not to be "on paper" only, but it should be an efficient tool enabling the product quality improvement. It is vital to take control over the so-called human factor in realized processes, and then there is a great possibility of proper procedure (conformable with requirements) in the area of the unconformables' supervision.

The pressure on the certified QMS on law requirements accomplishment should be underlined. According to the Act on General Product Safety [Ustawa... 2003], one should assume that product accomplishing requirements resulting from the norms and regulation is a safe product. Moreover, companies with the QMS have elaborated the rules of behaviour with unconformable products and surely are able to act more efficiently in case of appearance of a danger connected to the product. More efficiency will surely concern the activities related to the immediate identification of unconformable products, efficient internal and external communication (supervisory bodies, consumers) and withdrawal of a product from the market.

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**WYRÓB NIEZGODNY W ŚWIETLE WYMAGAŃ PRAWA ORAZ NORMY ISO SERII 9001: 2000**

**Streszczenie.** Nadzór nad wyrobem niezgodnym jest kluczowym zagadnieniem w dobie globalizacji. W Polsce nadzór nad bezpieczeństwem produktu został powierzony Prezesowi Urzędu Ochrony Konkurencji i Konsumentów (UOKiK), a organem wspomagającym jego działania jest Inspekcja Handlowa. Rosnąca popularność systemów jakości zgodnych z ISO 9000 sprawiła, że w dyrektywach Unii Europejskiej ujęto je jako kryterium oceny zgodności z wymaganiami. Certyfikat systemu zarządzania jakością jest niezbędnym firmom do działania w wielu obszarach rynku. Nie należy jednak zapominać, że system zarządzania jakością pomoże firmie nadzorować wyroby niezgodne tylko wtedy, kiedy będzie funkcjonował faktycznie, a nie tylko dokumentacyjnie i dopiero wówczas okaże się skuteczny i pomocny.

**Słowa kluczowe:** produkt niezgodny, norma ISO 9001:2000, regulacje polskie i UE, UOKiK, nadzór

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