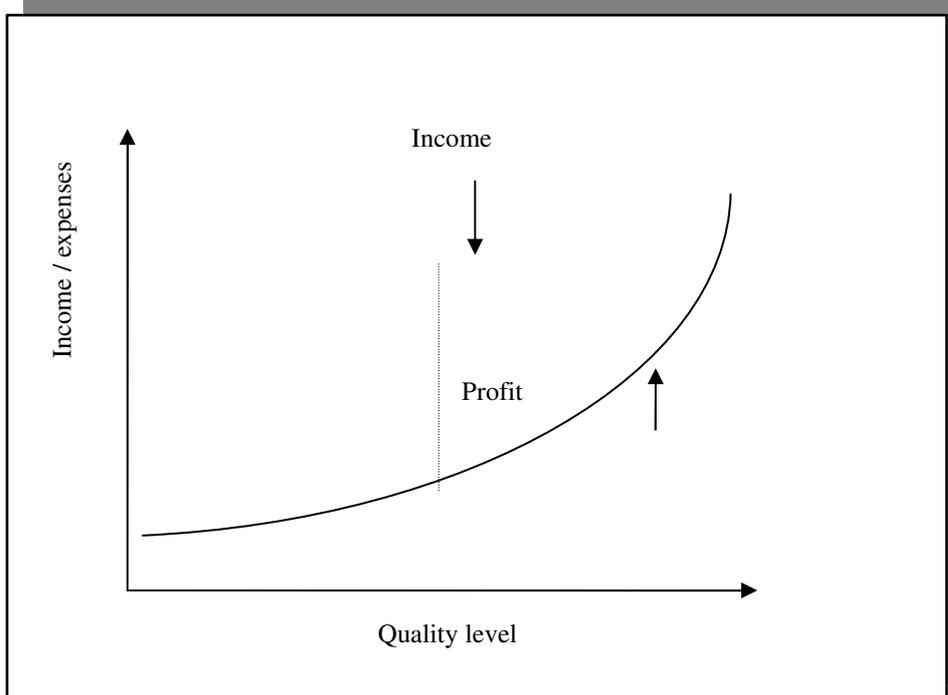


MODULE IV

**Economic Aspects of Quality.
Quality Costs, their Types and Use in
Management Systems.
Legal Aspects Connected with Quality.
Assessment of Compliance in
Accordance with the New Approach
Directives (CE Marking)**

Introduction

The quality level of products influences on the one hand the amount of earned incomes, and the amounts of the costs incurred on the other hand. Therefore we can speak of the income and cost function of quality.



When the quality level increases, we can expect an increase in the income from the sales of this product but only to a certain limit. This limit is determined by:

- the market size,
- the purchasing power of the market,
- the prices of competitive and substitute products

and whether the buyers consider the higher quality level as satisfying their real needs.

The costs of obtaining quality grow proportionally to the increase in the quality level only to a certain level. After exceeding this level, there is usually a rapid increase in the costs of obtaining quality which makes further increase in the quality unprofitable.

To determine the quality which is economically optimal we have to make reference to an indicator of quality to the costs of obtaining it (quality costs).

The quality costs are the expenditure incurred for the implementation of measures related to obtaining a proper quality of production. Quality costs should constitute a constant element of the quality management system. On the basis of the information of the incurred costs, the management makes certain decisions on increasing the intensity of action where it is effective or a reduction in such action which causes losses. Each decision, and thus every action is connected with cost generation. The idea is to make decisions on the basis of complete and up-to-date decisions.

Reasons for quality cost calculation

- 1. Knowledge of the quality costs allows for the identification of quality-related and organisational problems.**
- 2. Knowledge of the cost structure allows for the selection of priorities in the corrective action to optimise operations.**
- 3. Expressing the states in numbers facilitates communication.**
- 4. Adequate presentation of the amount of the costs incurred has a strong motivational effect, it makes employees sensitive to errors.**
- 5. Constant tracking of quality facilitates management, improves quality service organisation, ensures the possibility of constant supervision.**

Efficient and effective management with the use of quality cost accounting requires keeping the records, analysis and optimisation.

1. Identification and types of quality costs

The records of quality costs are only possible when we can identify those costs, answer the question: which cost is the cost of quality? The standard PN-ISO 9004-1 distinguishes three approaches to the collection, presentation and analysis of data concerning the financing of quality aspects:

Three approaches to the cost data

- 1. Approach "quality costs"**
- 2. Approach "process costs"**
- 3. Approach "quality loss"**

Approach 1 "quality costs" – divides the costs associated with quality into those which result from conducting activities within the company and those which are related to the external activity; costs of prevention and assessment are among the investments, whereas damage is considered a loss. The total costs in this approach are divided into:

1. prevention costs, i.e. costs of measures aimed at avoiding damage, including the costs of:

- planning the quality of new and updated products j,
- ensuring the required quality of materials and raw materials,
- planning quality and managing quality,
- training within the scope of quality,
- conducting motivational and propaganda actions for quality,
- market research in order to understand the needs and requirements of users,
- control of processes,

2. quality assessment costs, i.e. the costs of checking whether the quality requirements have been met, including the costs of:

- testing and control of input materials,
- testing and control of own products.
- organisation of testing and control,
- maintenance of control equipment on standby,
- analysis of test results and control,

3. costs within the organisation, i.e. the costs of failure to meet the requirements for products, detected before they are delivered, including the costs of:

- irreparable failures,
- alterations and repairs,
- further control and confirmatory tests,
- searching for the causes of interference,
- re-qualification of products to a lower class,

4. costs of damage outside the organisation, i.e. the costs of failure to comply with the requirements for products, detected after these products are delivered, including the costs of:

- customer complaints,
- technical service for the users of defective products,
- processing of returned goods,
- contractual penalties,
- exchange of products under warranty,
- withdrawal of products from the market
- legal liability for defects.

Approach 2 "process costs" – connected with the analysis of compliance and non-compliance costs with the assumption that both categories may be a source of savings. Such an approach is convenient to be applied in the case of the process approach to the quality system regulation. The efficiency of the system achieves here an additional, direct dimension – the cost dimension, whereby the categories of costs are defined in the referenced standard in the following way:

Compliance costs: costs of meeting all the determined customer needs with a simultaneous correct course of the process

Non-compliance costs: costs caused by the improper course of a given process

Approach 3: "quality losses" – this approach focuses on the internal and external losses resulting from poor quality, whereby we determine tangible and intangible losses. According to Fujio Cho, the head of Toyota: "The losses in the activity of a company include everything apart from the minimum required equipment, components, materials, space and employee time which are necessary for generating the product value."

Types of losses

1. Losses caused by overproductions.
2. Losses caused by the waiting time.
3. Transport losses.
4. Losses during the process.
5. Losses resulting from excessive stocks.
6. Losses caused by excessive traffic.
7. Losses due to product defects.

Both tangible and intangible losses may be classified as:

- internal losses,
- external losses,
- losses on account of missed opportunities.

The causes of damage in the enterprise may for example be the following s:

1. Losses related to the equipment:

- excessive equipment - unused or very rarely used machinery, tools, computers; their amortisation, maintenance, ageing, etc.

- damage of machinery and equipment resulting from a negligent, untrained use or the use which is contrary to the purpose: the costs of repairs, downtime, tests after repairs overhauls, as well as withdrawal and purchase of new devices of the same type.
- idle runs resulting from the lack of rhythm in the processes, lack of materials, inadequate training of employees: labour, energy, amortisation costs, etc.,
- shortages of equipment and the consequent need to purchase services or lower the quality of products through the execution of maladjusted equipment, in the long run: costs of additional labour, costs of services,

2. Losses connected with the use of space:

- too large area of warehouses causing excessive rental, heating, lighting and personnel costs,
- too long transport roads making the process time longer, exceeding the costs of internal transport, increasing the personnel costs,
- too long ways of information flow which influences a longer time of information flow, increases the probability of error in the message and delays the decision-making process.

3. Losses connected with the staff:

- excessive employment causing too high costs of remuneration, influencing lowering of motivation, commitment to work and at the same time reducing the quality of work effects and increase in the costs of shortages,
 - under-utilisation of skills and abilities which affect excessive growth of remuneration, delaying or preventing the development of the company, reducing motivation,
 - deficiencies in employment - inability to accept more orders, loss of potential earnings, increasing competition, accumulation of works causing lowering their effects,
 - intentional adverse action - increased costs of material, energy, remuneration, service, etc., and also the possibility of losing profits,
 - absences - additional employment on commission or overtime due to absenteeism, costs of additional supervision, loss of rhythmicity,
 - shortages of skills mean the possibility of material, labour, energy, repair costs, etc.,

4. Losses connected with materials and their deliveries:

- delayed or incomplete deliveries - loss of rhythmicity, exceeded deadlines of work completion and the necessity to pay penalties and/or lower the price,
- defective materials causing additional material costs and/or costs of additional service, contractual penalties, discounts, etc..
- unrhythmic deliveries - causing disturbances in the production, failure to meet deadlines and thus excessive costs of remuneration, service, as well as penalties and discounts,
 - additional deliveries - not provided for in the plans, influence the increase in the overall costs and invalidity of effectiveness indicators, causing excessive costs of remunerations, storage, no rhythmicity of production,
 - excessive stocks influencing the personnel and space costs of storage,
 - bad material specifications causing an increase in the material and personnel costs, resulting from the necessity of re-ordering, transport, receipt and storage,
 - lack of the necessary materials causing downtime in the processes and thus an increase in the personnel costs,

5. Losses connected with the process organisation:

- lack of appropriate information in the workplaces causing errors and/or downtime, and at the same time an increase in the personnel, material, energy, service costs, etc.,
- wrong order of operations influencing the formation of defects, and at the same time increase in the personnel, material, energy costs, etc.
- additional operations, unexpected operations affecting the obsolescence of plans and schedules, and at the same time the personnel, energy service costs, etc.,

6. Losses connected with the execution:

- erroneously performed operations - necessity to improve or scrap, influencing the increase in all the production costs,
- too long preparation of operations and their performance - influencing the increase in labour, energy and service costs,
- mess at workplaces causing the extension or repeated operations, increase in the use of the means of production.

7. Losses connected with the management:

- wrong decisions causing an increase of all costs incurred by the company,
- poor motivation or lack of incentives lowering the quality of work and thus influencing the remuneration, material, service costs, etc.,
- wrong allocation of responsibility and overlapping of competence influencing the inability to decide in a correct and timely way,
- conflicts disrupting the proper, planned rhythm of work,
- too numerous and/or too long meetings affecting the growth of remuneration, energy and/or delegation costs,
- lack of plans and/or changes in the plans - influencing the loss of rhythmicity of works and increase of all the costs in the company.

Internal losses

- | | |
|-------------------------|---------------------------------------|
| - excessive staffing, | - corrective positions, |
| - ineffective machines, | - untrained personnel, |
| - defective materials, | - failure of machinery and equipment, |
| - excessive stocks, | - no rhythm, |

External losses

- | | |
|-------------------------------------|---|
| - warranty repairs, | - penalties for delays in implementation, |
| - returns, | - interest for late payment |
| - ineffective enforcement of debts. | |

Lost opportunities can only be estimated; it is very difficult but it is worth to know them. This could be for example:

- losses due to erroneous decisions,
- loss of customers,
- missing a market or product range niche,
- improper use of production capacity (including people),
- delayed introduction of the new product, inflexible organisational structure
- ineffective participation of tenders.

Studies conducted in GB revealed that about 4% in relation to the sold value constitute the losses which we are able to recognise. The remaining ones constitute the hidden part of the "iceberg" and accordance with the estimates they amount to about 30-50%.

3. Records of Quality-related Costs

The presented approaches are in accordance with the standard ..." are regarded as useful but not mutually exclusive; similarly to their adaptations and combinations." Regardless of how the costs connected with the quality will be identified and grouped, it is necessary to conduct the records in order to enable their analysis and optimisation. This requires the introduction of special balance or off-balance accounts, since the quality costs are usually not recognised by the normal accounting system of the company.

Methods of keeping records of costs

- * **Fixed system**
- * **Quick one-time cost diagnosis**
- * **Random records of costs**

The application of a constant, uniform method of cost registration allows for conducting analyses of their trends and fast reactions in the case of the occurrence of sudden deviations. At the same time, a too formalised accounting system may not react to the changes in the environment, since it is often too inflexible. We must also reckon with a long, costly and labour-intensive period of preparation and implementation of the system. The structure and layout of the developed and implemented constant system of quality cost accounting system are organically connected with a concrete enterprise and cannot be applied in any other enterprise. In many American and European enterprises such systems were implemented in the 1980s but with time it appeared that their effects do not compensate for the expenditures and therefore they were withdrawn from such rigorously conducted records.

A quick one-time diagnosis of costs is most often conducted with an internal audit of quality system. Thus, the assessment of the system efficiency gets an additional dimension - the cost dimension. The amount of the incurred costs is in this case determined in a certain approximation, which is quite sufficient for their analysis and assessment. The results of quality cost records conducted in this way may be used for the assessment of the potential opportunities of the company to conduct a motivational action under the slogan "We sleep on a goldmine," but above all they are a prelude to further work. A quick cost diagnosis is most often conducted with the participation of external consultants.

An introduction of a random quality cost records requires a separation of areas in which it is necessary and possible to keep accurate records. it can be done on the basis of a quick one-time diagnosis or through the analysis of accounting data. For the remaining activity the records are kept in a random way. It is usually the currently applied system of quality cost records. It is a flexible and less time- and cost-consuming but the trust towards it may be built only after some time of its using.

Methods of obtaining data on costs

- **introduction of new report types,**
- **division of data available on bookkeeping accounts,**
- **aggregation of data from different accounts,**
- **estimating.**

All these ways are used in practice. The introduction of new types of reports and the pooling of data from different accounts require detailed clarification of the actions taken within the scope of quality, since all the costs incurred during their implementation will be recorded as quality costs. These may be for example:

- separating a group of commissions for the removal of defects revealed after the delivery and a development of a form for recording costs of these commissions ,
- preparation of cards of reparable and irreparable defects,
- summing up the recruitment costs, the costs of training of newly employed persons and costs of the procedure connected with the leaving of employees in order to obtain data determining the personnel rotation costs.

The division of data available on the bookkeeping accounts requires stating which part of the action, the costs of which have been recorded on a given account, concerns the quality. For example, in one of the enterprises it was assumed that 30% of activity costs of the technological department constitute the costs of research, analyses and removing the causes of defects, in another one the costs of places of preventive activity cost generation have been separated from the overall costs .

Estimating the quality costs concerns first of all those costs which do not have a direct reflection in the existing bookkeeping records. The estimation of costs incurred is usually based on the analogy or the opinions of specialists. An example here would be estimating the costs of erroneous product installation.

Difficulties in the records

- **connected with unproductive work**
- **bad recognition of the reality**
- **structure of overall costs**
- **too extensive system**
- **misunderstanding of the system**

In the course of keeping records of quality costs we may be faced with numerous difficulties and make mistakes in the calculations. Especially difficult is keeping records of the quality costs incurred during non-production work (e.g. in designing and management). It is also necessary to recognise the reality e.g. in the common understanding the word "scrap" refers not only to products which are so defective that they have to be disposed of but also it is used to describe chips, waste materials, risers, etc. Therefore, we cannot count all these material costs with the costs of deficiencies. Also, the information about numerous returns from the customers does not necessarily mean that the product is defective. Sometimes returns are caused for example by surpluses at the distributor who miscalculated the inventories. A great difficulty is to determine what part of the overall costs constitutes the quality cost. They are sometimes very high and it is logical to take them into consideration. The starting point in estimating these costs should be the determining of the "normal activity level," and then the records of deviations from this level. However, it is necessary to pay attention to the fact that a part of deviations may be caused by factors being outside the enterprise, e.g. strikes in other companies or a change in the legislation. A common mistake made in the entry of quality cost records is also its excessive expansion causing the "information noise." Too many types of costs and accounts does not help in assuring quality but it causes darkening of the image.

A properly functioning quality cost recording system should:

- be known and accepted by all those who provide data (primarily by employees of the accounting department),
- ensure the acceptance of the calculated amounts because only then it is possible to count on cooperation and use quality costs for motivating,
- apply a uniform way of filling in forms, since it allows for the use of a common "language" by all the departments within the enterprise,
- be introduced with the use of a guide developed especially of a given employment establishment, including the applied definitions, ways of keeping records and providing information,
- providing as much information as it is really needed in order to ensure quality.

A thought out and carefully carried out records of quality costs is a prerequisite for an effective analysis and optimisation .

4. Analysis of the recorded costs

Recording the costs allows for getting to know their amount, however, it does not answer the question whether this amount is appropriate for a given plant. It is necessary to provide certain outlays for activities connected with quality but the point is that these outlays should possibly be as small as possible. Therefore an analysis of the recorded costs is necessary.

Types of analyses of registered costs

- according to places of cost generation,
- according to products and product groups,
- in relation to the plan,
- in time,
- according to the relationships between cost groups.

- in relation to other measures of company activity.

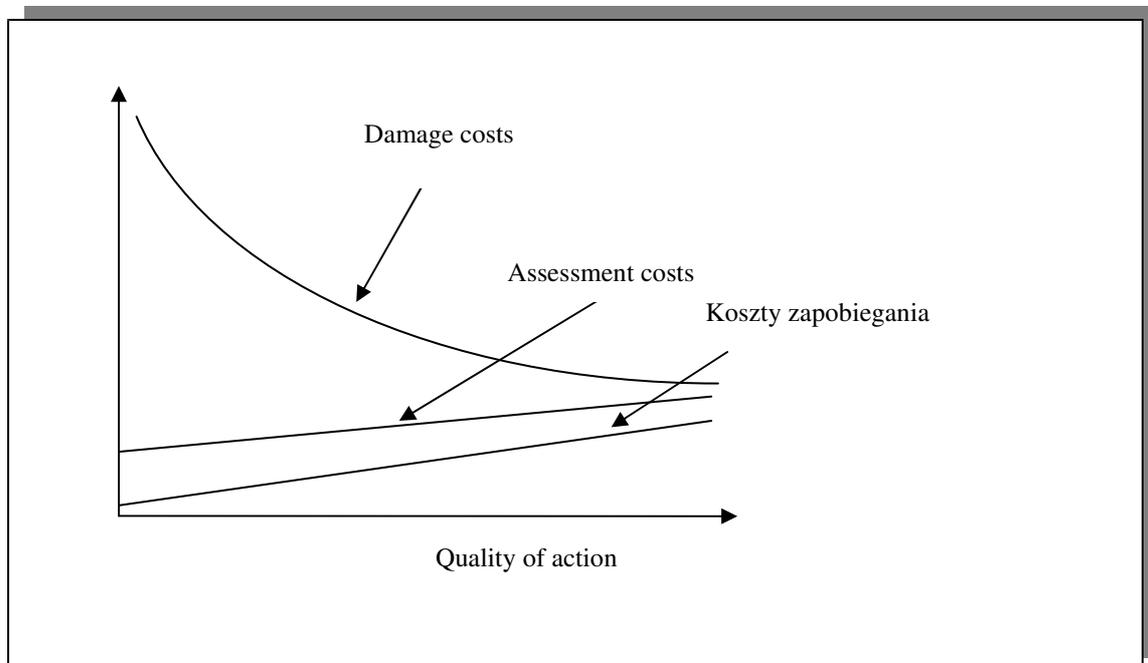
Cost analysis according to the place of formation and products uses a fact stated in many enterprises that unnecessary cost (losses) are not evenly distributed. They are generally distributed in such a way that a few basic factors are the cause of a large percentage of losses connected with quality. The phenomenon of such an unevenness is favourable to the management because it allows for directing the efforts towards weakening the actions or eliminate these factors. Upon their identification they - and only they - become problems which require solution. With a limited number of problems the costs of preventive activity are relatively small. However, since these problems concern the main part of the losses, there is a large possibility to limit the costs.

Recording quality costs in a longer period allows for their planning, and thus the analysis of deviations in relation to the plan. Each deviation is then a signal of an irregularity in conducting activities or in planning and it should lead to taking steps to improve the situation. Such an analysis ultimately leads to the improvement in the efficiency of performance.

An analysis of the recorded quality costs in time is based on tracking their trends with a simultaneous reference to the chances and the nature of the conducted pro-quality activities. Such an analysis should confirm the correctness of the decisions about the direction, scope and intensity of measures.

It is particularly helpful to connect the cost analysis in time with the analysis of the relationships between the kinds (types) of costs.

Proper relations between the types of costs and quality of action



The increase in the prevention costs should be the result of an extended substantive range of preventive measures. If the increase in these costs is reflected in a simultaneous decrease in the costs of damage or a decrease only slightly shifted in time and accordingly larger, it is beneficial for the enterprise. An increase of assessment costs in time may be the result of an extension of the control tasks, as well as the necessity of an additional product selection. However, a moderate increase in the quality assessment costs is favourable for an enterprise, since in most often affects a substantial decrease in damage costs, and as a result, influences the reductions in the overall manufacturing costs.

Analysing the changes in the costs of quality according to their types, we can also state whether an enterprise conducts an active or a passive pro-quality activity. If in a longer period, the relationship between the prevention and assessment costs and the damage costs is constant, it is a sign that the company is passive. Whereas a decrease in the damage costs with a simultaneous increase in the preventive activity costs and/or quality assessment costs, shows the activeness of the enterprise within the scope of quality. Each increase or even maintaining the same level of damage costs is a proof that the undertaken measures are ineffective.

Optimisation of Costs Connected with Quality

Optimisation of quality costs is determining the amount of outlays which are actually necessary to ensure an economically optimal quality of products and services.

If it is obvious that it is necessary to incur certain costs to ensure the required quality, it raises the problem of finding methods that allow to determine the optimum amounts. It is impossible to look for analogies of other companies, since the cost information is usually kept secret. In addition, each enterprise has a different technical, human and financial potential and due to these differences the data becomes incomparable. Optimisation of quality costs may be conducted only if an enterprise implemented and verified a system of their records and analysis which corresponds to its specificity.

Optimising costs means:

- 1. Determine the standard level**
- 2. Estimate lost opportunities**
- 3. Select the best solutions**

When the quality costs are well identified, there is a large temptation to eliminate them, however, it is necessary to consider the consequences. Sometimes a partial (fragmentary) elimination of costs may lead to their global increase. The fundamental issue in trying to optimise the costs of quality is the ability to determine the costs connected with each of the conducted actions with each of the conducted.

It is necessary to analyse the measures which are taken to ensure quality and the assessment of its level. It will allow for strengthening these measures which result in lowering the total costs and eliminate those which require outlays but do not bring the expected benefits.

The optimisation (elimination) of deficiency costs should concern the whole activity of the enterprise. It is necessary here to determine the model level of measures or determine such measures and in what scope they should be introduced in the enterprise, and then check how they take place in the reality.

Optimising quality costs it is necessary to:

- 1. Refer to specific actions**
- 2. Analyse trends**
- 3. Strengthen effective action**
- 4. Eliminate ineffective action**
- 5. Be careful not to optimise in part**

Determining the optimum level of action which is appropriate for a given enterprise and determining the necessary outlays on the one hand and the records of the costs actually incurred on the other hand will allow to estimate the lost opportunities as a result.

Cost optimisation may be performed by:

- the application of new technological solutions (new devices, technologies),**
- introduction of changes in the process organisation,**
- conducting motivational actions among the staff.**

A special role in the process of cost optimisation through the elimination of losses is played by the level of employee awareness.

Levels of awareness in solving the problems of losses

- 1. I do not know what a loss is, I do not know that my actions lead to the generation of losses.**
- 2. I know that I am causing some losses but I do not know their extent and mechanisms of formation**

3. **I know what losses arise, I am able to observe and analyse them.**
4. **I have the tools and skills which enable me to eliminate losses**

The first of the above levels occurs in enterprises which do not conduct the quality cost account, the second one occurs in those which only conduct the records of these costs. Companies conducting records and cost analysis are placed at solving the problem of losses, at the third level of awareness development. However, the optimisation of quality costs is connected with the fourth (the highest) level of awareness

LEGAL ASPECTS CONNECTED WITH QUALITY

New Approach Directives

These directives have been developed since 1985. A list of directives designed to date is included in Table 1.

Table 1. Selected Directives of the European Union

Number	Title
87/404/EEC	Simple pressure containers
88/378/EEC	Safety of toys
89/106/EEC	Construction products
89/339/EEC	Electromagnetic compatibility
89/382/EEC	Machines
89/686/EEC	Personal protection
90/384/EEC	Non-automatic weighing machines
90/385/EEC	Active implantable medical devices (implants)
90/396/EEC	Appliances burning gaseous fuels
91/263/EEC	Communications equipment
92/42/EEC	Efficiency of heating boilers
93/15/EEC	Explosives used for non-military purposes
93/42/EEC	Medical devices
93.68/EEC	Low voltage
94/9/EEC	Protective equipment and systems for use in potentially explosive atmospheres
94/25/EEC	Recreational boats

Currently, the Directives include about 65% of products which are marketed. Works are being conducted on the development of further directives concerning among others:

- measurement tools,

- marine equipment,
- upholstered furniture,
- equipment in playgrounds,
- packaging,
- incineration of hazardous products.

In the period from the adoption of a directive to the date of its validity there is the so-called transition period in which manufacturers have the right to use both the directive and the "old" regulation in accordance with the existing national law.

Content Elements of Directives:

- Scope (range of products covered with the Directive)
- General clause on the introduction to the market
 - safety of persons, domestic animals or goods cannot be put at risk by the product which is introduced to the market
- Basic safety requirements
 - the core of the "new approach" directive
 - protection of public interest
 - possibility to ensure compliance with the directive on the basis of the basic requirements
- Free movement clause

Proof of compliance

- – compliance with harmonised standards
- – lack of compliance
- – lack of standards
- Administering the list of standards (procedure applied in the case when the Commission or a Member State is not satisfied with the harmonised standard)
- Safety clause
- Means of attestation of conformity
- The Standing Committee (manages the Directive)

A Standing Committee is nominated for each Directive to supervise the development of harmonised standards, collects comments on the Directive and proposes amendments. The technical requirements of products which are subject to the Directive are included in the harmonised standards.

During the development of a European standard or a harmonisation document it is prohibited for the standardisation bodies of particular member states to undertake work or publish a standard on the same subject.

Each member state of the European standardisation organisations must implement a European standard to its collection of standards and withdraw all the standards which are contrary to the adopted standard.

Compliance assessment

Each Directive includes the procedures whereby a manufacturer or and importer may demonstrate to relative authorities that the product introduced into the market meets the basic requirements included in the directives. The modular approach was proposed in the case of the proposed procedures. The Directives determine the modules which may be applied and the final choice is up to the manufacturer.

The modular approach divides the procedures of compliance confirmation into 8 basic modules which differ depending on: the stage of product development, assessment type and the unit which conducts assessment. These modules have been presented in Table 2. They may be characterised as follows:

Module A (declaration of conformity)

The manufacturer declares the conformity of their products with the requirements of the directive. They keep the technical documentation available to the government authorities. The producer prepares a written declaration of conformity and marks the product with the CE marking.

Module B (type testing)

The manufacturer presents the technical documentation and/or product prototype to the authorised unit. The authorised unit checks and carries out research, issuing a type testing certificate.

Module C (type compatibility) applied with module B

The manufacturer declares the conformity of the product with the type for which he received a certificate. The producer prepares declaration of conformity and marks the product with the CE marking.

Module D (ensuring production quality) applied with module B

The manufacturer having a certified quality system declares the conformity of the product with the certified type. The producer prepares declaration of conformity and marks the product with the CE marking.

Module E (ensuring product quality) applied with module B

A manufacturer having a certified quality system declares the conformity of the product with a certified type, prepares a declaration of conformity and marks the product with the CE marking.

Module F (product verification) applied with module B

An authorised body examines the conformity of the product with the certified type. The producer prepares a declaration of conformity and marks the product with the CE marking.

Module G (unit production verification)

An authorised body examines the documentation and the product, and issues a compliance certificate. The producer prepares declaration of conformity and marks the product with the CE marking.

Module H (full quality assurance)

A producer having a certified quality system in accordance with ISO 9001 prepares a declaration of conformity and marks the product with the CE marking.

Table 2. Conformity assessment procedures in the legislation of the European Union

D E S I G N	A. INTERNAL CONTROL OF PRODUCTION	B. TYPE TESTING				G. UNIT CONTROL OF EACH PRODUCT	H. TOTAL QUALITY ASSURANCE
	Manufacturer: - stores technical documentation for the control of the national authorities	Manufacturer submits the following to the notified authority: - technical documentation - typical product Notified authority: - performs tests (if necessary) - certifies compliance with the basic requirements - issues the type testing certificate				Manufacturer: - submits technical documentation	ISO 9001 Manufacturer: - acts according to the approved quality system for design Notified authority: - controls the quality system system jakości - confirms the design compliance - issues a project certificate
P R O D U C T I O N		C. TYPE COMPATIBILITY	D. ENSURING QUALITY OF PRODUCTION	E. ENSURING QUALITY OF PRODUCT	F. PRODUCT CONTROL		
	Producent: - declares compliance with the requirements - places <u>CE marking</u>	Producent: - declares compliance with the approved type - places <u>CE marking</u>	Producent: - acts in accordance with the approved quality system for production and tests - declares compliance with the approved type - places <u>CE marking</u>	Producent: - acts in accordance with the approved quality system for control and testing - declares compliance with the approved type - places <u>CE marking</u>	Producent: - declares compliance with the approved type - places <u>CE marking</u>	Producent: - submits the product for control - declares compliance - places <u>CE marking</u>	Producent: - acts in accordance with the approved quality system for production and control - declares compliance - places <u>CE marking</u>
	Notified authority: - conducts random product checks	Notified authority: - tests the product in terms of the essential parameters and functions - conducts random product checks	Notified authority: - approves the quality system - conducts an inspection of the quality system	Notified authority: - approves the quality system - conducts an inspection of the quality system	Notified authority: - checks compliance with the requirements - issues a certificate of compliance	Notified authority: - checks compliance with the requirements - issues a certificate of compliance	Notified authority: - conducts an inspection of the quality system

"Recognised" or "notified" authorities participate in the assessment of compliance. These are units selected by the national authorities and notified to the Commission of the European Union. They are reported by the member states of the European Union for each directive. These units should be competent and recognised laboratories, inspection or certification units. These units are usually accredited units. Units outside the EU can be approved for a given directive on condition of concluding an agreement on a mutual recognition of research results and certificates of conformity between the interested parties and the EU. In Poland such a recognition procedure has been initiated by 4 laboratories.

CE Marking

Labelling a product with a CE marking means that the manufacturer ensures that the product which is subject to the requirements of one or several directives, meets them. It may be accompanied by a code identifying the notified authority.



This marking does not inform about the assessment procedure (which mode of assessment was selected by the manufacturer). This gives the right to the free circulation within the European Union. Products which are subject to the directives, regardless of the manufacturer, which have not undergone the conformity assessment procedures and have not been granted the right to label the product with the CE marking, cannot be traded on EU markets.

It is necessary to emphasise that countries (through their authorised notified authorities) have a supervision over the proper application of CE markings, regardless of the mode of obtaining them.

Product liability

The European Union legislation, and especially Directive 85/374/EEC on the liability for defective products requires its members to implement common liability rules for defective products to their national law. The Directive determines the following:

- a product is considered defective if it does not ensure safety, which can be expected by a person;
- it is required from the injured party to prove the existence of damage, a defect and a causal connection between the damage and the defect;
- the manufacturer is responsible for damage caused by the defect of their product;
- the manufacturer is obliged to prove that the product at the time of marketing did not have the defect which caused damage or that the defect could not be recognised with the contemporary state of knowledge and technology