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SAFETY OF IMPORTED MACHINES - SELECTED ISSUES IN THE CONTEXT OF POLISH (UE) REGULATION

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Abstract: The purpose of the paper is to present the issues of ensuring the safety of machinery and equipment in accordance with the requirements of the Machinery Directive 2006/42/EC of May 17, 2006 on the essential requirements for machines, with regard to the sphere of their import and distribution. This issue is related to the dynamically developing trade in cheaper new machines, mainly from countries outside the EEA (including China) and is a priority for ensuring safety and protecting the health and life of users of this type of equipment in accordance with EU regulations. The use of a variety of machines in industry, in addition to general safety requirements, which may also include quality criteria, care for the environment and industry-specific safety management requirements (e.g. food, automotive, medical devices).
Keywords: machines, import, distribution, production, operation

1. INTRODUCTION

Work safety requires a great deal of commitment to the proper design of the workplace as well as special care for the safe operation of all machines. Human work with the use of electronically controlled mechanical devices requires the use of appropriate safeguards and, above all, the improvement of employees' qualifications. Absolutely, however, requires a proper occupational risk assessment. (Lazányiand and Bilan, 2017; Madlovaand and Gebhart, 2016; Pacana, 2020; Rąb-Kettlerand and Lehnervp, 2019; Ulewicz et al., 2015; Woźny et al., 2017; Zaloga et al., 2019).

The obligation to meet the requirements of the New Approach directives and the CE marking are obligatory for imports from outside the European Union. It happens that goods are presented for customs clearance, which have a CE mark, but which means China Export - confusingly similar to the EU CE mark. This applies to many products, especially machines for which the development of construction documentation and their production, taking into account the applicable safety requirements, has an impact on the increase in manufacturing costs and product competitiveness. The CE marking also applies to a wide range of products such as toys, cosmetics, personal protective equipment, food products, batteries and accumulators, medical tools, packaging, construction products, etc.

2. METHODOLOGY

In this study, the desk research method has been used in the scope of: legal documents and information from accredited companies performing tests and assessment of machine safety.

3. RESULTS AND DISCUSSION

General product safety - EU legislation provides protection for the health and safety of consumers/users by implementing Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Official Journal L 11 of 15.1.2002), which sets out general safety requirements for products sold to consumers/ users - used products that have historic value or that need to be repaired are not subject to these requirements. The General Product Safety Directive has been supplemented by Regulation (EC) No 765/2008 of the European Parliament and of the Council setting requirements for the accreditation and market surveillance of the relationship with the placing on the market of products - repealing at the same time Regulations (EEC) No 339/93, (EC) No. 596/2009, (EC) No. 596/2009, (EC) No. 596/2009 adapting to Council Decision 1999/468/EC certain acts subject to the procedure referred to in Article 251 of the Treaty, regarding the regulatory procedure with scrutiny.

3.1. Conditions for recognizing the product/machine as safe

Safe product means any product which, under normal or foreseeable conditions of use, including storage and, where appropriate, putting into service, installation and maintenance requirements, presents no risk or only the minimum risk associated with its use, considered for permissible and corresponding to a high level of protection of the safety and health of persons. A product is considered safe if it complies with the European directive, standards and established procedures of this directive - and is confirmed by the manufacturer with the EC DECLARATION OF CONFORMITY and marked with the CE mark (Dźwiarek and Biernacki, 2008).In the absence of such standards, the product shall be assessed by the criteria:

- voluntary national standards transposing relevant European standards,
- standards developed by the Member States where the product is sold,
- Commission recommendations, which set out guidelines for safety assessment,
- principles of good practice for safety in this area,
- current level of knowledge and technology,
- possible consumer expectations regarding safety,

Issuing an EC declaration of conformity and granting a CE mark requires that each product (machine, toy, construction product, medical device, electrical device, etc.) be checked according to the appropriate conformity assessment procedure described in Annex 5 to the Regulation of the Minister of Economy of 21.10 .2008 on the essential requirements for machinery and in Annex 4 of Directive 2006/42/ EC (Gierasimiuk, 2007). Choosing the right procedure requires a review of the above attachments and analysis:

- is the machine listed in the annexes of the directive?
- which standard harmonized with the machinery directive covering all requirements?
- is this harmonized standard met by the machine?
- is the production of the machine carried out in a serial or individual way?

Answers to these questions allow to: perform the proper conformity assessment procedure, issue an EC declaration of conformity for a product / machine, and issue a CE mark.

The machinery sector is an important industry and is one of the industrial pillars of the Community economy, operating various machines in many industries. The social costs of a large number of accidents directly caused by the use of machinery can be reduced by designing and manufacturing safe machinery by design and proper installation and maintenance. In order to harmonize the requirements in the field of health and safety in relation to design, construction, use and maintenance as well as distribution, the Machinery Directive 2006/42/EC of May 17, 2006 on the essential requirements for machines has been introduced. The provisions of Directive 2006/42/EC apply to manufacturers of new machines, their authorized representatives, importers of new machines from EU countries and all machines, i.e. new, modified and used machines imported from third countries.

The directive specifies the assessment of compliance with the essential safety and health requirements which the manufacturer, authorized representative of the manufacturer or importer should carry out according to the appropriate procedure - alone or in cooperation with the notified body (the type of machine decides).

To assess the compliance of machinery with the essential requirements, procedures were established with a distinction between machines included and not included in Annex 5 to the Regulation (Journal of Laws No. 199, item 1228).

For machines not included in the Annex, the manufacturer/authorized representative or importer shall apply the conformity assessment procedure with internal control of machine manufacture provided for in point 1 of Annex 6 to the Regulation (Journal of Laws No. 199, item 1228).

In the case of machines included in Annex 5. to the Regulation which have been produced in breach of the relevant harmonized standards (mainly type C standards), the manufacturer or his representative may apply:

- the EC type-examination procedure provided for in point 2 Annex 6 to the Regulation together with the internal control of machine manufacture
- or the full quality assurance procedure provided for in point 3 Annex 6 to Regulation.

The manufacturer may, of own volition, request an external notified body to carry out tests and evaluation or to consult only. Directive 2006/42 / EC provides for three types of conformity assessment for machinery (Figure 1).

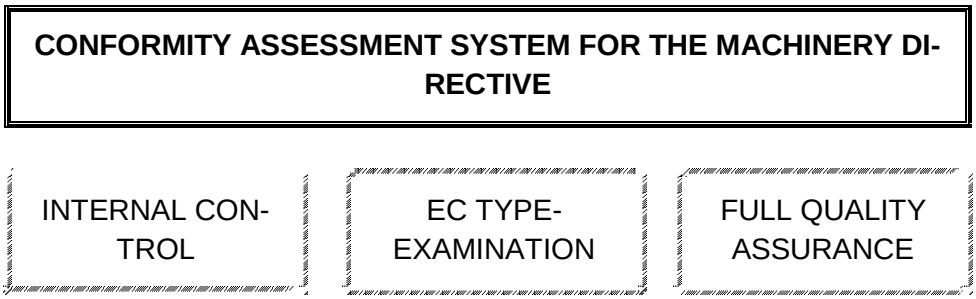

Fig. 1. Conformity assessment system of the Machinery Directive 2006/42/EC

Internal control - includes verification of compliance with the essential requirements for a given machine and is most often used by manufacturers / importers,

EC type-examination - requires the manufacturer to carry out specialist tests, through an authorized body. The purpose of certifying that the machine is safe and adapted to EU requirements. - The machine receives a CE Certificate.
Full quality assurance - requires obtaining a certificate (by the machine production organization - regarding design, manufacture, final inspection and testing) confirming the use of a quality management system (e.g. according to ISO 9001).
An important and obligatory element for assessing the compliance of a machine/ service with the requirements of the directive is the process of hazard analysis and risk assessment. The process of determining hazards related to working on the machine and assessing the risks for these hazards is a legal requirement to give the machine CE marking. The risk assessment carried out increases the safety of machine operators and bystanders who could potentially suffer in the event of a machine failure. General guidelines for the risk assessment of machines are included in the ISO 12100 standard (Dźwiarek, 2009).A safe machine is a device that meets:

- the requirements of the Machinery Directive 2006/42/EC - essential requirements,
- the requirements of Directive 2009/104/ EC, the "Tool" - minimum health and safety requirements
- and other directives that are required e.g. Directive 2004/108/EC electromagnetic compatibility, Directive 2006/95/ EC for electrical equipment/

Issuing an EC declaration of conformity and granting a CE mark requires that every product has been checked according to the appropriate conformity assessment procedure. Choosing the right procedure requires a review of the above attachments and analysis:
- is the machine listed in the annexes of the directive?
- does the harmonized standard cover all essential requirements?
- is this harmonized standard met by the machine?
- is the production of the machine carried out in a serial or individual way?

Reliable answers to these questions allow to: perform the proper conformity assessment procedure, issue an EC declaration of conformity for a product / machine, and issue a CE mark.
Machinery Directive 2006/42/EC, introduced into Polish law by the Regulation of the Minister of Economy of October 21, 2008 (Journal of Laws No. 199, item 1228), the provisions of which concern, among others: the definition of the machine according to 1 § 3 of Regulation (Journal of Laws No. 199, item 1228), exchangeable equipment, safety components.

3.2. Obligations of the importer

The importer, according to the Act on the conformity assessment system - is a natural or legal person who places on the market or puts into service products from third countries and becomes fully responsible for placing the machine on the market, even if it is a used machine. All obligations in accordance with legal requirements are then taken over by the importer (on behalf of the supplier/manufacturer).
Before placing the machine on the market or putting it into service, the manufacturer or importer is required to document compliance with all applicable provisions, i.e. the Regulation of the Minister of Economy of October 21, 2008 (regarding Directive 2006/42 /EC) and other implementing regulations New Approach directives related to the designated machine (e.g. Directive 2009/104/EC).The importer (supplier) of the

machine placed on the market within the EEA European Economic Area is obliged to provide (Obligations of importers and the process of placing machinery on the market and use in the EEA are detailed in Article R4 of Decision 768/2008 / EC of the European Parliament and of the Council of 9 July 2008 concerning the placing of products on the market):

1. Placing only products which comply with the requirements of the relevant safety regulations on the Community market
2. Before placing a product on the market, importers shall ensure that:
   - the manufacturer has carried out the appropriate conformity assessment procedure,
   - the manufacturer has prepared technical documentation,
   - the machine has the required conformity marking,
   - the machine has documents, i.e. translation of the EC declaration of conformity and the user manual into the user's language, documenting compliance with the provisions and regulations implementing directives relating to the machine.
   - the manufacturer has met the requirements set out in Article R2 of Acts 5 and 6.
3. Importers shall ensure that the operating instructions are attached to the product and that safety information is provided in a language that the end user understands.
4. Importers shall ensure that its storage and transport conditions do not adversely affect its compliance with safety requirements
5. Importers are obliged to carry out tests on machines placed on the market in relation to the protection of health and safety and risk that the product may constitute and to keep records of complaints testing, if necessary, to keep records of products which do not comply with the requirements.
6. Importers who consider or have reason to believe that a product placed on the market does not comply with applicable Community legislation shall be required to immediately take the necessary corrective measures to ensure that the product conforms or shall be withdrawn as appropriate. If the product presents a threat, importers shall inform the competent national authorities of the countries in which the product was made available.
7. Importers shall keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities for a period of 10 years and ensure that the technical documentation is available to those authorities, upon request.
8. At the reasoned request of the national authority, importers shall provide it with all the information and access to the documentation necessary to establish the conformity of the device concerned with the requirements in a language easily understood by that national authority. At the request of the competent authorities, they shall cooperate with them in activities aimed at removing the risks posed by equipment which they have placed on the market.

In summary, the importer's obligation is:

- placing on the EU market only products that comply with applicable regulations and safety requirements,
- availability of technical documentation,
- provide machine identification information and provide machine instructions,
- conducting machine tests and appropriate conformity assessment procedures,

- after positive assessment results, draw up an EC declaration of conformity and attach it to the machine (keep a copy of the EC declaration of conformity for a period of 10 years),
- affix the CE marking to the machine,
- inform the manufacturer and market surveillance authorities if the product presents a risk.

The manufacturer/importer is obliged to ensure that the products bear the type name, batch or serial number or other information enabling their identification, that the required information is included in the document attached to the product and they are obliged to affix the product with their registered trade name or trademark and put their contact address on the machine, and/ or in the document attached to the machine. If the importer has reason to believe that the product is not in compliance with the regulations or poses a threat, he cannot place it on the market until the product compliance
is ensured.

3.3. Used machines in the EU

The Machinery Directive covers all newly manufactured machines and machines placed on the market for the first time on the Common Market of the European Union (e.g. imported), even if they were manufactured long before the creation of any machinery directive - i.e.: “Any used machine placed on the market, and originating from outside the European Economic Area is treated as a new machine and therefore every imported machine should be checked in detail for its compliance with the relevant requirements and harmonized standards and treated individually each time”.
However, Directive 2006/42/ EC does not cover old machines already present in the EU - which means that when the machine:

- has been at the same level of safety since manufacture (conformity assessment according to Directive 2009/104/ EC) - meets the minimum health and safety requirements,
- has not been reconstructed in a way that changed the original safety features,

Such a machine can be placed on the market without a CE mark and without an EC declaration of conformity. However, if the safety of the machine has been changed, then the person who is responsible for it becomes the manufacturer of the new machine and assumes all the manufacturer's obligations in relation to that machine.

3.4. Essential safety requirements and harmonized standards

Ensuring compliance with the harmonized standards requirements of a given machine (if these standards cover the whole range of requirements included in the directives), the presumption of compliance with the essential requirements is assumed. Detailed technical requirements are included in European harmonized standards (lists of standards are published as announcements of e.g. the President of the Polish Committee for Standardization, in Monitor Polski, as well as on PKN websites.
European standards on safety and ergonomics for machines are divided into:

- type A standards - containing design principles and general aspects applicable to all machines (eg PN-EN ISO 12100-1, PN-EN ISO 12100-2, PN-EN 614-1),
- type B standards - for one aspect of safety or one type of protective devices that can be used on many different machines, including:
  - B1 standards - concern specific safety aspects (e.g. safety distances)

- B2 type standards - they apply to protective devices (e.g. two-hand control devices - PN-EN 574, locking devices PN-EN 1088, covers - PN-EN 953)
- C type standards - containing detailed safety requirements for machines of a specific type (e.g. PN-EN 1870 standard for circular saws).

With regard to the technical documentation, it is assumed that the manufacturer/ importer should collect documentation of manufactured/imported machines and keep for 10 years, including:

- general description of the machine,
- assembly drawing with control circuit diagrams,
- risk assessment documentation containing:
  - list of essential safety requirements,
  - description of the measures taken to eliminate the threats,
  - residual risk indications related to the machine,
- list of technical standards and specifications (requirements) used,
- copies of the EC declaration of conformity of the machine and other products included in the machine.

Operating Instructions (DTR) - the machine placed on the market or put into service should be equipped with the "Original Instructions" and, if applicable, and "Translation of the Original Instructions". This allows the user to check the wording in case of doubt. The instructions should be drawn up in at least one of the 23 official languages of the EU Member States and bear the inscription "Original instructions".

The EC declaration of conformity is the manufacturer's or authorized representative's statement stating the sole responsibility that the product complies with the essential requirements. The declaration issued in languages identical to the operating instructions - must be attached to the machine before it is placed on the market and should contain:

- name and full address of the manufacturer / authorized representative,
- name and address of the person authorized to prepare the technical documentation who is entrusted with the task of completing and making available such documentation,
- full machine identification (marked on the machine, in full version; the machine must be clearly identified; the principle is to provide the serial number,
- a statement that the machine ensures compliance with the machinery directive and other relevant directives;
- name, address and number of the type examination notified body and certificate number,
- compliance with the standards that were used in the conformity assessment process,
  - name, surname and signature of the authorized person, place and date of preparation, in accordance with point 1 Annex 3 to the Regulation (Journal of Laws No. 199, item 1228) (point A Annex II to the Directive 2006/42/ EC).

The CE marking - should conform to the model given in Annex 4 to the Regulation (Journal of Laws No. 199, item 1228) and have a height of not less than 5 mm. The mark should be placed in close proximity to the name of the manufacturer/ authorized representative or importer, using the same technique. When the full quality assurance procedure is used in the conformity assessment, the number of the notified body that certified it is placed after the CE marking.

Evidence of tests and assessments carried out - may include both measurements and calculations, controls, analyzes, etc. Test documents - most often reports, should clearly specify the subject and scope of tests, methods and equipment used, and present the results obtained taking into account measurement uncertainty.

These documents, together with attestations, e.g. materials, declarations of conformity of the elements used, certificates, are sources of data for the collective assessment of machines should have clearly defined identification features, e.g. numbers, be dated, contain names and signatures of contractors, controlers and authorizing persons

4. CONCLUSIONS

The provisions of the Regulation (Journal of Laws No. 199, item 1228) implementing the Machinery Directive (Directive 2006/42/ EC) clearly indicate that the basis for the machines to meet the highest possible level of safety is the analysis of the results of the risk assessment. Only a positive result of the conformity assessment of machines authorizes the issuing of the EC declaration of conformity and CE marking of the machine and placing it on the market or directly for use.

It is the responsibility of the manufacturer or authorized representative as well as the importer to provide a machine that meets the provisions of Regulation (Journal of Laws No. 199, item 1228), together with the instruction manual, declaration of conformity and full marking (including CE) as well as the basic special equipment and accessories that enable it to be adjusted, maintained and used without creating a hazard.

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