

SAFETY OF MACHINERY REGARDING THE REQUIREMENTS OF THE REGULATION 2023/1230/EU

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Purpose: The purpose of the study is to present the changes resulting from the publication of Regulation 2023/1230/EU in the field of essential requirements for machinery.

Design/methodology/approach: As part of the conducted analyses, the changes resulting from the publication of the new Machinery Regulation 2023/1230/EU were summarized and the manufacturers' obligations regarding the conformity assessment process were summarized, as well as the possibilities of supporting work in the field of essential requirements using computer software.

Findings: Based on the analyzes carried out, differences in the scope of legal acts were summarized. It was also found that the new regulation's requirements include an additional group of products that the Machinery Directive did not explicitly cover.

Research limitation/implications: The conducted analyzes were limited to EU law requirements specified in the Machinery Directive and the regulation.

Practical implications: The research carried out may provide important information for manufacturers and employers regarding the changes resulting from the publication of the Machinery Regulation 2023/1230/EU, also adapted to the evolving technological changes. The study also summarizes additional aspects resulting from, among others, taking into account: new definitions, the introduction of a new conformity assessment procedure, third-party participation in the conformity assessment process, and digital instructions.

Originality/value: The article refers to the changes resulting from the 2023/1230/EU machinery regulation.

Keywords: machinery safety, machinery regulation, machinery, legal requirements.

Category of the paper: A review paper.

1. Introduction

Every day, technological machines are used in production enterprises, which should meet the requirements set out in legal regulations. According to the concept of security, in EU countries there are two types of requirements dedicated to employers or producers. From a practical point of view, each of the entities should limit all kinds of risks associated with the use of machinery in the enterprise. The employer is at the stage of installation and use, while the manufacturer is at the stage of design and production. Therefore, both the employer and the producer will be obliged to limit the risk by using solutions that reduce the risk (technical solutions, organizational solutions).

Effective preventive care allows you to reduce the accident risk, and thus reduce the costs incurred by enterprises in this respect. Therefore, manufacturers and employers should comply with applicable legal regulations in order to meet and maintain machines in terms of essential and minimum requirements. Legal regulations are changing; therefore, employers and producers should be aware that legal acts should be analyzed and their validity assessed. In the case of producers, this element is relatively important, because failure to meet the requirements of the acts of the applicable legal act may result in failure to meet the requirements set out by the legislator. Failure to comply with legal requirements may result in both practical and financial consequences.

The purpose of the study is to present changes resulting from legal regulations in the field of essential requirements set out in the machinery regulation 2023/1230/EU and to present the possibilities of supporting the work of manufacturers in relation to applicable legal regulations.

2. Literature review

Reducing the risk associated with manufactured and operated machines is the primary duty of manufacturers and employers providing technological machines in enterprises. The requirements of the legal provisions have been addressed to these entities and according to them, employers and manufacturers should take measures to reduce the risk at every stage of the machine's life. According to the applicable regulations, there are two types of requirements for machines, i.e., minimum requirements and essential requirements (Dyrektywa..., 2009; Dyrektywa..., 2006; Rozporządzenie 2023/1230/UE; Łabanowski, 2012; Nowak, 2008; Lis, 2007; Rączkowski, 2018; Małysa, 2020, Małysa et al., 2023).

The minimum requirements are set out in Directive 2009/104/EC (Directive..., 2009) and are addressed to employers - machine users. Due to the fact that these requirements were specified in the directive, the national legislator was obliged to implement them effectively into

national legislation. In Polish law, the minimum requirements for broadly understood work equipment are specified in the Regulation of the Minister of Economy (Regulation..., 2002). Other legal acts also refer to minimum requirements, such as the Labor Code (Act, 1974) and the Regulation of the Minister of Labor and Social Policy on general health and safety regulations (Regulation..., 1997). In accordance with applicable law (Directive..., 2009; Regulation..., 2002; Act..., 1974; Regulation..., 1997), it is the employer who is obliged to ensure safe and hygienic working conditions to protect against the risks associated with their operation. It is therefore the employer's responsibility to meet and maintain the machines throughout their life in terms of minimum requirements.

The essential requirements for machines are set out in the Machinery Regulation 2023/1230/EU (Regulation..., 2023), and due to the transition period and manufacturers' adaptation to the requirements of the new regulation, the Machinery Directive 2006/42/EC (Directive..., 2006) applies. Regulation 2023/1230/EU, on January 20, 2027, will replace the Machinery Directive 2006/42/EU and establishes a legal framework for placing on the EU market machines that are safe for users. The Machinery Regulation 2023/1230/EU does not require implementation into national law, it is directly applicable (GOV, 2023). In the case of the Machinery Directive 2006/42/EC, legal acts such as the Act on Conformity Assessment Systems and the Regulation of the Minister of Economy on the essential requirements for machines (Act..., 2002; Regulation..., 2008) were in force in national law, implementing the directive into national law. Therefore, the Directive needed to be transposed into the relevant provisions of national law (Hamrol, 2013). In terms of essential requirements, the provisions of the Labor Code (Act..., 1974) and the regulation on general health and safety regulations (Regulation..., 1997) also apply.

The issue of machine safety is an important issue where manufacturers and employers should reduce all types of risks associated with machinery. In the risk mitigation process, harmonized standards can be helpful, which contain technical details that are missing from legal regulations. Therefore, manufacturers and employers use the achievements of standardization, supporting themselves with the provisions of standards that contain technical details that allow risk reduction. As of the date of the machinery regulation, there is no list of standards harmonized with this legal act. The European Commission plans to issue harmonized standards by standardizes, in particular for the new areas covered by the regulation, before the date of its full application, i.e., January 20, 2027 (GOV, 2023).

3. Own work method

The implementation of the assumed goal of the work was possible with the developed method of own work. As part of my own work, legal acts such as the Machinery Directive 2006/42/EC and the Machinery Regulation 2023/1230/EU (first stage) were analysed. As part of this stage, changes resulting from the publication of the machinery regulation were identified in relation to the scope of application, selected definitions, the form of the operating manual, declaration of conformity, conformity assessment procedures, and the emergence of new technologies (Internet of Things, artificial intelligence, and robotics).

The second stage of the developed method of own work consisted in listing the manufacturer's obligations resulting from the conformity assessment for machines. The introduced changes include an additional conformity assessment module relating to the unit verification of the product.

As part of the third stage, an analysis was made of the possibility of using programs supporting work related to meeting the formal requirements resulting from legal regulations, including risk assessment.

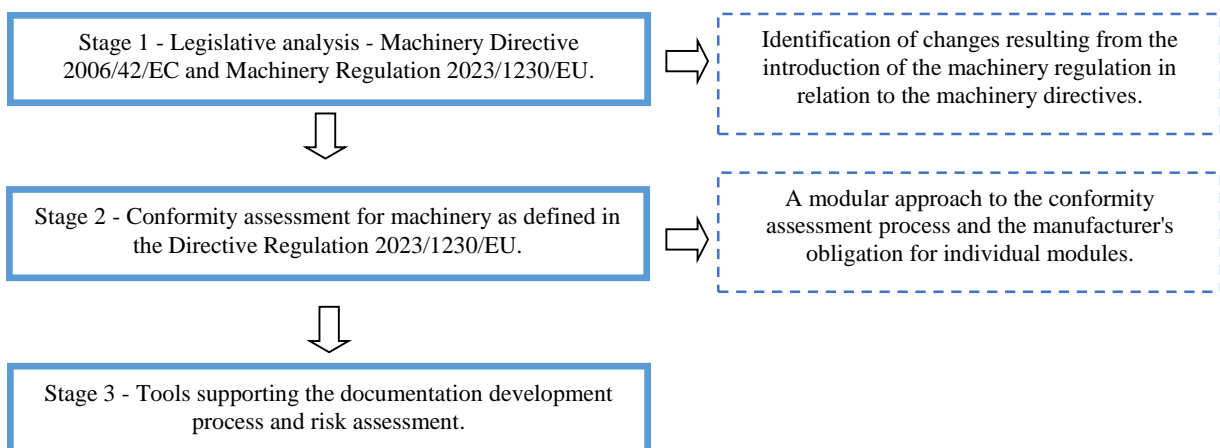


Figure 1. Own work method.

Source: Own elaboration.

4. Directive 2006/42/EC and Machinery Regulation 2023/1230/EU

4.1. Changes resulting from the introduction of the machinery regulation

Machine safety is an important topic from the point of view of occupational health and safety, due to the number of registered accidents (Statistic Poland, 2023; Wilaczarska, 2012). The key element is its reduction, which is why machine manufacturers apply the achievements

of science and technology in the field of risk reduction. The development of new technologies and products that meet the definition of a machine, in accordance with the Machinery Directive (Directive, 2006), was constantly developing, which is why the adaptation of legal regulations to changes appearing on the market became an important element. The new Machinery Regulation 2023/1230/EU applies to machinery and related products, i.e., interchangeable equipment, safety components, lifting accessories, chains, belts, ropes, detachable mechanical transmission devices, and partly completed machinery. The Machinery Directive 2006/42/EC, on the other hand, referred to machines, but the term related products did not appear (Table 1).

The Machinery Regulation 2023/1230/EU introduces new definitions as well as supplements and changes existing ones, e.g., machines, by the manufacturer (Table 1). An important definition introduced in the Machinery Regulation is the definition of a significant modification (Table 1), which has not yet appeared in the Machinery Directive. This term means a change to a machine or related product, physically or digitally made after it has been placed on the market or put into service, which was not foreseen or planned by the manufacturer and which affects the safety of the machine or related product, creating a new risk or increasing an existing one a risk that requires the addition of guards or protective devices to that machine or related product, the operation of which requires the modification of an existing safety-related system or the application of additional protective measures to ensure the stability or mechanical strength of that machine or related product (Regulation..., 2023).

The regulation distinguishes two concepts concerning harmonized standards and technical specifications. In the case of the Directive, only the definition of a harmonized standard was mentioned (Directive..., 2006), which referred to the specification. This distinction is important due to the fact that harmonized standards are developed by European standardization organizations, to which the definition set out in the Machinery Regulation also applies. On the other hand, the technical specification was defined as a document specifying the technical requirements that must be met by products falling within the scope of the Machinery Regulation. Technical specifications may be developed by the manufacturer himself, taking into account the standardization output.

The notion of a user's manual has also been introduced (Table 1), which can be made available in a digital version. However, if the user expresses a desire to have a paper version at the time of purchase, then the manufacturer provides it free of charge within a month.

Table 1.

Selected changes resulting from the introduction of the Machinery Regulation 2023/1230/EU

No.	Machinery Directive 2006/42/WE	Machinery regulation 2023/1230/UE
	Scope of application	
1	The Directive applies to the following products, i.e., machinery, interchangeable equipment, safety components, lifting accessories, chains, ropes, belts, removable mechanical transmission devices, and partly completed machinery.	The regulation applies to machinery and related products, i.e.: interchangeable equipment, safety components, lifting accessories, chains, belts, ropes, detachable mechanical transmission devices, and partly completed machinery.

Cont. table 1.

Selected definitions	
2	<p>Machinery means:</p> <ul style="list-style-type: none"> - an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort (...); - an assembly referred to in the first indent, missing only the components to connect it on-site or to sources of energy and motion; - an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only (...); - assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to (...); - an assembly of linked parts or components, at least one of which moves and which are joined together, intended (...).
	<p>Machinery means:</p> <ul style="list-style-type: none"> - an assembly fitted with or intended to be fitted with a drive system other than that directly applied human or animal effort (...); - an assembly referred to (...), missing only the components to connect in on-site or to source of energy and motion; - assembly referred to (...) ready to be installed (...); - assemblies of machinery referred in (...) or of partly completed machinery (...); - an assembly of linked parts or components, at least one of with moves (...); - <i>an assembly referred to (...) only uploading of the software intended for the specific application foreseen by the manufacturer.</i>
3	-
	<p><i>Substantial modification means a modification of machinery or a related product, by physical or digital means after that machinery or related product has been placed on the market or put into service, which is not foreseen or planned by the manufacturer, and which affects the safety of that machinery or related product, by creating a new hazard, or by increasing an existing risk (...).</i></p>
4	<p>Manufacturer means the natural or legal person who designs or manufactures machinery or partly completed machinery covered by the Directive and is responsible for the compliance of the machinery or partly completed machinery with the Directive with a view to its being placed on the market under his name or trademark or for his own use (...).</p>
	<p><i>Manufacturer means any natural or legal person who:</i></p> <ul style="list-style-type: none"> - <i>manufactures products within the scope of the Regulation or who has those products designed or manufactured, and markets those products under its name or trademark; or</i> - <i>manufactures products within the scope of Regulation, and puts those products into service for its own use.</i>
5	<p>A harmonized standard means a non-binding specification adopted by a standardization body (...).</p>
	<p><i>Technical specifications mean a document that prescribes technical requirements to be fulfilled by products within the scope of the Regulation.</i></p> <p><i>Harmonized standard means a European standard adopted on the basis of a request by the Commission for the application of Union harmonization legislation.</i></p>
6	-
	<p><i>Instructions for use means the information, provided by the manufacturer when the machinery or related product is placed on the market or put into service, to inform the user of the machinery or related product, of the intended and proper use of that machinery or related product (...).</i></p>
User manual and its form, the content of the user manual	
7	<p>The content of the instruction manual, p. 1.7.4.2</p>
	<p><i>Manufacturers shall ensure that the machinery or related products are accompanied by an instruction manual (...). The instruction manual may be provided in digital form. However, at the user's request expressed at the time of purchase, the manufacturer provides a manual in paper form free of charge within one month. The content of the manual, p. 1.7.4.2.</i></p>

Cont. table 1.

Declaration of Conformity		
8	EC declaration of conformity for machines (Annex II)	Manufacturers shall ensure that the machinery or related product is accompanied by an EU declaration of conformity (...), alternatively, provide the website address or machine-readable code for accessing that declaration (...). Digital EU declarations of conformity shall be made available online during the intended life cycle of the machinery or related product, and in any case for at least 10 years after the machinery has been placed on the market or put into service (...). EU Declaration of Conformity for machinery and related products (Annex V).
Conformity assessment		
9	- module A - internal production control (Annex VIII); - module B - EC type examination (Annex IX) + internal manufacturing control (VIII) - module H - full quality assurance (Annex X).	- module A - internal production control (Annex VI); - module B - EU-type examination (Annex VII) followed by conformity to type based on internal production control - module C (Annex VIII); - module H - full quality assurance (Annex IX); - <i>module G - conformity assessment based on unit verification (Annex X).</i>
The division into machine categories (high-risk machines)		
10	Annex IV	Annex 1 - part A Annex 1 - part B
Artificial intelligence, the Internet of Things, and robotics		
11	-	The emergence of new digital technologies such as artificial intelligence, the Internet of Things and robotics poses new challenges for product safety (...). The Regulation should therefore cover security risks arising from new digital technologies.

Source: Own study based on: Directive 2006/42/EC, Regulation 2023/1230/EU (Directive..., 2006; Regulation..., 2023).

The introduced changes also concern the marking of the declaration of conformity. In the Machinery Directive 2006/42/EC and the regulation of the Minister of Economy implementing it, the declaration of conformity is marked with the symbol "WE", in the case of a regulation it is the symbol "EU".

As regards the essential requirements, the manufacturer carries out the conformity assessment of the product within one of the modules (Regulation..., 2008; Directive..., 2006; Regulation..., 2023; Hamrol, 2008; Engel et al., 2009). Within the scope of the Machinery Directive 2006/42/EC, the legislator has provided for the following modules: A – internal production control; B+C type examination + internal production control and module H, full quality assurance. The new machinery regulation provides for the introduction of an additional module G - conformity assessment based on unit verification. An explanation of the scope of obligations in the field of conformity assessment based on module G is specified by the legislator in Annex X of the Machinery Regulation 2023/1230/EC (Table 1). The Machinery Regulation also includes a division of machines to which one of the conformity assessment procedures applies. For the categories of machinery or related products set out in Part A, the EU-type examination procedure (module B) followed by internal production control (module C) and the procedures for full quality assurance (module H) and conformity assessment

based on unit verification (module G). For the categories of machinery or related products set out in Annex I, Part B, the following procedures apply internal production control (module A), EU-type examination (module B) followed by conformity to type (module C), and full quality assurance (module H) and conformity assessment based on unit verification - module G (Regulation..., 2023). In the case of the Machinery Directive 2006/42/EC, the categories of machinery to which the procedures described under module A, module B+C, and module H were applied were listed in Annex IV, the new regulation changed, the categories and division of machines were defined in Annex I (Table 1).

The EU legislator in the Machinery Regulation 2023/1230/EU also refers to the use of new technologies, such as artificial intelligence, the Internet of Things, and robotics in terms of security threats. The changes are intended to fill gaps in the security risk posed by new digital technologies (Regulation..., 2023).

4.2. Machinery conformity assessment - Regulation 2023/1230/EU

The conformity assessment of the product, including machinery, is the responsibility of the entity that places it on the market or puts it into service. In accordance with the Machinery Regulation 2023/1230/EU, the manufacturer carries out a conformity assessment under one of the four modules and declares under his sole responsibility that the machine meets the requirements of the Machinery Regulation. Important aspects also appear in the annexes to the regulation, which indicate, among others, the need to draw up technical documentation, issue an EU declaration of conformity, CE marking, the need for a third party to participate in product testing, and the manufacturer to have a quality assurance system. The characteristics of individual modules and the manufacturer's obligations under the Machinery Regulation 2023/1230/EU are listed in Table 2. The selection of the conformity assessment procedure depends on the category of machinery to which the machine is classified in accordance with Annex I.

The key element to meet the requirements of the legislator is to reduce the risk to the machine. In accordance with the requirements of the Machinery Regulation 2023/1230/EU, the manufacturer is to ensure that a risk assessment is carried out for a product falling within the scope of the Machinery Regulation. In the case of the regulation, there is also mention of a risk assessment, which should apply to future updates or changes to the software installed on the machine (Regulation..., 2023). The regulation refers to the basic parameters characterizing the risk, i.e., the probability and severity of the consequences. The number of parameters characterizing the risk may change, depending on the applied risk assessment method. The choice of the risk assessment method is left to the manufacturer of the machinery.

Table 2.*Conformity assessment for machines - manufacturer's obligations*

No.	Conformity assessment procedure	Manufacturer's obligations	Machine risk assessment
1	Module A (internal production control)	<ul style="list-style-type: none"> - the manufacturer prepares the technical documentation in accordance with Annex IV, Part A; - the manufacturer monitors and ensures that he manufactures the product in accordance with the provisions contained in the technical documentation; - issues an EU declaration of conformity; - affixes the CE marking to the machine. 	
2	Module B (EU type-examination)	<ul style="list-style-type: none"> - the manufacturer prepares the technical documentation in accordance with Annex IV, Part A; - percent selects a notified body and prepares an application for EU-type examination (Annex VIII); - the manufacturer informs the notified body of any changes made to the machinery; - the manufacturer follows the procedure described under module C. 	
3	Module C (conformity to type based on internal production control)	<ul style="list-style-type: none"> - the manufacturer declares his responsibility for the machinery in conformity with the type described in the EU-type examination certificate; - the manufacturer ensures and monitors that the manufactured machine complies with the type described in the EU-type examination certificate and the relevant requirements of the Machinery Regulation; - issues an EU declaration of conformity; - affixes the CE marking to the machine. 	
4	Module H (conformity based on full quality assurance)	<ul style="list-style-type: none"> - the manufacturer prepares the technical documentation in accordance with Annex IV, Part A; - the manufacturer ensures and declares on his sole responsibility that the machinery complies with the requirements of the Regulation that apply to it; - the manufacturer has an approved quality system for the design, manufacture and final product inspection and testing of machinery; - the manufacturer selects a notified body to which he applies for assessment of his quality system for machinery; - the manufacturer keeps the notified body that approved the system informed of the intended modifications to the system; - the manufacturer provides the notified body with access to design, inspection, testing and storage locations; - issues an EU declaration of conformity; - affixes the CE marking to the machine. 	
5	Module G (conformity based on unit verification)	<ul style="list-style-type: none"> - the manufacturer ensures and declares on his sole responsibility that the machinery complies with the essential health and safety requirements set out in Annex III; - the manufacturer draws up the technical documentation and makes it available to the notified body; - the manufacturer takes measures so that the manufacturing process and its monitoring ensure compliance of the manufactured machinery with the essential requirements that apply to it; - makes the machine available to a notified body that carries out or has carried out the examinations and tests; issues an EU declaration of conformity; - affixes the CE marking to the machine. 	

Source: Own study based on Regulation 2023/1230/EU and Decision No 768/2008/EC (Regulation..., 2023, Decision No 768/2008/EC).

4.3. Tools supporting the preparation of documentation, risk assessment

In the process of preparing documentation for machines, risk assessment, computer tools supporting this type of work may be useful. The manufacturer of the machine chooses the method he will follow. Computer software in its scope has modules that enable:

- a summary of data on basic information related to the machine - data on the design, manufacturer, type, and machine number,
- a general description of the machinery, its technical characteristics, intended use and inappropriate, foreseeable use of the machinery, mode of operation, and limitations of the machinery, including space constraints,
- list of harmonized standards and technical specifications,
- essential requirements for machinery,
- identification, list of hazards - including measurements of measurable factors,
- information on the technical documentation of the machine, the operating instructions for the machine,
- threat analysis and machine risk assessment - a method developed by computer software developers,
- preparation of declarations of conformity.

The use of tools in the form of computer software significantly facilitates the implementation of the obligations imposed on machine manufacturers, due to the compilation of the manufacturer's obligations in individual software modules (Małysa et al., 2023). The software includes a so-called checklist (list of essential requirements) that allows you to assess which points of the regulatory act apply to the machine in question.

Summary

Ensuring safety in terms of design and operation is an important issue for the EU legislator, manufacturers, and users of machines. The expected level of safety during their operation will be possible thanks to the cooperation of entities having an impact on its construction, as well as the conditions in which they will be operated.

Within the scope of the essential requirements constituting the subject of this study, the Machinery Directive 2006/42/EC applies, which will be replaced by Regulation 2023/1230/EU, in which the legislator introduced additional requirements resulting from technological progress and also draws attention to new risks that should be taken into account machine manufacturers. The provisions will become fully applicable from January 27, 2027, however, machine manufacturers should adapt machines to the essential requirements during this transitional period, so that after that date they can introduce products that comply with its

requirements to the EU single market. An important element will also be access to harmonized standards and the emergence of standards that will cover issues not covered by the provisions of the Machinery Directive 2006/42/EC.

Manufacturers can support their work by using computer software supporting work related to the preparation of full documentation for the machine, instructions for the machine, risk assessment, etc. The use of computer software may facilitate the implementation of statutory obligations that rest on entities placing machines on the market or putting them into service.

Acknowledgments

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