

Occupational risk management and machinery technology in the digital age

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Abstract. The machinery sector is considered one of the main industrial pillars of the European Union. The design and manufacture of safe machinery guarantee the occupational safety and health of workers, resulting in a considerable reduction in the costs of occupational accidents caused by their use. The advanced technology of machinery enables the reduction of human operator intervention through improvements in emerging digital technologies, such as artificial intelligence, the Internet of Things, and robotics, which present new challenges in terms of machinery safety. The research study carried out aimed to identify the risks generated by digital technologies and the implications in terms of occupational safety and health and responsibility arising from the introduction of more advanced machinery already on the market or to be designed and manufactured with these new improvements, taking into account the latest regulations established by Regulation (EU) 2023/1230. Research study conducts a synthetic analysis of the safety implications of machinery in the digital age and the measures necessary to manage occupational risks, enabling safe use under conditions that allow for new actions and increased autonomy.

1 Introduction

A central industrial pillar of the European Union is the machinery sector, a field regulated at the European level through the application of the Machinery Directive 2006/42/EC.

This legal and technical regulation established in the Community area aimed to introduce products on the market that meet the needs of the Single Market, ensuring the safety and health of workers, consumers, and, where appropriate, property.

The considerable reduction in work accident costs resulting from the use of compliant products is a direct consequence of introducing safe machinery to the market, which meet

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essential safety and health requirements and guarantee the safety and health of users through design and manufacture.

Directive 2006/42/EC applies at the European level and in the Member States, starting with 29.12.2009 [4] and required transposition into the legislation of the Member States, being adopted in Romanian legislation by GD no. 1029/2008 [5]

By transposing Directive 2006/42/EC into national legislation, the manufacturer of a machine must ensure that the respective machine, through design and manufacture, ensures compliance with the applicable essential health and safety requirements to draw up and keep the technical design and manufacturing file, to draw up the Machine Instructions/Technical Book in a European language and to translate it into the language of the recipient Member State, to draw up the EC declaration of conformity and to affix the CE marking of conformity provided that it complies with the applicable technical and safety requirements.

For machinery covered in Annexe IV of Directive 2006/42/EC, the manufacturer is required to use a conformity assessment body notified to the European Commission through the NANDO register.

Suppose the machinery are not provided for in Annex IV of the Machinery Directive 2006/42/EC. In that case, the manufacturer is obliged to apply the conformity assessment procedure provided for in Annexe VII, with the possibility of addressing, by voluntary request, a competent body for conformity assessment, inspection, and technical diagnosis in order to certify compliance with the applicable technical and safety requirements.

In the case of this machinery, the manufacturer must comply with the exact provisions related to the preparation of the technical design and manufacturing file, the preparation of the Instructions for Use/Technical Book of the machine, the preparation of the EC declaration of conformity and the application of the EC conformity marking under the conditions of guaranteeing the conformity of the machine.

The machine manufacturer must transmit the Machine Instructions/Technical Book in printed format and the official language of the country of destination, as per Article 1.7.4 of Annexe I of Directive 2006/42/EC.

Directive 2006/42/EC does not provide for cybersecurity requirements or other software updates to be regulated.

Machinery Directive 2006/42/EC does not provide for detailed procedures regarding the manufacturer's responsibility regarding the control of the distribution chain, post-sale control, market surveillance regulations, the surveillance instruments being defined at a general level, the aspects related to cooperation between authorities not being clearly defined, based on art.4 of the directive, the obligations of economic operators being of a general nature.

EU Regulation 1230/2023 on the placing on the market of machinery [6] introduces significant changes compared to Directive 2006/42/EC, recognising digital technologies (automation, AI, software updates, and connectivity) and establishing essential health and safety requirements for new digital risks.

EU Regulation 1230/2023 establishes new requirements and conformity assessment procedures for machinery incorporating digital technologies, namely machinery that can operate autonomously, AI-based machinery, collaborative robots, drones or machinery connected to AI, IoT, including those controlled by applications, and related to remote software updates.

Artificial Intelligence (AI) is a priority for the European Union, given its potential to improve people's lives by contributing to better health and care services, more efficient administration, safer transportation, a more competitive industry, and sustainable agriculture [3]. The European Commission report of 19 February 2020 [9] analyses the legal framework. It discusses the risks generated by AI systems and other digital technologies, identifying several issues related to human control throughout the life cycle of AI systems, the need to impose explicit obligations on manufacturers to guarantee the safety and health of users, and

the need to introduce new requirements relating to digital risks and provisions aimed at increasing legal certainty in specific EU legislation [3].

The European Commission's report of 19 February 2020 identifies the need to introduce specific requirements on data use and transparency in relevant EU legislation, as well as establishing requirements on liability for damage caused by the operation of AI systems and other digital technologies, given that these digital technologies and AI are continually evolving.

2 Methodology

The research study conducted by the research team aimed to carry out a comparative analysis of the new EU Regulation 1230/2023 regarding the application of legislative and technical regulations in force, as provided for by Directive 2006/42/EC.

The problems faced by manufacturers of machines manufactured according to Directive 2006/42/EC have been identified, in order to apply the provisions of the new EU Regulation 1230/2023, in order to align with the new digital technologies AI and IoT.

The research conducted identified the obligations of manufacturers in relation to the design and manufacture of traditional machines, as well as those that are to introduce connected or AI-based, IoT-based machines on the market or to modernize machines in order to connect to new digital technologies or AI within the limits of current technical progress provided for by Directive 2006/42/EC.

The research methodology applied was mainly based on the analysis of the new EU Regulation 1230/2023, the European Commission Report on the "Safety and Liability Implications of Artificial Intelligence, the Internet of Things and Robotics" published in 2020 and the existing information at community and national level on new digital technologies and AI.

Research methodology:

- identification of the technical and legal aspects and applicability of the new EU Regulation 1230/2023 starting with January 2027 and regarding the transition period;
- identification of the essential health and safety requirements relating to the design and manufacture of machinery, in particular those connected or based on AI and IoT;
- identification of the risks specific to connected or based on AI, IoT machinery and establishment of a risk assessment matrix, in particular for machinery incorporating AI, being identified as "high risk" about the identified hazards;
- identification and establishment of the necessary measures to guarantee the compliance of the machinery provided for in Annex I, Section A and Section B, respectively, of the new regulation, in particular regarding connected or based on AI, IoT machinery;
- Identification of the conformity assessment procedures introduced for EU-type examination, Modules H and G, for the machinery specified in the new regulation.

3 Statistics of work accidents in the mechanical engineering industry

The analysis of statistical data on work accidents occurring at national level, during the period 2016 -2023, indicates that there is an increase in accidents resulting in temporary incapacity for work and a small decrease in collective and fatal accidents, according to INS records in the Manufacturing Industry (machinery and equipment) section, based on statistical data collected from the ACC102C form [7].

Figure 1 statistically represents the total number of victims (workers) registered in work accidents involving ITM, collective work accidents (in which at least three people were injured simultaneously and for the exact cause within the same event), and the number of deaths.

In recent years, there has been a decline in the number of workers involved in collective accidents and a decrease in the number of fatalities resulting from these accidents.

The analysis of work accident statistics registered at the national level for the Manufacturing Industry was conducted to identify and establish security measures, aiming to adopt technical solutions for worker safety.

The analysis was carried out based on data collected and registered at the national level by the INS and represented, within the research study carried out on the implications of the adoption of EU Regulation 1230/2023, a necessary indicator for the development of technical and security conditions necessary for the safe use of machinery, taking into account new digital risks.

The analysis also serves as an indicator for establishing technical and security rules that must be considered when assessing the conformity, testing, and certification of machinery designed and manufactured by the provisions of the new EU Regulation 1230/2023 to ensure protection against the risks of accidents and occupational diseases.

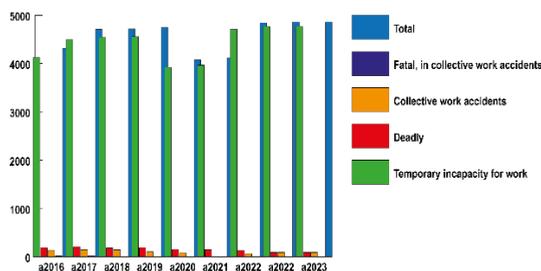


Fig.1 Total work accidents in the period 2016-2023 in the manufacturing industry in Romania [7]

An analysis was carried out of the security and liability implications of AI, the Internet of Things and robotics and the conclusions reached according to the Commission Report of 19 February 2020 [9] and the challenges faced by both manufacturers and users of machines incorporating digital and emerging technologies.

The studies found that the emergence of new digital technologies such as AI, the Internet of Things, and robotics raises new challenges in terms of product security and liability, such as connectivity, autonomy, data dependency, opacity, product and system complexity, software updates and the increased complexity of safety management systems and value chains represent new challenges that all stakeholders need to address.

The Regulation EU 2024/1689 laying down harmonised rules on artificial intelligence [10] aims to improve the functioning of the Internal Market and promote the adoption of human-centric and trustworthy AI, ensuring a high level of protection of health, safety and fundamental rights enshrined in the Charter, including democracy, the rule of law and the environment against the harmful effects of AI systems, providing support for innovation.

The Report on the safety and liability implications of artificial intelligence, the Internet of Things, and robotics [9], analysed the legislative provisions applicable to products, both under Directive 2006/42/EC and the General Product Safety Directive.

Fig. 2 presents the logic underlying Union legislation on product safety prior to the emergence of digital technologies, such as AI, IoT, or robotics.

Fig. 2 does not include legislative requirements relating to the use and maintenance of products, corresponding to their life cycle, being presented as a generic example [12].

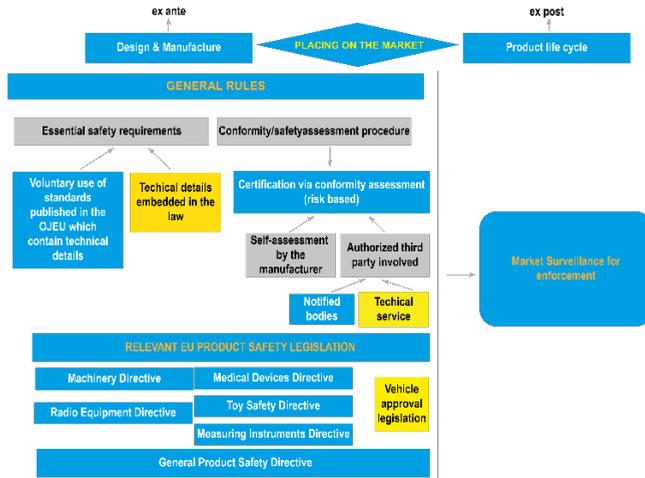


Fig.2 The logic behind Union product safety legislation (generic example) [9, 12]

The Report on the Safety and Liability Implications of Artificial Intelligence, the Internet of Things and Robotics states that emerging digital technologies such as artificial intelligence, the Internet of Things and robotics are creating new challenges for product security and that new legislative, legal and technical provisions are needed to establish a coherent and appropriate framework for specific approaches based on new digital risks, taking into account different digital technologies, including AI applications that present different risks.

Additionally, based on research conducted at the national level, it was found that the integration of Artificial Intelligence (AI) is rapidly changing how leadership and decision-making operate in organisations today. The emergence of AI has created a need to rethink traditional leadership approaches [1].

The research study identified the new aspects regulated by EU Regulation 1230/2023 regarding:

- technical and legal aspects and applicability;
- obligations of machine manufacturers in terms of guaranteeing the security and traceability of the manufacture of machinery, in particular, those connected or based on AI, IoT;
- changes made in terms of the essential health and safety requirements applicable in particular to those connected or based on AI, IoT;
- new technical and security provisions introduced about digital technologies and AI about the treatment of aspects related to software, cybersecurity or AI;
- new definitions of digital safety component products, autonomous machinery assisted by AI and "high-risk" products by explicitly incorporating machine learning systems;
- introduction of safety elements related to software by establishing new requirements that also take into account its updates;
- establishment of the list of high-risk machinery for which a notified conformity assessment body intervenes;
- new conformity assessment procedures introduced for EU type examination, module H, module G;
- introduction of delegation of acts for amending and/or updating the list of machinery for which a notified body intervenes;

- new requirements regarding the drawing up of the technical design and manufacturing file and regarding the drawing up of the EU declaration of conformity;
- new provisions regarding the responsibilities of economic operators - manufacturers, importers, distributors or authorized representatives;
- new provisions related to market surveillance and responsibilities of national surveillance bodies.

4 The impact of the implementation of the new Regulation 1230/2023 in the mechanical engineering industry

The research study aimed to compare the new EU Regulation 1230/2023 with the application of Directive 2006/42/EC up to 30 December 2026 and the impact of implementing the new provisions on emerging digital technologies, such as artificial intelligence, the Internet of Things, and robotics.

The high-level expert group that participated in the European study on liability related to artificial intelligence and other emerging technologies [8] identified several challenges related to:

- the operation of digital technology by a person may pose a risk of harm to others, for example, robots driven by artificial intelligence in public spaces. This person should be subject to strict liability for damages resulting from the operation of the permitted technology;
- the use by a person of a technology which does not pose a high risk of harm to others should comply with the obligations to select, operate, monitor and maintain the technology used appropriately, otherwise being liable for the breach of these obligations;
- the operation of a permitted technology with a degree of autonomy by a person entails a level of responsibility similar to the case in which another operator would have caused the resulting damage;
- the manufacturer of a product incorporating emerging digital technologies is liable for damages caused by them, even if the defect was caused by modifications made to the product under the manufacturer's control after the product was placed on the market;
- the operation of digital technology by a service provider should be taken into account in situations where it provides the necessary technical framework, where it has a higher degree of control than the owner or user of a real product or service equipped with artificial intelligence;
- civil liability in situations where third parties are exposed to an increased risk of harm through mandatory insurance that can provide victims with better access to compensation and protect potential perpetrators of damage against the risk of liability;
- victims should have the right to facilitation of proof where a particular technology increases the difficulties of proving the existence of an element of liability beyond what can be reasonably expected;
- equipping an emerging digital technology with recording functions, where appropriate in the circumstances, so as not to be to the detriment of the victim, failure to record or provide reasonable access to recorded data could lead to a reversal of the burden of proof;
- compensation under certain conditions in the event of damage being established as a result of the destruction of the victim's data;
- autonomous devices or systems should not be granted legal personality, as the damage they may cause can and should be attributed to existing persons or bodies.

The research conducted has led to the identification of areas of impact at both the level of machine manufacturers incorporating digital technologies and at the level of conformity

assessment bodies and market surveillance authorities. Table no. 1 briefly presents the identified areas of impact and the necessary measures that must be adopted by machine manufacturers at the design and manufacturing levels, as well as the management system implemented according to ISO 9001 [13].

Table 1. Identification of impact areas and necessary measures at the level of car manufacturers incorporating digital technologies [4, 6]

Domain	Impact	Impact assessment	Necessary measures
Legal compliance	Transition from Directive 2006/42/EC to EU Regulation 1230/2023 without national transposition	High	Updating internal legal and technical documents at the level of manufacturers and notified bodies
Machine design	New requirements regarding occupational health and safety related to digital risks	High	Design and manufacture of machinery incorporating emerging technologies Review of technical and quality assurance documentation, ISO 9001 procedures Perform internal audits
Technical design and manufacturing documentation	Acceptance of digital documentation	Medium	Document control review
Risk assessment for machinery incorporating emerging technologies	Digital Risks Advanced Ergonomics	High	Development of a risk assessment matrix for each category of machinery incorporating emerging technologies Update risk sheets and procedures related to occupational health and safety.

A risk assessment matrix for a machine using AI under Regulation (EU) 2023/1230 focuses on the essential health and safety requirements applicable, particularly the new ones concerning adaptive behaviour, autonomous decisions, cybersecurity, and human-machine interaction.

Table no.2 summarises the identified impact areas and the necessary measures to be adopted by machine manufacturers regarding their shared responsibility for ensuring software supplier compliance and the intervention of notified conformity assessment bodies.

Table 2. Identification of impact areas and necessary measures at the level of car manufacturers incorporating digital technologies [4,6]

Domain	Impact	Impact assessment	Necessary measures
Notified bodies	Mandatory for some products	Medium	Identification of the categories of machinery to which they fall according

			to Annex I, Section A or Section B, or Annex II The manufacturer is obliged to request the intervention of a notified body
Acquisitions and partners	Software vendors become a party to guarantee legal compliance	Medium	Updating supplier requirements
Personal skills	Need for specific staff training	High	Training planning

The comparative analysis carried out identified a series of significant differences between the essential health and safety requirements applicable to machinery, as specified in Directive 2006/42/EC and EU Regulation 1230/2023.

Regarding the analysis of essential health and safety requirements applicable to machinery incorporating emerging technologies related to digitalisation, cybersecurity, software, and AI, Table no.3 briefly presents the main differences identified about the use of these emerging technologies.

Table 3. Identification of significant differences between the requirements applicable to Directive 2006/42/EC and EU Regulation 1230/2023 [4,6]

Domain	Directive 2006/42/EC Annex I/Article	EU Regulation 120/2023 Annex III/Article	Differences
General principles	Art.1.1.2 Includes requirements relating to safe operation, of a general nature	Art.1.1.1 Includes requirements for predictability, transparency and AI behavior	Introducing requirements for AI and adaptive functions
Risk assessment	Preliminary remarks and Art.1.1.2 It is mentioned generically	Art.1.1.2 Establishes the performance of continuous evaluation and traceability of design decisions	Mandatory documentation and updating of risk assessment
Ergonomics	Art.1.1.6 General provisions	Art.1.1.6 Extends accessibility requirements (e.g. operators with disabilities)	Extensive and user-friendly ergonomics
Protection against corruption	This article is not mentioned	Art.1.1.9 Establishes obligations regarding cybersecurity and protection of safety functions	Clear introduction of cybersecurity requirements

Control systems	Art.1.2, 1.2.1, 1.2.1 Basic requirements for safety and control functions	Art.1.2, 1.2.1, 1.2.1 Establishes detailed requirements regarding functional safety, failure modes and performance	Introduces the concept of Functional Safety
Software	Not mentioned	Art.1.1.9, 3.2.4 Establishes requirements for updates, integrity and controlled changes to software	Introduces the surveillance function for machinery equipped with autonomous operation mode Introduces requirements for updating and validating software
Human-machine interface	Art.1.7, 1.7.1, 17.1.1, 1.7.1.2, 1.7.2, 3.6, 3.6.1 Limited processing in relation to optical and acoustic signals, displays and warnings	Art.1.7, 1.7.1, 17.1.1, 1.7.1.2, 1.7.2, 3.6, 3.6.1 Expands digital technology and communications Introduces requirements regarding digital technology and communication security	Introduces digital interfaces and communication security
Remote interventions	Not mentioned	Art.1.6, 1.6.1 taking into account Ar.1.2.5 in conjunction with Art.1.2, 1.2.1 and 1.2.2 Requirements for remote maintenance and upkeep	Clarifications for digitally assisted maintenance

Manufacturers of machinery incorporating emerging technologies (digital and AI) must assess, document and control all AI functions that may influence the safety of the machine, given that AI-based machinery are treated as high-risk systems and are subject to strict control over the design, documentation and updating of software.

Manufacturers of machinery incorporating emerging technologies must consider the digital risks specific to AI:

- modification of the system's behaviour after learning, given that these machinery have specific tasks and operate in structured environments, they can learn to perform new actions in that context and become more autonomous;
- unpredictable operation in new contexts;
- erroneous AI decisions based on incorrect data;
- adversarial attacks, such as introducing errors by minor modifications to the input data.

UE Regulation 1230/2023 establishes mechanisms to reset or return to safe settings and prevent uncontrolled behaviours of intelligent systems, making it mandatory to document learning and automated update scenarios.

Based on the analysis conducted by the research team, the essential safety and health requirements related to digital risks were identified, establishing the need to adopt protective measures against unauthorised access to machine software or the networks to which it is connected.

Essential health and safety requirements related to identified digital risks:

- authentication and authorization of access to machine software, including control software;
- protection against over-the-air (OTA) software updates;
- logging of automatic parameter changes made by AI.

For AI-based systems incorporated into machinery, new essential health and safety requirements are specified in EU Regulation 1230/2023, taking into account their impact on the machine's behaviour.

Autonomous, self-learning or cloud-connected machinery are identified as high-risk machinery if AI influences their movement, operational decisions, and interaction with the human operator.

When designing and manufacturing AI-based machinery that have fully or partially self-evolving behaviour or logic, the manufacturer must design the control systems to operate at different levels of autonomy.

The machine manufacturer must demonstrate the conformity of the machine, draw up a record of the data generated during the intervention, and of the safety software versions downloaded after the machine is placed on the market or put into service. The manufacturer must also keep this record active for five years after loading.

Transparency and control over AI must be guaranteed by the manufacturer of the AI-based or IoT-connected machine by informing users about the following:

- the incorporation of an emerging technology (AI) into the machinery if it includes the ability to learn or make autonomous decisions;
- the limits of machine learning and the purpose of the data collected;
- the mechanisms by which AI can be deactivated, controlled or overridden in case of emergency.

EU Regulation 1230/2023 expands the definition of safety/security components to include software functions, such as automatic braking software and collision avoidance algorithms. It establishes AI algorithms integrated into the machine control system.

The technical design and manufacturing file of the machine incorporating emerging technologies must contain according to Annex IV [6]:

- the source code or programming logic of the safety-related software to demonstrate the conformity of the machinery, in order to verify, at the request of the competent authorities, compliance with the applicable essential health and safety requirements set out in Annex III to EU Regulation 1230/2023;
- a description, where applicable, of the general characteristics, capabilities and limitations of the system, the data and the development, testing and validation processes used, in the case of sensor-powered, remotely driven or autonomous machinery, if the safety-related operations are controlled by the data transmitted by the sensors.

EU Regulation 1230/2023 establishes a series of changes related to the risks generated by noise emitted by machinery, such as:

- establishing explicit requirements for the quantification and declaration of noise levels in all cases, not only when the noise level exceeds 70dB (A);

- reporting of the A-weighted sound pressure level at the operator's working positions is required;
- reporting of the average sound power level emitted by the machine is required when measurement is possible;
- including precise requirements regarding the measurement methodology and associated uncertainties.

EU Regulation 1230/2023 establishes the obligation of manufacturers to provide in the technical documentation of the design and manufacture of machinery the methods used to determine the sound levels, the measurement uncertainty and the conditions under which the measurements were made so that users of the machinery can compare products and assess the real risks related to exposure to noise in working environments, about the provisions established in Directive 2003/10/EC [14]

Currently, according to the scope of Directive 2006/42/EC, the machinery must be designed and manufactured in such a way as to minimize the risks generated by noise emissions, information on the sound pressure level and sound power being established to be declared only for machinery exceeding 70 dB(A).

Within the research studies conducted by the research team's members at the level of machinery users, noise maps were produced that enabled real-time monitoring of the situation for each category of work equipment that may be a source of noise, as per the provisions of Directive 2006/42/EC.

The noise maps method helps design and locate workstations based on the acoustic field [2, 15].

In this sense, it is necessary that machine manufacturers, in terms of impact in terms of risk assessment and ensuring compliance with the provisions of EU Regulation 1230/2023, should:

- justify in the content of the technical file of the design and manufacture of the machine how it has reduced noise emissions;
- include the risks related to noise emissions in the overall risk assessment, in accordance with the provisions of Annex IV;
- apply the ergonomic and risk reduction principles to the noise source;
- revise its EC declaration of conformity and the instructions for the machine to reflect this requirement.

5 Conclusion

The research study carried out highlighted the need to develop research to identify the necessary tools, administrative, technical and security measures to be adopted at the level of machinery manufacturers, especially those incorporating emerging technologies, conformity assessment bodies, national authorities and market surveillance bodies, as well as to analyze the impact of implementing the provisions of EU Regulation 1230/2023 at the level of stakeholders, primarily manufacturers and users.

Studies carried out at the European level following the identification of gaps in European legislation on product safety, excluding Directive 2006/42/EC, have concluded that it is necessary to adopt a regulation on the placing on the market of machinery and related products that would cover the security risks generated by new digital technologies, including real-time information processing, problem-solving, mobility, sensor systems, learning, adaptability and the ability to operate in unstructured environments, such as co-construction sites, emerging digital technologies, given that emerging technologies such as AI, the Internet of Things and robotics generate new challenges in terms of product safety.

6 Future prospects

Based on the research conducted, it was found that there is a need to implement new provisions related to the conformity assessment and certification of advanced machinery that incorporate emerging technologies and are less dependent on human operators.

Both manufacturers, conformity assessment bodies, and market surveillance bodies in Romania must prepare themselves by adapting the necessary documentation and training specialised personnel on the implications and measures to be adopted from a legal, technical, and administrative perspective in order to apply the provisions of the new Regulation starting in 2027.

UE Regulation 1230/2023 represents a modernization of Directive 2006/42/EC, being adapted to current digital technologies, in terms of standardizing and strengthening the essential health and safety requirements regarding the security and traceability of machinery, especially those connected to IoT or based on AI.

Manufacturers must prepare for increased compliance and rigorous documentation by December 30, 2026 with the obligation to report consolidated risk assessments.

Manufacturers must cooperate with authorities and supervisory bodies, which are obliged to establish effective, proportionate and dissuasive sanctions, including criminal sanctions, about the placing on the market of non-compliant machinery.

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