

## INTER CONNECTIONS BETWEEN ERGONOMICS AND EU MACHINERY DIRECTIVE – A STANDPOINT OF THE FEDERATION OF EUROPEAN ERGONOMICS SOCIETIES (FEES)

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**Abstract** The topic of this paper is the EU Machinery Directive (MD) and the contribution of ergonomics and the Federation of European Ergonomics Societies (FEES) to the development of this Directive. At the beginning, the contribution of FEES to the process of development of this Directive is considered through the analysis of the activities of this European organization so far. Then, the key changes envisaged by the new MD were discussed, as well as the possible consequences of the planned changes. Aspects of the inclusion of artificial intelligence in MD, as well as the effects of MD on Industry 4.0 have also been taken into account. In addition, certain future possible contributions of ergonomics for the improvement of MD have been identified, primarily those based on the analysis of errors in the human - machine system.

**Keywords:** EU Machinery Directive; Ergonomics; Artificial Intelligence; Industry 4.0.

### 1. INTRODUCTION

Since its first issue in the 1980s, the Machinery Directive (MD) has generated multiple and profound changes across all industry sectors. Some of these changes like the new demands, costs and other related challenges for manufacturers sometimes are perceived as unwelcome and unnecessary. The machines sector is crucial on a global scale with regard to the competitiveness of the different economies. The upkeeping of a performing industry and high-level standards safeguards the concerned users and economies against low-cost competition from manufacturers which may not comply with the same high standards regarding social, safety, or environmental issues.

In the overall and in the longer term, unprecedented improvements to quality and safety have been achieved through the adoption of the MD. Naturally, many factors have contributed to these new challenges, as much as to the registered improvements. Some of those factors had little relation to the scope and implementation of the MD, whereas some were a very direct, anticipated, or unexpected consequence. From the perspective of Ergonomics, the MD has had important and rather direct impacts, both at the scientific and the applied levels.

Since 2015, the Federation of European Ergonomics Societies (FEES) has been actively involved in the ongoing discussions at the EU level, which will soon lead up to the implementation of a fundamentally revised version of the MD. As the industry rapidly adopts new and enhanced automation, as well as other integrated technologies, profound Ergonomics and Human Factors related impacts can be anticipated. The revised MD is expected to, on the one hand, encompass these new technologies, namely by broadening the scope of “high-risk machinery”. On the other hand, the requirements regarding safety and workers’ well-being are expanded, in particular by contemplating the need to update and review these requirements in view of the pace of transformation that technology and work systems register. While this is expected to open meaningful opportunities for the engagement of ergonomics in the design of machinery, it is also likely to bring along new challenges, as practitioners are pressured to meet heightened standards, namely by delivering more precise, timely and comprehensive input to these design processes.

This paper recalls the experience of the FEES with the ongoing revision of the MD and outlines the key transformations that this new version is expected to bring about. A discussion on the Ergonomics and Human Factors impacts of these transformations is then undertaken.

## **2. THE MACHINERY DIRECTIVE IN SHORT**

The evolution of technology raised new issues for security and human safety in these years. The compliance with the human functioning had to be ensured through emerging ergonomic principles expressed in the present point of annex 1, 1.1.6 section, concerning ergonomics:

“Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic principles: ...”.

Nowadays new issues are still present and adaptations of the legal and standard requirements are necessary. For instance, industry 4.0 leans on automatization and data exchanges between specific machines with European standards. The new company management and organization methods have consequences on the product and work quality, including in the area of psycho-social and musculoskeletal disorders.

## **3. THE CONTRIBUTION OF THE FEES FOR THE REVISION PROCESS OF MD**

### **3.1. Meetings with ETUI in Brussels and Paris (2015)**

Representatives of the European Trade Unions Institute (ETUI) and the FEES have met with the aim to set up a cooperation between FEES and ETUI in the field of the ergonomic design and use of machines. Both parties have presented their experiences and reflections in this field, taking into account ergonomic principles. They intended to foster a FEES/ETUI joint project on the issue of “workers representatives and ergonomists cooperation in Europe in the field of the design and use of machines: state of the art and ways of improvement”.

The feedback methodology used recently on products such as forklift trucks and agricultural machinery (harvester, tractors, woodworking...) by ETUI could be used in the project. "Ergonomics and machinery project" was expected to achieve the following:

- To do the mapping of organizations, institutions and individuals that deal with the connection between ergonomics and machinery in Europe, in order to enrich existing networks related to ergonomics and machines concerns, such as trade unionists, ergonomists, designers, specific users...
- To consider the social dialogue on these OSH issues, including worker representatives without the links (or with very weak links) with Trade unions, to have a better overview of this situation in Europe
- To prepare propositions for the next IEA 2018 Congress in Florence in order to present the results of common projects on this topics, following the workshops organized since 2015.

So FEES Executive Board (EB) asked the national member societies to provide information on the activities conducted by ergonomists in the field of machines and ergonomics, for example: inquiries or reports, debates inside the standardization groups on ergonomics issues, academic and expert resources in the field of machines and ergonomics, innovative projects/symposiums in the field of ergonomics design of machines, financial resources which may be mobilized in order to foster training sessions or researches in this field. A questionnaire has been spread by FEES EB among its members with few results.

### **3.2. Participation in the ETUI seminar in Italy, Colle di Val d'Elsa, October 2016**

In the workshop organized by ETUI, the European Trade Union Institute presented and discussed a sum up of the "feedback method" as specified in the CEN/TR 16710-1 : 2005 – Part 1. Fabio Stambi reminded that the project on the "feedback method" started with a TUTB project in 1997: the aim was to collect user experience to improve the woodworking machine safety. The work on the floor was made by the Italian Preventive Service, USL 7 and SindNova, an Italian Trade-Unions Institute. The project has been enhanced by the mandate 301 from the EU Commission to the CEN concerning the standards in the field of the revised Machinery Directive: within the EU Commission, the document was mentioned with the aim to obtain real feedback coming from the end-users. So ETUI was asked to provide a technical report. The outcome of the process is the CEN document (a "technical report"): TR 16110-1, adopted in December 2015.

The debate during the workshop was on several issues, such as the status of the document - the Technical report (TR), which does not allow free access and which is on several issues related to the Machinery Directive. It was mentioned that a guide could be a better solution to allow free access.

There was also a debate on the issue regarding the "Human factors and ergonomics". In particular, the question was: which name is the more appropriate to provide possibilities of action on the design of the machine in line with the OSH requirements: between "Ergonomics" and "Human factors", which name/concept allows the best to trigger actions with a wide scope?

A draft declaration was discussed, the content of which was published and presented during the next Machinery Directive working group, in November 2016 in Brussels. New issues appeared in the machinery field, in particular: the design and use of robots related to safety, which is discussed in many places, such as workshops and forums.

Several general declarations were presented on the issue of "workers participation in the machine design", including the one presented by FEES on the ergonomic principles; a presentation of the feedback method by Fabio Strambi; a presentation from Georg Krämer (former chair of the TC 122)

on the Ergonomic Essential Safety Requirements and the concerned standards in the CEN and ISO field; a trade-unionist (from the European Federation of the construction workers) presented the results of an inquiry documented with 200 accidents. The report has been followed by a project aiming to improve ergonomics, safety, work organization and training, based on field studies related to the feedback method.

### **3.3. Participation in the ETUI seminar on the issue of Machinery Safety in Brussels, 11 – 12 February 2019**

The seminar, organized by ETUI in cooperation with EFFAT and EFBWW – European unions of agricultural and construction workers - gathered about 50 participants, mainly trade-unionist or trade-union experts in the OHS field, but also governmental experts, employers, certain public bodies (INRS, KAN, INAIL, AUVA), and consultants. In the introduction, the organizers underlined the historical involvement of the trade unionists on two issues, that are managed in the present seminar: the management of technological changes and the fight for the OSH goals, against fatal outcomes and injuries at work.

Both EU directives, the framework and the MD, are the lever for trade unionists to act on the OHS issues and for the democracy at work, which is part of a more global fight for democracy, particularly up to the year 2019. Therefore, for the organizers, it is crucial to maintain the common heritage of the Machinery Directive principles. The main issues dealt with during the seminar were:

- The maintenance of the wind turbines and the consequences for the health and safety of the operators (presentation from ISTAS - Spain)

The presentation stressed the importance of heat stress during the maintenance operations, due to the inadequate design of many wind turbines. The following discussion was centered on the difficulty to implement the requirements of the Machinery Directive on such devices (due to the lack of specific expert knowledge of the manufacturers, the difficulty for trade union experts to form proposals in the frame of the CENELEC standardization process, etc.).

- The safety problems with the Power Take-Off (PTO) drive shafts (Leonardo Vita - INAIL – Italy)  
The presentation showed the difficulty to maintain and access the protective devices, and the lack of specifications in the present standards, where the useful proposals were mainly optional.

- The feedback method application in agriculture and construction (Fabio Strambi and Massimo Bartalini - USL Toscana - Italy)

The presentation reminded the main traits of the feedback method (the document adopted by the CEN TC 122). The main statements concerned the stability and the visibility of the machines. Again, the issue discussed was the difficulty to obtain substantial changes in the standard (in particular ISO 4257- 2008 parts 7 and 8) although the European Commission asked the CEN to take into account the feedback from the users and in particular the results obtained with the so-called “feedback method”.

- The revision of the Machinery Directive (Felicia Stoica - European Commission DG GROW)  
The EC representative presented the ongoing process of the revision of the Machinery Directive. Several participants (including FEES) stressed the necessity to solve in the new Directive some of the issues that haven't been involved correctly till now, such as: the changes in the machines, the

feedback from users, the quality of certain standards (with the role of the consultants appointed by the EC), the reliability of the notified bodies and the possibility to set up relevant European databases due to the new means given by IA... The EC representative seemed to be open to proposals on these issues and asked for feedback on the databases from different countries.

- Safety issues concerning collaborative robots (Federico Vicentini, researcher and consultant, STIIMA-CNR – Italy)

The presentation, according to the ISO 8373 definition dealt only with collaborative robots. He presented several functions in the design of the cobots that should be considered: awareness, understanding, experience, and acceptance. In addition, he identified protective devices (padding, tool orientation, force/speed limitation) and protective functions (free escape spaces, as well as signals).

- Using robots to remove asbestos in construction sites (David Chauvin – Direccte – France)

The purpose of the presentation was to demonstrate that it is technically possible to comply with the aim of reducing exposure to as low a level as possible by using the various types of robots that are used by specialized companies. The report based on field interventions from a labor inspector raised several issues, such as the machines' maintenance, the acknowledgment of the operators' skills and their training, and the machine validation function by the public authorities.

- The impact of escalators maintenance on the operators' health and safety (Abderrafik Zaïgouche – CGT – France)

The risk assessment of such activity shows various risks, such as: falling from a height, biological risks and CMR, manual handling, mechanical and electrical risks, co-activity, pressure from the public... Several technical solutions were presented, that were implemented in some companies, i.e.: separation from the public, and plexiglass protective devices integrated into the machines.

- Treatment tables/quick couplers (KAN – Germany)

Accidents were reported during the maintenance operation of treatment tables (operators trapped during the cleaning or repairing of the tables). The issue of the quick couplers for earthmoving machines was also presented, with severe risks for the operators. It was concluded that technical solutions exist and that should be discussed in the standardization and market surveillance groups: the CEN - EN 474-1 working group and the MD ADCO group.

### **3.4. Presentation of a paper in the IEA Congress 2021 by the EB of the FEES**

The paper [1] presented the objective of the European Machinery Directive (EC/2006/42 Directive) which is intended for the free movement of products in the 27 member states of the European Union, provided that they comply with the minimum health and safety requirements for the users of these machines. All equipment imported into Europe must meet these requirements. Ergonomics and human factors are at the core of this Directive, as an increasing number of design and operation factors are considered. For instance, a condition to satisfy is the “reasonably forecastable misuse”.

Industry 4.0 has many strong points to valorize about this directive, and all machine manufacturers have to deal with this directive in order to be successful in Europe. The industrial and commercial

implications of the Directive are, therefore, increasingly meaningful for both manufacturers within and outside Europe.

### **3.5. Attendance to several MD expert group meetings in Brussels and the changes in the MD**

FEES is a member of the European machinery expert group since the year 2019. In the new and more formal context, the FEES representatives are considered as « type C members », which are organizations in the broad sense of the word, if operating at the European level and performing specific activities or representing specific interests in relation to the internal market for machineries, such as the interests of manufacturers, importers, consumers and other end-users, industrial users, suppliers, retailers, as well as repair and maintenance providers.

This participation in the machinery expert group allows FEES to be informed on the follow-up of the revision process of the Machinery Directive and to issue proposals. In a new context, an impact study ordered by the European Commission has proposed to challenge the new stakes in front of technological developments, adapting the Essential Health and Safety Requirements (EHSR) of the Machinery Directive in the new Annex III, and to address the challenges posed by innovation in digitization through public regulation in order to avoid diverging situations.

After a long consultation process, the European Commission has issued a draft regulation proposal in order to replace the present Machinery Directive. The main substantial changes in the draft regulation proposal are to take into account the digital technologies in the essential health and safety requirements and to treat them as safety components.

The draft regulation contains several formal and editorial changes such as - the Directive will be replaced by a « Regulation » which will be enforced without any change in the national law of every member state and the EU Commission will be empowered to modify the list of the “High-risk machinery” and the indicative list of safety components.

In conclusion, the main results of these activities may be summarized as follows:

- Identification of the stakes connected with the issue
- Identification of the main stakeholders
- Communication of a standpoint that is based on ergonomics
- Creation of the summaries of the meetings that have been posted on the FEES website; presentation of these activities have been mentioned in the activity reports in each of the FEES Council meetings in order to inform ergonomics associations.

## **4. IMPLICATIONS OF THE NEW MACHINERY DIRECTIVE REGARDING HIGH-RISK MACHINES**

Regarding high-risk machinery, the New Machinery Directive (NMD) in relation to the Current Machinery Directive (CMD) brings two main changes. The first change refers to the obligations of manufacturers (producers) of such machines and their representatives. The second change refers to the appearance of new categories of machines that have entered the list of high-risk machines. In order to explain what are possible consequences of those changes, firstly we will start from the background of the problem.

For this purpose, we will start by explaining the obligations of the producers of high risk machines (or their representatives) according to the CMD [2]. The main obligation of the manufacturer of high risk machines or his representative is to provide an assessment of the conformity of the machine with the requirements contained in the MD. At the beginning, we will explain what are the possible options of the manufacturer in this direction, according to the CMD. These options we will show by describing sequential steps that should be undertaken by the manufacturer, in order to perform the conformity assessment.

1. step. The manufacturer should check if his machine is on the list of high-risk machines, which is given in ANNEX IV of CMD. If yes, he should follow the next steps.
2. step. The manufacturer should check if his machine has been designed and produced in accordance with harmonized standards, the references to which have been published in the Official Journal of the European Union (Article 7(2) of CMD). If yes, he can choose one of the variants described in steps 3a, 3b, or 3c. If not, he can only choose variants 3b or 3c.
- 3a. step. The manufacturer can apply the procedure for assessment of conformity with internal checks on the manufacture of machinery, provided for in Annex VIII of CMD.
- 3b. step. The manufacturer can apply the EC type-examination procedure provided for in Annex IX of CMD, plus to perform the internal checks on the manufacture of machinery provided for in Annex VIII point 3 of CMD.
- 3c. step. The manufacturer can apply the full quality assurance procedure that is provided in Annex X of CMD.

EC type-examination that is mentioned in step 3b is the procedure whereby a notified body ascertains and certifies that a representative model of machinery referred to in Annex IV satisfies the provisions of CMD. Each EU country designates notified bodies to assess products' conformity before they are made available for sale. Notified bodies are responsible for implementing the conformity assessment procedures outlined in law. Annex 10 which has been mentioned in step 3c describes the conformity assessment of machinery referred to in Annex IV, manufactured using a full quality assurance system, and the procedure whereby a notified body assesses and approves the quality system and monitors its application.

The outcome of steps 3a, 3b and 3c is the same – EU declaration of conformity. This is a paper that allows the manufacturer to put the machine on the EU market and to place CE marking on the machine. However, what is the main difference between steps 3a, 3b and 3c? The main difference is that steps 3b and 3c require the involvement of the notified body, ie engagement and participation of an external company. In this case, the external company should carry out all necessary tasks in terms of achievement and approval of conformity instead of the manufacturer's company.

In practice, almost all companies have decided to use option 3a. In this case, notified bodies just served as consultation service if needed, or when the manufacturer wanted to check if they performed the final conformity assessment properly. However, according to the NMD [3], the role of the manufacturer and notified body considerably will change. If the manufacturer wants to perform the conformity assessment, option 3a does not exist anymore. It means that the possibility of self-assessment is not an option now in the case of high risk machinery. Instead, there is an obligation of the manufacturer to engage a notified body to perform the conformity assessment, according to steps 3b or 3c.

However, in such a case, it is important to consider what are the possible problems and implications of such a change. Some of already identified problems are [3]:

- According to certain Member States and stakeholders, third party conformity assessments are deemed more suitable for addressing the high risks associated with certain types of machines.
- There are some overlaps or inconsistencies with other EU specific legislation.

In addition to the aforementioned problems, here are identified several implications that are the direct result of the elimination of the self-assessment option from the conformity assessment. These implications can negatively affect manufacturers and their representatives, and they may involve:

- Increased costs of business
- Increased time to enter the market
- Liability redistribution
- Potential conflicts with a notified body.

Increased costs of business are incurred as a result of the need to engage notified body, i.e. a company that needs to carry out the procedure related to the conformity assessment. Instead of having that job done by the staff of the Manufacturing Company, that job is now being entrusted to an external company. Financial expenses are understandably higher in case 3c than in case 2c option. However, these costs increase if the company needs to implement the procedure for a range of products. In addition, in the case of NMD, the period of validity of the certificate is limited to a period of 5 years, after which the production company has to perform the conformity assessment procedure again. Any subsequent modification of the machine also makes it necessary to repeat this verification process. In the case of software applications that may have an impact on the safety of the machine operation, even an update of the software may require a new check, which may cost the company dearly, especially when considering that in the case of self-assessment the company had no costs.

Increased time to enter the market may arise as a result of a discrepancy in the number of firms labeled as "notified bodies" and the volume of conformity applications by manufacturers. Notified bodies in the previous period did not have many job requirements related to options 3b and 3c. However, since NMD option 3a for high-risk machines no longer exists, they will now be much more burdened in terms of workload than in the previous period. Consequentially, it reduces the available time that they can devote to each individual company for which they now not only need to ensure that the final product meets the requirements, but must (especially in the case of option 3c) ensure that the production process meets all necessary regulations. In this way, they can become the company's "bottleneck" and disrupt the company's planning or already completed plans to enter the market. One way to solve this problem could be to increase the number of notified bodies, or increase the number of employees working at those companies. However, it probably cannot be a quick process, because the conditions for working in such a company according to the NMD imply that an employee has experience in this area (which certainly cannot be acquired in a short period of time).

In terms of liability, CMD foresees strict accountability of manufacturers and their representatives for the machine they produce. However, since in the case of high-risk machines option 3a in NMD is omitted, this means a much greater role of the notified body in creating the final product. In both cases, 3b and 3c, the declaration of conformity must bear the name of the company that was the



notified body. Since the manufacturing company had to act on the order of the notified body during the conformity assessment process, the manufacturing company may consider that its share of responsibility for the product has been reduced. Thus, in the event of unsafe conditions when using the machine and the occurrence of damage or injury to people, the manufacturing company may consider that the occurrence of damage is caused by some of the requirements of the notified body. Although such situations are probably not common, the probability of their occurrence is far from impossible.

Potential conflicts with a notified body are possible during the process of harmonizing the production process and other procedures, as well as the measures that the notified body dictates to the manufacturing company. In some cases, manufacturing companies may find the demands made by the manufacturing company unnecessary, or that they cause unnecessarily high costs. In such situations, there may be a conflict between the manufacturing company and the notified body. Under the law, a manufacturing company must comply with the requirement of a notified body. It would imply that in every situation a notified body is without exception right. Is that really the case? If so, then accidents on high-risk machines in the future would theoretically not exist. It seems that the NMD should anticipate the issue of resolving the possibilities of this conflict and offer an appropriate solution. One possible solution would be the arbitration inclusion of another notified body as a mediator in resolving such a conflict.

The second main change refers to the appearance of new categories of machines that have entered the list of high-risk machines. Annex IV of OMD contains the list of 23 high-risk machines. However, Annex I of NMD contains the list of 25 high-risk machines. It means that two new high-risk machines are added to the list. These are:

- Software ensuring safety functions, including AI systems
- Machinery embedding AI systems ensuring safety functions.

Directive 89/392/EEC of 14/06/89 was the first Machinery Directive to be published in 1989. Afterwards, Directive 89/392/EEC was amended by the following directives [3]:

- In accordance with Directive 91/368/EEC, the Machinery Directive was expanded to include interchangeable equipment, machinery moving and lifting machinery (excluding people). Consequently, Annex I has been expanded (parts 3, 4 and 5 of Annex I have been added/modified).
- A directive 93/44/EEC further extended the scope of the Machinery Directive:
  - The safety components
  - Lifting machinery
  - The movement of people.
- "CE" marking has been harmonized under Directive 93/68/EEC.
- The Machinery Directive was published a second time in 1998. The Directive 98/37/EC harmonized the laws of all Member States concerning machinery on 22 June 1998. This directive is the codified version of Directive 89/392/EEC modified by the directives listed above. A minor amendment to Directive 98/79/EC has been made regarding the exclusion of medical devices. Until 29 December 2009, the Machinery Directive 98/37/EC remained in force.
- The third publication of the Machine Directive was in 2006, when it was renamed New Directive 2006/42/EC, which was published in the Official Journal of the EU on April 9 and June 9 of that year.

As noted in the first recital of Directive 2006/42/EC, this "new Machinery Directive" is not entirely new, but is based on Directive 98/37/EC, which codified Directive "Machinery" 89/392/EEC amended by Directives 91/368/EEC, 93/44/EEC, 93/68/EEC and 98/79/EC. Each country in the European Union has incorporated the amended Machinery Directive's requirements into national law (translations had to be completed before June 29, 2008), which will take effect on December 29, 2009 and replace the previous Machinery Directive 98/37/EC.

According to [4], another problem is that the current list of high-risk machines given in "Annex I" have elaborated 15 years ago, and the market has much evolved since then. It is necessary to consider removing machines no longer considered high risk and/or introduce new ones (such as machinery embedding AI systems, which fulfill a safety function). In connection with this issue, additional analysis in the next period should be performed.

## **5. THE USER-CENTRIC DESIGN OF MACHINES WITH ARTIFICIAL INTELLIGENCE**

According to the Council of Europe, Artificial Intelligence (AI) "systems are software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. "AI systems can either use symbolic rules or learn a numeric model. They can also adapt their behaviour by analyzing how the environment is affected by their previous actions." [5]

The various AI mistakes attract widespread press interest. Failures in data processing and services dominate in summaries of AI failures; only a few notable examples cover AI applications with physical components, mainly self-driving vehicles. A few industrial fatal accidents, such as with a car manufacturer in 2015, appeared in databases collecting AI incidents. The incidents recorded were with equipment still in the experimental development stage. We assume that many events will remain hidden because they are not yet required to report artificial intelligence errors in the testing phase.

There's a contradiction that, on the one hand, traditionally, when placing a machine on the market, the manufacturer can influence the commissioning or use. On the other hand, an AI may produce the opposite operation from the same initial state, depending on the input data, even with the software running correctly.

Scott and Yampolskiy showed the evolution and diversity of classification of AI-related failures [6]. According to Zachary and Toner, AI systems can fail unexpectedly for reasons fitting into one of the categories below [7]:

- Robustness failures: the system is abnormal or there are unexpected inputs that cause a malfunction.
- Specification failures: The system is trying to do something other than what the worker wanted, leading to unpredictable behavior or consequence.
- Assurance failures: The system may not be monitored or controlled during operation.

Artificial intelligence can exist without a physical reality as an agent, contributing to a virtual service. When artificial intelligence is applied, this poses a new risk, and the risks arising from the nature of

artificial intelligence also appear in engineering. In the Industry 5.0 concept, robotics, one of the most prominent areas of mechanical engineering, is converging with AI.

Safe machinery is key to the production of safe machinery. Like all machinery, the ones with AI systems must integrate security and inherently-safe solutions. They must ensure the physical and mental safety of all concerned at an acceptable level throughout the life cycle [8]. AI-supported machinery must meet the usual software quality criteria and essential health and safety requirements, including compliance with IEC 62061:2021 to validate control elements [9].

Adequate AI training is required to ensure robustness. When setting up a machine using artificial intelligence, we need a clear system objective and appropriate training dataset and inputs with the correct outputs. In industrial applications, training is site-specific, requiring a thorough understanding of the operating conditions.

To avoid specification errors, the user must have adequate knowledge of the equipment's functionality, operation, and possible conditions. In machine design, the specification should include foreseeable operator failures and prediction of potential malfunctions of artificial intelligence. The supervision of the machine also requires significant operator skills, which the machine manufacturer can define as an operational requirement. In the wake of the revision of the Machinery Directive [10], machine manufacturers have more opportunities to verify the appropriateness of their AI products.

## **6. INDUSTRY 4.0 AND MACHINERY DIRECTIVE**

Projects relating to the factory of the future are in full swing and are very varied. New technologies, robotization, digitalization, interconnections, and so on. They open doors for totally innovative achievements. These changes will require the integrated pooling of the various engineering professions. Associated to this factory of the future is emerging the engineering of the future. It will integrate the built environment, the systems, the networks, the environment, the energy, the human factor, the spheres of professional and private life... For projects of this order, it is the whole system that we will have to study, more than one of the points that compose it. Interdisciplinarity will be a condition for the success of the projects.

Our civilization has experienced many technological changes throughout its history. The means classified in the category "artificial intelligence" and "robots" generate many questions and concerns, particularly regarding the future of jobs, the role of humans in production units, in the services area, etc., and quite simply, the future of the human species.

We must be aware that what is at stake is not only of a technological nature. It is also a social project. The revolutions ahead of us involve transformations in our modes of training and learning, of cooperation; they question the division of labor, the segmentation between life and work...

The Machinery Directive requires a design taking into account human functioning. In connection with this, the capacity and limitations of operators require constant control and audit. Our organizations and industries viewed as a whole are at "risk" due to the imperative of the preservation of workers' health.

In Industry 4.0, the human factor is recognized as an important link related to the optimal functioning of the machine. Similarly, MD also has recognized workers as a factor that is related to the safety of the human-machine system. Due to that, for designers working in the Industry 4.0, one of the crucial things is to design almost every machine component with the human properties in mind, because the safety of the operation of a machine is dependent on the human understanding of the process, in addition to the aforementioned constraints and limitations. For example, Lisanne Bainbridge pointed out in 1983 what can be called a major design mistake, in her article "The Ironies of Automation". She shows that the operator, who is considered as the error factor to be eliminated (period around 1950-1980, with the rise of knowledge in robotics), is placed in an impossible situation. He is positioned in a "press button" role, and he is asked to follow a strict procedure, where it is the machine with its automation that will ensure the treatments. But when the machine finds itself in an unforeseen situation, it cannot process it. And in this case, the operator is asked to "take over", and to straighten out the situation, but he has no information about what is happening in the machine; he does not have the knowledge and skills allowing him to make sense of this situation, since he is positioned as a "press button" subject.

The designs that followed this type of discovery repositioned the operator in the control loops. But we still too often find, including in sensitive industries, obsolete and dangerous approaches. Today, design targets the best possible coupling between the constraints and resources of equipment, spaces, the constraints and resources linked to people and organizations, including the variability of possible situations. We can no longer afford to design for an "everything will be fine" situation. We must foresee the degraded situation.

As a result of this coupling, the operators may be exposed to errors, or robust to them. The fact that we make mistakes is the price of our immense adaptability. Performance in operation, including productivity, reliability, etc., but also the capacity for development, satisfaction and commitment of the teams are the result of the quality of that coupling.

Here are some questions relevant to Industry 4.0 that are connected with the Directive:

- What will be the coupling between the robots and the humans?
- What supervision system is necessary? What information should be available to the operator? How is it possible to not overload the operator?
- What will be the training for operators, for teams?
- Which are the ways to forecast the future functioning? How can we have a vision enough accurate on the "reasonably forecastable" misuse?

## 7. CONCLUSION

Undoubtedly, the EU Machinery Directive has played a major role in raising the quality and safety of machine products. However, as with any other law, it is not only the content of the law that matters, but also the way it is applied. This circumstance is taken into account by the new MD, because it envisages changes in the manner of application of the Directive. The Directive also brings about certain changes in content, primarily in terms of expanding the categories of machines that are considered high risk.

The primary goal of MD is to ensure the safety of machines. Ergonomics can make one of the biggest contributions to achieving this goal. There are two main reasons for this - theoretical and practical. From the theoretical aspect, it should be emphasized that ergonomics is a science that in its definition [11] as one of the fundamental aspects of its study includes the aspect of safety. In addition, the safety of machines cannot be viewed only as a static process, but as a dynamic one, through human-machine interaction. It should be borne in mind that human-machine interaction is one of the synonyms for ergonomics. Therefore, this and any other amendment to the Machinery Directive should include contributions from the field of ergonomics, in order to achieve safer operation of machinery in the working context.

It can be expected that the new MD will achieve some improvements in the field of machine safety. However, this directive should not be seen as a final (unchangeable) act, but as an important stage on the path to greater safety. Subsequent revisions of the MD should to a greater extent include knowledge in the field of ergonomics, primarily in the field of errors in the functioning of the human-machine system. Some of these errors can lead to production delays, material losses, and some of the errors can also affect safety. The classification of such errors can serve as a starting point for such analyzes. One of the classifications of errors of this type related to the human-robot system is given in [12]. On the other hand, it can be expected that the new MD will contribute to the development of ergonomic theory and practice.

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