EVOLUTION OF EUROPEAN PRODUCT DIRECTIVES IN PERSPECTIVE OF INDUSTRY 4.0

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ABSTRACT
Many observers believe that Europe is at the beginning of a new industrial revolution, considered to be the fourth such leap forward and hence labelled Industry 4.0. The ubiquitous use of sensors, the expansion of wireless communication and networks, the deployment of increasingly intelligent robots and machines – as well as increased computing power at lower cost and the development of 'big data' analytics – has the potential to transform the way products are manufactured in Europe, with a widely impact on the framework of the European products directives. In fact, for example, the currently industrial automation is a consolidated reality, with approximately 90% of machines in factories being unconnected. Today the Essential Health and Safety Requirements (EHSRs) of the machine directive mean that isolated and static systems safety can be comfortably assessed. The Industry 4.0s smart factories will add a new dimension of complexity in terms of the challenges machinery safety and in this new context the European legislation have to move to innovative EHSRs to guarantee safety levels at least equivalent with these current achieved. This work presents the evolution of European product directive, in particular the machine directive, in the new vision of industry 4.0.
Keywords: industry 4.0, safety, machinery directive.

1 INTRODUCTION

The industrial revolution and so the products evolution have always been very much driven by changes relating to technological capabilities and processes: the steam engine powered factories in nineteenth century, electrification led to mass production in the early part of the nineteenth century and automation to the mechatronic industry in the 1970s. Now we are in the midst of a forth wave of technological advancement: industry 4.0 [1].

So now is widely accepted as the Industry 4.0 includes many pillars of technological advancement. Big data and analytics, autonomous robots, horizontal and vertical system integration, additive manufacturing, augmented reality, simulation, cyber-physical systems, the Internet of Things (IoT) and cloud are the news technological capabilities and processes [2].

Industry 4.0 will enable smart factories to digitize processes that improve both efficiency and quality, while reducing manufacturing costs. They will support highly flexible, automated “plug and produce” manufacturing, taking just-in-time manufacturing to a new level [3]. These updating can generate a potential substantial modification of the machineries or production lines already used in work environment. Not only the factories are smart but also the products. These new machineries, be placed on the market and/or put into service, will embed with sensors, identifiable components, and processors which carry information and knowledge to convey the functional guidance the customers and transmits the uses feedback to the manufacturing system [4]. With these elements, many functions could be added to the products, for example, measuring the state of products, carrying this information, tracking the products, and analyzing the results depending on the information. In addition, a full production information log can be embedded with product assisting product developer in optimizing the design, the prediction and the maintenance. However, the connected world of Industry 4.0’s smart factories and products adds a new dimension of complexity in terms of machinery safety challenges with the potential to transform the way

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products are manufactured and used in Europe, with a widely impact on the new legislative framework of the European products directives. Based on these considerations, this work presents some impacts of the vision of industry 4.0 on the products in the scope of machinery directive.

2 THE FRAMEWORK OF THE EUROPEAN PRODUCTS DIRECTIVES AND MACHINERY DIRECTIVE.

Historically, EU legislation for goods has progressed through three most relevant phases:

- the traditional approach or "Old Approach" with detailed texts containing all the necessary technical and administrative requirements;
- the "New Approach" which restricted the content of legislation to "essential requirements" leaving the technical details to European harmonized standards;
- the "New Legislative Framework", which built on the New Approach and completed the overall legislative framework with all the necessary elements for effective conformity assessment, accreditation and market surveillance including the control of products from outside the Union [5].

The Machinery Directive (2006/42/EC) is an example of the product directive of the New Legislative Framework that enables the EU to adopt measures to harmonize the legislation of the Member States in order to ensure the establishment and functioning of the machinery internal market. Such measures must take as a base a high level of protection of the health and safety of people and of the environment.

The Directive has the dual aim of harmonizing the health and safety requirements applicable to machinery on the basis of a high level of protection of health and safety, while ensuring the free circulation of machinery on the EU market. The establishment of a harmonized regulatory framework for the design and construction of machinery is of vital economic importance to the European engineering industry. At the same time, safer machinery makes an important contribution to the reduction of the social cost of accidents and damage to health, both in the workplace and in the home.

In the scope of machinery directive, in addition at the new machineries be placed on the market and/or put into service, are included also the machineries already used are involved in substantial modifications. In some cases, in fact, the user modifies the machinery or production lines already used in work environment. If the modifications were covered by the manufacturer's risk assessment, technical documentation and EC Declaration of Conformity, the original manufacturer's CE marking remains valid. On the other hand, if the modification is substantial (for example, a change of function and/or performance of the machinery), the original manufacturer's CE-marking becomes invalid and has to be renewed. The modifier is then considered as the manufacturer and must fulfil all the obligations set out in machinery directive [6].

3 IMPACTS OF THE INDUSTRY 4.0 ON THE PRODUCTS IN THE SCOPE OF MACHINERY DIRECTIVE

In this following section, we review the pillars of technological advancement of the Industry 4.0 and we prospect the potential impacts of these news technological capabilities and processes on the products in the scope of machinery directive, both already used in work environment or to be placed on the market. For the firsts we try to clarify when an updating of the machineries or production lines already used in work environment can be considered substantial modification and the original manufacturer's CE-marking becomes invalid. For

the seconds we hypothesize potential modifications of the Essential Health and Safety Requirements (EHSRs) of the machinery directive today not meant to smart machineries.

3.1 The safety of the smart factories

The future factory is going to involve a new integrative solution of Industry 4.0, where not only all manufacturing resources (sensors, actuators, robots, etc.) are connected and exchange information automatically, but also the factory will become conscious and intelligent enough to predict and maintain the machines, to control the production process and to manage the factory system. In addition, many manufacturing processes, such as product design, production planning, production engineering and production and services, are going to be simulated as modular, and then connected closely end-to-end, which means these processes are not only commanded by a decentralized system but also controlled interdependently. This kind of future factory is known as a Smart Factory.

Based on the above considerations we can assume that in the factories the potential updating of the machineries or production lines already used in work environment will be mainly related on implementation of:

- Horizontal and vertical system integration: most of today's IT systems are not fully integrated. Departments such as engineering, production, and service, companies, suppliers, and customers are rarely closely linked. But in the vision 4.0, companies, departments, functions, and capabilities will become much more cohesive, as cross-company, universal data-integration networks evolve and enable truly automated value chains. In the future, we will have a common workspace for design and manufacturing collaboration and is available as a service on a private cloud. It manages the complex task of exchanging product and production data among multiple partners. This evolution is non-directly connected on the function and/or performance of the machineries already used in work environment and so there could not be substantial modification and the original manufacturer’s CE-marking remain valid.
- Internet of Things: currently, industrial automation is a consolidated reality, with approximately 90 per cent of machines in factories being unconnected. But with the industrial IoT, more devices-sometimes including even unfinished products-will be enriched with embedded computing and connected using standard technologies. This allows field devices to communicate and interact both with one another and with more centralized controllers, as necessary. It also decentralizes analytics and decision making, enabling real-time responses. IoT will connect people and machines, enabling bidirectional flow of information and real-time decisions. The implementation of Iot on actually static machinery could be a substantial modification of control function and/or performance of the machinery, not covered by the manufacturer’s risk assessment, so the original manufacturer’s CE-marking becomes invalid and has to be renewed. The modifier is a new manufacturer and must fulfil all the obligations set out in machinery directive.
- Cyber-physical systems: many companies still rely on management and production systems that are unconnected or closed. With the increased connectivity and use of standard communications protocols that come with Industry 4.0, the need to protect critical industrial systems and manufacturing lines from cybersecurity threats increases dramatically. As a result, secure, reliable communications as well as sophisticated identity and access management of machines and users are essential.

However, if this dynamic approach of Industry 4.0's cyber physical systems will be implemented, where with a simple press of a button, easily machinery and production lines can be instantly configured, this work equipment is substantially modified and the original manufacturer's CE-marking will become invalid and has to be renewed. Therefore, the person who carry out the modification must to fulfil the obligations set out in machinery directive.

- The cloud: companies are already using cloud-based software for some enterprise and analytics applications, but with Industry 4.0, more production-related undertakings will require increased data sharing across sites and company boundaries. At the same time, the performance of cloud technologies will improve, achieving reaction times of just several milliseconds. A cloud computing as a system of collaborating computational elements that include mechanical and electrical elements that are connected in a smart cloud and are able to communicate in real time. As a result, machine data and functionality will increasingly be deployed to the cloud, enabling more data driven services for production systems. Even systems that monitor and control processes may become cloud based. Also in this case, as for horizontal and vertical system integration, this evolution is not directly connected on the function and/or performance of the machineries already used in work environment and so there could not be substantial modification and the original manufacturer's CE-marking remain valid.
- Augmented reality: augmented-reality-based systems support a variety of services, such as selecting parts in a warehouse and sending repair instructions over mobile devices. These systems are currently in their infancy, also for cost impact, but in the future, companies will make much broader use of augmented reality to provide workers with real-time information to improve decision making and work procedures. For example, operator can use these supports to control the machine or workers may receive repair instructions on how to replace a particular part as are looking at the actual system needing repair. If an augmented-reality-based systems support will be implement on machineries or production lines already used in work environment, this upgrade could be considered an improvement of safety level of the work equipment and not a substantial modification. In fact, with this evolution for example the operator is potential always outside of the danger zones of the machine. In this case, the original manufacturer's CE marking remains valid.

3.2 The safety of the smart machine

Benefitting from Industry 4.0, new type of product will be manufactured: the smart machine. In this following text, we prospect the potential evolution of EHSRs of the machinery directive or of the related harmonized standards, today meant for isolated and static machine, relating on implementation of some of the pillars of the Industry 4.0 in the near future visions:

- Big data and analytics: the smart machine can be upgraded with support that transmits information for analytics based on large data sets. This is emerged only recently in the manufacturing world, where it optimizes quality, saves energy, and improves equipment service. In an Industry 4.0 context, the collection and comprehensive evaluation of data from many different sources-production equipment and material work in progress, final product become standard to support real-time decision making. This evolution will not influence substantial the design

and the manufactured of the machine and consequently of EHSRs of the machinery directive.

- Additive manufacturing: companies have begun to adopt additive manufacturing, such as 3-D printing, which they use mostly to prototype and produce individual components. With Industry 4.0, these additive-manufacturing methods will be widely used. For example, decentralized additive manufacturing systems will reduce transport distances and stock on hand. We can suppose that also in the future the current EHSRs of the machinery directive could guarantee a safety design and manufacturing of this equipment.
- Autonomous robots: many Industries have long used robots to tackle complex assignments, but robots are evolving for even greater utility. Typically, they are behind safety fences (in cells) with interlocked doors or photoelectric barriers, such that when access is gained to the work zone the robotic system is rendered safe by removing power to the actuators. And for many industrial applications this remains the preferred strategy as it meets the hierarchy of protection outlined in the EHSRs of the Machinery Directive (EHSR 1.1.2, Annex I, 2006/42/EC). They are becoming more autonomous, flexible and cooperative. Eventually, they will interact each other and work safely side by side with humans and learn from them. Existing applications include autonomous vehicles in warehousing, mining, quarry, and now farming. The robots will become more complex, with more and more degrees of freedom (e.g., humanoid robots) and for example the risk of trapping in-between two joints will increase; higher complexity in robot's range of motion will make it more difficult for humans to predict the robot's displacement. Just as in the automotive sector (cars and trucks) development work is fast advancing. Such collaborative working may have advantages, just as in the traditional applications (e.g., to avoid or reduce musculoskeletal strain or repetitive injury), or permit much finer control (e.g., in the field of medicine assisting the surgeon during operations) or to assist, (e.g., exoskeletal in rehabilitation applications in enabling the less able to walk again). There are still no harmonized standards dedicated to defining the autonomous robot safety requirements. The ISO standards 10218 could partially be applied, as it defines collaborative requirements between humans and robots and ISO/TS 15066:2016 specifies safety requirements only for collaborative industrial robot systems and the work environment, define the force and pressure limits for a safe contact between human and robot. Therefore, for the autonomous robots will be to desirable limiting the hierarchy of protection of the EHSR 1.1.2 to eliminate the risks with inherently safe machinery design and construction. In addition, it will be appropriate to improvement of the Machinery Directive EHRSs or define a specifics harmonized standards to manage the safety issues associated with control system integrity and reliability (EHSR 1.2 and 3.3 – Annex I, 2006/42/EC) and risks related to moving parts (EHSR 1.3.7 – Annex I, 2006/42/EC).
- Augmented reality: as already above described, this pillar can improve the application on new machinery of the EHSRs about the operator safety instructions and training (EHSR 1.7.4 – Annex I, 2006/42/EC). On the other hand, if the operator with augmented-reality-based systems support can control the machine, the harmonized standards about the safety-related parts of control systems will have to improve with specific safety requirements.
- The internet of thigs: today only few machines are placed on the market networked and make use of embedded computing. They are typically organized in a vertical

automation pyramid in which sensors and field devices with limited intelligence and automation controllers feed into an overarching manufacturing-process control system. Also for this technological advancement the harmonized standards about the safety-related parts of control systems will have to improve with specific safety requirements.

4 CONCLUSIONS

This paper focuses on the potential impacts of Industry 4.0 on the safety of products in the scope of machinery directive. The analysis identifies when probably the original manufacturer's CE-marking will become invalid because of implementation of a technological advancement of Industry 4.0 on machineries already used in a work environment and which EHSRs of the machine directive more likely will be affected in the new vision 4.0 to guarantee new safety machineries to place on the market.

From this examination, it is obvious that the current machine directive and its specifics harmonized standards, and in general many European product directive, are to improve to guarantee safety levels of machineries or products at least equivalent with these current achieved.

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