Position Paper on the Revision of the Machinery Directive 2006/42/EC

Introduction

The independent Testing, Inspection and Certification (TIC) sector welcomes the European Commission's initiative to revise the Machinery Directive (MD) 2006/42/EC. With this position paper we would like to provide our views on the ideas raised in the inception impact assessment.

Alignment with the New Legislative Framework (NLF)

We consider that the alignment of the MD with the NLF would provide further clarity on the information requirements for placing machinery on the EU market, on accreditation, the role of notified bodies and on market surveillance.

In this framework, it is important to revise the methodology for choosing the procedures for assessing the conformity of machinery (article 12 of the current MD) to ensure that it is aligned with the risk-based system of the New Legislative Framework.

A risk-based approach for the determination of applied conformity assessment procedures is more flexible than the current system of the MD. Thereby, it would correspond to the increasingly complex and interconnected environment within which machinery operates today, as well as to the changing of risk exposure of machines operating in public areas, such as escalators.

Overall, we strongly believe that a risk-based approach would illustrate that conformity assessment modules involving notified bodies are best suited to address all risks related to machinery.

Revision of definitions and achieving legal clarity

We support the European Commission's suggestion to introduce changes the MD's scope and definitions, including a better and sharper definition of logic units and of partly completed machinery.

Our experience shows that further clarification is necessary in these areas. For example, robots without end effectors are often placed on the market as complete machines. The corresponding end effector is not assembled until the moment it is put into service. This contradicts the definition of partly completed machinery underlying the MD. A complete machine must be provided for a specific application that hardly applies to robots without end effector, as without it they cannot perform a function.

Taking into account process manufacturing

We suggest revising the MD in a way that takes into account that nowadays machines are often operated as part of a system or a process, such as in production lines.

This is particularly important for provisions relevant to conformity assessment procedures. Within the framework of a suitable conformity assessment procedure, notified bodies would be able to assess all hazards to ensure safe production and the prevent industrial accidents and commercial damages.

Modifications of machinery

Practical experience shows that operators are increasingly making changes to machines after the product has been initially put into service, for example during the product's operation. These changes

CEOC International Aisbl
Rue du Commerce 20-22 \ BE-1000 Brussels
info@ceoc.com \ www.ceoc.com
EU Transparency Register: 96818506624-46

IFIA – International Federation of Inspection Agencies
Boulevard du Régent 37 | B-1000 Brussels
secretariat@ifia-federation.org | wwwi.fia-federation.org
EU Transparency Register: 840667012559-60

may be so significant that the machine may be considered as a new product that requires to undergo conformity assessment.

Therefore, we recommend that the future MD contains precise provisions regarding the factors of assessing the machine's modifications, particularly when notified bodies are involved in the conformity assessment.

Low Voltage Directive (LVD)

We consider that it is not practical to include a list of products in the MD that are not covered by the LVD due to their low voltage range. The current directive already covers these products. In addition, such a list would need to be continuously adapted.

To this extent, we also suggest that interfacing between MD and LVD should be well described in both acts and in the relevant guidance documents.

Digital transformation of industry and cybersecurity

We highly support the Commission's intention to ensure the full implementation of the Cybersecurity Act to products covered by the scope of the MD.

The Cybersecurity Act should operate as framework legislation for the certification against cybersecurity risks for all products and should prevail on cybersecurity issues against all sector-specific directives.

Overall, we support the Commission's intention to adapt the health and safety requirements in the light of challenges posed by increasingly used technologies, such as artificial intelligence and connected devices. A robust regulatory framework, that addresses the public's and operators' trust in new technologies can ensure that the EU would benefit from the digital transformation's potential.

Radio Equipment Directive (RED)

We consider it important that the MD stipulates the mandatory application of RED. Thereby, the essential requirements of RED for radio, electromagnetic compatibility and health will apply in addition to the MD's essential requirements, whenever radio modules are installed in a machine (wireless interconnections).

Digital documentation

We support the use of digital documentation to prove the fulfillment of the essential health and safety requirements by manufacturers to the market surveillance authorities, such as the machine's technical file.

However, we consider that instructions and safety information should accompany products covered by harmonisation legislation in paper format. Not all consumers or professional operators, such as craftsmen, have access to a digital manual when using a machine.

Regulation versus Directive

We strongly believe that turning the MD into a Regulation will further improve the functioning of the Single Market, as its application by Member States would be fully harmonised. It will be more effective in creating a level playing field for economic operators.