

## FEM input on the Machinery Directive's fitness for purpose in the face of digitisation challenges

Brussels, 31st January 2018

FEM represents European manufacturers of materials handling, lifting and storage equipment. More and more types of such equipment are integrated into partly or fully automated systems that provide tailor-made solutions for complex production, storage and logistic requirements. In addition to mechatronic products, special attention is given to system controls, information processing and telecommunication. Materials handling equipment manufacturers have thus been experiencing different aspects and effects of digitisation (cybersecurity, artificial intelligence...) both in their manufacturing processes and in the equipment that they produce. They are aware of the present questions and uncertainties related to the interactions between the Machinery Directive (MD) and digitisation, which were pointed out in the main findings of the MD evaluation study.

For most FEM manufacturers the MD is the main reference legislation prescribing mandatory essential requirements to ensure the safe design and operation of the equipment they produce. We firmly believe that the MD is fit to fulfil this purpose, even in the context of ever more digitised equipment.

Indeed, from a safety point of view, the different forms that digitisation can take (software, artificial intelligence, deep learning algorithms...) can only express a physical impact through the behaviour of a (physically existing) machine. Safety risks are therefore the same whether the machine is operated by a human or autonomously within a network.

The MD precisely addresses all types of risks and covers the physical hazards which might arise from the intended use and the foreseeable misuse of that machinery, regardless of the origin – digital or human – of such physical hazards. By prescribing essential health and safety requirements, the MD aims at mitigating physical hazards through the design of machinery. Therefore, and since digitisation as such is not the source of additional physical hazards of a machine, there is no need to address it specifically in the MD.

The principles and requirements laid down in Annex I (1.2.1) suffice to ensure the safety and reliability of control systems. Regarding the software of the control system, it is the manufacturer's responsibility to design his/her machine in such a way as to prevent hazardous situations that could be generated by a fault in the software.

Certainly, data or algorithms can be used to increase the safety of machinery, and reduce risks or hazards. Further safety of autonomous machines can be enhanced via standardisation. For instance, there is an ongoing standardisation work, under the responsibility of CEN TC 150, to develop an ISO EN standard on "Industrial trucks - Safety requirements and verification - Part 4: Driverless industrial trucks and their systems". The project plan for this standard is annexed to this paper.

This goes to show that standards are the appropriate means to address specific needs arising from the interaction between the MD and advanced autonomous robotics. Furthermore, questions related to product liability in the case of accidents provoked by equipment communicating with intelligent systems outside the factory should be treated in specific legislation dealing with product liability issues.

In a nutshell, the MD remains fit for purpose in the face of digitisation, addressing all risks regardless of whether a machine is autonomous or not. It is crucial that the Directive's essential health and safety requirements are not altered by digitisation aspects. Standardisation is the right channel to address digitisation challenges for machine manufacturers (e.g. machine behaviour communicating with AI systems outside established networks).