



Digital Transition: Regulation of the European Parliament and of the Council on Machinery Products

by Silvia Rigano

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In February 2020, the European Commission published a White Paper on Artificial Intelligence, along with a [“Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics”](#).

The analysis showed that current European legislation on product safety, in particular Directive 2006/42/EC (henceforth: the Machinery Directive), needs to be adapted to ongoing technological changes and to the new requirements of the single market. Even though the Machinery Directive ensures the free movement of machinery within the internal market and a high level of protection for users, the Commission considered it necessary to improve, simplify and adapt the provisions currently in force.

In this sent, on April 21st the Commission released a [proposal for a regulation on machinery products](#) (henceforth: the Machinery Regulation) following a review of the directive and a consultation with stakeholders, including Member States, social partners, certified bodies and experts of the sector. The proposal, which is based on art.114 of the TFUE, considers the Commission's aim of simplifying the regulatory framework and the need to ensure uniform implementation of the proposed legislative act¹.

The first innovation is about the form of the new act, i.e. a regulation that does not require internal transposition as it is directly applicable throughout the Union.

The Commission believes that a change from a Directive to a Regulation will not lead to any change in the regulatory approach, avoiding the risk of over-regulation and establishing a clearer regulatory environment for economic operators. The reason of this choice is, therefore, the need to ensure the clarity of the rules on the essential requirements of health and safety for machinery products, as well as the conformity assessment procedures which should be certain and not subject to individual interpretation.

The Commission specifies that the proposed regulation is consistent with the Union policy on artificial intelligence (AI) and the upcoming Regulation on artificial intelligence, which will address the risks having an impact on safety for high-risk AI systems embedded in a machinery or that are safety components under the future regulation on

¹ Point 2.4 of the Explanatory Memorandum to the Regulation p.6.

machinery products. Moreover, the proposal is coherent with the Union's cybersecurity policy and with the Directive 2014/35/EU (Low Voltage Directive)².

For what concerns the scope of the Act, the provisions contained in the proposal should cover machinery products which are new to the Union market when placed on the market, i.e. either new machinery products made by a manufacturer established in the Union or machinery products, whether new or second-hand, imported from a third country³.

Regarding the strategic objectives of the proposal, the first one is the need to sufficiently and adequately address the new risks generated by emerging technologies, which are divided as follow: (a) the potential risks that originate from a direct human-robot collaboration as the collaborative robots (co-bots); (b) potential risks that originate from connected machinery; (c) risks related to software updates that affect the 'behaviour' of the machinery after its placing on the market; (d) risks related to the ability of manufacturers to conduct a full risk assessment on machine learning applications before the product is placed on the market; (e) risks related to the autonomous machines.

Secondly, the Commission highlighted the legal uncertainty due to a lack of clarity on the scope and definitions and possible safety gaps in traditional technologies.

The evolution of usable technologies does not seem to go along with the provisions of a directive that is considered obsolete and that could be an obstacle to innovative processes. This aspect is linked to inconsistencies and overlaps in the terminology used, especially in relation to other specific EU regulations also in the field of product safety (e.g. concepts of machine, quasi-machine and substantial modification of the machine).

In addition, the revision of the directive and the subsequent proposal for a regulation are based on the inadequacy of the provisions dedicated to machinery presenting high risks, listed about fifteen years ago. It seems clear the need to update the legislation, considering the evolution of the market and the integration of artificial intelligence and safety systems.

Finally, the Commission stresses the need to digitalize the information tools, adjusting the monetary and environmental costs due, for example, to the printing of the instructions or to the EU declarations of conformity. For this purpose, the regulation gives the users the possibility to have information in digital format, still leaving the users the availability of printed version upon request. The language of the information should be easily understood by users and market surveillance authorities.

Considering this short illustration of the main purposes of the proposal, the new regulation should aim to regulate most of the aspects linked to the development of new technologies, as well as the possible risks related to artificial intelligence, data exchange and exposure to cyber-attacks capable of compromising machine safety.

This regulation should have an impact on a lot of sectors and on the interests of manufacturers and users, since the machinery sector is an essential part of the engineering industry and one of the industrial mainstays of the EU economy.

² Point 1.3 of the Explanatory Memorandum to the Regulation p.4.

³ Point 9 of the Proposal, p.15.

Indeed, social partners continue to follow, both at national and European level, the evolution of the regulatory process: on 4th October 2021, Business Europe, together with many trade associations that mainly protect the interests of machinery manufacturers, has published a [statement](#) in which identified strengths and weaknesses of the forthcoming regulation, even if the revision of the directive is welcome.

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