



CCMI/172
Revision of the Machinery Directive

INFORMATION REPORT

Consultative Commission on Industrial Change (CCMI)

Revision of the Machinery Directive

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1. **Conclusions and recommendations**

- 1.1 The EESC welcomes the Commission's current efforts to analyse and possibly improve the performance of the Machinery Directive 2006/42/EC as part of its regulatory fitness and performance (REFIT) programme. The EESC consider that the Machinery Directive is a very important and successful instrument for European industry, and its basic approach must be left unchanged. While EESC agree some changes are needed, massive changes of the Machinery Directive, in particular to the Essential Health and Safety Requirements (EHSRs) in Annex I, would have a deep negative impact on the work of developing needed harmonised standards and must be avoided.
- 1.2 The EESC is aware of the pressure being exerted by some experts who are convinced that the Machinery Directive needs updating because of the challenges arising from progress in digital technologies, and calls on the Commission to acquire and share the factual arguments that could justify the necessity to do so. The EESC is aware of the different opinions of stakeholders shared during the meeting of the European Parliament Internal Market and Consumer Protection Committee (IMCO) that took place on the 4 December 2019 in Brussels. This IMCO meeting showed diversity of views on issues connected to new technologies which seem to suggest that state of the technology is not sufficiently developed to the point where specific proposals could be made supported by a substantial body of evidence other than issues with cyber security (see point 1.3).
- 1.3 The EESC endorses the European Commission's opinion that there is a risk of malicious or accidental operation of machinery connected to the Internet. This is a general risk that can affect a wide range of equipment and apparatus and is not specific to machinery. Also, cybersecurity is an issue involving several actors and its control does not only depend on machine manufacturers. The EESC recommends that the issue of cybersecurity be dealt with in a separate horizontal item of legislation, including a reference to it in the revised Machinery Directive. The EESC recommends clarifying, however, that the "external influences" specified in Annex I, §1.2.1, which the control system must withstand, is amended to specifically include cyber-attacks.
- 1.4 The EESC points out that, although the use of Artificial Intelligence (AI) is not new, its development and use as part of digital technology is evolve rapidly. This development is still at an early stage in much of the EU machine tool and manufacturing industry and it is important for the EU that it is encouraged. The EESC believe the current Machinery Directive's well known and used methodology to control risk does not need to be changed to accommodate this technology. This is because the principles of Risk Assessment and Risk Reduction (RA&RR) – in which the Machinery Directive is rooted – remain constant. The iterative combination of these principles is technology-neutral: RA&RR can be successfully applied to assess and decide whether any digital technology can be incorporated into machinery design in order to ensure that machinery is compliant with the Machinery Directive. Accordingly, no technology (including new digital applications) can be introduced in machinery design if it cannot be verified and validated – for all of the phases of a machine's life cycle – by the conformity assessment procedures (which always include RA&RR), described in Article 12 of the Machinery Directive.

- 1.5 The EESC invites the European Commission to establish a clearer connection between the two legislative domains regulating the design and use of machinery, namely the Machinery Directive 2006/42/EC and the Use of Work Equipment Directive 2009/104/EC, thus making it completely unambiguous that *the safe design of machinery for all the phases of its life cycle is a precondition for safe use*. This principle must not be challenged by controversial topics such as the modification of machines, including machines with learning capabilities, during their operational service life. The EESC points out that without such clarification of the interrelation between Directives 2006/42/EC and 2009/104/EC, ambiguity will continue to surround the risk assessment duties of manufacturers, employers, market surveillance authorities and labour inspectors in respect of machinery.
- 1.6 When manufacturers are not aware of the actual conditions in which machines operate, it is highly likely that the result will be an unsafe machine. The EESC invites the Commission's DG Employment and DG Grow to establish a joint coordinated strategy centred on the application of the ISO/CEN Technical Report on the Feedback Method to identify risks in the use of machinery and create the missing link between the Machinery Directive (safe design) and the Use of Work Equipment Directive 2009/104/EC (safe use), as the latter requires work equipment (including machinery) to be maintained to meet the requirements of the Machinery Directive and so places this responsibility on the companies using machinery.
- 1.7 The EESC invites the Commission to improve the text of the Machinery Directive by stressing the importance of ergonomic risks. Although the present Directive allocates a section to ergonomics (Annex I, §1.1.6), this change seems to have had little effect on most manufacturers' attitudes, meaning that the chronic harm caused by poor ergonomic design remains a major challenge. The EESC suggests giving the Machinery ADCO Group (Machinery Administrative and Cooperation Group this is a closed EU Group of EU and EFTA market surveillance authorities) the role of initiating proactive international project work to identify ergonomic issues associated with machinery design. Ideally this would involve the Senior Labour Inspectors Committee's MACHEX (MACHinery EXchange) Group, which is best placed to identify the ergonomic risks of machinery in use. Further discussions on this issue are needed and it is suggested that the EU Commission (DG Employment and DG Grow jointly) hold a seminar to explore the possibilities and implications for the revised Machinery Directive.
- 1.8 The EESC believes that a major revision of the Machinery Directive is not to be recommended before resolving the chronic understaffing, underfunding and poor performance of machinery inspections and controls (either before or after putting machinery into service) in the overwhelming majority of Member States. Insufficient market surveillance would make any improvement and change unenforceable, would have limited effects, particularly on items imported from outside the EU, and law-abiding companies and their workers would fall victim to unfair competition. Finally, it would divert resources away from more urgent endeavours, with no practicable gains in safety.
- 1.9 The EESC is aware that over 700 harmonised standards have been developed to describe how machinery can meet Directive 2006/42/EC: at best they aim to codify the state of the art to be considered should a manufacturer decide to follow an alternative, non-standard approach. The

EESC invites the Commission to contribute to the involvement of the social partners (machinery users), market surveillance authorities and SMEs in standardisation, and move from words to action by enforcing Article 7 of the Machinery Directive. This article expressly requires Member States to ensure appropriate involvement of the social partners in standardisation, as inclusiveness is one of the pillars contributing to the acceptance and uptake of harmonised standards.

2. General comments

- 2.1 The EESC considers that only minor revisions of the text of the Machinery Directive are required. The Directive has stood the test of time and in general is fit for purpose: the approach of setting objectives to be achieved in the text – leaving standardisation to adapt and flesh out the details of how they can be achieved – has worked well. In its current form, the Directive makes a significant contribution to the safety of workers as well as to revenue contributions for EU manufacturers and it is questionable whether changes to the Essential Health and Safety Requirements (EHSR) in Annex I should be made unless considered indispensable by both sides of industry and by the public authorities. As the REFIT programme calls for modifying legislation only on the basis of careful evaluation rooted in facts and substantial evidence, the EESC recommends that the Commission collect and assess *facts and concrete case studies before proposing changes*, making optimum use of the knowledge and experience available from a wide range of stakeholders.
- 2.2 The EESC recommends not revising the Machinery Directive (articles or annexes) to attempt to cover technological developments for which nobody can make sufficiently accurate forecasts. The Directive's health and safety requirement duties on the manufacturer deal adequately with developing technologies such as self-learning algorithms and robotics that are designed to work within safe boundaries and predetermined operational envelopes, as they can go through the RA&RR process before being placed on the market. The EESC is aware of the many indicators pointing to a call to revise legislation to cover unrealistic projections and untestable applications such as autonomous robots able to learn without operating boundaries: *for these products no risk assessment will be possible at the production phase as their future operation cannot be predicted, verified and validated*. The safe control of such machines would require *adaptive or dynamic risk management* methods that are incompatible not only with the current safe design approach of the Machinery Directive, but also with the New Legislative Framework (NLF) and the product safety philosophy of the European Union. In other words, the Machinery Directive is perfectly able to differentiate between compliant and non-compliant digital applications by means of RA&RR. At another level, the EESC shares the European Commission's concerns about the unexplainable nature of decisions taken by current machine learning systems, and therefore the *impossibility* of tracking back to the root causes of an incident or accident of a machine steered by a machine-learning system. The fact that it is impossible to track back to the root causes seriously undermines the improvement cycle of safety based on the ex-post analysis of incidents or accidents.
- 2.3 Insofar as its technical rules mainly relate to protection of users, the Machinery Directive is also a social measure intended to promote the health and safety of individuals. The economic and social operators who, in the late 1980s, negotiated what was to become the Machinery Directive

were in the same period also involved in drafting the prospective Framework Directive on the health and safety of workers. The fact that the two resulting directives, the Machinery Directive (89/392/EEC) and the Directive on the health and safety of workers (89/391/EEC), then appeared together in the Official Journal of the European Communities of 29 June 1989 signalled the desire – even the need – for safe integrated machinery design to complement the safe installation and safe use of such machinery in the workplace. For this reason, the EESC invites the Commission to multiply its efforts to explain the connection between the two directives on safe design and safe use.

- 2.4 Feedback from users of machinery to both manufacturers and standard setters is needed for continuous improvement: this should be explicitly mentioned in the Machinery Directive as an indispensable tool to be applied by manufacturers during the mandatory risk assessment and risk reduction phase, incorporating the knowledge necessary to uncover all hazards associated with the whole of the machine's lifetime. It is a fact that machinery accident statistics show how human factors are not perceived or incorporated by machinery designers as a fundamental and essential part of machinery design. In general, the need for functional design dominates the design process, but unfortunately functional design does not include the needs and limitations of the machine users as a fundamental part of the design process. During design, manufacturers should carry out task analyses to develop a clear understanding of how people will use, maintain and – obviously – misuse machines. In practice, only experience can uncover the hazards associated with normal use, the unintended behaviour of operators and the reasonably foreseeable misuse of the machine.
- 2.5 Ergonomic problems caused by machinery that may result in chronic illness tend not to be identified and investigated. This issue has been debated in both the ADCO and the Machinery Directive Working Group but mainly with respect to visibility and the design of controls on mobile machinery where people have been hit or crushed. The issues that have given rise to discussion are "acute" risks that will have been subject to accident investigations. Lack of resources and political pressure at both EU and national level have resulted in market surveillance authorities and labour inspectorates having to concentrate on risks identified in accident investigations at the expense of proactive work on the causes of chronic harm such as musculoskeletal problems, but also mental health and stress-related disorders which could be further affected by the introduction of collaborative AI technology. Therefore, the revision of the Machinery Directive should provide an opportunity to make it clear that the MACHEX Group (i.e. the labour inspectors' group under DG Employment) are key to feeding information to market surveillance authorities on problems arising in the use of machinery at work.
- 2.6 At present the performance of market surveillance varies widely across the EU Member States, the majority of which carry out very little proactive work within the EU and at its borders. The EESC WARNS that if insufficient controls and inspections are performed and there are no attempts to withdraw or ban specific machinery, this will (a) lead to a rise in the amount of defective machinery in circulation; (b) encourage non-conformity with the legislative requirements; (c) increase the likelihood of accidents and injury; and (d) create unfair competition for law-abiding companies, placing them and their workers at risk. In addition, insufficient surveillance will result in low-quality harmonised standards.

- 2.7 The EESC is aware that the concept of partly completed machinery (PCM) was introduced for the first time in the current Directive. Discussions with players who were involved in the negotiations of the Directive show it was not their intention that a partly completed machine could be placed on the market with absolutely no legal requirements being addressed and passing all of the requirements on to the person/company installing the PCM, as is the current interpretation. The EESC recommends that the revision of the Machinery Directive should require that all the relevant EHSRs and risk reduction measures be applied to any PCM placed on the market, as detailed in the technical file, with the exception of those that can only be applied as part of the process of combining the PCM to produce a machine under the scope of the Directive. Such a change would make it clear that a PCM is sufficiently close to being a machine to warrant being considered one, as opposed to just being "part" of a machine, and that it thus has a clear status that will help the installer to meet the requirements of the Directive.
- 2.8 The concept of assemblies of machines has been a cause for concern over the years and has been made more complicated by the modern computer-controlled operation of whole industrial sites. Previously, each assembly had its own control panel, one reason why the Commission suggested demarcating different assemblies in a factory site. The main worker safety issue is the control of risks caused by putting the assembly parts together so that extra guarding, crushing risks, sequencing of operation and isolation of operation are adequately addressed. The EESC recommends formulating a revised definition that concentrates on defining an assembly by the interfaces and risks introduced between, and posed by, new items added.
- 2.9 Refurbishment of machinery does not require a new conformity assessment and CE mark provided equivalent parts (these may be newer parts with improved safety features etc., but with the same function) are used. There is no agreement between Member States on when the new conformity assessment is needed, something that should be made clear in the revised Directive so that a common approach is taken. The EESC recommends that a new conformity assessment and CE mark are needed when new functions are added, or the operating range is extended, so that significant hazards that were not considered previously can be added.
- 2.10 The section on working conditions in Annex I (§1.1.7) is poorly formulated: although it requires the operator to have good working conditions and be protected against any foreseeable hazards, the level of working conditions is in practice very variable. The EESC recommends specifically mentioning heating, cooling, noise, dust, hazardous chemicals and a body position compatible with long operating periods to specify what is meant by "good working conditions" for the operator.
- 2.11 State of the art is a key concept but is not defined fully, with only a loose explanation in a Recital that there is an economic aspect to be taken into account. The EESC recommends introducing a definition of the term "state of the art" to avoid confusion and abuse.
- 2.12 The EESC stresses that the definition of "reasonably foreseeable misuse," whether intentional or unintentional, should be improved by taking into account the body of experience acquired through past use of the same type of machinery or of similar machinery, accident investigations and knowledge about human behaviour.

- 2.13 The Directive does not specify the format of instructions, but it has been assumed that they must be in hard paper format. Progress in telecommunication enables other options to be useful (such as the use of videos to explain installing, dismantling or maintenance operations), as these may be better understood by operators with limited language skills. The EESC recommends requiring that the paper format of the essential operator guide (quick start guide) containing more detailed and comprehensive information also be provided in digital format, but with the safeguard of providing a hard copy of the instructions to any end user requesting it.
- 2.14 the EESC invites the European Commission to improve the current format of the Guide supporting the application of the Machinery Directive – available from the DG Growth website – by introducing a web-based version associated with the revised Directive: this would facilitate prompt updates, while hypertext links could point to key documents (such as the Blue Guide) and relevant references in the Guide itself.

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The president of the European Economic and Social Committee
