

The Machinery Directive and Conformity Assessment: addressing the facts

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The TIC Council is the international trade association representing third party testing, inspection and certification services, among which bodies notified under the Machinery Directive and with vast experience in conformity assessment of machinery equipment.

We welcome the European Commission's proposal for a Regulation on Machinery Products and look forward to being able to support the implementation of the new rules in a cost-effective manner for the industry and to further the goal of protecting the users of machinery equipment in the Single Market.

General considerations

- All of the products listed in Annex I of the proposed Machinery Regulation are high-risk products and should therefore not be subject to self-declaration of conformity. We consider that conformity assessment by notified bodies is the best possible way to prevent non-compliant and dangerous machines from entering the Single Market. This approach is fully aligned with the risk-based approach of other EU NLF-aligned legislation, such as the Medical Devices Regulation, the Lifts Directive, or the Pressure equipment Directive.
- Compliance with safety, security and privacy requirements should not be a matter of costs. Every serious accident or injury of a machinery user is undoubtedly much more “costly”. An [independent study](#) commissioned by IFIA and CEOC (the current TIC Council) found an 80% rate of non-compliance of consumer products self-assessed by manufacturers vs 1% for those evaluated by third party conformity assessment bodies.

Conformity assessment in practice

- TIC Council members are aware of cases where manufacturers conducted internal production control in accordance with Annex IV:
 - did not comply with the essential health and safety requirements, despite existing technological solutions.
 - used the conformity assessment procedure in Annex VIII, despite deviating from the harmonised standards that they applied.
- Conformity assessment by third parties concerns only a small part of machines: in total, this represents 20% of all machines and half of Annex IV-machines.
- Many manufacturers are already today using the services of Notified Bodies beyond cases mandated by the Directive. TIC Council members report that many SMEs use NBs for reputational reasons, as well as due to their lack of expertise on the procedure of performing these services themselves. Therefore, the inclusion of third parties can be highly beneficial for manufacturers while paying an adequate and fair price. TIC services enable a cost-effective market access especially for those SMEs and smaller manufacturers, for whom the potential cost barriers associated with market entry may be too substantial relative to their size.
- As a matter of fact, according to the evaluation of the directive, 50% of the conformity assessment for Annex IV machines is already done with third party involvement.
- The system is proven to work, thanks to the long-standing expertise of TIC Council

members, and we expect that the proposed Regulation will continue on the path of excellent relationships between manufacturers, Notified Bodies and the users of machinery equipment.

The costs of safety

- Compliance comes with a cost whether done internally (in-house) or outsourced to professional Conformity Assessment Bodies.
- Looking at the details, only a proportion of the conformity assessment costs to the product manufacturing costs must be taken into account; the average fees taken in isolation are of no economic relevance. The average fees for one conformity assessment in relation to Annex IV machinery cannot be quantified exactly. Due to the large diversity of machines in Annex IV, the costs are in the four- to five-digit range.
- These arguments are supported by the European Commission's impact assessment report, which states that "the evaluation of the MD also showed that obligatory third-party assessment does not add significant costs to industry" (p. 62). In addition, data from French authorities, presented at the European Parliament's Internal Market and Consumer Protection committee meeting at the end of May, shows that the cost factor for manufacturers of including Notified Bodies represents only about 0,07-1% of the entire product development costs.
- The cost of conformity assessment cannot disappear: manufacturers have to bear the costs for conformity assessment regardless of whether they perform it in-house or externally, especially in view of the many complex requirements which demand specific competences that TIC services can provide. The responsibility to comply with the requirements always lies with the manufacturer, importer or distributor.

Finally, we would like to draw your attention to the position paper of our association, the TIC Council, which brings together the most important discussion points of our industry on the new Regulation on machinery products. Please find the document below.

Editor's Note About TIC Council

TIC Council is the global trade federation representing the independent third-party Testing, Inspection and Certification (TIC) industry which brings together more than 90-member companies and organizations from around the world to speak with one voice. Its members provide services across a wide range of sectors: consumer products, medical devices, petroleum, mining and metals, food, and agriculture among others. Through provision of these services, TIC Council members assure that not only regulatory requirements are met, but also that reliability, economic value, and sustainability are enhanced. TIC Council's members are present in more than 160 countries and employ more than 300,000 people across the globe.

The Value of TIC Report

To learn more about TIC Council and its member's activities, the landmark report on the Value of the TIC sector, developed jointly by the international law firm Steptoe and the London-based consultancy Europe Economics is now available to read. This report illustrates, by using data and case studies, how the TIC sector benefits a variety of stakeholders and industries around the world. You can find the study [here](#), and we welcome you to share it with anyone who might be interested.

TIC Council Position on Proposal for a Regulation on Machinery Products

TIC Council, representing the testing, inspection and certification organisations globally, including the notified bodies for Machinery legislation, welcomes the European Commission's proposal for a Regulation on Machinery Products. With this position paper, we would like to provide our general comments and recommendations on this proposal tabled by the European Commission.

High risk products

We would like to express our strong support for establishing that high-risk machinery should only be subject to third-party certification.

Indeed, we consider that depending on the risk potential of the respective machinery, in particular if connected, a mandatory involvement of an independent notified body is best suited to address the risks related to machinery for a higher level of safety.

Integration of new technology & Alignment with the New Legislative Framework (NLF)

We are pleased to see that the list of high-risk machinery in Annex I will take into account the progress of technical knowledge and other types of high-risk machinery such as machinery with AI ensuring safety functions. Moreover, the delegated acts which will enable the European Commission to identify new risks and continuously amend the list of high-risk machinery products as well as the list of safety components, will ensure that risks for the users and the environment can be kept as low as reasonable possible.

TIC Council also welcomes the alignment of the Machinery legislation with the New Legislative Framework (NLF) which will strengthen the European regulatory framework to ensure the application and implementation of harmonized and uniform requirements in the EU single market.

Relations with other legislation applicable on machinery

We fully agree with the proposal that the Machinery Regulation should be coherent with the Cybersecurity Act (CSA), as well as the upcoming artificial intelligence (AI) rules and the Radio Equipment Directive.

Particularly the CSA 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. It is worth mentioning that the CSA provides for the application of conformity assessment programs developed by expert groups and (to be) adopted as legislation by the EU Commission, such as the Industrial Automated Control Systems schemes. Therefore, the future Machinery legislation should not override CSA's provisions in any sense.

Independent and accredited conformity assessment bodies provide compliance services for all machinery and safety components based on their competence, qualifications and expertise on Machinery legislation, guidelines, and standards. We stand at your disposal for any further information, and we would be glad to discuss our comments in detail with you.

Contact person: Martin Michelot - mmichelot@tic-council.org - +32 493 30 99 11