

Product Risk Radar

Machinery Regulation

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On 19 July 2023, a new regulation on machinery products (the "**Machinery Regulation**") came into force, updating the Machinery Directive 2006 / 42 / EC (the "**2006 Directive**"). With the Machinery Regulation, the EU intends to address the new risks linked to emerging technologies such as autonomous mobile machinery (i.e., robots) and AI, and to regulate machine and plant safety in a more harmonised way.

What are the key takeaways?

- **Risks from new technology** – the definitions of terms such as “machinery” and “safety component” have been revised, while concepts such as “related products” and “substantial modification” have been defined, in order to encompass emerging technologies, and to recognise that technology changes rapidly (and in some cases, after it has gone to market). These changes have a significant impact and will oblige those who modify machinery to risk assess.
- **Changes to the lists of machinery** – Annex I to the 2006 Directive lists machinery considered high-risk, to which enhanced conformity assessment requirements apply. Under the Machinery Regulation, that list now includes various AI-related machinery, including:
 - *"safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions" and*
 - *"machinery that has embedded systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only of those systems".*
- **Conformity** – the Machinery Regulation allows manufacturers to self-assess conformity for most products, with the involvement of third-party conformity assessment bodies being mandatory for six categories of “high risk” machinery.
- **Digitisation** – manufacturers can provide technical documentation in a digital format, unless customers request them in paper format. This is likely to be welcomed by the industry from an environmental and sustainability perspective.

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Why should your business care?

It is indisputable that legislation must keep pace with technological advancement and address any risks that accompany such progress. As such, the Machinery Regulation is a laudable step in this direction. For businesses, whilst changes to the definition of “high-risk” machinery may increase the costs of obtaining third party conformity assessments, including for non-physical safety risks, the retained ability for companies to self-assess in lower risk areas should provide manufacturers with some reassurance.

What comes next?

The rules in the Machinery Regulation will apply from 20 January 2027, meaning that manufacturers must comply with the 2006 Directive until the day before the Machinery Regulation applies. In the meantime, the European Commission will publish guidance on the application of the Machinery Regulation to avoid a divergence in the interpretation of the text. The European Commission will also update the harmonised standards in order to link them to the rules in the Machinery Regulation.

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