

# EU Machinery Regulation

<p><b>Purpose</b></p> <p>The proposed revision, part of an EU 'Artificial Intelligence Package', addresses safety challenges posed by digital advancements like AI, IoT, and robotics. It aims to clarify scope and definitions, enhance safety for traditional technologies, reassess 'high-risk' machines, streamline conformity assessments, reduce paperwork, align with other safety legislation, and promote consistent interpretation. The Regulation was agreed by the Parliament and Council in December 2022 and approved by relevant committees in January and March 2023.</p> <p><b>Scope</b></p> <p>This Regulation covers machinery and the following related products: interchangeable equipment, safety components, lifting accessories, chains, ropes, webbing, and removable mechanical transmission devices. These are collectively referred to as "machinery or related products". The regulation also applies to partly completed machinery. However, a number of products are expressly excluded, including transport by air, on water, and on rail networks, although the regulation still applies to the machinery mounted on those means of transport.</p> <p><b>Application</b></p> <p>Applies mainly from 14 January 2024 with some provisions taking effect on different dates.</p>	<p><b>Main improvements in the new Regulation</b></p> <p><b>Obligations on manufacturers</b> <b>Manufacturers</b> must ensure that machinery or related products are designed and constructed in accordance with the essential health and safety requirements outlined in Annex III when placing them on the market or putting them into service. This also applies to partly completed machinery. Voluntary harmonised standards or common specifications cited or published in the Official Journal of the European Union, if applied, provide a presumption of conformity with these essential requirements. The European Commission may establish common specifications through implementing acts under certain conditions.</p> <p><b>Obligations on importers</b> <b>Importers</b> are responsible for ensuring that the machinery or related products they bring into the EU market comply with the essential health and safety requirements. They must verify that the manufacturer has conducted the appropriate conformity assessment procedures and that the necessary documentation, such as the EU declaration of conformity and technical files, are available. Importers must also ensure that their contact information is included with the product and that the product bears the required CE marking.</p> <p><b>Obligations on distributors</b> <b>Distributors</b> must act with due care to ensure that the products they supply comply with the Regulation's requirements. This includes verifying that the product bears the CE marking, is accompanied by the required documentation, and that the manufacturer and importer have met their obligations. Distributors must also inform manufacturers, importers, and national surveillance authorities through the Safety Business Gateway if they believe a product is dangerous and ensure suitable action is taken.</p> <p><b>Notable changes</b></p> <ul style="list-style-type: none"> <li>Alignment with the regulatory framework of the new legislative framework like definitions, obligations for economic operators and safeguard procedures.</li> <li>Instructions can be provided either digitally or on paper.</li> <li>Updates on mandatory "essential health and safety requirements" (EHSRs) for machinery.</li> <li>After a "substantial modification" (when machinery products are modified by physical or digital means in a way that is not envisaged by the manufacturer, and that may imply that it is no longer in conformity with the EHSR), the person that carried out such modification is required to perform a new conformity assessment before placing the modified machinery product on the market and becomes a manufacturer.</li> </ul> <p><b>New elements</b> The new Machinery Regulation introduces several key elements:</p> <ul style="list-style-type: none"> <li>It designates certain machinery as high-risk in Annex I, including software and AI systems. The Commission is empowered to update this list via delegated acts for quicker adaptation to technical progress.</li> <li>High-risk machinery now requires third-party conformity assessments instead of internal checks.</li> <li>Safety improvements address digital technologies, requiring manufacturers to consider hazards from evolving behaviour and autonomy throughout the machinery's lifecycle</li> <li>Ergonomic design must minimise operator stress and adapt to human-machine interactions.</li> <li>Updated safety and reliability requirements ensure autonomous machinery does not act beyond defined tasks and allow corrections to maintain safety, with five-year data traceability for safety software updates.</li> <li>Post-market safety-related decision-making data must be retained for one year.</li> <li>Technical documentation must now include safety software source code.</li> <li>The Regulation also adds software and AI systems to the safety components list, with cyber attack protections to ensure safe connections.</li> <li>Machinery certified under the Cybersecurity Act is presumed to conform to relevant safety requirements.</li> <li>Driverless mobile machines are explicitly covered, including remote supervision, ensuring comprehensive safety measures for modern machinery.</li> </ul> <p><b>High-risk machinery</b> Annex I on high-risk machinery is split into two parts. Part A includes six categories of machinery subject to mandatory third-party certification:</p> <ol style="list-style-type: none"> <li>removable mechanical transmission devices and their guards</li> <li>guards for removable mechanical transmission devices</li> <li>vehicle servicing lifts</li> <li>portable cartridge-operated fixing and impact machinery</li> <li>safety components using machine learning for safety functions</li> <li>machinery embedding machine learning systems for safety functions not independently placed on the market. For the 19 categories in Part B, manufacturers can choose to self-assess conformity.</li> </ol>
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