



Commission welcomes political agreement on new rules to ensure the safety of machinery and robots

Brussels, 15 December 2022

The Commission welcomes the political agreement reached by the European Parliament and the Council of the European Union on a new Machinery Regulation. It revises the existing Machinery Directive and adapts the rules to address the emerging risks and challenges posed by new technologies to machinery products and ensure these can be operated safely.

The Regulation covers machinery consumer products and industrial machinery, ranging from heavy-duty construction machines to entire industrial production lines, as well as highly digitalised products like robots or manufacturing 3D-printers. The new rules will reinforce people's trust in the next generation of machines, foster innovation and boost the machinery sector's competitiveness in the single market and globally.

The new Machinery Regulation will:

- **Ensure machines are safe and increase users' trust in new technologies.** Manufacturers will have to ensure that machinery products fully respect the essential health and safety requirements set out in the Regulation. Six categories of machinery will be subject to mandatory third-party certification, complemented with a future proof process to update this number. The rules introduce new safety requirements for autonomous machines, human-machine collaboration and, for the first time, the safe use of Artificial Intelligence systems in machinery. To demonstrate compliance with the legal requirements, manufacturers can continue to rely on a stock of harmonised standards, continuously updated to technical progress, facilitating innovation and strengthening the competitiveness of the sector.
- **Reduce administrative burden and costs for manufacturers.** The rules introduce administrative simplifications like allowing digital formats for user manual instructions. This will help industry to save up to €16.6 billion per year. The new rules also set the path for adapting the conformity assessment fees to the needs of SMEs, which represent 98% of the machinery sector. In addition, the new rules enhance coherence with the Artificial Intelligence and Cyber Resilience Regulations.
- **Foster legal certainty.** The new Regulation establishes clear and proportionate rules, which will be uniformly applied across the EU, and increases legal certainty for manufacturers. It clarifies issues related to scope, definitions, essential requirements and conformity assessment procedures. The final text further clarifies the notion of substantial modification of products.
- **Establish more effective market surveillance.** The new rules align the safeguards against non-compliant machinery products to those used in the wider EU legislative framework on products.

Next Steps

The European Parliament and the Council will now formally have to adopt the new Machinery Regulation. The Regulation will enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. It will apply 42 months after the date of its entry into force.

Background

Machines are indispensable in our daily lives and are needed for the good functioning of our industry and the wellbeing of EU citizens. However, the emergence of new digital technologies raises new challenges for products' safety, including ensuring their safe connectivity, autonomy, data dependency, or opacity.

The EU industry is a world leader in the manufacturing of machinery. The machinery sector records a yearly turnover of over €740 billion, 9.4% of the total EU manufacturing turnover. In the EU, it employs 2.8 million people, 9.9% of all people employed in manufacturing, and includes over 80,000

companies, 4.1% of all manufacturing companies. The EU has consistently registered a positive trade balance in the sector, with exports of over €276 billion to non-EU countries in 2019.

Since 1989, the [EU machinery directive](#), revised several times, promotes the free movement of machinery within the single market and guarantees a high level of protection for EU workers and citizens. However, a REFIT exercise in 2018 established many areas for improvement and a need for a revision. The Commission also published in 2020 a [Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics](#), accompanying a white paper on Artificial Intelligence, concluding that a number of gaps in the existing legislative framework needed to be addressed.

The Commission presented the new machinery regulation, revising the directive, in April 2021, as part of the bigger [AI package](#). This also included a proposal for a regulation laying down harmonised rules on Artificial Intelligence ([AI Act](#)), a Communication on fostering a European approach to Artificial Intelligence, and a review of the Coordinated Plan on Artificial Intelligence.

For More Information

[Proposal for a Regulation](#) of the European Parliament and of the Council on machinery products

IP/22/7741

Quotes:

The new Machinery Regulation will make sure that advanced machines, such as autonomous machines or collaborative robots can be safely placed in the EU market. Also, the regulation will boost innovation and ensure the competitiveness of machinery in which the EU industry is a world leader.

Margrethe Vestager, Executive Vice-President for a Europe Fit for the Digital Age - 15/12/2022

The new Machinery Regulation will increase trust in digital technologies including AI, human/robot collaboration, connected and self-learning machinery and hence increase their uptake. The rules will ensure that Europe's machinery industry can continue to innovate, set standards and strengthen the competitiveness of the sector. A strong machinery sector plays a crucial role in delivering the digital and green transition of the European industry.

Thierry Breton, Commissioner for Internal Market - 15/12/2022

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