

Proposal for a Regulation on machinery products COM(2021) 202 final

Small Business Standards association

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MAIN CHANGES



- Regulation v. Directive
- Alignment to the New Legislative Framework
- Digital technologies
- Substantial modification concept
- Commission empowerment to issue technical specifications
- High-risk machinery products
- Few aspects traditional machinery

NEW LEGISLATIVE FRAMEWORK



- General definitions
- Obligations of economic operators
- Conformity assessment bodies
- Market surveillance

Digital Technologies

- Risk assessment
 - ✓ *Also risks due to machinery's evolving and autonomous behavior may appear **after** the machinery is placed on the market*
 - ✓ If those risks cannot be foreseen, the machinery **cannot** be placed on the market

- Cybersecurity when impact on safety
 - ✓ *Safety against external influences includes malicious third party actions*
 - ✓ *Protection against lack of connection*

- Human - machinery interaction
 - ✓ *More powerful, autonomous, humanoid machinery*
 - ✓ *Closer cooperation with operators/ users*
 - ✓ *Adapting EHSRs to:*
 - *prevent psychological stress*
 - *respond to people adequately*
 - *inform on the planned actions*

- Autonomous mobile machinery
 - ✓ *Prevention of hazards related to the area where it is intended to move and work*
 - ✓ *Protection against a failure in the steering system*
 - ✓ *Mandatory supervisory control function*
 - ✓ *Adapted instructions*

- Machinery with evolving capacity
 - ✓ *AI safety aspects – AI regulation*
 - ✓ *Whole safety of machinery including AI risks:*
 - *Principle of safety integration*
 - *Reliability and safety of control systems*
 - *Contact human-machine*

Scope - exclusions

SCOPE



- *Same scope - more clarity*
 - ✓ Subject matter
 - ✓ Machinery products v. machinery
 - ✓ New indent in the definition of machinery:
'assembly missing only the upload of a software intended for its specific application'

EXCLUSIONS



- Means of transport on road:
 - ✓ if only transport function of persons or goods (no machinery function)
 - ✓ beyond the Union type approval legislation
- Low Voltage Directive products with Wi-Fi

Definitions

DEFINITIONS



- New indent for machinery definition
- Safety component
 - ✓ Also digital - software
- Substantial modification of a machinery
 - ✓ Definition
 - ✓ Conformity assessment

Commission

Technical specifications

- Commission empowerment to elaborate technical specifications
- ✓ *Give presumption of conformity with the relevant Essential Health and Safety requirements*
- ✓ *Only if absence of harmonised standards*

High-risk machinery products

Annex I

- Content
 - ✓ New: AI standalone system & embedded in the machinery
ONLY if ensuring safety functions
 - ✓ List may be adapted to the technical progress
- Conformity assessment
 - ✓ Third party only

*Essential
Health and Safety Requirements (EHSRs)
Traditional machinery*

EHSRs traditional machinery



- Digital documentation:
 - ✓ Instructions (paper version upon request)
 - ✓ Declaration of conformity
- Portable hand-held and/or hand-guided machinery
 - ✓ Adaptation of vibration values
 - ✓ Capture emissions of hazardous substances

EHSRs traditional machinery



- Mobile machinery
 - ✓ Integrating autonomous machinery risks
 - ✓ Improving seating safety measures
- Risks of contact with live overhead power lines
- Adapting slow-speed lifts control devices

Implementation of the Regulation

IMPLEMENTATION OF THE REGULATION



- Enter into force on **20th day** from OJEU publication
- Application **30 months** from OJEU publication
- Evaluation **every 4 years:**
Report to the Council and the European Parliament

To be remembered



- **Conformity assessment**
 - ✓ Only machinery products in Annex I will be subject to notified bodies
 - ✓ Notified bodies must adapt fees for SMEs
- **Standardisation system**
 - ✓ *Same system*
(New Approach/ Regulation (EU) No 1025/2012)
 - ✓ *Commission technical specifications **if NOT** harmonised standards*

THANK YOU