



# EU regulatory system for robots

*CE marking of robots today and in the future*

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# Summary

- Access to the EU market - **CE** marking for robots
- EU safety laws for robots and role of EN standards
- Future trends in robotics and EU legislation

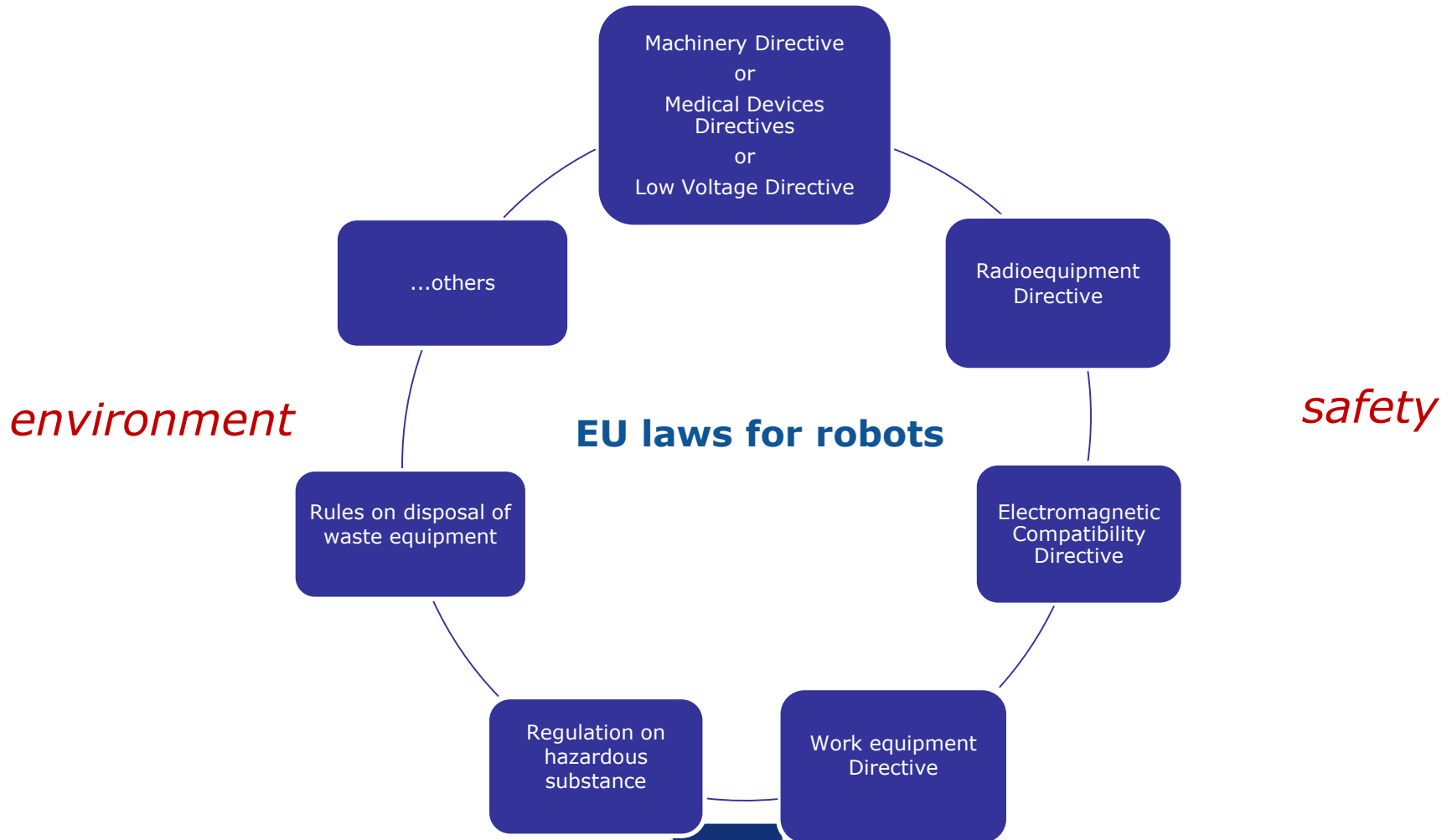
# Robots

## Access to the EU market - CE marking

- Robots placed on the EU market have to fulfill all applicable EU legislation
- No EU dedicated rules on robotics
- EU legislation applies to certain robotics products

# Robots

## Outlook on EU regulatory framework



# Robots Safety legislation (I)

## General

- Mandatory policy objectives
- Technical specifications embedded into EU laws or prescribed in European harmonised standards (developed by the ESOs)
- Manufacturer is responsible for safety of robots placed on the EU market
- (!) CE marking issued after applying all relevant EU legislation (e.g. safety, environment, etc)

# Robots Safety legislation (II)

## *Specific – Machinery Directive*

EU safety legislation based on new approach principles

- Policy objectives: Essential Health and Safety Requirements for predictable and controlled robots (including software)
- *Voluntary* use of European harmonised standards
- No requirements for involving third party entity for CE marking

# Robots Safety legislation (III)

## *Specific –Machinery Directive Working Group*

- Forum of experts from Member States, industry, standardizers, consumers, workers, etc.
- Key role in implementation and enforcement of Machinery Directive (meets twice per year)
- Monitors the development or revision of EN standards for machinery industry
- Produces or approves guidance, also to feed into standardization activities

# Robots: Safety and EN standards

- ✓ European harmonised standards (EN) are developed by the *European Standardisation Organisations* on a specific request from the Commission
- ✓ *EN development is mainly industry driven*
- ✓ *EN standards give presumption of conformity with the EU legislation only if published in the Official Journal of the EU*
- ✓ *No automatic ISO transposition into EU system.*
- ✓ *Some of the EN standards for robots are based on ISO standards (global relevance)*



# Robots: Safety and EN standards

- ✓ *EN standards for robots based on ISO standards*
- *EN ISO 12100, Safety of machinery – General principles for design – Risk assessment and risk reduction*
- *EN ISO 10218-1:2011 Robots and robotic devices - Safety requirements for industrial robots - Part 1: Robots*
- *EN ISO 10218-2:2011 Robots and robotic devices - Safety requirements for industrial robots - Part 2: Safety of Robot integration*
- *EN ISO 13482:2014 Robots and robotic devices - Safety requirements for personal care robots*
- *Etc...*

# Robots

## State of the art and future trends

Industrial robots →

- Installed in factories
- Repetitive tasks - autonomously
- Behind fences – no human contact

*Controlled, Predictable,  
Automated, Autonomous*

Collaborative robots →

- Without cages - close proximity to humans
- Professional service robots (healthcare)
- Consumer robots (at home)

*No direct human control, Fully autonomous, Self-learning, Exhibit intelligent behavior*

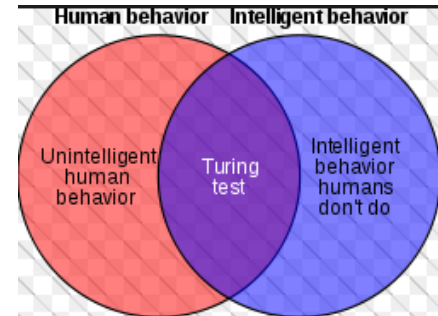
AI

Software based robots with sophisticated sensors and connectivity

**Internet of Things**

# Robots

## Future trends and EU legislation



- AI systems have progressed a lot recently, but they don't seem to pass the Turing test yet
- Futuristic vision is under debate - Commission is engaged in broad consultations with stakeholders
- Machinery safety Directive is under evaluation to check its fitness for purpose to IoT or Industry 4.0 also
- Liability Directive is under evaluation
- Cybersecurity legislation for certification and labeling is being produced



European  
Commission

**Thank you!**