



EU product safety framework for advanced robots & autonomous systems

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Basic rule



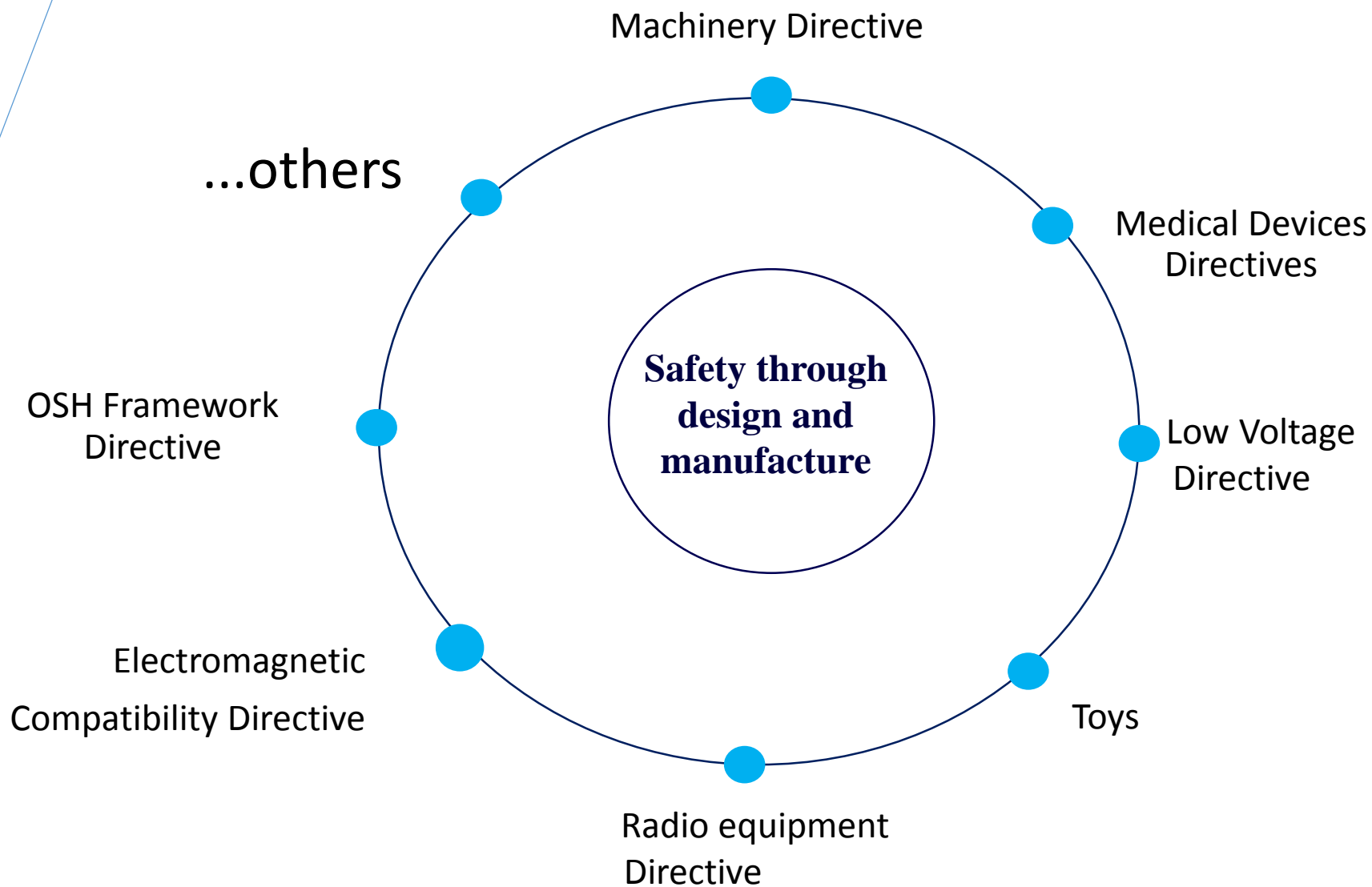
Safety and liability - both considered in the design stage

Accidents may or may not happen

Improving safety prevents liability exposure

EU safety Regulatory landscape

Case study
Robots



Responsibilities



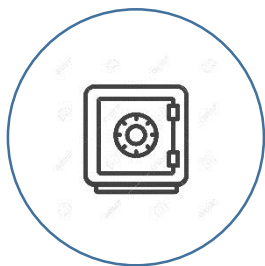
The main responsibility for product safety falls on producers.
This includes:

- Manufacturers that supply products on the market
- Manufacturers that supply products for own use
- Importers (on certain cases)
- Businesses/users that change the safety of a product (e.g. customising it)

Principles of safety integration

"Products cannot be made absolutely safe, but can be made as safe as they should be"

The 3-step method for risks identified on intended use & foreseeable misuse



1. Safe design



2. Protective measures



3. Warnings & instructions

Robots safety legislation

General rules

- **Mandatory safety requirements**
- **Technical specifications to meet the safety requirements embedded into EU laws or prescribed in European harmonised standards**
- **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)**

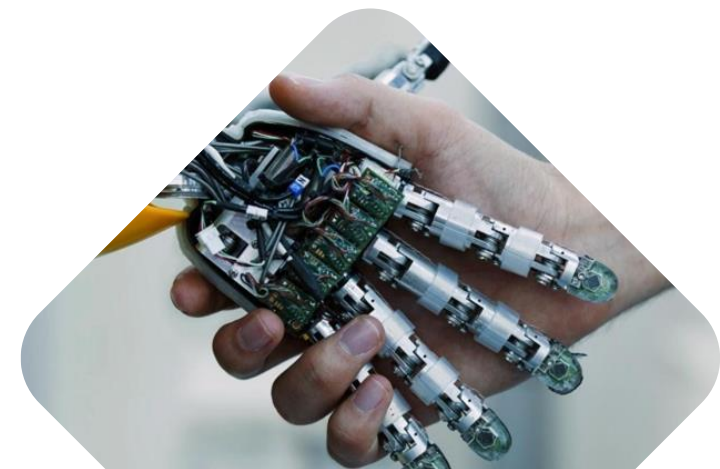
Robots safety legislation

General rules

- ✓ **European harmonized standards (EN) are developed by the European Standardization Organizations 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**

Robots safety legislation

Specific – Machinery Directive 2006/42/EC (MD)



Robots safety legislation

Specific – Machinery Directive 2006/42/EC (MD)

- EU safety legislation based on new approach principles
- Policy objectives: free movement of highly safe products within the EU
- *Voluntary* use of European harmonised standards
- No requirements for involving third party entity for CE marking

Robots safety legislation

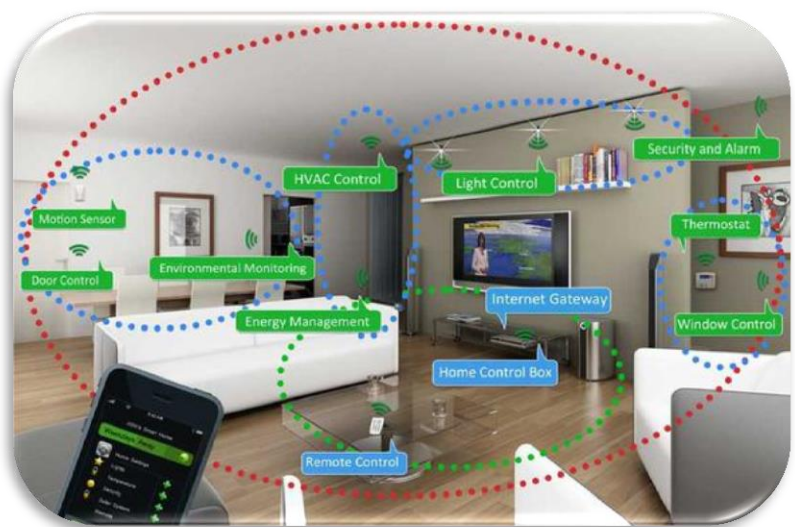
Machinery Directive EN safety standards for robots (HRC*) based or adapted on ISO standards

- ✓ EN ISO 12100, Safety of machinery – General principles for design – Risk assessment and risk reduction
- ✓ EN ISO 10218 Robots and robotic devices - Safety requirements for industrial robots (principles of protection in HRC)
- ✓ EN ISO 13849-1:2008 Safety of Machinery - Safety-related parts of control systems
- ✓ EN ISO 13482:2014 Robots and robotic devices - Safety requirements for personal care robots
- ✓ Etc...

* *HRC: human-robot collaboration*

Robots safety legislation

Specific – The Radio Equipment Directive 2014/53/EU (RED)



Robots safety legislation

Specific – The Radio Equipment Directive 2014/53/EU (RED)

- legislative framework for (i) the safety, (ii) the interoperability, (iii) the interconnectivity and (iv) the efficient use of the spectrum of radio equipment between 0 and 3000 GHz.

- Additional delegated acts in Article 3(3) can cover a broad range of topics and can be proportionate as they can be applied to classes or categories of products. In more details:
 - (a) radio equipment interworks with accessories, [...];
 - (b) radio equipment interworks via networks with other radio equipment;
 - (e) radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected;
 - (f) radio equipment supports certain features ensuring protection from fraud;
 - g) radio equipment supports certain features ensuring access to emergency services;
 - (i) radio equipment supports certain features in order to ensure that software can only be loaded into the radio equipment where the compliance of the combination of the radio equipment and software has been demonstrated.

Robotics evolution

State of the art and future trends (I)



Industrial robots

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



Collaborative robots

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



AI

Software based robots - sophisticated sensors and connectivity

Controlled, Predictable, Automated, Autonomous

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

Internet of Things

Robotics evolution

Robotics evolution - State of the art & future trends (II)

Machinery Directive under evaluation:

- Check fitness for purpose to new emerging technologies (robotics, IoT, Industry 4.0)
- Consultation activities finalized
 - positive perception on how the Directive copes with innovation
 - is generally seen as relevant in the face of changing technology over long periods (20+yrs)
 - areas of concerns focused around innovations: digitisation, cybersecurity, software
- Final report (SWD) to be published in Q1 2018
- Potential revision.
- Questions (e.g) under discussion in the machinery community (Machinery Directive WG)
 - Psychological aspects of human-machine collaboration
 - Classification of applications in robotics (possible new standardization request)

Robotics evolution State of the art and future trends (III)

- MD and RED can be applied jointly, providing a thorough legislative framework for the safety of robotics products and autonomous systems, as part of IoT ecosystem.
 - The Liability Directive applies in conjunction to these Directives.
 - The Liability and the MD are being evaluated in order to verify whether there is a need to adapt some provisions to the new challenges of interconnected products (IoT)
 - Delegated Acts foreseen under the RED can provide further flexibility to follow the fast-evolving trends in the DSM.
- The essential requirements and the scope of the MD and the RED are already broad enough and the existing legislative framework may only need minor updates to tackle the challenges ahead.

Thank you!



Improving safety ⇔ reducing liability exposure