ROCK eu²

RockEU2
Robotics Coordination Action for Europe Two

Grant Agreement Number: 688441

01.02.2016 – 31.01.2018

Instrument: Coordination and Support Action

Report on regulatory barriers

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Deliverable D1.12

Lead contractor for this deliverable:	Fraunhofer IPA
Due date of deliverable:	January 31, 2018
Actual submission date:	February 5, 2018
Dissemination level:	Confidential
Revision:	1.1

Executive summary

Robot-related regulation includes regulation on product safety, occupational safety and process safety. While the first is relevant for manufacturers of robots and integrators building automation systems, the other types of regulation apply for companies using robots. For each area a certain amount of regulation is considered necessary. On the other hand, overregulation can hinder innovation and market development. Other regulatory barriers are inconsistent regulation which leads to overlapping or unclear boundaries.

Most potential market barriers arise from the regulation for the product safety of robots. As creation of safety standards requires considerable time, standards are usually lacking behind the technological development. New applications gradually lead to overlaps in the scopes of existing standardisation committees and standards. Therefore, considerable effort will be necessary in the coming years to streamline activities of ISO and IEC so that overlaps and unclear boundaries are removed and resources are efficiently used. As all safety standardisation happens on an international level, no deviation between countries inside and outside Europe exists. Safety standards for robots also do not contain any blocking requirements. A problematic regulation is however the ban of autonomous vehicles on public roads.

In the areas of occupation safety, regulation inside the European Union is mostly done on a national level. While the regulation is well-established and problems regarding gaps and overlaps have been solved in the past for existing products, future products and applications may lead to individual national solutions that are contradicting. Regarding process safety, regulation is almost entirely harmonized in the EU, so that the risk of deviating requirements is small. Currently, no blocking regulation exists in these areas.

Content

1. Introduction

Regulation will shape a number of key robotics markets. Where robots work in close collaboration with people, safety regulations will set necessary requirements on design and system performance. Furthermore, regulations not only govern the technical properties that a robot system needs to comply with, but also the required procedures to validate the fulfilment of the compliance. While safety standards such as ISO 10218 are international, accident prevention is most often regulated on a national level with considerable difference between European countries. Furthermore, in many pre-existing markets existing regulation is based on established practice and often assumes that a person is the prime actor rather than an autonomous machine. In each of these cases it is important to understand the impact of regulation on the design of systems, their deployment and the value chain of the application.

Regulation that affects robots can be divided into three different categories, namely regulations related to product safety, occupational safety and process safety (see Figure 1). Regulation on product safety establishes requirements on the design of the robot system itself and is mostly relevant for robot manufacturers but also system integrators. Regulation on occupational safety defines how the safety of a robot as work equipment has to be validated, a process that is mostly carried out by the customer who uses the robot. Regulation on processes relates not to the safety of the robot itself but to the goods being manufactured with the robot. Examples are legislation for food safety or the manufacturing of drugs and medical products.

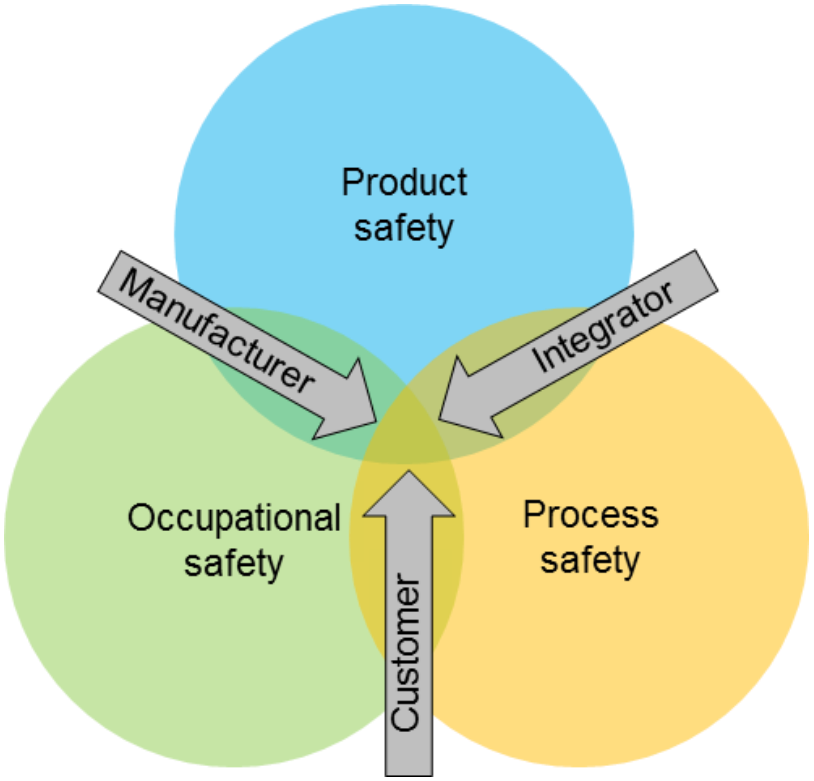

Fig. 1 Types of regulation and affected stakeholders

Regulatory barriers that can be expected in the domains of product safety, occupational safety and process safety are

- Deviation of regulation: Issues arising from differences between European member countries or other countries. Manufacturing goods for trade on markets with different regulation usually requires substantial effort to adjust the product to each market.
- Unclear boundaries: Issues leading to uncertainty, which regulation needs to be applied or situations in which more than one regulation may be applicable, leading to legal uncertainty and risks.
- Missing regulation: Gaps in standards and laws which occur frequently in newly established market areas, e.g. service robots. This usually also leads to legal uncertainties and additional effort for the stakeholders to find applicable regulation.
- Blocking requirements: Statements in regulatory documents that exclude technologies used for robots, thus hindering innovative products being brought onto the market.

2. Regulation related to Product Safety

2.1. Robots

In the area of product safety for robots, all regulation currently exists almost exclusively on an international level. Safety standards are developed mostly by ISO, some also by IEC. Via the European Machinery Directive, the international standards are transferred into national law. For classical industrial robots, ISO 10218 covers all relevant applications on the market. However for the evolving field of service robots, only for a limited number of domains safety standards exist. Figure 2 shows existing standards and gaps between these documents.

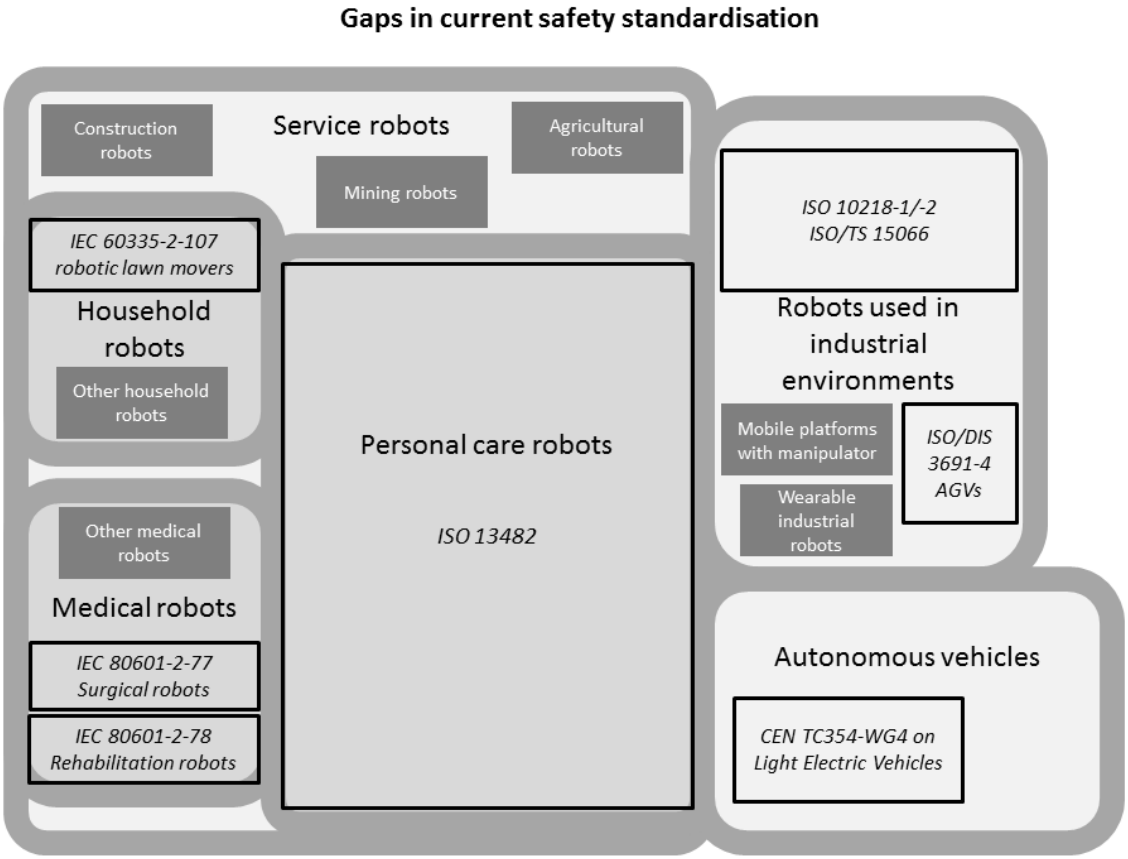

Fig. 2 Existing standards and gaps (dark grey) between them in the field of robotics (Source: ISO/TR 23482-2 draft)

Where no specific standards for a certain robot type exist, manufacturers can look for similar standards which can be taken as a reference. For example, ISO 10218 has in past frequently being used as a reference for the design of non-industrial robots in various domains. If no reference standard can be found, design requirements need to be derived from general regulation such as the Machinery Directive or ISO 12100. This approach however is very time consuming and leaves many decisions to the judgement of the manufacturer. ISO committee TC 299, where most of the safety standards are developed, is aware of these gaps. Possible strategies to fill the gaps are the creation of standards in a domain, when a critical mass of products and technical experts is reached to form a new working group. In addition it is also discussed to extend the scope of ISO 13482 “Personal care robots”, so that all land-based service robots are covered.

ISO TC 299 has also registered several issues of unclear boundaries between standards, which lead to frequent inquiries from users, if a certain product is covered by a certain standard. The overlap between safety standards becomes especially problematic when it is unclear if a robot might fall under the Medical Directive or has to be considered as a machine, because of the big differences between these two directives. Figure 3 shows examples of robots with similar properties which fall under different standards.

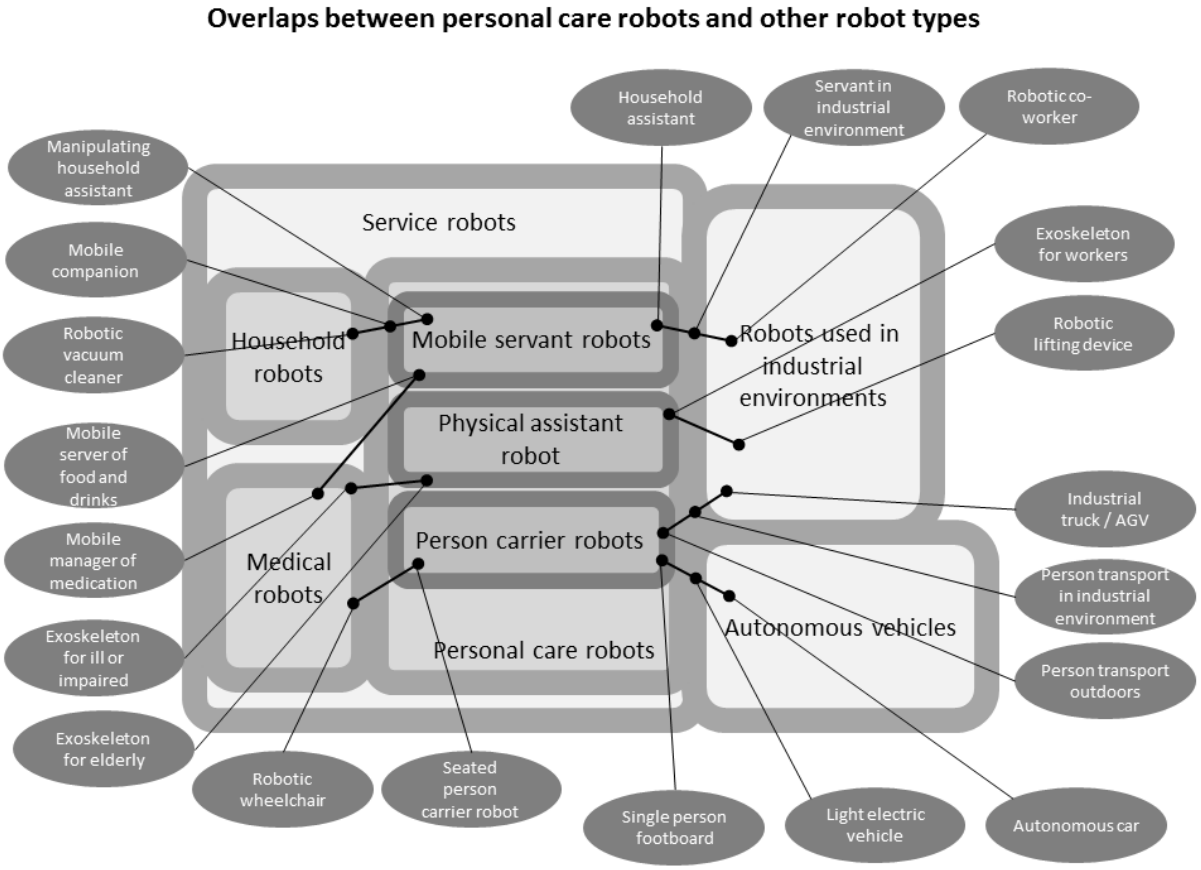

Fig 3 Robotic applications that are close to the boundary between standards (Source: ISO/TR 23482-2 draft).

In order to clarify situations in which a potential overlap occurs, TC 299 has created a study group (SG1) which will collect and discuss the scopes of all working groups and standards within TC 299. Based on the finding, recommendations will be provided, how scopes should be clarified or adjusted to reduce overlaps or unclear boundaries. First discussions within the committee show, that also the different interpretation of definitions can lead to gaps and overlaps. For example the term “industrial environment” mentioned in the the definition of industrial robots can be interpreted widely so that it includes all kinds of workplaces where the general public is not allowed and persons are trained, e.g. in the mining, construction or agricultural industry. Similar work but on a higher level has before been done by the IEC advisory committee for robots (ACART) which has created some recommendations how to coordinate future work between IEC and ISO.

2.2. Other domains

Besides the safety standards on robotics, robots also frequently come in contact with safety standards in other domains. Where robots are intended to operate on public roads, traffic regulations apply. Other than the Machinery directive, which allows a self-certification by the manufacturer, traffic regulations usually require that devices operating on roads are registered and assessed by respective authorities already in prototype state. One of the biggest barriers in traffic regulation is clearly the Vienna Convention on road traffic from 1968, which requires that a driver is always in control of a vehicle, thus precluding any autonomous driving. This affects for example driverless trucks operating on factory premises accessible by the public or agricultural robots that need to travel from one acre to the next by crossing a farm track. For operating a mobile robot in such a scenario, manufacturers and customers need to request an exceptional permission for each robot system put into operation which impedes the development of the market for serial products. Against the background of the recent evolution of autonomous cars, it can be noted, that regulation precluding autonomous driving of mobile robots on public roads is currently relaxing. More and more countries have created regulation for testing of autonomous vehicles on public roads. Several cities have given special permission for certain projects, such as the city of Bad Birnbach for an autonomous bus[1].

For flying robots or “drones”, regulation for aviation safety becomes relevant. Regulation in this area refers to the building of such unmanned aircrafts (product safety) as well as regulation on the use of the products (regulation for operators). In the European Union the safety of unmanned aircrafts are regulated by the member countries so that a fragmented regulation exists. First steps have however been undergone by the European Aviation Safety Agency EASA to harmonize regulation and to create a set of minimum requirements that national regulation has to define.[2]

Furthermore, artificial intelligence plays an increasing role in the field of robotics. From simple neural networks used for object or face detection up to complex virtual companions that can understand and answer like a human being, several issues are touched that include ethical, legal and social issues. Currently the discussion is based on scientific work. Regulation in form of standards for artificial intelligence does currently not exist. However some other regulation applies, such as rules for data security and data privacy where personal data is processed or regulation for liability and legal entities. Some laws for juridical

[1] http://www.badbirnbach.de/index.php?menu_id=10&artikel_id=1453
[2] https://www.easa.europa.eu/easa-and-you/civil-drones-rpas

persons may become a regulatory barrier in the future, if issues of artificial intelligences acting as agents for humans cannot be sufficiently solved.

3. Regulation related to Occupational Safety

In contrast to the regulation on product safety, regulation on occupational safety is mostly established on a national level. In the Directive 89/391/EEC the European Council defined basic requirements for safety and health for workers at work but left it to the member states to implement these requirements on a national level. A study under the REFIT program of the European Commission[3] points out, that this affects for example the categories of workers that are covered by the regulation, e.g. domestic servants or self-employed persons.

This diversity is a potential barrier for manufactures developing robots for the European market and for enterprises with facilities in different European countries. In particular it requires that companies make themselves familiar with the regulation and also the relevant stakeholders such as governmental authorities but also worker's health insurances they have to deal with. Companies which would like to transfer a robot from one facility to another in a different European country would need to undergo a complete different certification process with other types of stakeholders. In case of Germany, occupational safety is assigned to the accident insurance institutions which are bodies under public law. National and federal administrative bodies play only a minor role. In Spain on the other hand, occupational safety is checked by independent governmental departments on the municipal level. In the United Kingdom, the Health and Safety Executive is again centrally organized.

In general, the REFIT evaluation comes to the conclusion that the existing system is working well. Against the background of emerging new robotic applications and new products, each member country may however come to different rules for new products which may lead to more differences between national regulations.

4. Regulation related to Process Safety

4.1. Food safety

When robots are used for food production, regulation for food safety applies. The rules for food safety are defined in the regulations 852/2004 (hygiene for foodstuffs), 853/2004 (rules for foodstuff with animal origin) and 854/2004 (rules for official controls of foodstuff with animal origin). The main rationale of the regulation is the application of the HACCP principle (Hazard analysis and critical control points), which incorporates that a hazard analysis is performed for production processes and measures are defined for critical steps. The regulation is directly converted to national law. Differences exist only on the operative side (e.g. structure of the administration responsible for controls). As the regulation for food is harmonized on a European level, manufacturers, integrators and users of robots intended for food processing can easily put robots into operation in several member countries without any adjustment of the machine.

[3] European Commission: „Ex-post evaluation of the European Union occupational safety and health Directives (REFIT evaluation), Brussels 2017

4.2. Pharmaceutical and medical products

The regulation for drug manufacturing and the fabrication of medical products is also mostly harmonized in the European Union. While medical products are covered by the medical device directive (93/68/EEC), regulation for pharmaceutical products comprises the “Good manufacturing practice” which is written in directive 91/356/EEC. The directives establish high requirements for quality management and the retraceability of products. Where robots are integrated in a production system, they may also be affected by certain requirements. Similar to the regulation on food safety, there is no deviation of regulation in the EU.

5. Conclusion

Most potential market barriers arise from the regulation for the product safety of robots. As the market for robots is emerging, the regulation lacks behind and is not yet consolidated, so that there are gaps and overlaps between standards. In the coming years, considerable effort will be necessary to coordinate the standardisation work and restructure committees where necessary to remove them – a task that has already been picked up by study groups founded at IEC and ISO. It can be stated as a positive fact, that safety regulation for robots is entirely performed on an international level, e.g. at the standardisation organisations ISO and IEC. This does not only prevent any deviation of regulation inside the European Union but also allows European manufacturers to enter other markets in the world. Safety standards for robots do not contain any blocking requirements. A problematic regulation is however the ban of autonomous vehicles on public roads.

It can further be stated that different domains follow different approaches for regulation. While machinery safety traditionally relies on safety standards and the instrument of “self-certification” by manufacturers, regulation for road vehicles or aviation are based on supervision and certification by governmental institutions. For robot developers the application of regulation from different domains and working according to the required processes requires knowledge of all these systems and makes it likely to encounter barriers that originate from contradicting requirements.

From the areas of occupational safety and process safety, the chance to encounter market barriers is rather small. In both sectors the relevant regulation is well-established so that any issues related gaps and overlaps should have been solved by now. As the regulation for process safety is mostly harmonized in the EU, also the risk of deviating requirements is small. For occupational safety however, deviations between member countries may arise, if new products are treated differently by different regulators. To the knowledge of the authors of this deliverable there is currently no blocking regulation in the areas of occupational safety and process safety.