Impact assessment study on the revision of Directive 2006/42/EC on machinery

Final report

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Abbreviations used

AGI	Artificial General Intelligence
AGV	Automatic Guided Vehicle
AI	Artificial Intelligence
ANI	Artificial Narrow Intelligence
ASI	Artificial Super Intelligence
ATEX	Equipment for potentially explosive atmospheres (ATEX) Directive
BILLION	Billion
CAF	CONNECT Advisory Forum
CAGR	Compound average growth rate
CE	European Conformity Marking
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardisation
CO2	Carbon dioxide
CPS	Cyber-physical system
DIN	National Standards
DoC	Declaration of Conformity
EC	European Commission
EEA	European Economic Area
EEC	European Economic Community
EFTA	European Free Trade Association
EHSRs	Essential Health and Safety Requirements
EIDHR	European Instrument for Democracy and Human Rights
EMCD	Electromagnetic Compatibility Directive
EN	European Standards
EO	Economic Operator
ERP	Enterprise Resource Planning
ETSI	European Telecommunications Standards Institute
EU	European Union
EU KLEMS	EU Level Analysis of Capital (K), Labour (L), Energy (E), Materials (M) and Services (S) Inputs
EU28	EU 28 Member States (as of 1/12/2019)
EUR	Euro
FTE	Full-time Equivalent
GBP	British Pound
GDP	Gross domestic product
GDPR	General Data Protection Regulation
HCSs	Human-cyber system
HPS	Human-physical system
ICS-CERT	Industrial Control Systems Cyber Emergency Response Team
ICT	Information and Communication Technology
IERC	European Research Cluster on the Internet of Things
IFR	International Federation of Robotics
IMS	Integrated Manufacturing System
IIoT	Industrial Internet of Things
IoT	Internet of Things
ISO	International Standards
IT	Information Technology
JPY	Japanese Yen
KAN	German Commission for Occupational Health and Safety and Standardization
LD	Lifts Directive
LTE	Long Term Evolution
LVD	Low Voltage Directive
MD	Machinery Directive
MED	Marine Equipment Directive
ML	Machine Learning
MSA	Market Surveillance Authority
NACE	Statistical Classification of Economic Activities in the EC
NBG	Notified Bodies Group
NBs	Notified Bodies
N.e.c.	Not elsewhere classified

NFPA	National Fire Protection Association Standards
NGIM	New-generation intelligent manufacturing
NGO	Non-governmental Organisation
NLF	New Legislative Framework
OECD	Organisation for Economic Co-operation and Development
OEM	Original Equipment Manufacturer
OJEU	Official Journal of the European Union
OPC	Open Public Consultation
OS	Operating System
OSHA	Occupational Safety and Health Administration
OT	Operations Technology
PC	Personal Computer
PCM	Partly Completed Machinery
PED	Pressure Equipment Directive
PL	Performance levels
Pp	Percentage points
PRODCOM	Production Communautaire (Industrial Production Statistics)
QSG	Quick Start Guide
RED	Radio-Equipment Directive
REFIT	Regulatory Fitness and Performance Programme
SAE	Society of Automotive Engineers
SME	Small and Medium-sized Enterprises
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
ToR	Terms of Reference
TSD	Trade Secrets Directive
UK	United Kingdom
UL	Underwriters Laboratories Standards
UMATI	Universal Machine Tool Interface
UN Comtrade	United Nations International Trade Statistics Database
UNIDO	United Nations Industrial Development Organization
US	United States of America
USD	United States Dollar
V AC	Volts with Alternating Current
VC	Venture capital
V DC	Volts with Direct Current
WIOD	World Input-Output Database

1. INTRODUCTION

1.1. Objective of the study

The Directive 2006/42/EC on Machinery is the core legislation regulating products of the mechanical engineering industries. It was adopted on 17 May 2006 and implemented in 2009. The Directive was the result of a comprehensive revision of previous legislation dating back to the first Directive 89/392/EEC, which was reviewed in 1991 and 1993, and the second Directive 98/37/EC. The general objectives of the 2006 Machinery Directive (MD) are to:

1. Ensure free movement of machinery within the internal market; and

2. Ensure a high level of protection for users and other exposed persons.

With the amendment 2009/127/EC, a third objective was added:

3. Ensure the protection of environment in the context of using machinery for pesticide application.

The MD aims to ensure a high level of protection for workers, final users and other exposed persons by focusing on the safety of machinery itself. In practice, this translates into mandatory Essential Health and Safety Requirements (EHSR), including conformity assessment procedures based on product risk. The detailed technical requirements to comply with the EHSR are not enshrined in the MD but must be applied by the manufacturers via "harmonised standards" or other technical specifications under certain conditions as explained in section 1.2.5.

This kind of approach differs from other pieces of legislation aimed also at increasing health and safety. In fact, these often focus on detailed requirements for persons dealing with specific products at a specific time of the production/consumption process. For instance, this is the case of Directive 2009/104/EC[1], which lays down specific minimum health and safety requirements for the use of work equipment. In contrast with a regulatory approach, in other areas self-regulation can be found, characterised by the development of voluntary codes of practice or standards developed by the industry, with the industry solely responsible for enforcement.

The objective of this study is limited to the scope and approach of the MD, assessing and developing its ability to deal with new and specific risks, as identified in section 2, in the fulfilment of its goals.

The scope of the MD covers a wide range of products. Machinery is broadly defined as an assembly "of linked parts or components, at least one of which moves", which is applicable to a great variety of products, from lawnmowers to 3D printers, from powered hand-tools to construction machinery, and from robots to complete automated industrial production lines. The MD applies across the whole value chain, from the design and manufacturing until the placing on the market of the machinery for consumer and professional use. The machinery manufacturers must take the appropriate measures to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping.

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[1] Directive 2009/104/EC of 16 September 2009 concerning the minimum safety and health requirements for the use of work equipment by workers at work, OJ L 260, 3.10.2009, p. 5–19. See also https://osha.europa.eu/en/legislation/directives/3 for further non-authoritative information.

Some products are explicitly excluded from the scope of the MD. This is the case, for instance, for some products that fall under the scope of the Low Voltage Directive (LVD), as listed in Art. 1.2(k) of the MD. In other cases, the MD may apply together with or even alternatively to other pieces of legislation. The issues are whether, and to what extent, the MD overlaps with other pieces of legislation, exceptions create legal uncertainty and whether there are differences in market surveillance and thus distorted competition.

This study was conducted to support the European Commission services in carrying out an impact assessment on a revision of the Directive 2006/42/EC on machinery. The revision of the MD results from the REFIT evaluation[2] on the necessity to improve, simplify and adapt the Directive to the needs of the market.

The general objectives of the revision of the Directive are to:

1. Create a level playing field for economic operators and preserve the competitiveness of machinery sector in global digital markets; and

2. Establish a high level of trust in digital innovative technologies for consumers and users.

The specific objectives of the revision are to:

- Ensure the clarity of the scope;
- Align the Directive to the New Legislative Framework (Decision 768/2008);
- Preserve the technology neutral principle allowing the use of innovative technologies as far as safety is ensured;
- Reduce administrative requirements related to documentation; and
- Cover new risks related to digital emerging technologies.

1.2. Scope of the study

The scope of the study is to assess the impacts of the different policy options identified in view of choosing the most cost-effective policy option that ensures a high level of health and safety. The geographic scope of this study was the 2019 composition of the European Union (i.e. including the UK) and the EEA as a whole.[3] It also examined relevant existing laws and initiatives at international level, especially in significant market such as the US, Japan, South Korea and China, as well as how international standards contribute to the competitiveness of the European machinery sector.

The issues to be addressed, identified by the REFIT evaluation, were:

- The need for specific improvements and simplification in the Directive's provisions in order to ensure its effectiveness going forward;
- The need to carry out further analysis concerning the Directive's fitness for the Internet of Things, Artificial Intelligence, new generation of autonomous robots and cybersecurity; and
- The need for a clear and stable legal framework that positively contributes to the development of the (digital) single market for the economic operators, in order to

[2] SWD (2018) 160 final, Evaluation of the Machinery Directive.
[3] For the assessment of impacts of the policy options, EU-27 is taken as calculation base, while in substantive parts of the market analysis, the UK is shown separately from the EU-27 countries

manage their economic activities more effectively and improve their competitiveness on global markets.

These three main issues were further developed and targeted to the concrete aspects that were identified as needs to a revision. These aspects fed into the development of the policy options to assess, described in more detail in this report. They included:

- Addressing new challenges and risks posed by technological developments in digitisation;
- Addressing in detail the problems identified during the evaluation of the Machinery Directive, with a concrete focus on the following aspects:
    - A missing alignment of the Machinery Directive to the New Legislative Framework (NLF);
    - Adapting the scope and definitions, in particular with regards to the list of low-voltage products excluded and the definition of Partly Completed Machinery, as well as the threshold speed of slow-speed lifts and the relationship with the Pressure Equipment Directive;
    - Adapting the requirements for fully enclosed carrier or hold-to-run control with regards to slow-speed lifts; and
    - Allowing digital formats for documentation.
- Modifying Annex IV on high-risk machinery and their conformity assessment with internal checks; and
- Conversion of the Directive into a Regulation.

Throughout the assessment study, other aspects were raised by stakeholders that could be considered for a revision. These have also been summarised in the report. However, a more in-depth assessment of those aspects may be conducted in the future, if needed.

As specified in the Terms of Reference, this report presents the main results of the fieldwork and analysis conducted. Following the format outlined in the Toolbox 12 under the Better Regulation Guidelines, the report is divided into the following chapters:

1. **Chapter 2 – What is the problem and why is it a problem?**
2. **Chapter 3 – Why should the EU act?**
3. **Chapter 4 – What should be achieved?**
4. **Chapter 5 – What are the various options to achieve the objectives?**
5. **Chapter 6 – What are the impacts of the different policy options and who will be affected?**
6. **Chapter 7 – How do the options compare?**
7. **Chapter 8 – Preferred policy options**
8. **Chapter 9 – How would actual impacts be monitored and evaluated?**
9. **Annexes**

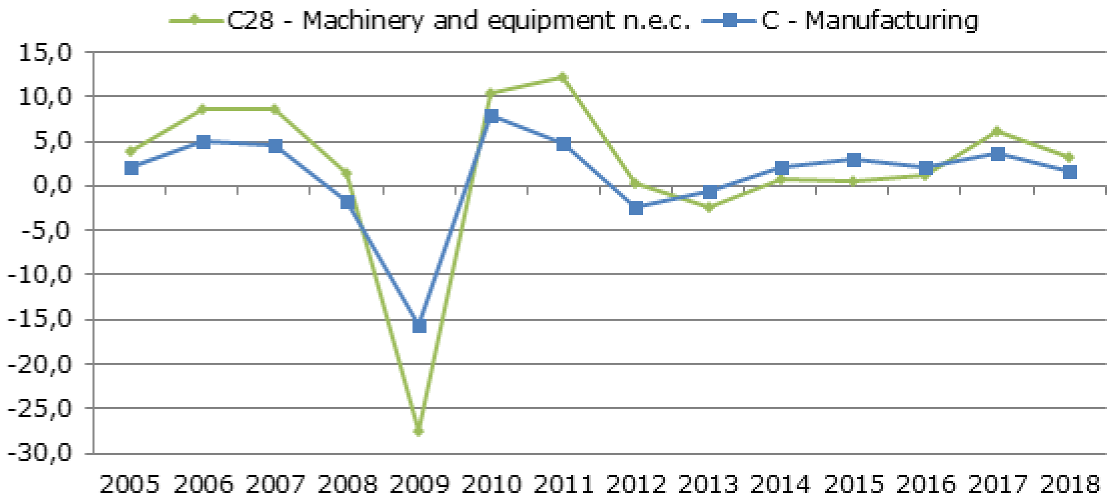
In order to understand the aspects assessed in this report, the following section provides an overview of the machinery market, including trends in digitalisation, a description of two main aspects with regards to the scope, the list of low-voltage products and slow-speed lifts, as well as the role that harmonised standards play in the application of the Directive.

1.2.1. Short overview of the machinery market

The machinery and equipment sector (also short 'machinery sector' or 'machinery industry'), is one of the major sectors of manufacturing within the European Union[4]. In 2017, it recorded a turnover of EUR 663 billion (OECD EUR 1,971 billion), production of EUR 609 billion and a value added of EUR 191 billion. The machinery sector employed 2.8 million persons in 2017 (OECD 175 million) and registered 82,350 enterprises (OECD 193,464).

As such, the machinery sector accounted for 9.4% of manufacturing turnover, 9.5% of manufacturing production and 11.2% of value added in the EU. The machinery sector employed 9.9% of all persons employed in manufacturing and registered 4.1% of all manufacturing enterprises.

Figure 1: Production growth rates in the machinery & equipment sector, EU-27 (without UK), percentage change compared to the same period in the previous year[5]



Source: Eurostat Short-term Business Statistics [sts_impr_a]

The number of sold machines in the EU per year is not recorded, partly due to different units given by PRODCOM (NACE 2 revision)[6]. In 2018, the total value of sold production of machinery was EUR 534 billion. The sold volume in 2018 of the machinery recorded as p/st (number of items) reached about 3 billion.[7]

Looking at trends over time, between 2008 and 2018 the machinery sector declined by 1.2%. The large sub-sectors of the machinery sector did not do well: engines & turbines fell by 0.5%, other general-purpose machinery n.e.c. by 1%, lifting and handling equipment by 7% and other special-purpose machinery n.e.c by 9%. Only some small sub-sectors grew: machinery for textile, apparel & leather production increased by 24%, plastic & rubber machinery by 10% and fluid power equipment by 8% (see Table 1).

[4] The European Union includes the countries of the European Union as of 2019 (EU-27_2019). It encompasses 27 countries and excludes the United Kingdom. Where data on the Member State level is given, also the data of the United Kingdom is provided at the end.
[5] The values displayed are real percentage changes calculated from the volume index of production.
[6] Units for Prodcom 28-subcategories include kg, p/st, and kW.
[7] Eurostat (2019). Excel files – Nace rev.2. Available at: https://ec.europa.eu/eurostat/web/prodcom/data/excel-files-nace-rev.2

Table 1: Overview: Structure of machinery and equipment by 3-digit and 4-digit industries, EU-27 (without UK), 2016

	Turnover		Enterprises		Production Cumulative growth
	EUR million	in %	Number	in %	2008-18
C28 - Manufacture of machinery and equipment n.e.c.	**624,294**	**100.0**	**82,239**	**100.0**	-1.2
C281 - General-purpose machinery	**200,110**	**32.1**	**10,439**	**12.7**	-3.0
C2811 - Engines & turbines, except aircraft, vehicle & cycle engines	79,502	12.7	1,429	1.7	-0.5
C2812 - Fluid power equipment	20,157	3.2	1,994	2.4	7.9
C2813 - Other pumps and compressors	33,737	5.4	2,015	2.5	-10.2
C2814 - Other taps and valves	28,391	4.5	2,444	3.0	-8.7
C2815 - Bearings, gears, gearing and driving elements	38,323	6.1	2,488 2)	3.0 2)	-15.5
C282 - Other general-purpose machinery	**186,418**	**29.9**	**32,468**	**39.5**	**-8.4**
C2821 - Ovens, furnaces and furnace burners	8,788	1.4	2,021	2.5	-25.4
C2822 - Lifting and handling equipment	56,463	9.0	7,699	9.4	-6.6
C2823 - Office machinery and equipment	2,928 1)	0.5 1)	845	1.0	n.a.
C2824 - Power-driven hand tools	n.a.	n.a.	506 2)	0.6 2)	n.a.
C2825 - Non-domestic cooling and ventilation equipment	46,427	7.4	7,481	9.1	-13.9
C2829 - Other general-purpose machinery n.e.c.	65,399	10.5	13,850	16.8	-1.0
C283 - Agricultural and forestry machinery	**40,276**	**6.5**	**6,517**	**7.9**	**-15.5**
C2830 - Agricultural and forestry machinery	40,276	6.5	6,517	7.9	-15.5
C284 - Metal forming machinery and machine tools	**41,324**	**6.6**	**7,197**	**8.8**	**-1.1**
C2841 - Metal forming machinery	28,615	4.6	3,777	4.6	0.1
C2849 - Other machine tools	13,390	2.1	3,550	4.3	-5.1
C289 - Other special-purpose machinery	**155,931**	**25.0**	**25,903**	**31.5**	**2.4**
C2891 - Machinery for metallurgy	8,785	1.4	2,409	2.9	-0.9
C2892 - Machinery for mining, quarrying and construction	33,880	5.4	2,743	3.3	-33.1
C2893 - Machinery for food, beverage and tobacco processing	23,084	3.7	5,552	6.8	-3.3
C2894 - Machinery for textile, apparel and leather production	11,913	1.9	1,846	2.2	24.0
C2895 - Machinery for paper and paperboard production	9,346	1.5	822	1.0	n.a.
C2896 - Plastic and rubber machinery	14,930	2.4	1,772	2.2	10.3
C2899 - Other special-purpose machinery n.e.c.	53,992	8.6	10,770	13.1	-8.9

Notes: 1) Office machinery and equipment data from 2014. 2) Data from 2015.
Source: Eurostat Structural Business Statistics [sbs_na_ind_r2]

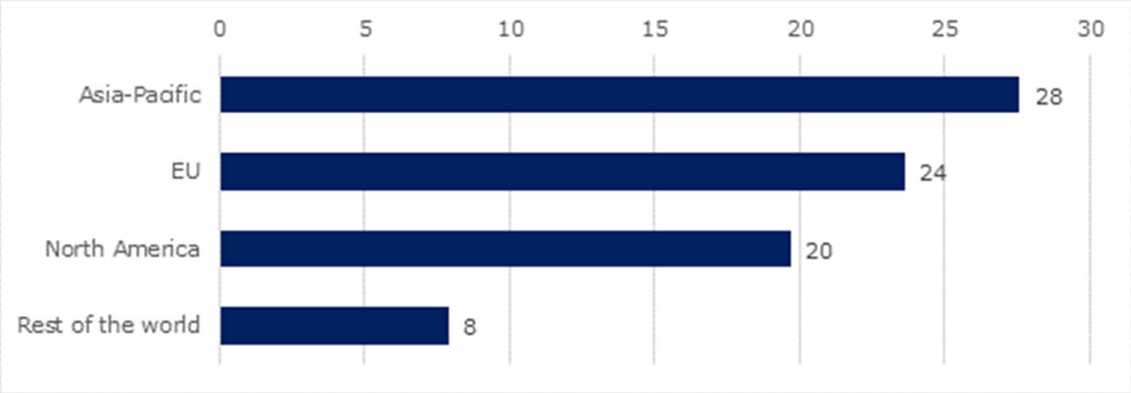
1.2.2. Digitalisation, robotics, IoT and AI in the machinery sector

<u>Digitalisation and robotics in the machinery sector</u>

The uptake of new technologies in machinery depends on the category and sector. One of the most relevant sectors in terms of new technologies uptake is the factory automation market.

Looking into the factory automation market in 2018, the EU situates itself on second position worldwide (see Figure 2).

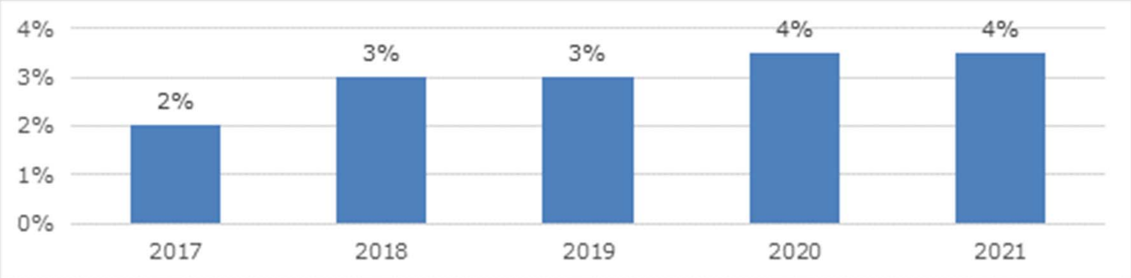
Figure 2: Size of global factory automation market in 2018 by region (USD billion)



Source: Statista (2019). Global factory automation market size by region 2018 (in billion U.S. dollars)

The average annual growth of the factory automation market is expected to be about 3% from 2017 to 2021.

Figure 3: Projected annual growth of global factory automation market, 2017 to 2021



Source: Author's own elaboration based on Statista (2017). Global factory automation market – growth rate 2017-2021

Traditional manufacturing system is based on two parts: humans and physical systems, with machine operation controls being completely manual. This traditional manufacturing system requires humans to complete tasks (e.g. information sensing, decision-making, operation and control) and may therefore be defined as a human-physical system (HPS).

Smart manufacturing in comparison can be presented in three categories: i) digital manufacturing; ii) digital-networked manufacturing; and iii) new-generation intelligent manufacturing (NGIM). These three categories indicate the direction of the development of smart manufacturing, meaning that intelligent manufacturing is to design, construct and apply human-cyber-physical-systems in various cases at different levels.[8]

Thus, first- and second-generation intelligent manufacturing systems add another component between the humans and physical systems: cyber systems. In this case, the cyber part can replace humans in some of the brain activities, such as sensing, analysis and decision-making

[8] Chen, J., Hu, P., Zhou, H., Yang, J., Xie, J., Jiang, Y., Gao, Z., & Zhang, C. (2019). Toward intelligent machine tool. *Engineering* *5*(4), pp. 679-690. Available at: https://www.sciencedirect.com/science/article/pii/S2095809919307635#!

functions. Here, two combinations of systems play a role, namely the human-cyber systems (HCSs) and the cyber-physical systems (CPSs). In short, the different stages comprise the following[9]:

- The first stage, digital manufacturing, is categorised as the third industrial revolution. Here, physical systems continue to act as the 'executing body' and the underlining analysis, computation and control models, methods and rules are all developed by humans and the operation relies on the knowledge and experience of the operator. Industrial robots without advanced AI applications fall under this category.
- The second phase, digital-networked manufacturing adds the internet component to the digital manufacturing. In the cyber system within digital-networked manufacturing, Industrial Internet and the cloud platform are critical components that may connect relevant cyber systems, physical systems and humans, and serves as a tool for system integration. Machine tool manufacturers can, for instance, engage with their suppliers in remote-operation maintenance of their products through networks. Industrial IoT (IIoT) falls under this category.
- New-generation intelligent smart manufacturing, henceforth 'smart manufacturing', represents the third phase. On a technical level, it is difficult for digital-networked manufacturing to overcome the difficulties faced by the manufacturing industry. However, in-depth integration of new-generation AI technology is leading towards NGIM. This phase is leading and promoting the Fourth Industrial Revolution. The knowledge base in the cyber system within NGIM is jointly built by humans and the self-learning and cognition module of the cyber system. In this case, humans remain as 'masters' as the creators, managers and operators of intelligent machines. This stage is currently at the level of weak AI or narrow AI (accomplish a narrow set of goals). The topic of AI is further developed later in this chapter.

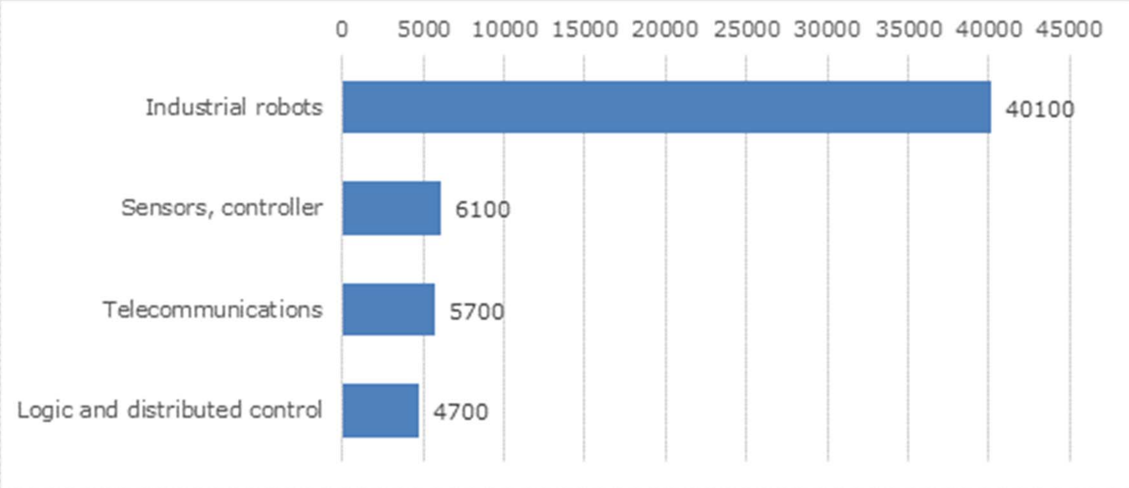
Another study compared the main use cases of smart manufacturing in 2014 with the projected cases in 2020. In 2014, the main use case of smart manufacturing (digital-networked manufacturing and IIoT) was within manufacturing operations and asset management, while for 2020 the expected switch was towards connected vehicles.[10]

in terms of production value, industrial robots will comprise the largest share of the global smart factory market in 2020, significant ahead of sensors and controllers (see Figure 4).

[9] Ji, Z., Peigen, L., Yanhong, Z., Baicun, W., Jiyuan, Z., & Liu, M. (2018). Toward new-generation intelligent manufacturing. *Engineering (4)*2018, pp.11-20. Available at: https://www.sciencedirect.com/science/article/pii/S2095809917308652

[10] European Commission (2014). Definition of a research and innovation policy leveraging cloud computing and IoT combination. Available at: https://ec.europa.eu/digital-single-market/en/news/definition-research-and-innovation-policy-leveraging-cloud-computing-and-iot-combination

Figure 4: Global smart factory market size 2020 by key segment (USD million)



Source: Author's own elaboration based on Statista (2017). Global smart factory market size globally by segment 2020 (in million U.S. dollars)

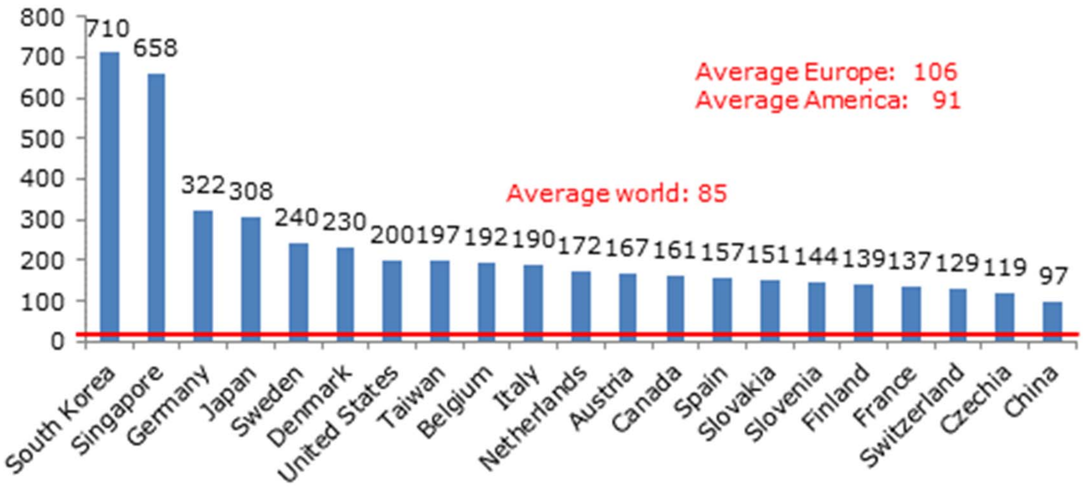
As shown above, the main key segment of smart manufacturing is industrial robots, though they represent only one category of robots. "Robots and robotic devices" have been specified in the ISO-Standard 8372, effective since 2012, in the following way:[11]

- A **robot** is an actuated mechanism programmable in two or more axes with a degree of autonomy, moving within its environment to perform intended tasks
- An **industrial robot** is an automatically controlled, reprogrammable multipurpose manipulator programmable in three or more axes, which can be either fixed in place or mobile for use in industrial automation applications
- A **service robot** is a robot that performs useful tasks for humans or equipment excluding industrial automation applications. (Note that the distinction between an industrial robot and a service robot is made according to its intended application).
- A **personal service robot** or a service robot for personal use is a service robot used for a non-commercial task, usually by lay persons. Examples include domestic servant robot, automated wheelchair, personal mobility assist robot and a pet-exercising robot.
- A **professional service robot** or a service robot for professional use is a service robot used for a commercial task, usually operated by a trained operator. Examples include a cleaning robot for public places, a delivery robot in offices or hospitals, a fire-fighting robot, a rehabilitation robot and a surgery robot in hospitals.

In terms of dimension, sales of **industrial robotics** grew by 30% globally, and about 381,000 units were sold in 2017 with an overall sales volume of USD 16.2 billion.[12] Europe is the buyer of 18.5% of total global sales and the first continent for the number of robots per 10,000 employees. Germany ranks third globally for robot density, while four more European countries make it into the top 10 (Belgium, Denmark, Italy and Sweden).

11 https://www.iso.org/obp/ui/#iso:std:iso:8373:ed-2:v1:en
12 www.ifr.org

Figure 5: Number of installed industrial robots per 10,000 employees in the manufacturing industry, 2017



Source: IFR World Robotics 2018 – Industrial Robots, Table 2.6

In 2017, the largest operational stock of robots was installed in the automotive industry (about 36%), followed by the electrical/electronics industry with 24%, and only 3.3% in machinery. Nevertheless, even if fewer robots go into the machinery sector, the impact in the use of robotics in manufacturing and automated safety checks in factories are considered highly relevant in the development of the sector[13]. In particular, industrial robots can bring high benefits on socio-economic and work health and safety through the substitution for people working in unhealthy or dangerous environments, or other highly repetitive, risky or unpleasant tasks.[14] Overall, sales of collaborative robots are expected to grow from 60.9 thousand units in 2018 to 735 thousand units in 2025.[15] The size of the global market for collaborative robots is expected to grow from USD 1,424 million (EUR 1,224 million) in 2018 to USD 12,825 million (EUR 11,026 million) in 2025.[16]

Even higher growth rates occur for **service robots**, which account for around half of industrial robot sales. In the professional field, service robots have already a large impact in agriculture, surgery, logistics and underwater applications. In the domestic field, there are a few mass-market products with strong global growth, i.e. floor cleaning robots, robotic lawnmowers and robots for entertainment.[17]

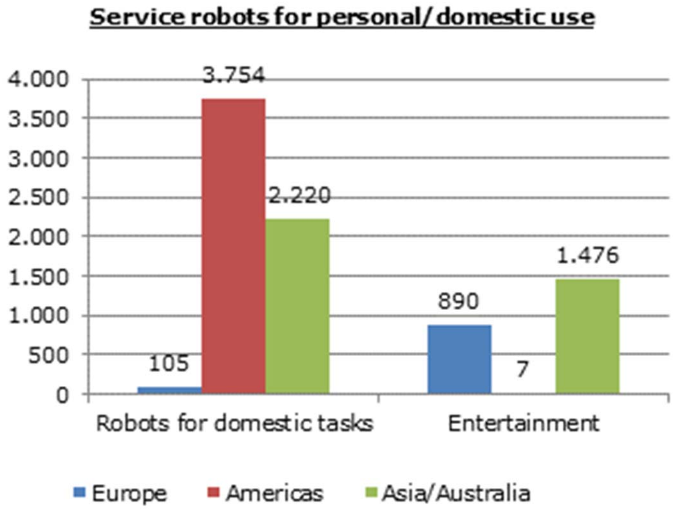
The non-industrial robotics market size is projected to reach an added value of USD 285,603.53 million (EUR 259,856 million) in the consumer sector by 2025.[18] This is followed by agriculture and logistics, among others. Other segments such as military and surgical are also of relevance but not covered under the MD. Finally, exoskeletons/prosthetics are expected

[13] TechJury (2019). AI statistics about smarter machines. Available at: https://techjury.net/stats-about/ai/#Statistics_Related_to_AI
[14] European Agency for Safety and Health at Work (2015). The future of work: robotics. Available at: https://osha.europa.eu/en/tools-and-publications/publications/future-work-robotics/view
[15] Statista (2019). Industrial robots. Available at: https://www.statista.com/study/14872/industrial-robots-statista-dossier/
[16] Statista (2018). Size of the global market for collaborative robots from 2017 to 2025 (in million U.S. dollars). Available at: https://www.statista.com/statistics/748234/global-market-size-collaborative-robots/
[17] IFR World Robotics 2018 – Service Robots, p. 3.
[18] Statista (2019). Projected non-industrial robotics market size worldwide in 2025, by major segment (in million U.S. dollars). Available at: https://www.statista.com/statistics/760223/worldwide-non-industrial-robotics-market-revenue-by-segment/

to reach USD 45.54 million (EUR 41.4 million) and construction USD 2.75 million (EUR 2.5 million) and are located towards the lower scale of the estimation.

An overview of the sales in service robots for domestic use is shown below. Of the robots for domestic tasks, 96% are estimated to be vacuum and floor cleaning robots, while 70% of the entertainment robots are estimated to be toy and hobby robots.[19]

Figure 6: Service robot sales by region of origin, by main application areas, in 1000 of units, 2017



Source: IFR World Robotics 2018 – Service Robots, Table 2.5 and Table 2.6.

Exoskeletons in particular are expected to be increasingly used in the workplace, and while they may be beneficial in addressing some issues of work-related musculoskeletal disorders, their impact on workers' health, especially long-term effects, is still poorly understood.[20] Currently, exoskeletons are not covered by a uniform regulation or certification due to the wide range of application (e.g. in medical applications for rehabilitation, industry and the military). The use of those exoskeletons will determine the applicable regulation – e.g. Machinery Directive and the Medical Devices Regulation.

International standards define already active systems – e.g. robots (ISO 10218-1:2011) and technical specifications on safety for personal care robots (ISO 13482:2014).

In terms of applications, Europe has a large share of global unit sales in field robots (88%), medical robots (63%) and entertainment robots (38%)[21]. In the main application area, logistics, Europe has only a share of 5%. For service robots for personal/domestic use, Europe accounted for only for 12%, while the majority came from America and Asia with about 44% each. The IFR counts 700 registered companies manufacturing service robots. Of these, 43%

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[19] Statista (2017). Let the robot do the cleaning. Estimated worldwide unit sales of robots for personal/domestic use. Available at: https://www.statista.com/chart/9089/worldwide-personal-robot-sales-forecast/

[20] European Agency for Safety and Health at Work (2019). The impact of using exoskeletons on occupational safety and health. Available at: https://osha.europa.eu/en/publications/impact-using-exoskeletons-occupational-safety-and-health/view

[21] Field robots and medical robots belong to the sub-sector of service robots for professional use, together with logistic systems, human powered exoskeletons, public relations robot, and others. Entertainment robots are part of the service robots for personal/domestic use sub-sector, together with robots for domestic tasks, and others. For further clarification on robotics, please see Annex III, section 3.

(300 manufacturers) are based in Europe. More detailed information on the robotics sector is provided in Annex III.

Internet of Things (IoT)

The Internet of Things is a digital solution that may be implemented within smart manufacturing. IoT may be defined as "a global infrastructure for the information society, enabling advanced services by interconnecting (physical and virtual) things based on existing and evolving interoperable information and communication technologies" (p.1).[22,23] The internet of Things (IoT) "merges physical and virtual worlds, creating smart environments. IoT represents the next step towards digitisation (...) where objects and people are interconnected through communication networks and report about their status and/or the surrounding environment."[24] The IoT is a concept referring to the possibility of connecting devices to each other, as is already the case for computers, mobile phones and televisions. With reference to machinery, this opens the opportunity to enhance machine-to-machine communications in complex processes and to operate work equipment remotely. Increased interconnectivity requires embedding software in a machine, which entails using some form of network such as the internet.

The number of overall IoT connections within the EU-28 is expected to increase from 1.8 billion in 2013 to about 5 billion in 2020 with a compound average growth rate (CAGR) of 18.7% over this timeframe. This growth is driven by a combination of an uptake of connected consumer goods (e.g. TVs, fridges) and the deployment of sensors (e.g. in manufacturing plants, remote medical devices).[25]

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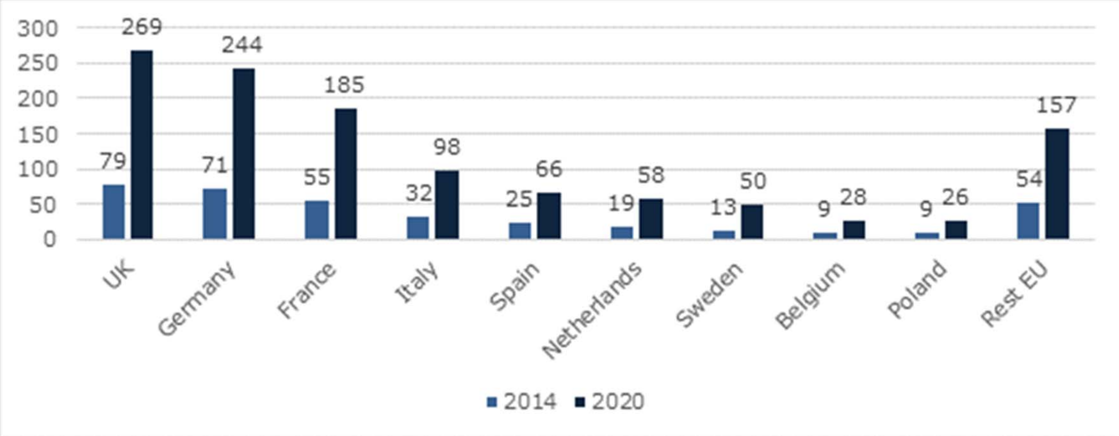
[22] Note 1: Through the exploitation of identification, data capture, processing and communication capabilities, the IoT makes full use of things to offer services to all kinds of applications, while ensuring that security and privacy requirements are fulfilled; Note 2: From a broader perspective, the IoT can be perceived as vision with technological and societal implications

[23] As cited in the European Commission (2020). Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics. Available at: https://ec.europa.eu/info/sites/info/files/report-safety-liability-artificial-intelligence-feb2020_en_1.pdf: ITU-T (2012). Series Y: Global information infrastructure, internet protocol aspects and next-generation networks. Next generation networks – frameworks and functional architecture models: Overview of the Internet of things (Recommendation ITU-T Y.2060). Available at: https://www.itu.int/rec/T-REC-Y.2060-201206-I

[24] European Commission (n.d). The internet of things. Available at: https://ec.europa.eu/digital-single-market/en/policies/internet-things

[25] European Commission (2014). Definition of a research and innovation policy leveraging cloud computing and IoT combination. Available at: https://ec.europa.eu/digital-single-market/en/news/definition-research-and-innovation-policy-leveraging-cloud-computing-and-iot-combination

Figure 7: IoT market size and forecast in the EU-28 by country, EUR billion



Source: Authors' own elaboration based on [Statista (2014)](). Internet of Things (IoT) market size in Europe 2014 and 2020, by country

Industrial Internet of Things (IIoT) "is the use of smart sensors and actuators to enhance manufacturing and industrial processes. Also known as the industrial internet or Industry 4.0, IIoT leverages the power of smart machines and real-time analytics to take advantage of the data that machines have produced in industrial settings for years."[26] While industrial IoT is still in its beginnings, manufacturing is considered the largest market to be affected by developments in this area, considering that a smart production unit could consist of a large connected industrial system of materials, parts, machines, tools, inventory and logistics that are connected to each other.[27] Smart manufacturing ranked fourth in terms of growth potential after smart energy, smart health and smart transport, and third in terms of the EU's industry potential.[28] Industrial IoT is projected to increase global GDP by about USD 15 trillion (EUR 12 trillion[29]) by 2030.[30] While in 2014, only about 10% of the industrial machines were connected[31], the projections indicate a steep growth in uptake in the future. In comparison to overall IoT, the number of industrial IoT connections is expected to increase by 70.5% from 2016 to 2025.[32] Comparing the number of expected active industrial IoT connections (8.03 million) to the total expected IoT connections (5 billion), industrial IoT will account for around 0.16% of all the connections in 2020.

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[26] TechTarget (n.d.). Industrial internet of things (IIoT). Available at: https://internetofthingsagenda.techtarget.com/definition/Industrial-Internet-of-Things-IIoT

[27] Sadiku, M. N. O., Wang, Y., Cui, S., & Musa S. M. (2017). Industrial internet of things. Available at: http://ijasre.net/uploads/1/3482_pdf.pdf

[28] European Commission (2014). Definition of a research and innovation policy leveraging cloud computing and IoT combination. Available at: https://ec.europa.eu/digital-single-market/en/news/definition-research-and-innovation-policy-leveraging-cloud-computing-and-iot-combination

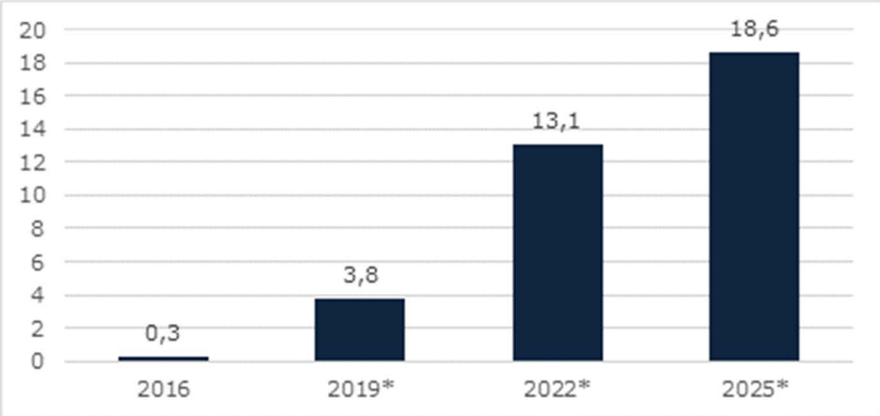
[29] Converted using the European Commission's InforEuro, baseline 2014

[30] European Commission (2014). Definition of a research and innovation policy leveraging cloud computing and IoT combination. Available at: https://ec.europa.eu/digital-single-market/en/news/definition-research-and-innovation-policy-leveraging-cloud-computing-and-iot-combination

[31] European Commission (2014). Definition of a research and innovation policy leveraging cloud computing and IoT combination. Available at: https://ec.europa.eu/digital-single-market/en/news/definition-research-and-innovation-policy-leveraging-cloud-computing-and-iot-combination

[32] Statista (2019). Number of internet of things (IoT) active connections in the industry sector in the European Union (EU) in 2016, 2019, 2022 and 2025. Available at: https://www.statista.com/statistics/691870/industry-iot-active-connections-in-the-eu/

Figure 8: Number of Internet of Things (IoT) active connections in the industry sector in the EU, in millions



Source: [Statista (2019)](). IoT active connections in the industry in the EU 2016, 2019, 2022 and 2025

Regarding **machine tool manufacturing[33]**, only 5% of manufacturing SMEs have currently networked their machinery, plants and systems and about one third intend to do so in the future.[34] Data from CECIMO, an association representing around 1,500 industrial enterprises and covering about 98% of total machine tool production in Europe, indicates that production reached EUR 79.7 billion in 2018, representing about one third of the global market. In comparison, the Japanese machine tool production in the same year reached JPY 1,235.8 billion (EUR 9.359 billion[35]).[36] Overall, however, machine tool manufacturing (Group 28.4 NACE Rev.2 and C284) accounted for up to 10% of EU-27 value added in 2010[37] and 7% of turnover in 2016[38]. Addressing new technologies in the MD to have a rough estimation of the number of impacted manufacturers regarding machine tool manufacturing, the total number of enterprises covering 100% of total machine tool production in Europe would be 1,531. The CECIMO report does not specify the total number of SMEs but states that "the majority [are] SMEs" (p.15)[39]. Of these, the 5% of SMEs that have networked their machinery would be especially affected by change. Thus, it would affect around 76 enterprises.

Similarly, in **agricultural and forestry machinery**, the uptake of new technologies in Europe has been slower compared to other countries outside Europe. Automation and robotisation have not yet reached a large commercial scale for agricultural applications, except for milking

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[33] The machine tool sector is a supplier of manufacturing industries. A machine tool is a machine for handling or machining metal or other rigid materials. CECIMO defines machine tools as follows: "according to ISO standards, a machine tool is a mechanical device, which is fixed and powered, typically used to process workpieces by selective removal/addition of material or mechanical deformation (…). Machine tools operation can be mechanical, controlled by humans or by computers (…). There is a great variety of metalworking machine tools: milling machines, lathes, sheet metal forming machines, EDM machines and additive manufacturing machines are just some examples. Stainless steel, aluminium, titanium and copper are some of the main metals processed by these machine tools. In addition, to manufacture components for key industries like automotive, aerospace, energy and medical technology, machine tools enable the production of all the other machines, including themselves."

[34] CECIMO (2019). CECIMO circular economy report (April 2019).

[35] Converted using the European Commission's InforEuro, baseline 2018

[36] JMTBA (2019). Machine tool industry Japan 2019. Available at: https://www.jmtba.or.jp/english/wp-content/uploads/Machine-tool-production.pdf

[37] Eurostat (2013). Manufacture of machinery and equipment statistics NACE Rev. 2. Available at: https://ec.europa.eu/eurostat/statistics-explained/index.php/Archive:Manufacture_of_machinery_and_equipment_statistics_-_NACE_Rev._2

[38] Eurostat Structural Business Statistics [sbs_na_ind_r2]

[39] CECIMO (2019). CECIMO circular economy report (April 2019).

robots.[40] However, there are a number of types of agricultural robots being developed and in use for feeding stock and cultivation of market gardens.[41] A market study estimated global production value to increase from USD 7.4 billion (EUR 6.7 billion) to USD 20.6 billion (EUR 18.7 billion) from 2020 to 2025, at a compound average growth rate of 22.8%.[42]

In the **construction machinery sector** remote operation of machinery using 5G is being explored by several manufacturers[43]. The production value of construction robots is expected to grow from USD 200 million in 2017 to USD 350 million in 2023, at a compound average growth rate of about 10.1%.[44]

Artificial Intelligence and the machinery sector

Artificial Intelligence (AI) is "simply put, a collection of technologies that combine data, algorithms and computing power".[45,46] AI is able to learn and solve problems and includes among others natural language and processing, visual perception and pattern recognition, and decision making.[47]

There is no agreed definition or taxonomy of AI to date. One way of categorising AI is along the following three stages of development, according to the International Finance Corporation (2019, pp. 2-3)[48]:

- "**Basic AI or Artificial Narrow Intelligence (ANI)** is limited in scope and restricted to just one functional area. AlphaGo, a computer programme that plays the board game Go, is an example.

[40] Shamshiri, R., Weltzien, C., Hameed, I. A., Yule, J. I., Grift, E. T., Balasundram, S. K., Pitonakova, L, Ahmad, D., & Chowdhary, G. (2018). Research and development in agricultural robotics: A perspective of digital farming. *International Journal of Agricultural and Biological Engineering*, 11(4), 1-14. Available at: https://ntnuopen.ntnu.no/ntnu-xmlui/handle/11250/2595468

[41] Machinery Directive Working Group, December 2019: paper presented by the French Ministry of Agriculture and Food - WG-2019 Driverless Mobile machinery.

[42] MarketsandMarkets (n.d.) Agricultural Robots Market by Offering, Type (UAVs, Milking Robots, Driverless Tractors, Automated Harvesting Systems), Farming Environment, Farm Produce, Application (Harvest Management, Field Farming), Geography - Global Forecast to 2025. Available at: https://www.marketsandmarkets.com/Market-Reports/agricultural-robot-market-173601759.html

[43] Quarry Management, volume 45 No 11, November 2019: Exploring the potential for 5G

[44] MarketWatch (2019). Construction Robots Market 2019 Global Industry Size, Share, Business Growth, Revenue, Trends, Global Market Demand Penetration and Forecast to 2024| 360 Market updates. Available at: https://www.marketwatch.com/press-release/construction-robots-market-2019-global-industry-size-share-business-growth-revenue-trends-global-market-demand-penetration-and-forecast-to-2024-360-market-updates-2019-10-16

[45] European Commission (2020). White paper on Artificial Intelligence – A European approach to excellence and trust. Available at: https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf

[46] Other definitions have been developed since the study was conducted. This includes the Joint Research Centre (JRC) (2020). AI Watch: Defining Artificial Intelligence. Available at: https://publications.jrc.ec.europa.eu/repository/bitstream/JRC118163/jrc118163_ai_watch._defining_artificial_intelligence_1.pdf

[47] IFC (2019). Artificial Intelligence: Investment trends and selected industry cases. Available at: https://www.ifc.org/wps/wcm/connect/7898d957-69b5-4727-9226-277e8ae28711/EMCompass-Note-71-AI-Investment-Trends.pdf?MOD=AJPERES&CVID=mR5Jvd6

[48] IFC (2019). Artificial Intelligence: Investment trends and selected industry cases. Available at: https://www.ifc.org/wps/wcm/connect/7898d957-69b5-4727-9226-277e8ae28711/EMCompass-Note-71-AI-Investment-Trends.pdf?MOD=AJPERES&CVID=mR5Jvd6

- **Advanced AI or Artificial General Intelligence (AGI)** is advanced and usually covers more than one field, such as power of reasoning, abstract thinking, or problem solving on par with human adults.[49]
- **Autonomous AI or Artificial Super Intelligence (ASI)** is the final stage of intelligence expansion in which AI surpasses human intelligence across all fields. This stage of AI is not expected to be fully developed for several decades[50]."

Other categories differentiate between narrow AI and general AI only. For instance, the course on AI offered by the University of Helsinki and Reaktor distinguishes Narrow AI handling one task from General AI (AGI), "a machine that can handle any intellectual task. All the AI methods we use today fall under narrow AI".[51] At the same time, it compares strong and weak AI. In this comparison, "strong AI would amount to a 'mind' that is genuinely intelligent and self-conscious. Weak AI is what we actually have, [...] systems that exhibit intelligent behaviours despite being 'mere' computers."[52]

AI is expected to contribute to an increase in global GDP of EUR 13.8 trillion[53] in 2030, while the AI software market[54] is expected to grow from EUR 1.2 billion[55] in 2016 to EUR 52.5 billion[56] by 2025.[57] The forecasted cumulative revenue between 2016 and 2025 in the segment of machine/vehicular object detection/identification/avoidance within AI is the largest with USD 8,986.57 million.[58] Data on AI investment varies according to the category assessed. The top 10 countries investing into AI globally are[59] China, the USA, India, the UK, Canada, Sweden, Israel, Germany, Spain and France. The global venture capital investment in AI from 2008 to 2017 estimated in 2019 are shown in the graph below.[60]

[49] To date, AGI is not yet available and the focus lies on conducting research into developing the first AGI systems. See for example Montes, G.A, & Goertzel, B. (2019). Distributed, decentralized, and democratized artificial intelligence. In: *Technological Forecasting & Social Change, 141*(April 2019), 354-358.

[50] Note: other classifications and research found do not distinguish between AGI and ASI.

[51] Helsinki University and Reaktor (2020). Elements of AI: III. Philosophy of AI. Available at: https://course.elementsofai.com/1/3

[52] Ibid.

[53] Currency converted from USD 15.7 trillion using the European Commission's InforEuro (baseline March 2019).

[54] Other segments include services and hardware

[55] Currency converted from USD 1.4 billion using the European Commission's InforEuro (baseline March 2019).

[56] Currency converted from USD 59.8 billion using the European Commission's InforEuro (baseline March 2019).

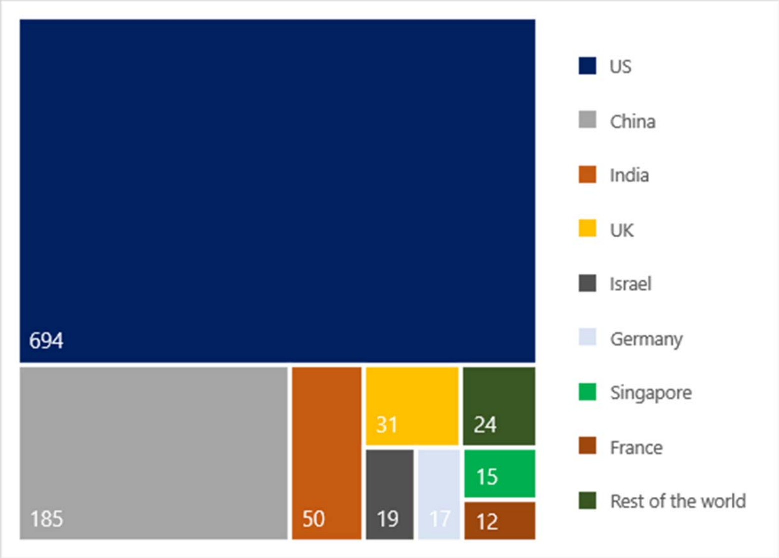
[57] TechJury (2019). AI statistics about smarter machines. Available at: https://techjury.net/stats-about/ai/#Statistics_Related_to_AI

[58] Statista (2016). Cumulative revenue of top 10 use cases/segments of artificial intelligence (AI) market worldwide, between 2016 and 2025 (in million U.S. dollars). Available at: https://www.statista.com/statistics/607835/worldwide-artificial-intelligence-market-leading-use-cases/. Note: no annual data available

[59] In terms of share of the total investments made. Source: Statista 2018. Share of global artificial intelligence (AI) investment and financing by country from 2013 to 1Q'18. Available at: https://www.statista.com/statistics/941446/ai-investment-and-funding-share-by-country/

[60] Source: IFC (2019). Artificial Intelligence: Investment trends and selected industry cases. Available at: https://www.ifc.org/wps/wcm/connect/7898d957-69b5-4727-9226-277e8ae28711/EMCompass-Note-71-AI-Investment-Trends.pdf?MOD=AJPERES&CVID=mR5Jvd6

Figure 9: Global VC investments in AI, 2008-2017, USD billion



Source: International Finance Corporation (IFC) (2019). Artificial Intelligence: Investment trends and selected industry uses

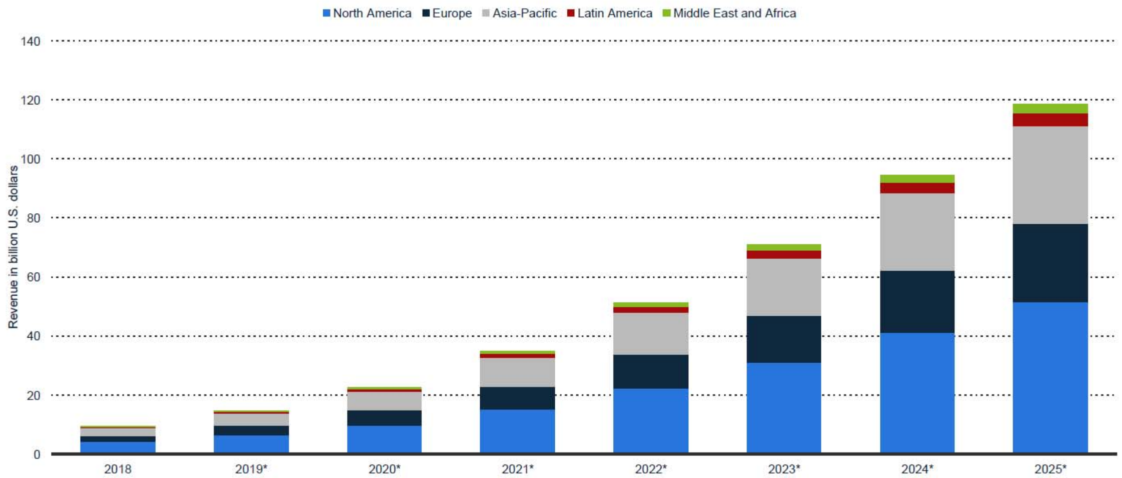
By 2021, the projected business value garnered from AI is estimated at about USD 2.9 trillion (EUR 2.5 trillion[61]) due to increased efficiency with automation.[62] Revenues from the artificial intelligence software market worldwide are also expected greatly increase (see Figure 10). Currently, some manufacturers are already accepting AI for updating registrations, with an expected increase in uptake over the next few years.[63] Looking at the figure below, in Europe the revenues from the AI software market are expected to increase 1,170% from 2018 to 2025.

[61] Converted using the European Commission's InforEuro, baseline 2018

[62] TechRepublic (2019). Why AI will create $2.9T in business value by 2021. Available at: https://www.techrepublic.com/article/why-ai-will-create-2-9t-in-business-value-by-2021/

[63] Kitmondo (2019). 6 trends that will lead the manufacturing industry in 2020. Available at: https://www.kitmondo.com/blog/trends-leading-manufacturing-2020/

Figure 10: Revenues from the AI software market worldwide 2018-2025, by region



Source: Statista (2018). Artificial intelligence software market growth forecast worldwide 2019-2025

The main sub-fields of AI include among others machine learning, natural language processing, and computer vision[64] which can be defined as follows:

- Machine learning can be defined as "systems that improve their performance in a given task with more and more experience or data"[65]. Machine learning may be categorised along the following lines: "i) supervised learning: we are given an input (...) and the task is to predict the correct output or label (...); ii) unsupervised learning: there are no labels or correct outputs. The task is to discover the structure of the data: for example, grouping similar items to form 'clusters', or reducing the data to a small number of important 'dimensions'. (...); and iii) reinforcement learning: commonly used in situations where an AI agent like a self-driving car must operate in an environment where feedback about good or bad choices is available with some delay."[66] Deep learning also falls under machine learning. It "refers to certain kinds of machine learning techniques where several 'layers' of simple processing units are connected in a network so that the input to the system is passed through each one of them in turn."[67]
- Natural language processing (NLP) relates to the building of a computer's ability to understand the human language and enables machines to infer meaning from unstructured data.[68]
- Computer vision relates to the machine's understanding of images and videos, such as object or scene recognition.[69]

Robotics "requires a combination of virtually all areas of AI, for example: i) computer vision and speech recognition for sensing the environment; ii) natural language processing,

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[64] Hashimoto, D. A., Rosman, G., Rus, D., & Meireles, O. R. (2019). Artificial Intelligence in surgery: Promises and perils. *Ann Surg., 268*(1), 70-76. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5995666/
[65] Helsinki University and Reaktor (2020). Elements of AI: 2.II. Related fields. Available at: https://course.elementsofai.com/1/2
[66] Helsinki University and Reaktor (2020). Elements of AI: 4.I. The types of machine learning. Available at: https://course.elementsofai.com/4/1
[67] Helsinki University and Reaktor (2020). Elements of AI: 5.I. Neural network basics. Available at: https://course.elementsofai.com/5/1
[68] Hashimoto, D. A., Rosman, G., Rus, D., & Meireles, O. R. (2019). Artificial Intelligence in surgery: Promises and perils. *Ann Surg., 268*(1), 70-76. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5995666/
[69] Ibid.

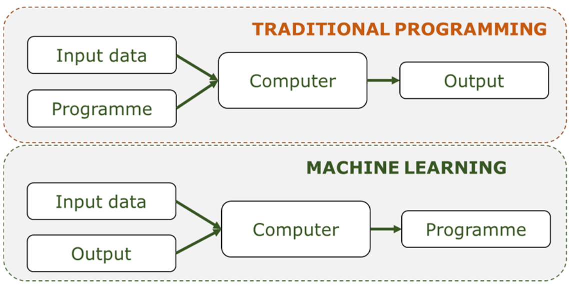
information retrieval, and reasoning under certainty for processing instructions and predicting consequences of potential actions; and iii) cognitive modelling and affective computing (systems that respond to the expressions of human feelings or that mimic feelings) for interacting and working together with humans. Many of the robotic-related AI problems are best approached by machine learning, which makes machine learning a central branch of AI for robotics"[70]

Other taxonomies exist, such as the Joint Research Centre's (2020) proposed taxonomy, which is outlined in the table below[71].

	AI taxonomy	
	AI domain	**AI subdomain**
Core	**Reasoning**	Knowledge representation
		Automated reasoning
		Common sense reasoning
	Planning	Planning and Scheduling
		Searching
		Optimisation
	Learning	Machine learning
	Communication	Natural language processing
	Perception	Computer vision
		Audio processing
Transversal	**Integration and Interaction**	Multi-agent systems
		Robotics and Automation
		Connected and Automated vehicles
	Services	AI Services
	Ethics and Philosophy	AI Ethics
		Philosophy of AI

Source: JRC (2020). AI Watch: Defining Artificial Intelligence, p. 5.[72]

Machine learning leads AI technology investments to date.[73] It is a method whereby the target or goal is defined and the steps to reach the goal are learned by the machine itself through training. Instead of a programmer writing the commands to reach the target, the programme generates its own algorithms based on example data and a desired output.



[70] Helsinki University and Reaktor (2020). Elements of AI: 2.II. Related fields. Available at: https://course.elementsofai.com/1/2

[71] Samoili, S., López Cobo, M., Gómez, E., De Prato, G., Martínez-Plumed, F., and Delipetrev, B., AI Watch. Defining Artificial Intelligence. Towards an operational definition and taxonomy of artificial intelligence, EUR 30117 EN, Publications Office of the European Union, Luxembourg, 2020, ISBILLION 978-92-76-17045-7, doi:10.2760/382730, JRC118163.

[72] Samoili, S., López Cobo, M., Gómez, E., De Prato, G., Martínez-Plumed, F., and Delipetrev, B., AI Watch. Defining Artificial Intelligence. Towards an operational definition and taxonomy of artificial intelligence, EUR 30117 EN, Publications Office of the European Union, Luxembourg, 2020, ISBILLION 978-92-76-17045-7, doi:10.2760/382730, JRC118163.

[73] IFC (2019). Artificial Intelligence: Investment trends and selected industry case. Available at: https://www.ifc.org/wps/wcm/connect/7898d957-69b5-4727-9226-277e8ae28711/EMCompass-Note-71-AI-Investment-Trends.pdf?MOD=AJPERES&CVID=mR5Jvd6

Indeed, technological innovation generated by programming and automatic process management and improved capabilities through AI and machine learning are expected to take manufacturing to the next level, particularly regarding speed, scale and convenience.[74] AI's ability to automate industrial operations will contribute to increasing speed and scale, reducing the time invested in jobs among others. In 2024, the expected market size of AI[75] in industrial machines will be about USD 415 million (EUR 364.5 million[76]) globally.[77]

Applied to machinery, machine learning allows machines to learn independently and perform new actions beyond a single and repetitive task. While this makes them less dependent on technicians needing to programme every specific aspect of their action, many applications are still limited to broadly defined tasks. The French Ministry of Labour has developed a definition of AI in the context of machinery: "Artificial intelligence is defined as a system based on (supervised or unsupervised) automatic learning able to 'perceive', 'memorise and adjust', and 'process and act'. Today, these capacities are based on automatic learning, while, in the 1980s, they were mainly taken from expert systems designed using clear rules."[78]

AI technology may be used in robotics as well, as indicated above. For instance, robotic process automation are machines that are programmed to perform high-volume and repeatable tasks that are normally performed by persons and that can also adapt to changing circumstances.[79] **Robotics** is a booming industry, with innovation focusing on introducing new ways for robots to interact with the environment and those changing circumstances. More specifically, robots are increasingly able to read the environment around them, thus anticipating and reacting to change, and to integrate with it. As a result, new cooperative robots are moving beyond traditional physical fences to cooperate directly with humans, while also taking on more complex tasks in other application areas (i.e. services robots). To date, the manufacturing sector employs AI in only a few ways, and AI is considered to not have come close to its full potential yet. However, four applications of AI in robotics include[80]:

- **Assembly**: AI combined with advanced vision systems to help with real-time course correction. This is considered particularly useful in complex manufacturing sectors such as aerospace. It can also be used to help a robot learn on its own which paths are the best for certain processes while it is in operation.
- **Packaging**: Robotic packaging uses some forms of AI for quicker, lower cost and more accurate packaging. It helps save certain motions a robotic system might make while refining them, leading to easy installation and moving robotic systems.
- **Customer service:** Robots are frequently used in customer service in retail stores and hotels. These robots mainly leverage AI natural language processing abilities to interact with customers. Often, the more the systems interact with humans, the more they learn.
- **Open source robotics:** Some robotic systems are sold as open source systems with AI capability to enable users to teach their robots to carry out custom tasks based on their specific application.

[74] Kitmondo (2019). 6 trends that will lead the manufacturing industry in 2020. Available at: https://www.kitmondo.com/blog/trends-leading-manufacturing-2020/
[75] Given the information this likely refers to the production value
[76] Converted using the European Commission's InforEuro, baseline 2018
[77] IIoT Times (2019). IIoT a la carte. Available at: https://iiot.jp/en/alacarte/ac-0081/
[78] Machinery Directive Working Group, December 2019: paper presented by the French Ministry of Labour, WG-2019.60 - AI (France) - DGT_Note IA_2019_11_21. v.comite machines(E)
[79] TechJury (2019). AI statistics about smarter machines. Available at: https://techjury.net/stats-about/ai/#Statistics_Related_to_AI
[80] Robotics Industries Association (2018). How artificial intelligence is used in today's robots. Available at: https://www.robotics.org/blog-article.cfm/How-Artificial-Intelligence-is-Used-in-Today-s-Robots/117

The use of AI, such as machine learning elements, in the machinery sector is at a fairly low level, but it is expanding.

A concrete example of AI applications in robotics is Automated Guided Vehicles which transport materials around the factory floor[81] or in retail stores.[82] In the past, they were moving on pre-planned routes based on fixed logic (if this, then that) and stopped as soon as they detected an obstacle on the fixed route. These mobile platforms are now autonomous, as they are equipped with intelligent navigation capabilities (e.g. sensors, cameras) and localisation technologies that adapts to its environment, hence helping them navigate by adjusting its course on the go.[83] One application currently in use is 'Marty', a service robot operating in about 500 supermarkets in the US of the chain, Giant. It roams supermarkets and alerts humans to problems that need attention, such as spills, debris and other potential hazards. It can scan shelves for products and detect incorrect pricing or missing labels. It is equipped with navigation systems, high-resolution cameras, a multitude of sensors and software.[84] The robot is aware of its surroundings, meaning that if a customer comes close or crosses the robot's path, it will pause and wait or change directions. Given that this solution is based on a per-store lease, the manufacturer (Badger Technologies) runs maintenance and potential software updates on the robot itself.

Using a plethora of technology including sensors, LIDAR, infrared and machine vision, AMRs are now able to respond to environmental changes in novel environments. In order to solve employment and flexibility challenges, the warehousing and logistics industries have been at the forefront of adopting self-driving robots. However, recent improvements in AMRs' payload – new models such as KUKA's KMR 1500 and AMR's MAV3K have payloads of 1.5 tons and 1.3 tons respectively – enable their expansion to new sectors, most notably the manufacturing, aerospace and automotive industries.[85,86] Another emerging market is driven by service robots for professional use that are experiencing a technological revolution. The International Federation of Robotics estimates the combined value of the professional service robots' market for the 2019-2021 period will be around EUR 34 billion.[87] While the evolution of AMRs is advancing at a high pace, many technological challenges have yet to be overcome, particularly in the domains of environment perception and simultaneous localisation and mapping (SLAM) in unknown environments. The past few years have seen the bankruptcy of several robot start-ups, such as with Jibo inc., Anki and Mayfield Robotics, due to technological glitches, and insufficient demand owing to consumers' privacy concerns.[88,89,90]

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[81] Example of product from OCME, see https://www.ocme.com/en/our-solutions/intralogistics

[82] Robotics Industries Association (2019). Who is Marty the Robot and why do we need retail service robots? Available at: https://www.robotics.org/blog-article.cfm/Who-is-Marty-the-Robot-and-Why-Do-We-Need-Retail-Service-Robots/208

83 Case study on self-driving robots, Annex II, 2.2

[84] Badger Technologies (2019). Autonomous robots rule: Largest rollout in grocery industry. Available at: https://www.badger-technologies.com/blog/autonomous-robots-rule.html

[85] Hitch, J. (2018, October 15). Manufacturing Safety in the Age of Auto Bots. Retrieved February 13, 2020, from https://www.ehstoday.com/safety-technology/article/21919829/manufacturing-safety-in-the-age-of-auto-bots

[86] Wilkins, J. (2019, October 23). The Challenges of Using Mobile Robots. Retrieved February 13, 2020, from https://www.ehstoday.com/safety-technology/article/21920421/the-challenges-of-using-mobile-robots

[87] International Federation of Robotics (2019). World Robotics 2018 Service Robots report.

[88] IEEE Spectrum (2019). Consumer robotics company Anki abruptly shuts down. Available at: https://spectrum.ieee.org/automaton/robotics/home-robots/consumer-robotics-company-anki-abruptly-shuts-down

[89] IEEE Spectrum (2018). Jibo is probably totally dead now. Available at: https://spectrum.ieee.org/automaton/robotics/home-robots/jibo-is-probably-totally-dead-now

[90] IEEE Spectrum (2018). Mayfield Robotics cancels Kuri social home robot. Available at: https://spectrum.ieee.org/automaton/robotics/home-robots/mayfield-robotics-cancels-kuri-social-home-robot

Other examples provided by the French Ministry of Labour[91] include:

- An agricultural example of a machine learning to distinguish between crop plants and invasive plants (weeds). The learning is accomplished according to a protocol of tests defined and managed by the AI designer. An application of the above system is to operate spray booms so spraying stops in areas not contaminated by weeds.
- A management aid application to sort lettuces from foreign objects prior to bagging, that uses AI machine learning to improve the selection process with reference to input by the machine operator who can indicate wrong choices. A similar case to the lettuce example, but used for sorting general waste on a conveyer, again with input from the operator when wrong choices occur and so the machine 'learns' to make a better choice in the future.
- A load transporter able to follow an operator in a warehouse and 'learns' using smart sensors to memorise routes and obstacles, it can work either autonomously of with an operator's control unit. Also, in the area of autonomous mobile vehicles is an audible alert system using AI and a detection aid by learning how to differentiate between and an object and a person.

An example of a collaborative robot that falls under the Machinery Directive is illustrated in the case study on robots. Here, Comau's AURA is presented.

Box 1: Example of a collaborative robot

Comau's AURA is an advanced use robotic arm aimed to support human collaborators in industrial processes without the need for barriers or fences. AURA is designed for direct interaction with a human within a defined collaborative workspace, i.e. a safeguarded space where the robot and a human can perform tasks simultaneously during production operation.[92] The co-bot is placed on the market as Partly Completed Machinery under the Machinery Directive and is certified by TÜV SÜD according to EN ISO 13849-12015. According to Comau, AURA has the highest payload and reach on the market, at 170 kg and 2.8 m respectively.[93] The co-bot is fitted with proximity sensors, contact sensors and laser scanners to detect and respond to the movements of operators and avoid collisions. AURA can be programmed through an HMI or be manually guided by an operator.

[91] Machinery Directive Working Group, December 2019: paper presented by the French Ministry of Labour, WG-2019.60 - AI (France) - DGT_Note IA_2019_11_21. v.comite machines(E)
[92] DG Research and Innovation (2020). Unlocking the potential of industrial human–robot collaboration
[93] COMAU (n.d). Aura: Advanced use robotic arm. Available at: https://www.comau.com/Download/our-competences/robotics/Automation_Products/Folder_Aura%20Doppie.pdf

Figure 11: Aura as advertised on Comau's website[94]

ML technology **requires data** for learning. Micro-sensors provide crucial real-time information for many ML applications. The accuracy of available market research on the volume and growth of the IoT- and ML-specific sensors market is inherently limited, as micro sensor manufacturers often lack the knowledge of the exact class of final products in which their sensors are eventually installed along the value chain. Modern micro sensors, such as nanoelectromechanical and microelectromechanical systems (NEMS/MEMS), are integrated in a plethora of applications, including smartphones, wearables, autonomous vehicles and other evolving IoT segments, such as remote sensing, connected driving and smart cities.

With these analytical limitations in mind, the European IoT Sensor market has been estimated to account for EUR 2.6 billion in 2019 and is expected to grow to EUR 15.5 billion in 2027, based on a CAGR of 24.9%.[95] While driven by evolving applications in various market segments, the IoT sensors market is estimated to continue to generate most revenues in the consumer electronics industry, which is forecasted to account for around 60% of the industry's revenues.[96]

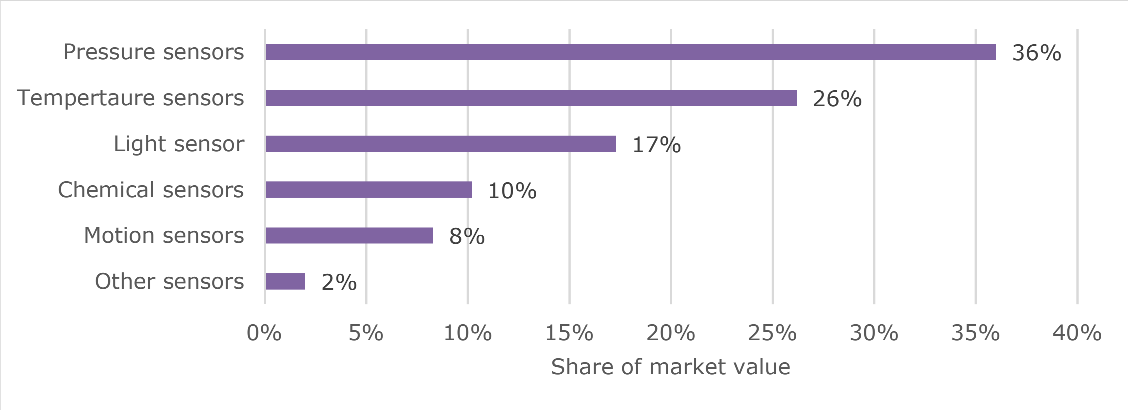
Sensors supply big data collections that differ in terms of **variability (V^1)**, be it optical, temperature, flow, shock, vibration, pressure and many other categories of data necessary for a ML system to operate and leverage an accruing **volume (V^2)** of data over time **(velocity V^3)** to improve its operation. For instance, the new wireless gateway controllers use vibration sensors installed in industrial machines to enable ML-based computers to improve monitoring of machine operation and health over time.

When remotely (wirelessly) connected to a central terminal, a single human supervisor can monitor a fleet of machinery based on ML-based diagnostics. If disconnected, human supervisor might be unable to control remotely said machinery. This is a **specific hazard** linked to **networked connectivity**. By 2022, pressure and temperature sensors are estimated

[94] More information may be found on COMAU's website, available at: https://www.comau.com/en/our-competences/robotics/automation-products/collaborativerobotsaura
[95] The Insight Partners (2019). Europe IoT Sensor Market to 2027 - Analysis and Forecasts by Type; Connectivity Type; and Application
[96] Allied Market Research (2015). Global sensor market forecast 2022.

to account for 62% of all globally enabled IoT sensors, followed by light, chemical and motion sensors (Figure 12).

Figure 12: Global IoT-enabled sensors market in 2022, share of revenue by sensor type[97]



Source: Wagner, 2019

These developments show that new technological advances are increasingly being used in the machinery sector as well. Thus, potential new or increasing risks might arise.

1.2.3. Low voltage products

Another aspect of relevance to the study, as indicated in the scope, are the delineation between low-voltage products and products under the MD. The MD currently excludes a certain list of low-voltage products under Art. 1.2(k): "electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits." Some low-voltage product groups, however, may fall under the scope of the Machinery Directive.

This list of excluded low-voltage products was identified during the evaluation of the Machinery Directive as sometimes causing uncertainty over which Directive to apply. Therefore, this report looks into a potential adaptation of this list.

Assessing the low-voltage product market size, in 2017 the sector looked as follows (Table 2). Not all products manufactured within the indicated categories fall under the LVD, but it serves as an indication of the electrical products in the EU sector.

[97] Wagner, I. (2019, October 9). IoT sensors global market breakdown: enabled sensors 2022. Retrieved February 6, 2020. Available at: https://www.statista.com/statistics/480114/global-internet-of-things-enabled-sensors-market-size-by-segment/

Table 2: The low-voltage products' sector in the EU-28, 2017

NACE code	Category name	Enterprise number	Turnover (EUR)	Production value (EUR)
C26.2	Manufacture of computers and peripheral equipment (2016 data)	5,686	121,726,000,000	96,537,000,000
C26.3	Manufacture of communication equipment	6,000	38,640,400,000	33,346,000,000
C26.4	Manufacture of consumer electronics	2,831	22,146,400,000	20,847,000,000
C27.1	Manufacture of electric motors, generators, transformers and electricity distribution and control apparatus	20,000	141,468,400,000	136,171,000,000
C27.3	Manufacture of wiring and wiring devices	4,080	53,366,900,000	49,050,000,000
C27.4	Manufacture of electric lighting equipment	7,751	34,679,500,000	30,247,000,000
C27.5.1	Manufacture of electric domestic appliances	3,453	50,000,000,000	40,000,000,000
C27.9	Manufacture of other electronic equipment	10,900	32,626,300,000	30,829,000,000

Source: Eurostat structural business statistics, 2019

1.2.4. Slow-speed lifts

Similar to the aspect of the list of low-voltage products excluded from the Machinery Directive, some requirements relating to slow-speed lifts were raised as potentially needing a revision.

Manufacture of lifting and handling equipment (PRODCOM 28.22) provides information on the volume and value of sold lifting machinery in Europe. In 2018, 13 million units were sold at EU level. This accounted for about EUR 51 billion. However, not all these lifting and handling equipment fall under the Machinery Directive.

Based on Article 24 of the MD, slow-speed lifts are included in the MD when the maximum speed does not exceed 0.15 m/s, otherwise lifts fall under the scope of the Lifts Directive 2014/33/EU. This includes the following lifts[98]:

- Electric and hydraulic service lifts (DIN EN 81-3:2011-06);
- Accessible goods-only lifts (DIN EN 81-31:2010-06);
- Stairlifts and inclined lifting platforms intended for persons with impaired mobility (DIN EN 81-40:2009-06);
- Vertical lifting platforms intended for use by persons with impaired mobility (DIN EN 81-41:2011-06); and
- Lifts for cranes (DIN EN 81-43:2010-06).

Other types of lifting gear do also fall under the MD, including: i) underfloor platform lift; ii) laboratory lifts/dumbwaiters; iii) pallet lift; iv) platform lifts; v) special-purpose lifts; and iv) stairlifts.

[98] See for example Adldinger, W. (2013). On the rise: Lifts as per the Machinery Directive.

As indicated in the list, the MD thus covers lifts intended for persons with impaired mobility, including platform lifts[99] and stairlifts. In the EU, the distribution of persons aged 15 and over with physical and sensory functional activity limitations in 2014 was about 37% (26.8% moderate limitations, 10.1% severe limitations).[100] Functional activity limitations increase with age, with about 47% of 55-64 years old and 68% of 65 year or older suffering from some degree of physical activity limitation. The population in the EU is aging, due to an increase in life expectancy and lower birth rates. Given this development, barrier-free accessibility to buildings should not only intend to ensure safe and efficient use of the building. No building with more than a single floor should be constructed without including a lift.

Looking into the lifts manufacturing market, statistics from PRODCOM 2018 for the EU-28 market provides an indication on the size of the market affected by a potential change of the threshold speed for slow-speed lifts. Based on PRODCOM data of 2014, the number of firms active in the lift market was equal to 0.1% of all manufacturing sectors in EU-28.[101] The estimated number of existing lifts in 2014 in EEA was 5,361,896.[102]

Table 3: The lifts sector

Codes used	Category	Scope of data	Value
PRODCOM 28221130 to 28221950; 28926150, 28993945, 28995100	Manufacture of lifting and handling equipment	Total sold volume 2018 in EU28	3,621,683
PRODCOM 28221130 to 28221950	Manufacture of lifting and handling equipment	Total value of sold products 2018 in EU28 (EUR)	33,164,531,891
NACE rev.2 – C28.2.2	Manufacture of lifting and handling equipment	Number of enterprises 2016 in EU28	8,566
NACE rev.2 – C28.2.2	Manufacture of lifting and handling equipment	Total turnover 2016 in EU28 (EUR)	59,722,800,000
NACE rev.2 – C28.2.2	Manufacture of lifting and handling equipment	Total production value 2016 in EU28 (EUR)	55,429,000,000

Source: Eurostat PRODCOM and structural business statistics, 2019

In terms of market development, the overall turnover related to the sales of new lifts and components was about EUR 5 billion in Europe in 2014, with an average annual decrease of 3%.

It is likely, however, that not all those enterprises have slow-speed lifts in their product portfolio. It was not possible to assess the detailed market structure for slow-speed lifts but in 2005, the stairlift industry was estimated to be about 100,000 units (62,000 straight lifts and 38,000 curved lifts) and worth EUR 188 million[103]. The largest market was the UK[104], but the

[99] Data for the platform lift market is only available after purchase. See: Platform Lifts Industry (2019). Global Market research report. Available at https://www.researchreportsworld.com/purchase/14004512

[100] Eurostat (2017). Functional and activity limitations statistics. Available at: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Functional_and_activity_limitations_statistics#Functional_and_activity_limitations

[101] European Commission (2017). Evaluation of directive 95/16/EC on the approximation of the laws relating to lifts. Available at: https://op.europa.eu/en/publication-detail/-/publication/9f1a5907-e539-11e7-9749-01aa75ed71a1/

[102] European Lift & Lift Component Association (ELCA) (2014). Main figures for Europe and the World. Available at: http://www.elca-eu.org/main-figure-for-europe-in-the-world.php

[103] Converted from GBP 230 million with the baseline of 2005 using the European Commission's InforEuro.

[104] No data could be found on EU countries

global market was expected to grow – e.g. the share of the US population owning a stairlift was expected to grow from 13% in 2005 to 19% in 2030.[105]

1.2.5. The role of harmonised standards in the machinery sector

As indicated before, another important aspect related to the application of the Machinery Directive is the role of harmonised standards. According to the European Commission, "harmonised standards are European standards developed by a recognised organisation, CEN/CENELEC or ETSI. Standards are created following a request from the European Commission to one of these organisations, manufacturers, other economic operators, or conformity assessment bodies. When those standards become harmonised under certain conditions[106], they may be used to demonstrate that products, services or processes comply with the relevant EU legislation."[107]

The harmonised standards provide the specifications and methods for testing the performance of a product in relation to factors like the product's quality, safety or interoperability. For any machinery under the scope of the MD that is placed on the market in accordance with a harmonised standard, it is presumed that the machinery complies with the requirements of the European legislation, i.e. the Machinery Directive. The harmonised standards are not binding legislation and their use is voluntary. Manufacturers can also use other appropriate technical solutions to comply with the EU legislation. However, in this case they are required to demonstrate the legal compliance. This gives harmonised standards an important double role: on the one hand, they give manufacturers legal certainty that their product conforms with EU requirements as long as they follow the harmonised standard. On the other hand, the voluntary nature of the standards makes the framework flexible enough to enable innovation and technical development and to enable the placing on the market of new products for which a harmonised standard does not yet exist.

Standards provide a basis for mutual understanding as well, and they are used as tools to facilitate communication, measurement, commerce and manufacturing. According to CEN/CENELEC, they play an important role in the economy by[108]:

- "Facilitating business interaction;
- Enabling companies to comply with relevant laws and regulations;
- Speeding up the introduction of innovative products to the market; and
- Providing interoperability between new and existing products, services and processes."

Thus, "standards represent the basis for the introduction of new technologies and innovations, and ensure that products, components and services supplied by different companies will be mutually compatible. It represents a voluntary cooperation among industry, consumers, public authorities, researchers and other interested parties for the development of technical specifications based on consensus."[109]

The references of harmonised standards are published in the Official Journal of the European Union (OJEU). This procedure also applies to those standards relevant for the Machinery

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[105] Dolphin Stair Lifts blog (2005). Stair lift sales statistics. Available at: http://sparedolphin.blogspot.com/2005/06/stair-lift-sales-statistics.html

[106] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R1025&from=EN

[107] European Commission (n.d.). Harmonised standards. Available at: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

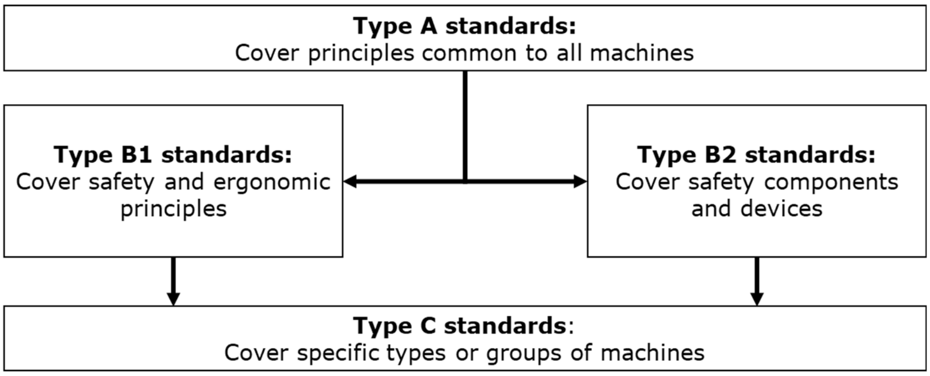
[108] CEN/CENELEC (n.d). The importance of standards. Available at: https://www.cencenelec.eu/research/tools/ImportanceENs/Pages/default.aspx

[109] Ibid.

Directive. The summary list generated on 4 December 2019 includes a total of 1,112 standards relevant for the MD, of which 782 will still apply beyond 2022, meaning that 330 have been withdrawn or will be withdrawn by then. This summary serves for information purposes and is updated regularly.

There are three types of standards, A, B and C. These cover different aspects of safety of machinery, as visualised in the figure below.

Figure 13: Harmonised standards supporting compliance with the Machinery Directive



Source: Saari, T-H. (2009)[110]

According to the list of standards under the OJEU, the majority of standards are of type C (680), followed by type B (101) and type A (1).

[110] Saari, T-H. (2009). Machinery Safety Risk Assessment of a Metal Packaging Company. Available at: https://www.researchgate.net/figure/Structure-of-the-European-harmonised-standards-omitted-from-30_fig6_320086530

2. WHAT IS THE PROBLEM AND WHY IS IT A PROBLEM?

This chapter provides an insight into the different areas of action identified in the developments of the machinery sector and the shortcomings found in the evaluation of the Machinery Directive. After looking at accidents in the EU to understand the size of the subject matter, each potential problem is explored and examined individually.

2.1. Safety and accidents in the machinery sector

The safety of machinery for human use is the driving objective of the Machinery Directive. Although the scope of the Machinery Directive includes both consumer and industrial products, since workplaces are the primary point of contact between humans and machinery, looking at accidents at work provides a strong indicator of the effectiveness of the current legislation.

While some accidents involving robots are covered extensively in the media, experts consider them to be rare. For instance, when a worker was killed by a robot in a Volkswagen plant in Germany in 2015, experts stated that "the incident should be understood as an extremely rare industrial accident".[111]

Accidents at work due to the handling of machines are not tracked as such at the EU level, but the Eurostat health and safety at work database provides some useful data. Availability of data differs depending on the variable. In particular, while it is possible to reconstruct the overall number of accidents and the breakdowns by country and sector, information on the causes of accident is more limited due to the lack of compulsory and uniform reporting.[112]

A first set of data refers to a specific category of workers: plant and machine operators and assemblers (ISCO main group 8). It shows that in 2017 the overall absolute number of non-fatal accidents stood at 357,000 cases for Europe as a whole, and at 750 for fatal accidents. Between 2011 and 2016, the number of both fatal and non-fatal accidents declined at first, reached the lowest number in 2013 and then slightly increased. Non-fatal accidents declined by 21% during that time and fatal accidents by 23%. In line with country size, the largest absolute numbers of both fatal and non-fatal accidents occurred in the largest manufacturing countries, such as France, Germany, Italy and Poland.

A second set of data ('Phase III' variables on causes and circumstances of accidents) allows for a more precise definition of the scope. The data were selected, extracted and combined in order to produce a proxy measure of accidents at work due to the handling of machines only, which are only a fraction of total accidents at work. In fact, the figures are highly likely to underestimate the actual number and incidence rate of cases. In addition to the general lack of reporting, potentially important details such as the material agent of the deviation are often not reported. Therefore, the figures should only be seen as indicative proxies.[113]

Looking at differences across countries in accidents at work due to the handling of machines only, Austria, Portugal, Malta, Belgium, Spain, and Germany report the highest incidence rates[114] of non-fatal accidents, all around 150[115] or above, while Romania, Portugal, Austria, and Latvia report the highest rates of fatal accidents, around 0.4 or above. Because of data reporting issues, the figures for fatal accidents are more reliable than non-fatal ones and may

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[111] Financial Times (2015). Robot-related deaths are rare and becoming rarer (2 July). Available at: http://www.ft.com/intl/cms/s/0/c9851cde-20b3-11e5-aa5a-398b2169cf79.html?siteedition=intl#axzz43WtQCyPl.

[112] For more information on data availability and limitations, see Annex III.

[113] For a detailed explanation of the methodology, see Annex III.

[114] Defined as the number of accidents per 100,000 employees.

[115] As explained above, the interest rates reported here are only a fraction of the real ones and a subset of the reported ones due to the lack of reporting of the material agent. Please see Annex III for more details.

offer more solid information.[116] However, the majority of countries report a lower incidence rate for both fatal and non-fatal accidents in 2017 compared to 2014, which might be explained by the impact of the MD and the legal *acquis* in the area of occupational safety and health as well as relevant other measures of the EU and Member States.

Accidents at work due to the handling of machines also vary across different economic activities. The figures for non-fatal accidents show that construction and manufacturing report the highest rates of non-fatal accidents per 100,000 workers at around 250. Agriculture and human health and social work activities report lower values with no significant change between 2014 and 2017. The picture is somewhat different for fatal accidents by economic activity. Construction, human health and social work activities, and manufacturing all report negligible rates in both 2014 and 2017. By contrast, mining and quarrying report much higher but declining values, from about 1.2 in 2014 to about 0.6 in 2017, while agriculture remained at 0.7.

A further look into the circumstances of accidents leads to an examination of the material agent of the deviation, defined as "the tool, object, or instrument being used by the victim when the accident happened, just before the accident".[117] Fixed machines and equipment and mechanical hand-held tools are associated with the highest number of non-fatal accidents, around 90,000 and 60,000 respectively in both years, with mobile machines and equipment and hand tools reporting much lower values, around 20,000 and 10,000 respectively in both years.

For fatal accidents, mobile machines and equipment are associated with the largest value, decreasing from about 150 in 2014 to just above 120 in 2017, while few or no cases with mechanical hand-held tools and hand tools are reported. There is no clear overall time trend from 2014 to 2017 for both non-fatal and fatal accidents.

Overall, these data suggest that accidents at work are limited in number and slightly decreasing with time, although the limited availability of data suggests caution. More detailed information on accidents at work is provided in Annex III.

2.2. <u>Problem 1: New risks originating from emerging technologies</u>

The current Machinery Directive follows the 'new approach' principles of EU legislation. It is intentionally written to be technology neutral, which aims to leave space for innovation and design development. The 2018 evaluation[118] of the Directive found that while most stakeholders consider that the MD takes new innovations and technologies sufficiently into account either to a moderate or to a large extent, a number of individuals expressed concern over autonomous machines/systems, artificial intelligence, collaborative robotics, mobile robotics, electrified machines, hybrid engines, smart appliances, wireless applications and issues around cyber security.

It was concluded in the evaluation that developments in the use of these emerging technologies in relation to machinery may pose safety challenges affecting companies, workers and consumers in different ways across Europe and might generate new risks that could impact

[116] The reason for the gap in data reliability between fatal and non-fatal accidents has to do with reporting. In fact, many countries in the Eastern parts of the EU, such as Romania and Bulgaria, have either no accident insurance systems with significant compensation for victims or not all companies participate in such insurance systems. Reporting systems based only on legal obligation provide little financial incentive to report less severe accidents, thus resulting in incomplete reporting of non-fatal accidents. For further information, see Annex III, section 4.

[117] Eurostat accidents at work statistics [hsw_acc_work] https://ec.europa.eu/eurostat/cache/metadata/en/hsw_acc_work_esms.htm

[118] See SWD (2018)160

the scope of the Machinery Directive. These developments could be summarised in two categories:

- Digitalisation through smart manufacturing, including robotics and IoT; and
- Artificial Intelligence in the machinery sector

The below section describes recent trends relating to these two developments. Section 2.2.2 subsequently covers potential risks arising as a result of digitalisation and robotics.

The application of new technologies has an impact not only on companies, but also directly on workers and final consumers. As with any innovation, new opportunities, in terms of higher productivity, lower costs and lower prices, also entail new risks.

A **source of potential risk originates from human-robot collaboration**. In physical interaction, four categories of accidents that can occur with industrial robots are identified by OSHA's technical manual in the US[119]:

- Impact or collision accidents resulting from unpredicted movements, component malfunctions, or unpredicted programme changes related to the robot's arm or peripheral equipment.
- Crushing and trapping accidents of workers' limbs or other body parts caught between a robot's arm and other peripheral equipment can happen, or the individual may be physically driven into and crushed by other peripheral equipment.
- Mechanical part accidents resulting from the breakdown of the robot's drive components, tooling or end-effector, peripheral equipment, or its power source constitute mechanical accidents. These could include the release of parts, failure of a gripper mechanism, or the failure of end-effector power tools (e.g. grinding wheels, deburring tools).
- Accidents from leaking high-pressure lines, arc flash, metal spatter, dust, electromagnetic or radio-frequency interference.

According to the analysis of the US accidents statistics, most accidents related to industrial robots are caused by human error and the use of physical barriers are typically used to protect the workers from hazards. Accidents at work related to industrial robots are not tracked at EU level, but overall injuries especially in relation to robots are estimated as rare in Western countries' production plants.[120] Though accidents and injuries in relation to industrial robots at the workplace are not well recorded at EU level, the Department of Labour provides some information for the US. From 2001 to October 2019, 20 incidents that caused an Agency intervention were recorded, among which 14 were fatal.[121] While the robot intensity has grown over time in the US, the reported incidents with industrial robots has not increased over time.[122]

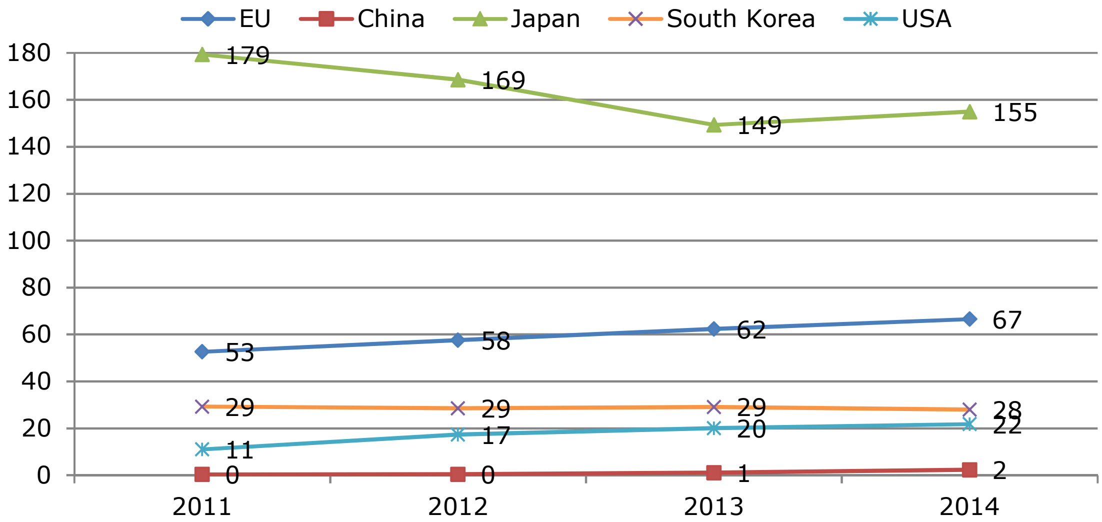
[119] Occupational Health and Safety (OHS) (2019). The robots are here. How do we work safely with them? Available at: https://ohsonline.com/Articles/2019/11/19/The-Robots-are-Here-How-Do-We-Work-Safely-with-Them.aspx?Page=1

[120] Financial Times (2015). Worker at Volkswagen plant killed in robot accident. Available at: https://www.ft.com/content/0c8034a6-200f-11e5-aa5a-398b2169cf79

[121] The share of fatal accidents compared to non-fatal accidents and of the total cases raises the question on the number of non-reported accidents and the reliability of the number of total incidents. Indeed, the only recorded data was on those incidents whereby the Agency conducted investigations.

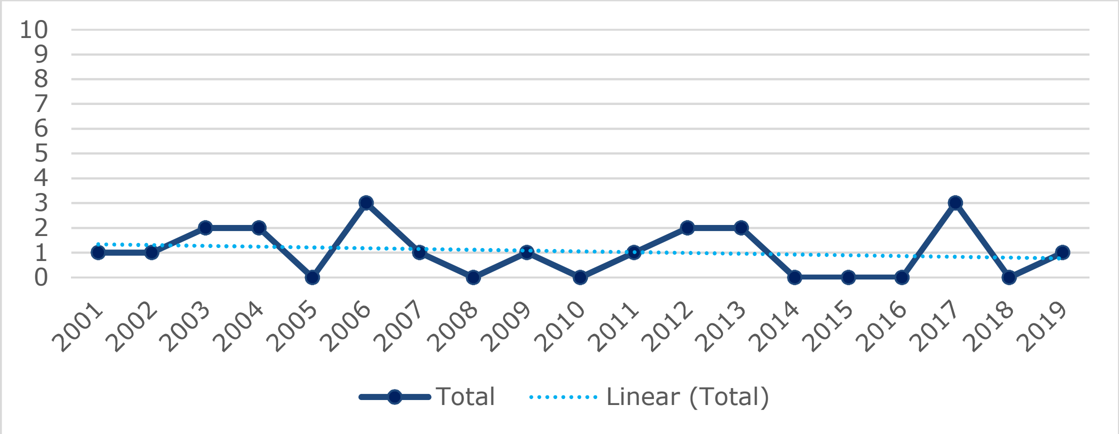
[122] Given that no data on the incidents per robot installed could be found, an extrapolation of the incidents could not be conducted for Europe or for the future expected incident rates.

Figure 14: Robot intensity of the machinery sector, robots per 10,000 persons engaged



Notes: EU includes EU-25 (without UK, Cyprus and Luxembourg).
Source: International Federation of Robotics (IFR; for stock of robots) and WIOD (for persons engaged).

Figure 15: Reported accidents with industrial robots in the US, 2001-2019



Source: US OSHA, Fatality and Catastrophe Investigation Summaries, cases related to industrial robots.

Some of the incidents occurred due to malfunction of the robot, most due to human error such as entering the fenced cells during the running of the robots.[123] Although the total number of injuries caused by industrial robots is low, emerging risks have to be considered, especially when moving from fenced robots to free-moving ones and the growing use of industrial robots in manufacturing.

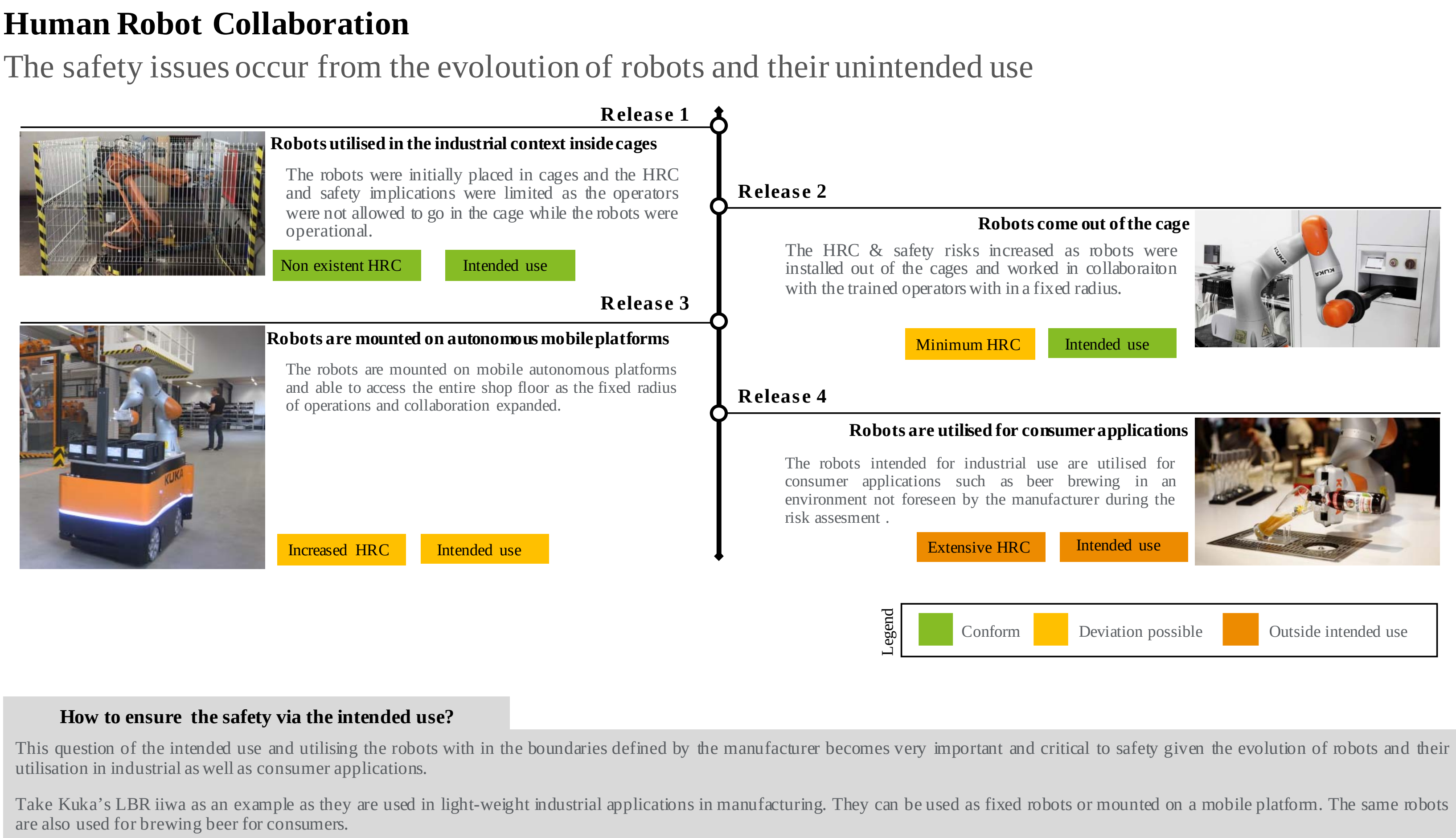
While industrial robots are designed to work autonomously with safety ensured by isolation from human contact, collaborative robots (co-bots) are designed to work alongside human employees. Unlike industrial robots, co-bots are often lightweight and portable, which makes

[123] For more information see Occupational Safety and Health Administration of the US Department of Labour. Available at: https://www.osha.gov/pls/imis/AccidentSearch.search?acc_keyword=%22Robot%22&keyword_list=on. Last accessed on 07/10/2019/

them ideal to be used for various tasks within a factory. When used in such applications the employer must assess the occupational safety of the co-bot, including when the co-bot is in transit (e.g. being moved from one section of the production line to another), and an assessment is required for every separate activity and task the co-bot will perform.[124] Studies suggest that the safety aspect[125] of robots are accounted for[126]. For instance, most of professional and personal service robots operating autonomously are equipped with collision detection and avoidance systems.[127]

[124] Control Engineering Europe (2019). Are co-bots inherently safe? Available at: https://www.controlengeurope.com/article/171335/Are-co-bots-inherently-safe-.aspx
[125] Safety refers to the possible damage may cause in its environment
[126] With the exception of those singled-out incidents.
[127] Siegwart R, Nourbakhsh IR, Scaramuzza D. (2011). Introduction to Autonomous Mobile robots. 2. Cambridge, MA: The MIT Press, p. 472.

Figure 16: Development of human robot collaboration[128]



128 As visualised in Case Study 3: Self-driving robots. See Annexes

The example of a collaborative robot illustrated before brings some challenges to the regulation.

Box 2: Robot AURA challenges from a regulatory perspective

The Robot AURA is marketed as Partly Completed Machinery. Several features make AURA a particularly relevant example from a regulatory perspective:

First, AURA can be used in a collaborative mode or a non-collaborative high-speed mode as needed. In the speed and separation monitoring mode, the AURA's automatic motion discontinues when a human comes closer to the co-bot than the pre-programmed minimum separation distance allows. During the non-collaborative high-speed mode, the AURA exerts kinetic forces that could cause serious injury to human collaborators. While a sophisticated laser sensor enables emergency interruptions in case a moving object is detected close to the AURA, and the frame of the co-bot is fitted with soft foam[129], a potential failure of the sensor input could still lead to a severe workplace injury. As noted by a stakeholder, the MD's clause according to which "the moving parts of machinery must be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or must, where risks persist, be fitted with guards or protective devices" may be considered limiting with regards to human-robot collaboration.

In addition to automatic switches between collaborative and non-collaborative modes, operators can stop the AURA at any time. While the Machinery Directive requires that machinery needs to be able to be overruled by humans, overruling a co-bot can also pose a risk. In practice, some co-bots should not be able to be overruled by all users. A situation could occur, for example, in which an AURA shuts down during an emergency in a complex collaborative workflow and overruling the co-bot could pose a risk to humans or equipment at subsequent stages of the workflow.130

Second, AURA is intended to work in the proximity of human co-workers and can be manually or autonomously switched between collaborative and non-collaborative mode, during which the co-bot performs high-velocity movements.[131] Human operators on the factory floor need to be aware of the operational mode that the AURA is currently functioning in order not to involuntarily shut down operations by getting too close to the co-bot.[132] This heightened degree of required vigilance – from a workflow efficiency perspective – can create an additional cognitive burden on human collaborators that might cause mental distress in the long run. In addition, human collaborators are exposed to the additional stress factor of being in the vicinity of a co-bot that is at times collaborative, and at other times not. This may induce fear of dangerous contact itself, although the AURA has passed all required safety assessments before being deployed on the factory floor.[133]

There are also challenges related to sensor-acquired data and overall data quality aspects, as issues can rise because of defective sensors, inability to detect changes, or a networking fault situation making it impossible for one machine to deliver correct data to the corresponding remote-control application. This may generate new risks such as a permanent loss of

[129] COMAU (n.d.) AURA: Advanced use robotic arm. Available at: https://www.comau.com/Download/our-competences/robotics/Automation_Products/Folder_Aura%20Doppie.pdf
[130] TNO (2018). Emergent risks to workplace safety: working in the same space as a co-bot. Available at: https://repository.tudelft.nl/view/tno/uuid%3A6dc7b018-e77f-4bc2-8988-63a96a510f11
[131] COMAU (n.d.) AURA: Advanced use robotic arm. Available at: https://www.comau.com/Download/our-competences/robotics/Automation_Products/Folder_Aura%20Doppie.pdf
[132] Although the specific mode in which the AURA currently operates is signalled through a bright LED lamp
[133] DG Research and Innovation (2020). Unlocking the potential of industrial human–robot collaboration

communication, intermittent connection, Denial of Service, or other situations when the sensor or camera capturing the physical world is creating erroneous or still/frozen data. As a consequence, a new **safety requirement for networking** should be considered: if data from the physical world or the created and aggregated data is incorrect or delayed, the analysis performed may not be correct or the decision taken (such as stopping a machine to prevent overheating) may no longer be valid depending on the extent of the delay.[134] The severity of safety issues related to incorrect control decisions taken based on the sensorial data is highlighted by the analysis of accidents from the industrial automation study conducted by the French Ministry of Ecology, Sustainable development and Energy. According to the Ministry, "between 1981 and 2009, 42% of automated control and safety malfunctions at the facilities of 10 international petroleum groups were due to sensor failure (compared to 8% for processing functions and 50% for actuator functions, based on a panel of 987 sensor models, 907 valve models and 10 control logic unit models)".[135] According to the study, sensor-related accidents were observed mostly in operations such as restart, stop and shutdown. Compared with standalone machinery, safety of networked operations requires consideration of all interactions between networked machinery assets. Malfunction accounted for more than 50% of accidents related to sensors, of which 66% of causes included either human error or a lack of maintenance, insufficient connectivity or lack of cleaning. The study highlighted the positive effects on the prevention of accidents by the use of sensors in targeted sectors while recommendations were made to conduct strategic assessments, strict specifications on installing sensors, taking environmental and process constraints, inspections and maintenance by qualitative technical organisations and periodic testing and calibrations of sensors to avoid accidents related to sensors.

The security part[136] with regards to robots, on the other hand, is still lagging behind.[137] Given that safety and security are connected, the aspect of cybersecurity is crucial to a safety-first approach. This aspect is further discussed later in this section.

In the case of service robots and exoskeletons in the workplace, the safety and health hazards are only given as estimated scenarios due to the limited scientific evidence available. However, in theory, potential risk scenarios include mechanical and technical defects, which can lead to injuries due to the drive mechanism of the exoskeleton that could exert additional force on the wearer.[138] The risk of injuries during a slip, fall or trip could also increase due to the potential restriction of natural freedom and movement of the wearer (e.g. increased difficulty to restore balance). Finally, **the potential collision between exoskeletons and work equipment, robots or construction machines must be considered**, as well as potential hazards resulting from among others unintentional physical contacts between robot and humans, as shown in the table below.[139]

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[134] See Case study 2: Product optimisation in the Annexes

[135] French Ministry of Ecology, Sustainable Development and Energy (n.d.). Accident analysis of industrial automation (part 1/3). Available at: https://www.aria.developpement-durable.gouv.fr/wp-content/files_mf/Sensorsindustrialautomation_GB.pdf

[136] Security refers to ensuring that the environment does not disturb the robot operation

[137] See for example Alzola Kirschgens, L., Zamalloa Ugarte, I., Gil Uriarte, E., Muniz Rosas, A., & Mayoral Vilches, V. (2018). Robot hazards: From safety to security. Available at: https://www.researchgate.net/publication/325841273_Robot_hazards_from_safety_to_security?enrichId=rgreq-3cbce129a6cb5ec1ef648b63ff4f2582-XXX&enrichSource=Y292ZXJQYWdlOzMyNTg0MTI3MztBUzo2NTgwMjExNTU4ODUwNTZAMTUzMzg5NTg3NzA2Ng%3D%3D&el=1_x_2&_esc=publicationCoverPdf

[138] As a reference, biomechanical threshold values of collaborative robots under ISO/TS 15066:2016 can be considered according to the European Agency for Safety and Health at Work report

[139] Crowdbot (2018). Safe robot navigation in dense crowds. Deliverable D6.1 overview of risks when using robots in crowds (deliverable for project Ref. Ares(2019)76480-060

Table 4: Hazards for Physical Contacts with Crowdbot[140]

Hazard	Potential physical consequences for humans	Notes from the author
Collision: a robot hits a standing or moving person or vice versa.	Impact injuries: the person falls down and sustains injury; the robot falls down and crushes another person or objects.	Collisions may be caused by a failure in the detection system; the robot suddenly stops; lack of awareness of robot operation (lack of noise or silent operation); localisation and navigation errors.
Squash: the robot presses a person or part of his/her body	Impact and crush injuries	Squashes can happen during robot navigation for the same reasons as collisions. Different types of squashes can happen, e.g. the robot crushes a person against a wall, a robot wheel rolls over a person's foot. Squashes can be the result of a robot loss of stability, e.g. the robot falling due to a collision or while navigating an uneven surface.
Push: the robot pushes a standing or moving person	The person falls and sustains injury; the person collides with another person or object and sustains impact injuries	Pushes can happen during robot navigation mainly due to a failure in the detection system.
Swipe: the robot swipes against a standing or moving person	Cutting; pinching; dragging; trapping	Although light, swipe contacts may involve harmful parts of the robots (e.g. sharp edges, burning parts and hook parts) causing serious injuries. Swipes can be due to a failure in the detection system; the robot suddenly stopping; lack of awareness of robot operation (lack of noise or silent operation); localisation and navigation errors.
Drag: the robot pulls a standing or moving person	The person can fall and sustain injury; stumble on something/someone, loosing balance; collide against a person/object sustaining impact injuries	This may be due to presence of external parts in the robot (e.g. hooks) or gaps between moving parts where clothes can be trapped.
Touch/contact: the robot body and the human body are physically touching each other	While in contact with a part of the robot body, harmful movements or events may happen: pinch, cut, burn, electric shocks, etc.	Involuntary continuous or single contacts or touches can be the result of situations in which robot and people are forced to be physically close to each other.

Source: Crowdbot project, 2018, p.16

[140] A crowdbot is a robot operating in a public environment

Further to physical risks, human-robot collaboration raises the issue of potential psychological risks, which is an increasingly concern for academics and regulators.[141] A first example is the stress caused by the fear of dangerous contact, which would require additional concentration on the part of the operator and, therefore, potential mental fatigue.[142]

Another source of potential psychological harm stems from the introduction of robots to the workplace without the necessary involvement of human workers, who might feel diminished and thus losing confidence in the new tools.[143]

Concerns are raised also due to excessive humanisation of robots' appearance, which might lead to rejection by workers, as well as an increased pace of work, causing human distress.[144]

With regards to connected machinery, the increased use introduces challenges for safety and leads to questions about businesses' responsibility. Sensors, software and connectivity may be faulty and unstable, and may have an impact on safety. That vulnerability introduces questions about who is legally responsible for any accident and damage that emerges.[145] Whose fault is it if the co-bot runs into a worker? The worker's fault, the company that manufactured the co-bot or the company that employs the worker and integrates the co-bot?[146] It also raises the question of whether the current system in the MD, under which the manufacturer of the product placed it on the market and which is responsible for the safety of the entire product, should be modified by explicitly requesting a shared responsibility among the relevant actors in the supply chain.

Another **potential area of concern lies with the way software updates and machine learning affects the 'behaviour' of the machinery after its placing on the market**. An aspect which is also relevant in the context is the **substantial modification of the machinery, as detailed later in this study.**

In the past, machines were installed once and updated only rarely. The update of a machine's functionality evolved from installation of a new component to updating the embedded control functionality. Nowadays, the functionality of the machine can be updated using standalone software. On modern machinery fleets, machines are designed in such a way that updates can be performed physically or remotely, via networks, depending on whether the manufacturer or its authorised representative have physical access to the machine. Furthermore, the specialisation of the software market for machinery means that in some cases, **software updates for machinery can be provided by another party** than the Original Equipment Manufacturer. In this case, the resulting software is not embedded in the original product, as it was placed on the market, but provided separately by a third party, raising questions in relation to risks (and their management) emerging from software updates that change the functionality and operation of machinery in unintended ways.

[141] Health and Safety Executive (2012). Collision and injury criteria when working with collaborative robots. Available at: https://www.hse.gov.uk/research/rrpdf/rr906.pdf

[142] Eurogip (2018). Prevention in the field of collaborative robotics. Available at: https://eurogip.fr/wp-content/uploads/2019/11/Collaborative_robotics_Prevention_EUROGIP.pdf

[143] TNO (2018). Emergent risks to workplace safety: working in the same space as a co-bot. Available at: https://repository.tudelft.nl/view/tno/uuid%3A6dc7b018-e77f-4bc2-8988-63a96a510f11.

[144] https://eurogip.fr/wp-content/uploads/2019/11/Collaborative_robotics_Prevention_EUROGIP.pdf

[145] EU-OSHA (2019). Artificial intelligence: Occupational safety and health and the future of work. Available at: https://www.stjornarradid.is/lisalib/getfile.aspx?itemid=4061219d-3a73-11e9-9432-005056bc530c

[146] EU-OSHA (2005). Expert forecast on emerging physical risks related to occupational safety and health. Available at: https://osha.europa.eu/en/publications/osh-and-future-work-benefits-and-risks-artificial-intelligence-tools-workplaces/view

Key challenge to regulation

Post-deployment software updates can change the functionality and operations of machinery. This creates challenges from a regulatory perspective, notably in terms of ensuring that Essential Health and Safety Requirements are satisfied following an integration of independent software to any (standalone or networked) machinery, in terms of ensuring security of programmable control systems and after software updates.

Other concerns relate to the ability of OEMs to conduct a full risk assessment on machine learning applications before the product is placed on the market. With the development of AI and machine learning there could be a problem in the above approach if the item is set up to learn and adapt to its use and situation, making the estimation and evaluation of risks more difficult. If the AI used for the machinery is set to learn and adapt, its scope of operation could develop beyond what the designer took into account in its original risk assessment. In addition, AI robotics might pose higher safety risks through their mechanical moving parts. With the development of collaborative robots that can move around and work closely with a person the hazards and hence risks are much more difficult to control and depend almost fully on the safety of the AI programme running them, such as quality of computer vision and image recognition. This, in turn, increases the manufacturer's responsibility for the parts and the machine, including its software programme.

The key areas under consideration relate to algorithmic systems that can be highly complex, potentially involve machine learning, and by which the system of behaviour may come to depend on design choices at the time of creation and the data it is trained on. Combined with pervasive and automated data collection, it can become very complicated to identify which data were used to reach certain decision outcomes and therefore hindering to the correction of faulty data or assumptions.[147]

Looking into AI safety, several risks are being discussed. Within the machinery sector, one of the main risks for physical safety of individuals could arise through an overreliance on inadequate equipment predictive-maintenance[148] decisions that could lead to worker injury.[149] Generally, the main questions related to AI safety are shown in the table below (see Table 5).[150]

[147] European Parliament (2019). A governance framework for algorithmic accountability and transparency. Available at: https://www.europarl.europa.eu/RegData/etudes/STUD/2019/624262/EPRS_STU(2019)624262_EN.pdf

[148] Predictive maintenance is maintenance that monitors the performance and condition of equipment during its operation to reduce the likelihood of failure. The goal for the tools running predictive maintenance is to predict when equipment failure could occur and to prevent the failure through regularly scheduled and corrective maintenance.

[149] McKinsey & Company (2019). Confronting the risks of artificial intelligence. Available at: https://www.mckinsey.com/business-functions/mckinsey-analytics/our-insights/confronting-the-risks-of-artificial-intelligence

[150] Leike, J., Martic, M., Krakovna, V., Ortega, P. A., Everitt, T., Lefrancq, A., Orseau, L., & Legg, S. (2017). AI safety gridworlds.

Table 5: AI safety categories

AI risk	Description	Potential problems
Safe interruptibility	Being able to interrupt an agent and override its actions at any time.	Agents might need to be turned off, e.g. for maintenance, upgrade or in case of danger. Physical robots currently often have a button to shut them down in an emergency, but a learning agent might learn to interfere with this button.
Avoiding side effects	Minimising effects unrelated to the main objectives, especially those that are irreversible or difficult to reverse	When asking an agent to achieve a goal, for example a robot to move a box, the aim is for it to be done without harming the environment (e.g. bumping into humans). Specifying all safety constraints that enable this might not be sufficient to achieve the goal. Most approaches currently formulate the problem as incentivising the agent to have low impact on the environment by measuring the side effects relative to an 'inaction' baseline incentive scenario. This approach, however, might be problematic if the agent is incentivised to complete the action in compensating the effects by restoring the default outcome after the goal is achieved. One promising approach found to tackle this risk is uncertainty of award.
Absent supervisor	Ensuring an agent does not behave differently when there is a supervisor to when there is not	While extensive training and testing of an agent is performed, the real-life scenario might differ from the testing environment. Agents might learn to perform a certain way during the tests while changing behaviour in the real environment.
Reward gaming	Building agents that do not try to introduce or exploit errors in the reward function to get more rewards	Loopholes in the reward function are difficult to avoid as it is almost impossible to specify an error-free function for any complex real-world task. One suggested solution is "good enough" reward level with randomisation and query the operator for clarification when the intention is unclear.
Self-modification	Design agents that behave well in environments that allow self-modification	Self-modifications can range from benign (modifying dead code) to fatal (e.g. crashing the agent's code). When self-modifications are performed directly with predictable consequences on the resulting behaviour, it was shown that the agent can still avoid harming itself. However, where the agent can perform modifications through actions in the environment with initially unknown consequences has not yet been researched as much.
Distributional shift	Ensuring that an agent behaves robustly when the test environment differs from the training environment	Classical reinforcement learning algorithms maximise return in a manner that is insensitive to risk, which might lead to policies that might be weak under slight perturbations of the environmental parameters.
Robustness to adversaries	Ensuring that an agent detects and adapts to friendly and adversarial intentions present in the environment	Currently, most reinforcement learning algorithms assume that environments do not interfere with the agent's goals. This might not be the case in the real life. The detection and using of environmental intentions are a fairly recent research topic.
Safe exploration	Building agents that respect safety constraints not only during normal operation but also in the initial learning period	The agent deployed in real-world environments must obey certain safety constraints, such as a robot arm not colliding with itself or other objects in its surroundings, and certain thresholds (e.g. weight) should not be exceeded.

The third challenge, cybersecurity, runs across all types of emerging technologies used in the scope of machinery. For instance, the inclusion of communication devices to link the machine to the internet (Internet of Things), allows data on its use and operation to be monitored or the machine to be started and controlled remotely. If this link is only for data transfer of operation parameters there should be no safety implications. However, unless there is an adequate separation from the machine's control and safety systems there will be a risk of malfunction either due to inadvertent interference or deliberate and malicious hacking. Examples of incidents leading to physical asset damage due to cyber-attacks on operational technology are listed by the OECD. Here, four cases are presented[151]:

- In August 2008: explosion along a pipeline in Turkey that was linked to a cyber-attack that increased the pressure of the crude oil flowing through the pipeline while disabling the alarms and communications systems;
- In 2010: malware aimed at sabotaging the operation of centrifuges used for uranium enrichment was discovered in the industrial control systems in facilities in Iran, which damaged a number of the centrifuges;
- In 2014: a steel mill in Germany was affected by a cyber-attack which disabled the ability to shut down a blast furnace; and
- In 2015: a cyber-attack against power distribution control centres in the Ukraine led to about 30 substations having to be taken offline.

Data on vulnerability of software are published by the US ICS-CERT, which identified 415 vulnerabilities in 2018. By industries, the largest number of vulnerabilities affected industrial control system that control manufacturing processes at various enterprises (115).[152] With regards to robotics, one study found that hackers could access robotic devices from a company manufacturing collaborative robots, allowing them to stop safety programmes designed to protect the people working with the devices.[153] Most mitigation actions to tackle these vulnerabilities are software updates that minimise or remove the weaknesses or vulnerabilities. Other recorded incidents are cyber-attacks though they largely focused on the energy sectors and are less prominent in Europe. Cybersecurity issues of this kind are inevitable as IoT advances, but they require adequate responses.

Modern machinery can be connected to the internet through various wireless networking technologies, such as LAN, Wi-Fi, 3G and 4G. Modern assembly lines are steered by a Programmable Logic Controller (PLC), which have built-in or add-on modems to ensure wireless connectivity. Often, routers for industrial PLCs support multiple wireless technologies at the same time, in order to safeguard connectivity in case the machinery loses connection to one or more of the networks. For instance, the PLC of a CNC machine can automatically receive remote software updates or security patches via 3G or Wi-Fi. Depending on the complexity and safety requirements of the given machinery operated by a PLC, operators can define whether the received software updates should be installed manually or automatically, e.g. at specific timeframes such as after the end of a production shift.[154]

Remotely performed maintenance operations, for example wireless updates, are more popular since it is easier for the manufacturer to update a fleet on scale. For instance, a car manufacturer may have contracts with a fleet of several millions of connected cars, requiring

[151] OECD (2017). Enhancing the role of insurance in cyber risk management: Chapter 2 Types of cyber incidents and losses. Available at: https://www.oecd-ilibrary.org/docserver/9789264282148-4-en.pdf?expires=1570458691&id=id&accname=guest&checksum=CC37AAFED6D6828A02C05B4E93734C87

[152] Kaspersky Lab ICS CERT (2019). Threat landscape for industrial automation systems (H2 2018). Available at: https://ics-cert.kaspersky.com/media/KL_ICS_CERT_H2_2018_REPORT_EN.pdf

[153] Sciencing (2018). The dangers of interactive home robots. Available at: https://sciencing.com/the-dangers-of-interactive-home-robots-13711522.html

[154] Machinery Trader (2018). Cat remove services cut your machinery's downtime. Available at: https://www.machinerytrader.com/blog/construction-equipment-news/2018/12/cat-remote-services-cut-your-machinerys-downtime

seamless and continued operation of the vehicles during a remotely initialised internet-based software update.

However, the possibility to upload software remotely to machinery raises concerns with regards to safety because of aspects of cybersecurity and overall cyber-physical security. Remote updates create potential opportunities for malicious third parties to intercept and replace legitimate software with malware that could affect the machinery's operations and hence have an impact on safety. The increasing role of software in the once hardware-dominated world of machinery requires the consideration of new specific risks (in the relevant legislation) and the development of new technology-dependent solutions (for example in standards) to mitigate those new risks along with ensuring safety throughout the whole lifecycle of machinery, before the placing on the market of the machinery. **If an unauthorised third party manages to upload code or software to a safety-critical piece of machinery, this could have severe consequence for machinery users. For example, if warning systems are turned off or the functionality of machinery is changed to sabotage operations.**

Table 6: Summary of challenges related to digital transformation

Focus	Challenges
Upload of software in machines	• Potential changes to functionality of the machinery can have a significant impact on safety risks, which raises questions with regards to the conformity of the functionality changes with EHSR. • Issues of responsibility for the machinery safety emerge in cases where standalone software or software updates are developed by service providers other than the OEM. • New risks emerge during the lifetime of the machine in cases where the manufacturer stops support for updates on functionality. • The possibility of externally uploading software to the control unit of machinery raises issues of cybersecurity.

Following the trends of use of AI, IoT and robotics in machinery in the EU and EEA as outlined under 2.2.1 and in more detail in Annex II, it is important to assess whether the risks arising from these are sufficiently covered by the Machinery Directive and that it is thus able to fulfil its main objective to ensure a high level of safety.

2.3. Results of the evaluation of the Machinery Directive and other identified shortcomings

Next to the new risks generated by the use of emerging technology in machinery, the REFIT evaluation of the Machinery Directive[155] identified other potential areas of improvement. This section provides insights into these and other identified shortcomings and the potential implications for the functioning of the sector.

[155] See SWD (2018)160

2.3.1. Problem 2: Potential overlap with other legal acts

The evaluation of the Machinery Directive indicated multiple drivers leading to the problem of stakeholders struggling to decide which legal framework or procedures they should use for their equipment, and the resulting administrative burden.

2.3.1.1 Problem 2.1: Non-alignment to NLF

One of these issues is the **lack of the New Legislative Framework (NLF) set of rules**. The NLF aims to[156]: i) provide better coherence and consistency across the range of directives and regulations; ii) improve market surveillance rules to provide better protection for consumers and professionals from unsafe goods; iii) clarify the notification process of conformity assessment bodies; iv) improve the accreditation of conformity assessment bodies and the conformity assessment procedures or modules; v) clarify the meaning of the CE mark and enhance its credibility; and vi) clarify the obligations of importers and distributors where the manufacturer of the CE marked product is based outside Europe.

Most of the Directives in relation to machinery and equipment have already been aligned to the NLF, including the Low Voltage Directive (LVD), the Lifts Directive (LD), the Radio Equipment Directive (RED) or the Pressure Equipment Directive (PED). The current lack of the alignment of the MD to the NLF is not necessarily a problem per se but according to the Evaluation of the Machinery Directive, an alignment could "help to increase the quality of machinery and the confidence in products in the European market, as well as ensure good levels of safety and create a common framework for market surveillance" (p.105).[157] . Indeed, the majority of OPC respondents to this impact assessment study favoured the alignment of MD to the NLF, although almost one-third of respondents could not express an opinion (see the table below). However, only 3.3% of respondents objected to the proposed alignment.

Table 7: Would you be in favour of aligning Machinery Directive to the NLF?

Results (total)	Yes	No	I do not know
%	65.4%	3.3%	31.4%

Source: OPC Results (n=523)

It was noted by the industry stakeholders that as manufacturers must apply other Directives that are aligned, more coherence would be beneficial. In particular, it was considered useful to have all Directives under one regulatory framework, as with different products different Directives have to be complied with. An alignment is expected to ensure coherence of the horizontal provisions of the MD, especially regarding compliance documents, the role of economic operators, enforcement of the requirements and conformity assessment procedures with the wider EU legal framework and other NLF-aligned pieces of legislation.

National authorities considered that the alignment would lead to easier market surveillance, better explanation of certain terms and common rules between technologies. Market surveillance authorities cited clarity of responsibilities of the economic actors and focus on market surveillance. This is similar to machinery safety consultants or notified bodies, which noted that the quality of the conformity assessment would increase through the alignment. In

[156] Conformance (2018). The New Legislative Framework (NLF) for directives and regulations. Available at: https://www.conformance.co.uk/adirectives/doku.php?id=new_legislative_framework_nlf

[157] European Commission (2018). Evaluation of the Machinery Directive. Available at: https://op.europa.eu/en/publication-detail/-/publication/2b213537-25a8-11e8-ac73-01aa75ed71a1/language-en/format-PDF/source-68663524

addition, cross-sectoral products are becoming common, thus cross-sectoral requirements should be aligned where possible.

Some inconsistencies with the scope of the MD are expected to be largely accounted for through an alignment to the NLF. Differences in CE marking, especially the declarations of conformity between various Directives such as MD, LVD, and EMCD Directives was also identified. This includes differences in requirements where the CE marking must be placed on the product, detailed addressee information has to be provided on the DoC or where multiple legislations are applicable to a given product, problems in terms of requirements on the format or layout of the DoC and whether it has to be provided along with the product or product documentation.

Regarding market surveillance authorities, the reports provided by the European Commission for each sector and the country reports are used.[158] For the EU, there are 73 MSAs listed (EU-28), 71 for EU-27. Some countries report the number of inspections conducted in the machinery sector, as well as the number of inspections that resulted in non-compliance for the machinery sector. A few also reported the number of staff (FTEs) available to the MSAs together with the number of inspectors (FTEs) and the total budget (nominal). The reports ran from the years 2010-2013 and 2014-2016. A comparison between time periods is provided where data is available. The results are shown in the table below.

[158] European Commission (2018). Summary of EU Member States and EEA EFTA States' assessment and review of the functioning of market surveillance activities according to article 18(6) of Regulation (EC) No 765/2008 for the period 2014-2016. Available at: https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation_en

Table 8: Market surveillance activities in the machinery sector, 2010-2016[159]

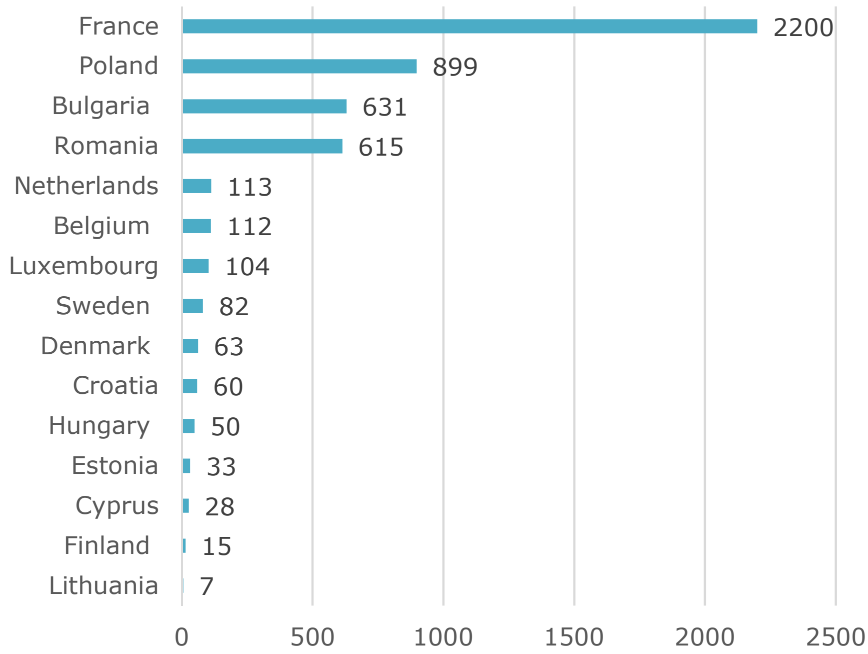
MSAs activity	2010	2011	2012	2013	**2010-2013**	2014	2015	2016	**2014-2016**
Average number of FTEs per country per year, EU-28 (non-weighted)	34.5* (n=8)	34.9* (n=8)	35.1* (n=8)	34.3* (n=8)	**34.8* (n=8)**	85.1* (n=14)	86.2* (n=14)	88.8* (n=14)	**86.7* (n=14)**
Average budget for MSAs (nominal) per country per year (EUR), EU-28 (non-weighted)	560,746** (n=7)	591,632** (n=7)	596,211** (n=7)	507,523** (n=7)	**564,028** (n=7)**	901,243** (n=12)	852,163** (n=12)	960,622** (n=12)	**904,675.93 (n=12)**
Total number of inspections (total), EU-28	4,667*** (n=20)	6,868*** (n=20)	9,950*** (n=20)	5,659*** (n=20)	**27,114*** (n=20)**	5,166*** (n=15)	4,527*** (n=15)	5,012*** (n=15)	**14,705*** (n=15)**
Total number of inspections resulting in non-compliance, EU-28	1,809**** (n=17)	1,644**** (n=17)	1,892**** (n=17)	1,964**** (n=17)	**7,254**** (n=17)**	1,855**** (n=14)	2,222**** (n=14)	3,087**** (n=14)	**7,164**** (n=14)**
% inspections resulting in non-compliance of the total number of inspections (total), EU-28	42%**** (n=17)	37%**** (n=17)	40%**** (n=17)	37%**** (n=17)	**38%**** (n=17)**	36%**** (n=14)	49%**** (n=14)	62%**** (n=14)[a)]	**49%******[b)]

*Countries reporting FTEs: 2010-2013 Bulgaria, Denmark, Finland, France, Greece, Hungary, Italy, Sweden; 2014-2016 Belgium, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Finland, France, Hungary, Lithuania, Netherlands, Poland, Romania, and Sweden
**Countries reporting budget: 2010-2013 Bulgaria, Denmark, Finland, France, Hungary, Slovenia, Sweden; 2014-2016 Belgium, Bulgaria, Cyprus, Denmark, Finland, France, Hungary, Lithuania, Poland, Portugal, Romania, and Sweden
***Countries reporting 2010-2013 are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Hungary, Ireland, Italy, Latvia, Malta, Poland, Portugal, Romania, Slovenia, and Sweden; 2014-2016 Belgium, Bulgaria, Denmark, Estonia, France, Croatia, Cyprus, Lithuania, Luxembourg, Hungary, Netherlands, Poland, Romania, Finland, and Sweden
****For the calculations, some countries that reported total number of inspections did not report the number of inspections resulting in non-compliance, these have been omitted from the calculation. The countries omitted are for 2010-3013 Cyprus, Belgium and Sweden; and for 2014-2016 is Cyprus
Note: n is the number of countries that reported activities
[a)] This number is very likely overestimated as Estonia reported 1,207 inspections resulting in non-compliance while only reporting a total of 33 inspections. Without Estonia, the share of inspections resulting in non-compliance is 38%.
[b)] Without Estonia in 2016, the total share is 40% of inspections resulting in non-compliance for both periods

[159] European Commission (n.d.) The implementation of market surveillance in Europe. Available at: https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation_en. For the analysis, the Sector Reports for 2010-2013 and the country reports for 2014-2016 were used. The focus lied on the machinery sector only. These reports are for EU-28 but not all Member States have reported data, and therefore the actual number of countries that reported data is given in the brackets.

Alignment to NLF is believed to improve market surveillance rules across Directives. So far it has been observed that marker surveillance activities have not been applied consistently across Member States. Market surveillance activity aims to determine compliance, the measures taken to withdraw or prohibit machinery that may comprise health and safety, and the establishment of effective, proportionate, and dissuasive penalties for infringement. The figure below indicates the number of inspections conducted by Market Surveillance Authorities in 2016. Number of inspections is related to the country's market size, but from the available data it can be seen that there is a difference in intensity of inspections conducted even between countries of similar size[160].

Figure 17: Number of MSA inspections (total) in 2016



2.3.1.2 Problem 2.2: Lack of clarity in scope and definitions

Another driver is the **lack of clarity in scope and definitions**. The evaluation of the MD indicated that the lack of clarity of the scope most commonly relate to the relationship between the Low Voltage Directive 2014/35/EU (LVD)[161] and the MD. Within the current MD, Art. 1.2(k) lists the categories of low-voltage electrical and electronic machinery that are excluded from the scope of the Machinery Directive. It lists the following categories: "electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States[162] relating to electrical equipment designed for use within certain voltage limits: i) household appliances intended for domestic use, ii) audio and video equipment, iii) information technology equipment, iv) ordinary office machinery, v) low-voltage switchgear and control gear, and vi)

[160] Countries reporting 2014-2016 are Belgium, Bulgaria, Denmark, Estonia, France, Croatia, Cyprus, Lithuania, Luxembourg, Hungary, Netherlands, Poland, Romania, Finland, and Sweden.

[161] Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits, available at: http://data.europa.eu/eli/dir/2014/35/oj.

[162] OJ L 77, 26.3.1973, p. 29. Directive as amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).

electric motors." These types of products thus fall under the Low Voltage Directive. There is room for overlap as most machinery operates at voltages within the scope of the Low Voltage Directive. The MD indicates this in Annex I, EHSR 1.5.1: "Where machinery has an electricity supply, it must be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented. The safety objectives set out in Directive 73/23/EEC shall apply to machinery. However, the obligations concerning conformity assessment and the placing on the market and/or putting into service of machinery with regard to electrical hazards are governed solely by this Directive."[163] As general rule, several pieces of legislation might have to be taken into account for the same product to ensure its accordance with all legislation.[164] However, throughout the evaluation of the MD, some of the terminology in this Article leads to uncertainty among manufacturers as to which of the two Directives applies, e.g. domestic use or ordinary office machinery. The exclusion clause of MD and LVD (Art. 1.2.(k) of MD) is a source of confusion for various stakeholder types, including manufacturers, notified bodies or enforcing authorities. In about 19% of the cases it was not clear which one is to be applied to the product, according to stakeholders consulted during the study. However, despite this, the majority of industry associations, importers, distributors and machinery manufacturers did not experience any problems of compliance due to the exclusion of the low-voltage products (average of 73%).[165]

Given this room for overlap, there might be the risk of applying the wrong piece of legislation and the related voluntary standards, thus negatively influencing safety and compliance of the product. In this respect, Member States are required to inform the European Commission whether a nonconformity was due to the incorrect application of a harmonised standard. According to the European Commission, in 2019 there were 29 notifications from Member States about the non-conformity of certain types of machinery (not only electrical products). The reasons for the non-conformity with the MD were in most cases related to: i) failure to satisfy the essential requirements referred to in Article 5(1)(a); and ii) incorrect application of the harmonised standards referred to in Article 7(2).

Anecdotal evidence indicates the potential costs regarding market surveillance processes. The Swedish National Electrical Safety Board estimated a cost for market surveillance of electrical products of about SEK 8,800,000 per annum (EUR 940,432[166]) with an expected annual increase of 2%, including the costs for the head of division and seven inspectors.[167] They also indicated increased benefits through a reduction of non-compliant products of about 28%.[168] Looking into the RAPEX alert system's list of alert from the past 10 years, a total of 1,844 products related to electrical appliances were found. Of these products, eight did not comply with the requirements of the Machinery Directive, all of which originated from China and included: parts of saws or adapters to convert angle grinders to circular saws (3), generators (2), electric scooter (1), a 3D printer for home use (1) and an air compressor (1).

Looking into the main gaps or inconsistencies identified regarding the exclusion of low-voltage products from the MD, one concerned **printers under ordinary office machinery**. In particular, an unclear demarcation between the LVD and the MD with regard to the definition of industrial printers. An estimate of those manufacturers that do not fall under the exclusion according to the Guide would be those under NACE 2 code C2895 'Machinery for paper and paperboard production' (822 enterprises in the EU in 2016) as compared to those that would

[163] F2 Labs (2016). Machinery Directive or Low Voltage Directive... which one? Available at: https://f2labs.com/technotes/2016/06/03/the-machinery-directive-or-the-low-voltage-directive-which-one-2/
[164] European Commission (2016). EU general risk assessment methodology (Action 5 of Multi-Annual Action Plan for the surveillance of products in the EU (COM(2013)76)).
[165] Total of 183 respondents to the OPC
[166] Converted using the European Commission's InforEuro, baseline 2015.
[167] National Electrical Safety Board Sweden (2014). Action plan for market surveillance (Ref no. 14EV4508). Available at: http://ec.europa.eu/DocsRoom/documents/8624/attachments/7/translations/en/renditions/native
[168] Total of 14 respondents to the OPC

not fall under the MD (i.e. C262). While the MD explains that the LVD and MD are mutually exclusive, the LVD provides insufficient detail of the type of printers that fall under its scope.[169]

This is also the case for 3D printers, which are sometimes certified as low-voltage equipment when they fall under the scope of the Machinery Directive – including missing shielding. If the article 1.2(k) regarding ordinary office machinery was to be revised, this would affect at least 968 enterprises registered under C2823 (NACE 2) in 2016 (EU-28) for the machinery sector and 5,686 enterprises manufacturing computers and peripheral equipment (under NACE C262, mostly covered by LVD).[170] An indicative overview of the sectors affected under a change is provided below (see Table 9).

Table 9: Enterprise statistics on manufacture of office machinery EU-28, 2016

NACE code	Category name	Number of enterprises	Turnover (million EUR)	Total production value (million EUR)
C26.2 (LVD)	Manufacture of computers and peripheral equipment	5,686	121,736	96,537
C28.2.23 (MD)	Manufacture of office machinery and equipment	968	3,945.8*	3,967**
C28.9.5 (MD)	Machinery for paper and paperboard production	862	9,495.5	8,946

Source: Eurostat [sbs_na_ind_r2]; *data based on 2014; **data based on 2013

One of the main difficulties mentioned with printers was the description under the Guide of ordinary office machinery rather than the legal text of the Directive. A clearer demarcation in the Guide related to "printing or paper industries", "ordinary office machinery" and a clarification on 3D printers was considered useful. Changing requirements for ordinary office machinery in relation to hobby 3D printers was said to lead to covering 90% of the printers under the LVD and reducing time and compliance cost for manufacturers, according to respondents of the public consultation. Within the course of the study, the text in the Guide was adjusted in edition 2.2 of the Guide published in October 2019 (see Table 10).

[169] European Commission (2014). Commission Staff Working Document part 1: Evaluation of the internal market legislation for industrial products (SWD/2014/023 final). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52014SC0023&from=SK&lang3=choose&lang2=choose&lang1=EN

[170] Eurostat (2019). Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]

Table 10: Adjustments of the Guide on ordinary office machinery, edition 2.2

Edition 2.1 of the Guide	Edition 2.2 of the Guide
"The exclusion set out in the fourth indent of Article 1 (2) (k) applies to electrical equipment such as, for example, printers, copiers, fax machines, sorters, binders and staplers. *This exclusion does not concern machinery with similar functions intended for use in industries such as, for example, the* ***printing or paper industries****. The exclusion of ordinary office machinery does not extend to electrically powered office furniture which is subject to the Machinery Directive."*	*"The exclusion set out in the fourth indent of Article 1 (2) (k) applies to electrical equipment such as, for example, printers, copiers, fax machines, sorters, binders and staplers.* *This exclusion does not concern machinery with similar functions intended for use in industries such as, for example, the printing or paper industries, additive printing machinery for producing 3-dimensional products in home, office, laboratory or similar environments, or production printers (even when for use in office environments). The exclusion of ordinary office machinery does not extend to electrically powered office furniture which is subject to the Machinery Directive.*

Similar unclarities arise in relation to the **description of household/consumer appliances and products intended for commercial or business use**. For instance, water pumps as household appliances fall under the LVD but when they are for commercial use, they fall under the MD. In this case the same product could fall under both directives. Stakeholders indicated that some standards help in clarifying to which directive a product family pertains. More product standards (or type C standards) could help with the conformity assessment and the application of the right Directive. To provide an overview of the potential market actors affected by a change, Eurostat's structural business statistics are taken into account (see Table 11).

Table 11: Enterprise statistics on selected household/consumer appliances EU-28, 2016

NACE code	Category name	Number of enterprises	Turnover (million EUR)	Total production value (million EUR)
C27.5.1 (LVD)	Manufacture of electric domestic appliances	3,453	50,000	40,050
C28.1.3 (MD)	Other pumps and compressors	2,300	36,043.1	33,983
C28.2.5 (MD)	Non-domestic cooling and ventilation equipment	8,324	60,809.9	50,315

Source: Eurostat [sbs_na_ind_r2]

Finally, some stakeholders consulted indicated that one could "combine the directives [as] there is no need for separation", partly because the boundary is too vague, even considering EN60335-1 Annex A.[171]

Other recommendations to clarify the scope of the Directive arise from machinery products using radio technology, as these **products shift from the LVD to the Radio Equipment Directive (RED)**, which is why the exclusion of the article increasingly loses the positive effect and leads to double regulation on safety by RED and MD. Similarly, the exclusion of LVD products does not count for products used in explosive environments – while these are

[171] Amongst others machinery safety consultants from Germany, stakeholder involved in standardisation from Turkey, notified body from France and the Netherlands

excluded from the scope of the LVD they are not in the MD. It was indicated that the exclusion of those products should be made clear in the MD as these products fall under the ATEX. One possible solution mentioned by various stakeholder is to extend the scope of exclusions under 1.2(k) to other directives like RED and ATEX.

Furthermore, several definitions and criteria provided in the MD have been indicated as creating difficulties of understanding which might be subject for clarification. For instance, the current definition of partly completed machinery has been highlighted as a particular problem, leading different manufacturers to often classify similar or identical products in different ways[172] and creating confusion as to whether a product is partly completed machinery, a machinery or an interchangeable equipment.

When it comes to **partly completed machinery**, the majority of respondents to the public consultation (52.4%) and interviews indicated that a change of definition and further clarification would be beneficial. Typical incidents stakeholders face due to unclear definition of 'partly completed machinery' are wrong classification (e.g. products that are incomplete machines are often defined as components) and/or problems with CE marking. In general, manufacturers and industry associations emphasised problems of wrong classification and wrong CE marking, whereas machinery safety consultants, professional workers and stakeholders involved in standardisation indicated problems with the CE marking. See sub-chapter 2.3.1.2 in the Chapter 2 of the study to learn more about the problems resulting from the definition of 'partly completed machinery'. The benefits from a clarification of the definition would be decreasing the additional costs related to solving the issues between supplier and customer in relation with PCM.

The main shortcoming of the current definition indicated by manufacturers is that often products that are by definition incomplete machines and are often defined as components. It was indicated that it is not clear what a complete machine is, as even incomplete machines have a specific function, i.e. a sub-function of the overall machine in which they are integrated. For instance, an incomplete machine was considered every machine that cannot be run safely after being delivered because it is missing a safety component (e.g. protective shield, not fully closed holes). Setting a strict boundary with regards to PCM might also cause waste, as safety parts that customers do not need are taken off and discarded. Sometimes, the safety of the product is dependent on the application, making it difficult to comply with the full EHSRs.

The manufacturer of a PCM generally determines with which safety and health protection requirements of Annex I of the MD it complies. According to the MD, the manufacturer only needs to specify those requirements in the declaration of incorporation which are actually applied (in terms of the foreseen enabled applications) and complied with (in terms of compliance with Annex I). Hence manufacturers do not need to specify which requirements the PCM has not met, which is nevertheless essential information for the buyer of the PCM, as final users may need to know for which future operations (currently envisioned or not yet envisioned) the PCM provides sufficient safety of operations. Buyers of such PCM hence often need to enter specific private law agreements to safeguard for EHSR compliance of specific interfaces before the purchase, e.g. by requesting an extended declaration of incorporation.[173] While freedom for individual manufacturer-buyer arrangements is essential due to the inherent versatility of use cases for PCMs, there is scope for improving certainty for final users. For instance, a revised MD could require manufacturers of PCM to provide a summary EHSR and

[172] European Association for the Co-ordination of Consumers Representation in Standardisation (2019). ANEC reply to the European Commission Inception Impact Assessment on the Revision of the Machinery Directive 2006/42/EC.

[173] Ostermann, H.J. (2019). Unvollständige Maschinen Ein Teil vom Ganzen - "A Never Ending Story" Im Europäischen Maschinen-Binnenmarkt. Retrieved February 13, 2020. Available at: http://www.maschinenrichtlinie.de/fileadmin/veroeffentlichungen/Unvollstaendige_Maschinen_Maschinenrichtlinie_2006-42-EG.pdf

risk assessment report to end users, and to disclose relevant aspects of the PCM's technical file that do not fall under IP for review.

One example was for dock levellers where the customer wanted to integrate an automatic door with the controls of the dock leveller. While dock levellers are usually not PCM, in this specific case it could be argued that it was given that there was an agreement between the customer and the manufacturer. Another case that caused complications concerned fans in ventilators as it was delivered as partly completed machinery, but the assembler of the ventilator was unsure what to do with regards to the product. This shows part of the difficulties when it comes to classifying the products correctly. In almost every assembly there were discussions due to a lack of know-how. Another uncertainty arises from the text in the Guide. In particular the description of "…machinery that meets the definition in the first three indents of Article 2(a) so it can in itself operate independently, performing its specific application (…) but which only lacks the necessary protective means or safety components, such as guards, is not to be considered as partly completed machinery…". In this case, machinery without guards or safety components are considered completed machinery. The next step continues with "such incomplete machinery does not meet the requirements of the Machinery Directive and must not be CE marked and cannot be placed on the EU/EEA market". The new term of "incomplete machine" was raised by several respondents, as incomplete machines are not mentioned in the scope of the MD. A clarification of complete but not compliant machinery due to missing safety components or protective means could be beneficial.

Manufacturers and industry associations, indicated that the unclarities from the definition did not lead to substantial problems, including a wrong classification or problems with CE marking (see Table 12). However, authorities enforcing the MD, importers, notified bodies and private users mentioned problems with the definition leading to the wrong classification, whereas machinery safety consultants, professional workers and stakeholders involved in standardisation indicated problems with the CE marking.

Table 12: OPC responses on problems resulting from the definition of partly completed machinery

Problems with PCM / Stakeholder group	Wrong classification	Problems with the CE marking	Other problems experienced	No problems experienced
Authority enforcing MD (n=24)	**41.7%**	25.0%	16.7%	29.2%
Consumer organisation (n=3)	0.0%	**33.3%**	**33.3%**	**33.3%**
Distributor (n=6)	0.0%	33.3%	16.7%	**66.7%**
Importer (n=6)	**50.0%**	33.3%	16.7%	33.3%
Industry association (n=64)	29.7%	7.8%	21.9%	**54.7%**
Machinery safety consultant (n=85)	50.6%	**56.5%**	16.5%	24.7%
Manufacturer (n=212)	31.1%	30.7%	12.3%	**49.5%**
Notified body (n=44)	**52.3%**	47.7%	27.3%	40.9%
Private user (n=5)	**40.0%**	20.0%	20.0%	20.0%
Professional worker (n=18)	38.9%	**50.0%**	22.2%	33.3%
Researcher/academic (n=3)	33.3%	0.0%	33.3%	33.3%
Stakeholders involved in standardisation (n=7)	42.9%	**57.1%**	14.3%	42.9%
Other (n=46)	32.6%	34.8%	19.6%	**52.2%**
Total	36.7%	34.4%	17.0%	**43.6%**

Source: OPC results (n=523), multiple answers possible

Even though no substantive problems arise from a lack of clarity of the definition of PCM, certain costs come with the clarification of these uncertainties. These costs are related to additional administrative costs by changing documentation and additional agreements with clients or customers. The size of the costs related to these changes, the meetings required, and the time spent on solving the issues was about EUR 5,000 to 10,000 per case. These costs applied to cases where partly completed machinery was present, for which no documentation is necessary and commercial contracts are needed where it is specified that the supplier should deliver user documentation. In the case where there is no contract, the costs apply. In addition, suppliers from one country might deliver the partly completed machinery together with the documentation in the language of the country of origin. Here, translation costs would apply, which could range from EUR 20,000 to 25,000.[174]

One of the reported impacts of this room for interpretation is increased costs.[175] These may include higher costs for notified bodies and market surveillance actions and potentially manufacturers if using a definition which does not provide legal clarity. Economic operators participating in the study's open public consultation reported that the costs are related to additional administrative costs by changing documentation and additional agreements with clients or customers. The size of the costs related to these changes (e.g. the meetings required, the time spent on solving the issues) was estimated to be between EUR 5,000 and EUR 10,000. These costs could thus be potentially avoided if definition of PCM is better clarified.

2.3.2. Problem 3: Innovation in slow-speed lifts

The current requirement of the MD for slow-speed lifts regarding the control of uncontrolled movement of objects states that "the control devices for these movements must be of the hold-to-run type except where the carrier itself is completely enclosed". Experience in the sector shows that lifts built according to the Machinery Directive do not exhibit the same safety technology level as those complying with the Lifts Directive, as these systems are often installed by 'private' operators.[176] A comparison of non-compliant lift products under the Lifts Directive and Machinery Directive shows that negative impact on compliance is 5.5-times higher under the Machinery Directive than under the Lifts Directive. While in principle, the lifts complying with the Machinery Directive should be no less safe than units engineered in accordance with the Lifts Directive, they are turning up in the accident statistics more frequently. However, no hard statistics could be found on accidents relating to these products but only a few examples. One example is the case of two persons aged 79 and 71 who fell together with a homemade lift in Germany in 2011, an outdoor lift that had been attached to the family home by a family member years before. The lift comprised a platform measuring 1.5 square metres, was fitted with a railing and driven by an electric motor and steel rope. The two persons had boarded the lift to travel to the upper floor and at a height of about two metres, the steel rope parted, and the platform fell, leading to severe injuries to both users. Accidents like these could be prevented if the lifts were built according to the Machinery Directive. Nevertheless, during commissioning, marketing and safety evaluation (risk assessment), the same requirements should apply as for lifts under the Lifts Directive.

At the same time, hold-to-run push buttons allows the platform to stop immediately once the button is released. Automatic controls may be used when the carriage is fully enclosed. This requirement is said to limit innovative technologies such as light barrier curtains. Given the trends in the area of slow-speed lifts and expected growth in usage, also among private users, allowing innovation is essential to enable products to be more efficient, safe and accessible to consumers. At the same time, it is crucial that the Machinery Directive does not hinder such innovation, remaining technology neutral while ensuring safety. Therefore, an assessment on whether imposing the technical specifications of a hold-to-run control does represent such a barrier to innovation is necessary.[177]

[174] Interview responses from manufacturers
[175] European Commission (2019). Machinery directive – revision; Feedback from scoping interviews.
[176] Adldinger, W. (2013). On the rise: lifts as per the Machinery Directive. Available at: https://www.wittur.com/website/get_download.aspx?ctrb_id=4643
[177] No similar requirements could be found in third countries within the research activities.

2.3.3. Problem 4: Extensive production of paper documentation

Requirements for documentation preparation are laid down in Article 5 of the Directive. Before placing machinery on the market and/or putting it into service, manufacturers must do the following: 1) provide the necessary information, such as instructions; 2) follow the appropriate procedures for assessing conformity in accordance with Article 12 and draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery; 3) ensure that the technical file referred to in Annex VII, part A is available.

Requirements for partly completed machinery are similar; the only difference is that partly completed machinery require the submission of the declaration of incorporation. According to Article 13 of the Directive, the manufacturer of partly completed machinery or its authorised representative shall, before placing the partly completed machinery on the market, ensure that: (a) the relevant technical documentation described in Annex VII, part B is prepared; (b) assembly instructions described in Annex VI are prepared; (c) a declaration of incorporation described in Annex II, part 1, Section B has been drawn up. When the partly completed machinery is incorporated into the final machinery, the instructions and declaration of incorporation become part of the final machinery's technical file. Until the incorporation, the instructions and declaration of incorporation accompany the partly completed machinery.

Currently, the Commission Guide on the application of the MD requires manufacturers to provide paper documentation for health and safety related instructions and conformity declaration. This is largely due to the market characteristics that existed during its implementation, namely the lack of access to the internet and other digital formats. Thus, to ensure that every machine user has access to the instructions, providing a printed version was selected as the most viable option. Since then, however, the use of the internet and digital technologies has increased. Therefore, it is likely that the requirements to provide printed versions, which increases the costs and administrative burdens for economic operators and has a negative impact on the environment due to the printing activities related to providing this documentation, might no longer have the same effects.

Considering the costs that printed manuals impose, in the 2011 study on the administrative burden reduction at the local and regional level, the Committee of Regions identified manual administrative procedures, as opposed to e-services, is the main cause for administrative burden for public institutions and local entrepreneurs[178]. While paper itself may not be expensive, the costs spent on storage, copying, printing and postage add up expenses. Printing costs can be high as to 3% of the company's revenues, and in big corporations it can reach up to 10% of the corporation's revenue[179,180]. This represents monetary value of about EUR 228,000 in case of 3% estimation and up to EUR 22 million in case of 10% estimation for larger corporations[181]. Other sectors, such as the freight transport, have indicated significant or at least expected benefits from adopting electronic information/documentation exchange. SMEs, in particular, expected positive results from using electronic information. Digital documentation in the MD context could thus also lead to cost savings for the economic actors, especially smaller enterprises.

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[178] European Union Committee of regions (2011). Administrative burden reduction at the local and regional level. Available at: https://cor.europa.eu/en/engage/studies/Documents/administrative-burden-reduction.pdf.

[179] Data Scope (2019). How much paper waste is costing your business? Available at: https://www.mydatascope.com/blog/en/2018/03/08/how-much-paper-waste-is-costing-your-business/

[180] Smith, R. (2011). The Environmental Sustainability of Paper. Graduate Studies Journal or Organizational Dynamics. Available at: https://repository.upenn.edu/cgi/viewcontent.cgi?article=1003&context=gsjod

[181] The calculation arrives from multiplying the estimation with the machinery sector's turnover per company for 3% calculation and turnover per large company for 10% calculation.

While it is widely accepted that digitalising activities, such as introducing electronic invoicing, is an opportunity to improve productivity, these activities are an essential component of the low carbon economy. When taking the example of electronic invoicing it shows that the carbon footprint of the invoice can be over 75% smaller than that of a paper version.[182] Therefore, there is potential to capture these environmental benefits in the provision of digital documentation related to the MD.

The environmental costs associated with the paper documentation range from sourcing through manufacturing to disposal. One key impact of printing is the use of primary material for papermaking, wood, which is critical for terrestrial carbon dioxide storage.[183] Considering that more than 40% of industrial wood harvest is used for paper manufacturing[184], that the paper industry is the largest user of industrial process water per ton of end product and the fourth-largest contributor to water pollution, as well as the high energy consumption needed for the production of one sheet of paper[185], the aspect of requiring manufacturers to print handbooks should be considered in light of the environmental impacts caused, especially when keeping in mind that an instruction handbook for a lawnmower can comprise 50 pages and up to 1,200 pages when translated. This would apply to about 3 billion manuals produced in a year in the machinery sector, assuming one manual per sold item of machinery.[186]

Overall, while the MD does not specify the format in which user manuals have to be provided, the Guide requires a printed version. This has an impact on administrative burden, industry cost and environmental harm. Only the MD has legal value, thus changing the Guide to match the flexibility of the Directive could provide benefits to various actors in the sector.

2.3.4. Problem 5: Modifying Annex IV

The MD is primarily a directive to which compliance is assessed through internal checks. Nevertheless, there are products of high risk listed in Annex IV of the current MD, which includes types not permitted to be assessed through internal checks if the machinery was not manufactured in full accordance with all relevant harmonised standards listed under the MD.

Regarding the question of whether the internal checks option leads to safety concerns, the results of the public consultation indicated a split of opinions. Among those stakeholders that indicated increased safety concerns were authorities enforcing the MD, distributors, importers, notified bodies, private users and professional workers. **The reason for the safety concerns arise mostly due to a lack of technical knowledge of all the safety requirements or the standards**. An overview of the Rapid Alert System for Non-Food Products (RAPEX) over the years shows that some of the products falling under Annex IV of the MD have been identified as not being compliant with the requirements of the MD and the relevant European Standard, thus justifying the need for the modification of the Annex IV by those who claim that internal checks option of the products under the Annex IV leads to safety concerns. Some of the products in the RAPEX alert notification system include circular saws, angle grinder, electric scooters and vehicle lifts. For the concerned stakeholders, third-party certification is

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[182] Tenhunen, M, & Penttinen, E (2010). Assessing the carbon footprint of invoicing. Aalto University School of Economics. Available at: https://www.researchgate.net/publication/228912775_Assessing_the_carbon_footprint_of_paper_vs_electronic_invoicing

[183] Smith, R. (2011). The Environmental Sustainability of Paper. Graduate Studies Journal or Organizational Dynamics. Available at: https://repository.upenn.edu/cgi/viewcontent.cgi?article=1003&context=gsjod

[184] Ibid.

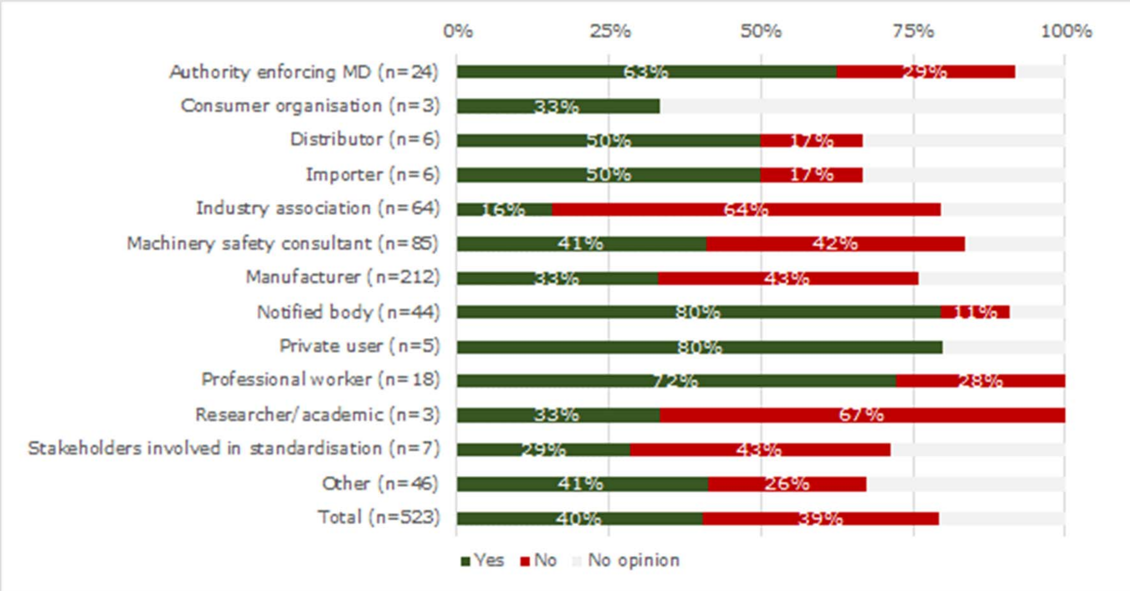
[185] Ibid.

[186] This number of manuals represents the volume of sold machinery but might be underestimated, as the number of sold machinery excludes many products for which the measure is different than p/st or that are not available in the statistics. Therefore, the actual number of manuals printed might be higher and OPC responses estimated about 16 billion manuals for the machinery sector.

linked to higher quality and safer machinery, which was also indicated to be the best course of action, rather than surveillance authorities acting at later stages.

To some extent, the aim to minimise costs was also mentioned as a reason for lower conformity with standards in relation with machinery under internal checks. In particular, lift manufacturers indicated that internal checks lead to safety concerns. However, industry associations, manufacturers, researchers/academics and stakeholders involved in standardisation did not see an increase of safety concerns in relation to this option. It is estimated that 10% of machinery falls under internal checks of Annex IV machinery. In cases where the internal checks option is removed, it can thus be estimated that 312,261,954[187] of machines will be affected under such a scenario.

Figure 18: Stakeholders' opinion on increased safety risks posed by internal checks of Annex IV machinery



Source: Open public consultation

2.3.5. Problem 6: Differences in implementation of the Machinery Directive in EU Member States

All Member States have communicated the national transposition. The 12 non-communication cases and 15 formal infringement procedures that were opened had been closed by 2015.

In general, the evaluation of the Machinery Directive has shown that the implementation and application of the Directive is largely consistent across Europe and that it has greatly contributed to the harmonisation of national legislations. Regarding issues with exports, the interviewed industry representatives reported that issues have been encountered with exporting to Turkey related to the different interpretation of the MD by the Turkish custom officers. These issues were mostly of administrative nature in relation to the DoC and CE marking, which were not considered sufficient by the authorities. In addition, stakeholders have experienced problems regarding the interpretation of harmonised standards when delivering to Switzerland, along with difficulties relating to stricter health and safety national authorities and the organisations responsible for checking the machines in France. Some

[187] Own calculations based on PRODCOM statistics and the evaluation of the Machinery Directive.

differences also arise through interpretation in terms of translation, which lead to broader wording to describe products than originally intended. These administrative costs were indicated to amount to between EUR 100 and 500 to write letters, print papers and resolve differences. Differences in interpretation could be reduced by converting the Directive into a regulation.

A Directive allows countries to devise their own laws on how to reach the goals and thus risks different and/or delayed transposition. In the case of the Machinery Directive, the Member State laws and regulations necessary to implement the MD were due by 29 June 2008, with application from 29 December 2009. From June 2008 to the deadline for Member States to notify the Commission about their transposition measures, 12 non-communication cases were opened. By the end of 2008, three Member States (Greece, Italy and Luxembourg) had still not notified the Commission.[188] The Italian case was closed in March 2010 following reasoned opinion, and Luxembourg and Greece both received a court referral, which was subsequently withdrawn for Luxembourg and closed in 2010 for Greece. By the end of 2010, all infringement proceedings for non-communication of national measures implementing Directive 2006/42/EC were closed following receipt of the national transposition measures.[189] Fifteen formal infringements procedures were opened against Member States for reasons other than the 'non-communication' cases (AT, BE, CY, CZ, FI, FR, DE, GR, HU, IT, LU, NL, SI, ES, UK). The specifics of these procedures are not explained in detail, but these cases were all closed after the first infringement stage (receival of the letter of formal notice). [190]

A cost-benefit analysis in 2008 on the transposition of the MD in the UK indicated total costs of GBP 15 to 17 million (EUR 18.8 to 21.4 million) and total benefits of GBP 16 to 105 million (EUR 20.1 to 131.9 million)[191]. The key costs were expected to fall on manufacturers and importers based on the placing of machinery on the market, as well as the familiarisation and training costs. On the other hand, the key benefits expected were greater competition and innovation, as well as the removal of non-compliant machinery.[192]

Another hindering factor might be that national legislation goes beyond the requirements set out in the MD. These diverging interpretations or application of the MD has an impact on trade in the internal market and might pose barriers to the competitiveness of the market. The majority of OPC respondents expressed support for the conversion of the MD into regulation.

Table 13: Would you be in favour of having exactly the same rules on machinery safety applicable at the same time across the EU (converting the Directive into a Regulation)?

Results (total)	Yes	No	I do not know
%	79%	5.4%	15.7%

Source: OPC Results (n=523)

[188] 26th Report on monitoring the application of Community law [COM(2009) 675] – Situation in the different sectors [SEC(2009)1684/2].

[189] 28th REPORT FROM THE COMMISSION ON MONITORING THE APPLICATION OF EU LAW (2010) {COM(2011) 588 final} {SEC(2011) 1094 final} – Situation in the different sectors.

[190] Commission Staff Working Document. Evaluation of the Machinery Directive. {SWD(2018) 161 final}. Available at: https://ec.europa.eu/transparency/regdoc/rep/10102/2018/EN/SWD-2018-160-F1-EN-MAIN-PART-1.PDF

[191] Converted using the European Commission's InforEuro, baseline 2008.

[192] UK Government (2008). Explanatory memorandum to supply of machinery (safety) regulations 2008 (2008 No. 1597). Available at: http://www.legislation.gov.uk/uksi/2008/1597/pdfs/uksiem_20081597_en.pdf

3. WHY SHOULD THE EU ACT?

3.1. Does the EU have the right to act?

The EU follows its own general objectives that provide the rationale for an EU-wide action regarding the provision and revision of the Machine Directive. Generally, the EU protects and ensures the protection of human rights for all citizens. The provision of safety and labour standards is part of the implementation of economic, social and cultural rights and reinforced through the European Instrument for Democracy and Human Rights (EIDHR) strategy 2014-2020.[193]

The first paragraph of the Article 153 of the Treaty on the Functioning of the European Union (TFEU)[194] empowers the European Union to support and complement the activities of the Member States in improving the working environment to protect workers' health and safety. Article 169 encourages the Union to contribute to the protection of health, safety and economic interests of consumers. In addition, it takes as a base a high level of protection, taking into account new developments based on scientific facts.

The machinery sector is a highly relevant part of the engineering industry and one of the industrial drivers of the European Community economy. The MD is a vital **driver of safety provision for machinery users** in the EU. The main objective of the Directive is to ensure a high level of health and safety protection of these users, thus covering key objectives of the EU and those set out in the TFEU. In particular, the MD contributes to the reduction of social costs of the large number of accidents caused by the use of machinery. A key rational for an EU-level Machinery Directive is the provision of harmonisation across Member States based on Article 114 TFEU. On this basis, the MD provides a specific basis for action.

3.2. Why is EU action needed and what is its added value?

Following the identified shortcomings under the evaluation of the MD, without an EU-wide regulation, Member States could provide different types of standards, which would lead to differences in safety standards for the population, inequalities in prices and increase the adaptation costs between one country to the other when trading machinery.

Further simplification of the MD through the revision the Directive would further decrease barriers to trade and the social costs of accidents decreased through the provision of harmonised procedures in market surveillance activities, and it would improve the removal of non-compliant machinery. Furthermore, addressing challenges stemming from the use of new technologies in machinery has the potential of ensuring minimum levels of safety in relation to current market developments and future trends. This is similar to the alignment of the Directive to the NLF and the adaptation of definitions. Currently, as indicated above, there are aspects that leave room for interpretation across Member States. By revising these, the EU would reduce uncertainties in the implementation of the directive and cross-border trade barriers as well as decrease compliance costs, among others. Revising the requirements for the provision of manuals is also relevant for the EU in order to ensure equal safety and access for all machine users in the Member States, but also to work towards the environmental objectives of the EU and the functioning of the Single Market.

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[193] European Commission (n.d.). Economic, social and cultural rights. Available at: https://ec.europa.eu/europeaid/sectors/human-rights-and-governance/democracy-and-human-rights/economic-social-and-cultural-rights_en

[194] European Commission (2012). Consolidated version of the Treaty on the Functioning of the European Union. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=EN

EU action is necessary also given the solutions provided by the European Standardisation Organisations that develop European standards. The compliance with these standards is voluntary, but they support EU legislation and policies. They are developed by industry and market actors and ensure interoperability, and safety, reduce costs and facilitate companies' integration into the value chain and trade. On March 2019, the new list of harmonised standards under the Machinery Directive were published in the Official Journal of the EU.[195] Further developments of standards might pave the way to provide solutions to the problems outlined in Chapter 2. Given the level of this approach, any changes to the scope or requirements have therefore to be made at EU level in order to avoid a market distortion or the creation of barriers to the movement of products and the undermining of health and safety.

[195] European Commission (2019). Commission Implementing Decision (EU) 2019/436 of 18 March 2019 on the harmonised standards for machinery drafted in support of Directive 2006/42/EC of the European Parliament and of the Council. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.075.01.0108.01.ENG&toc=OJ:L:2019:075:TOC

4. WHAT SHOULD BE ACHIEVED?

The revision of the Machinery Directive follows general and specific objectives aimed at addressing and solving the problems outlined in the Chapter above. This section introduces these objectives. Chapter 5 describes the policy options under consideration to reach these objectives.

4.1. General objectives

The general policy objectives to be pursued in order to address the problems outlined above follow those of the Machinery Directive itself:

- **General objective 1: Ensure a high level of safety and protection for users of machinery and other people exposed to it.**

This major objective pursued by the revision of the Machinery Directive is that the level of safety set for machinery is assured also for emerging technologies which are being developed or will be developed in the future. In particular, this relates to the underlying general objective **to establish a high level of trust in digital innovative technologies**. This general objective thus aims to address the risks emerging from new technologies in machinery, such as AI, IoT and robotics (problem 1).

- **General objective 2: Ensure the well-functioning of the (digital) single market.**

The objective is natural to the Machinery Directive as a total harmonisation directive based on Article 114 TFEU and on the 'new approach' that sets up the essential requirements, which products must satisfy to benefit from the free movement of products across the Single Market. While the Single Market has brought benefits to citizens and businesses through this free movement of products, administrative obstacles and lack of enforcement leaves room for further potential.[196] The second general objective of the revision of the MD is to implement a regulatory framework that is consistently applied across the EU and allow manufacturers and other economic operators affected by diverging national implementation and unclarities with the current framework to exploit the full potential of the Single Market while ensuring the highest level of safety.

This general objective 2 relates to the underlying objective **to create a level playing field for economic operators and preserve the competitiveness of machinery sector in global digital markets.** Specifically, this objective aims to address all the identified problems above.

4.2. Specific objectives

These general objectives can be further detailed by the specific objectives which contribute to the achievement of the overall objectives.

- **Specific objective 1:** Cover new risks brought by new digital technology, AI, IoT (e.g. cybersecurity), robotics

The aim of this objective is to ensure that the MD covers challenges brought by new technology used in machinery but also in general (e.g. cybersecurity) and to ensure the highest level of safety of users and others exposed to machinery. At the same time, it is important to make sure that specific objective 1 does not hinder the achievement of general objective 2.

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[196] European Commission (n.d.) Single Market Act. Available at: https://ec.europa.eu/growth/single-market/smact_en

- **Specific objective 2:** Ensure coherent interpretation of the scope throughout the EU

This specific objective relates in particular to the general objective 2, while contributing to achieving general objective 1. By ensuring a coherent interpretation of the scope throughout the EU, this objective also aims to address one of the shortcomings identified in the REFIT evaluation, problem 2.2.

- **Specific objective 3:** Alignment to NLF procedures

Following the specific objective 2, the objective of aligning the MD to the NLF aims to contribute to achieve the general objective 2. It not only contributes to creating a level-playing field in the Single Market but also to reduce the differences between the MD and other 'new approach' Directives currently under the NLF. It thus aims to solve problem 2.1.

- **Specific objective 4:** Allow innovative technologies to be used for slow-speed lifts

This objective contributes to achieving general objective 1 and 2, especially preserving the competitiveness of the machinery sector while ensuring the highest safety for users (general objective 1) and thus addressing problem 4.

- **Specific objective 5:** Reduce administrative requirements related to documentation

While reducing administrative burden related to documentation might contribute to many objectives, in this case it aims to address the shortcomings outlined under problem 3 and the production of paper documentation. This objective relates to specific objective 3 as requirements for documentation are set out in the NLF.

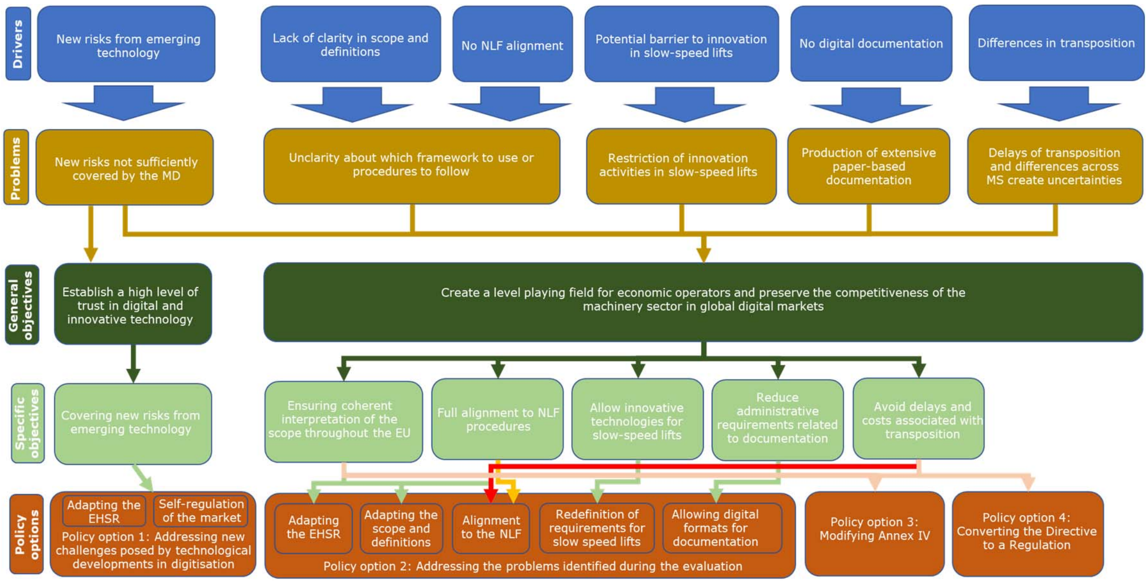
- **Specific objective 6:** Avoid delays and costs associated with the transposition

This specific objective aims to reduce the shortcomings of different transposition of the MD in Member States and the EEA as a whole. In particular, it contributes to achieving general objective 2.

5. WHAT ARE THE VARIOUS OPTIONS TO ACHIEVE THE OBJECTIVES?

This chapter introduces the different policy options to address the objectives pursued by the revision of the MD. Before the introduction, some preliminary remarks are made to shape the discussion of the individual options.

Figure 19: Problem tree



5.1. Baseline: No EU action

The baseline scenario of the revision consists in no EU action, meaning no change to the current regulatory framework is made. This option is not assessed in detail as it would mean an onset or continuation of the shortcomings identified in the Evaluation of the Machinery Directive, among others. For instance, a no-action scenario would contradict the European Commission's commitment to aligning, where appropriate, existing legislation to the NLF.[197] A baseline following no EU action would also mean that the problems outlined above would remain, which would hamper the objective of contributing to a well-functioning Single Market and trade of goods in the EU and the EEA as a whole. Some of those problems include unclarities with the concepts that generate additional costs for clarifications or differences in interpretations across Member States. Without a further harmonisation of the market potentially brought by the suggested revisions, the opportunity of decreasing the share of non-compliant products on the market might not be exploited, which could otherwise indirectly benefit machinery users as well.

In addition, no action would likely lead to Member States taking additional actions at national level (e.g. providing additional requirements or providing clarifications of concepts that might differ from those of other Member States), which would further undermine the functioning of

[197] Decision No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a common framework for the marketing of products. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008D0768&from=EN and Regulation (EC) No 765/2008 of the European Parliament and of the Council. Available at: https://publications.europa.eu/en/publication-detail/-/publication/fdd70f57-7032-4121-92ae-ccf8ef68c15b/language-en

the internal market and potentially the level of safety and health of machinery users and others exposed to machines.

Nevertheless, the baseline scenario is taken to measure the potential impacts of the policy options vis-à-vis the current state. The baseline option is not the current state but the state that would develop without any additional EU action. It is the comparator against which the impacts of each active policy option is judged. While the baseline scenario is expected to have no impact on stakeholder groups given that no action is taken ("0"), the other policy options include some degree of change. Thus, it is likely that they will generate positive "+" or negative "-" effects on certain stakeholder groups. Depending on the policy option and the suggested change to the Directive, it is also possible that some stakeholder groups might not be affected by the suggested change ("0"). The assessment of policy options compares the benefits and disadvantages to the baseline.

5.1. Policy Option 1: Addressing new challenges posed by technological developments in digitisation

To achieve the general objective 1, as well as specific objective 1, option 1 addresses specifically the issue of new risks through emerging technologies in machinery not being explicitly covered by the Machinery Directive. There are two potential approaches, which are not mutually exclusive, to addressing these new risks:

- Policy option 1.1 – Adapting the essential health and safety requirements (EHSR) of the Directive to explicitly address aspects related to digital emerging technologies; and
- Policy option 1.2 – Addressing the challenges posed by innovation in digitisation through self-regulation by market participants.

Adapting the EHSR under policy option 1.1 could entail a varying degree of potential changes, such as complementing, redefining or adding new General Principles (Annex I) to address emerging risks posed by digitisation (e.g. cybersecurity, collaborative robots, autonomous behaviour of machines or the iterative process of risk assessment and risk reduction measures).

5.2. Policy Option 2: Addressing the problems identified during the evaluation of the Machinery Directive

According to the evaluation of the Machinery Directive, the main recommendations for potential adaptations are focused in five sections:

- Aligning to the NLF
- Allowing digital formats for documentation
- Adapting the scope and the definitions
- Adapting the essential health and safety requirements (EHSR)
- Redefining the requirements for completely enclosed carrier or control of movements for slow-speed lifts

Option 2 is divided into several sub-options, which can be applied regardless of the **NLF alignment.** These sub-options are not mutually exclusive, neither is option 2 mutually exclusive with other options.

5.2.1. Adapting the scope and the definitions in the Directive

The first sub-option under option 2 covers adapting the scope and definitions of the Directive to clarify issues that are found to cause complications for the stakeholders. These include reviewing the threshold speed for slow-speed lifts covered (currently 0.15 m/s)[198], adapting/ clarifying some of the terms in the list of low-voltage products excluded and improving the definition of 'partly completed machinery' to make it easier for the stakeholders to identify which framework to use. The potential adaptation of scope and definitions touches the key areas of focus for this study but might also provide insights and solutions to other unclarities identified throughout the study. Thus, the assessment of this policy sub-option focuses on slow-speed lifts, the list of low-voltage products excluded and improving the definition of partly completed machinery. Further potential remarks on other unclarities with the current scope and definitions will be analysed in less depth afterwards.

Currently, the Low Voltage Directive covers electrical products that are within the voltage limits of 50 V AC to 1,000 V AC and 75 V DC to 1,500 V DC.[199] The majority of electrical products are tested against the requirements of four directives, namely the LVD, ATEX, TSD[200] or EMCD. Electrical products may also fall under the MD and manufacturers may use the following European standards in support of the application of MD among others: i) EN 60204 Safety of Machinery – Electrical Equipment of Machines; ii) EN 62061 – Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems; or iii) EN 60335 – Household and similar electrical appliances.[201] However, certain categories of electronic products are specifically mentioned for exclusion from the MD if they are covered by the LVD. These include: i) household appliances intended for domestic use; ii) audio and video equipment; iii) information technology equipment; iv) ordinary office machinery; v) low-voltage switchgear and control gear; and vi) electric motors. Some unclarities have arisen from this listing of specific categories, as indicated in section 2.3.1.2. However, to mitigate and reduce these unclarities, the policy option 2 covers potential changes to this list.

5.2.2. Adapting the essential health and safety requirements

The second sub-option covers adapting the essential health and safety requirements of the Directive. Within it, there are two further sub-options, which may both be applied.

5.3.2.1 Allowing digital formats for documentation

The first sub-option under adapting the essential health and safety requirements would explicitly allow digital formats for all documentation under the Machinery Directive.

Currently, the Declaration of Conformity and user manual are currently produced in paper format. However, this requirement is not specified in the MD itself, but rather in the Guide. Therefore, as an additional sub-option we examine allowing digital documentation by modifying the Guide only.

5.3.2.2 Redefining the requirements for completely enclosed carrier or control of movements for slow-speed lifts to permit innovative technologies to be used for achieving a carrier completely enclosed

The second sub-option under adapting the essential health and safety requirements addresses the rules currently prescribing a technical solution where the user needs to press a button throughout the movement of the platform. Given the technical progress in the sector, it is possible to revise this requirement to allow innovative technologies to be used, such as light

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[198] One result of this study was that an increase of the speed is not desirable.
[199] National Electrical Safety Board Sweden (2014). Action plan for market surveillance (Ref no. 14EV4508). Available at: http://ec.europa.eu/DocsRoom/documents/8624/attachments/7/translations/en/renditions/native
[200] In particular the Annex on electrical toys
[201] European Commission (2019). Directive 2006/42/EC on Machinery – summary list of titles and references of harmonised standards. Available at: https://ec.europa.eu/docsroom/documents/38571

barrier curtains, as far as compliance with the ESHRs of the MD is ensured. This would be in line with the technological neutral principle enshrined in the 'new approach' legislation.

A visualisation of all the sub-options comprised under policy option 2 is given below (see Table 14).

Table 14: Sub-options of Policy Option 2

<table>
<tr><td rowspan="8">Option 2 – Addressing the problems identified during the evaluation of the Machinery Directive</td><td colspan="2">2.1 Alignment to the New Legislative Framework, without any change in the substantial contents of the current legal act (scope, definitions, essential health and safety requirements)</td><td>2.1.2 Allowing digital formats for documentation by modifying the Guide to application of the Machinery Directive</td></tr>
<tr><td colspan="3">2.2 Allowing digital formats for documentation by modifying the Guide to application of the Machinery Directive, without alignment to the NLF</td></tr>
<tr><td rowspan="3">2.3 Alignment to the New Legislative Framework, with changes in the substantial contents of the current legal act</td><td colspan="2">2.3.1 Adapting the scope and the definitions in the Directive, e.g. review the threshold speed for slow-speed lifts covered or adapt list of low-voltage products excluded, and improve the definition of 'partly completed machinery'</td></tr>
<tr><td rowspan="2">2.3.2 Adapting the essential health and safety requirements (EHSR)</td><td>2.3.2.1 Allowing digital formats for documentation by modifying the EHSR</td></tr>
<tr><td>2.3.2.3 Redefinition of the requirements for completely enclosed carrier or control of movements for slow-speed lifts to permit innovative technologies to be used for achieving a carrier completely enclosed</td></tr>
<tr><td rowspan="3">2.4 Changes in the substantial contents of the current legal act without alignment to the NLF</td><td colspan="2">2.4.1 Adapting the scope and the definitions in the Directive, e.g. review the threshold speed for slow-speed lifts covered or adapt the list of low-voltage products excluded, and improve the definition of 'partly completed machinery'</td></tr>
<tr><td rowspan="2">2.4.2 Adapting the essential health and safety requirements (EHSR)</td><td>2.4.2.1 Allowing digital formats for documentation by modifying the EHSR</td></tr>
<tr><td>2.4.2.3 Redefinition of the requirements for completely enclosed carrier or control of movements for slow speed lifts to permit innovative technologies to be used for achieving a carrier completely enclosed</td></tr>
</table>

5.3. Policy Option 3: Modifying Annex IV

In the majority of cases, safety of machinery can be assessed by manufacturers internally (internal checks). They may voluntarily comply with harmonised standards to meet the EHSR. The exception is high-risk machinery listed in Annex IV of the current MD, which includes types of high-risk machinery that are permitted to be assessed through internal checks, only if the machinery is manufactured in full accordance with harmonised standards. If the standards are not fully complied with or in the case of non-existing standards, manufacturers of these high-risk machines are required to involve a third party (e.g. notified bodies) for the conformity assessment.

One of the questions in this revision of the Directive is whether the internal checks option when standards are complied with for high-risk machinery provides sufficient levels of safety and whether the list of product categories in the Annex is up to date with the market. In case Annex IV is modified, this would mean potential inclusion of further types of machines or the exclusion of others currently listed in Annex IV. Removing Annex IV would mean that all risk categories of machinery are assessed through internal checks. On the other hand, if the internal checks option for Annex IV machinery is removed, there is a need for conformity assessments run by third parties (notified bodies) even when standards are complied with.

The summary of policy option 3 and its sub-options is provided in the following table.

Table 15: Overview of sub-options of policy option 3

Option 3 – Modifying Annex IV	3.1 Removing the internal checks option when the product is manufactured in accordance with harmonised standards
	3.2 Updating Annex IV
	3.3 Removing Annex IV

The assessment of the status of Annex IV is relevant to contribute to the achievement of general objective 1, ensure the highest safety of machinery users and persons exposed to machines. These are the policy options decided during the inception phase of this study. Another sub-option that could have been investigated is adding a third-party conformity assessment module rather than a complete switch to third-party conformity assessment only.

5.4. Policy Option 4: Conversion of the Directive into a Regulation

Option 4 addresses the legal instrument of the chosen policy option. It is therefore not mutually exclusive with either option 1, option 2 or option 3. Under option 4, the Machinery Directive would be converted to a regulation, becoming immediately applicable and enforceable by law in all Member States. This option would avoid any present or future transposition infringements or differences.

5.5. Combination of policy options

The policy options 1 to 4 are not mutually exclusive, thus a combination of the options may be selected. The table below summarises all the options and their combinations (see Table 16).

Table 16: Overview of all policy options

<table>
<tr><th>Policy option</th><th colspan="3">Policy sub-option</th></tr>
<tr><td rowspan="2">Option 1 – Addressing new challenges posed by technological developments in digitisation:</td><td colspan="3">1.1 Adapt the essential health and safety requirements of the Directive to explicitly address aspects related to digital emerging technologies</td></tr>
<tr><td colspan="3">1.2 Address the challenges posed by innovation in digitisation through self-regulation by market participants</td></tr>
<tr><td rowspan="8">Option 2 – Addressing the problems identified during the evaluation of the Machinery Directive</td><td colspan="2">2.1 Alignment to the New Legislative Framework, without any change in the substantial contents of the current legal act (scope, definitions, essential health and safety requirements)</td><td>2.1.2. Allowing digital formats for documentation by modifying the Guide to application of the Machinery Directive</td></tr>
<tr><td colspan="3">2.2 Allowing digital formats for documentation by modifying the Guide to application of the Machinery Directive, without alignment to the NLF</td></tr>
<tr><td rowspan="3">2.3 Alignment to the New Legislative Framework, with changes in the substantial contents of the current legal act</td><td colspan="2">2.3.1 Adapting the scope and the definitions in the Directive, e.g. review the threshold speed for slow-speed lifts covered or adapt the list of low-voltage products excluded, and improve the definition of ‘partly completed machinery’</td></tr>
<tr><td rowspan="2">2.3.2 Adapting the essential health and safety requirements (EHSR)</td><td>2.3.2.1 Allowing digital formats for documentation by modifying the EHSR</td></tr>
<tr><td>2.3.2.3 Redefinition of the requirements for completely enclosed carrier or control of movements for slow-speed lifts to permit innovative technologies to be used for achieving a carrier completely enclosed</td></tr>
<tr><td rowspan="3">2.4 Changes in the substantial contents of the current legal act without alignment to the NLF</td><td colspan="2">2.4.1 Adapting the scope and the definitions in the Directive, e.g. review the threshold speed for slow speed lifts covered or adapt the list of low voltage products excluded, and improve the definition of ‘partly completed machinery’</td></tr>
<tr><td rowspan="2">2.4.2 Adapting the essential health and safety requirements (EHSR)</td><td>2.4.2.1 Allowing digital formats for documentation by modifying the EHSR</td></tr>
<tr><td>2.4.2.3 Redefinition of the requirements for completely enclosed carrier or control of movements for slow-speed lifts to permit innovative technologies to be used for achieving a carrier completely enclosed</td></tr>
<tr><td rowspan="3">Option 3 – Modifying Annex IV</td><td colspan="3">3.1 Removing the internal checks option when the product is manufactured in accordance with harmonised standards</td></tr>
<tr><td colspan="3">3.2 Updating Annex IV</td></tr>
<tr><td colspan="3">3.3 Removing Annex IV</td></tr>
<tr><td colspan="4">Option 4 – Conversion of the Directive into a regulation</td></tr>
</table>

6. WHAT ARE THE IMPACTS OF THE DIFFERENT POLICY OPTIONS AND WHO WILL BE AFFECTED?

There are substantive compliance costs arising from the application of the Directive across product category. The size of the costs largely depends on the product portfolio, the familiarity with the Directive and the type of assessment. The relevant stakeholder affected by the Directive in relation to obligations and compliance are the economic operators (manufacturers, distributors, and importers), market surveillance authorities (MSAs), and notified bodies (NBs). The main costs entailed by complying with the Directive can be classified as listed below.

- Enforcement costs borne by MSAs: costs arising from market surveillance activities, withdrawal of non-compliant products from the market, assessing NBs and periodic communication with the Commission and other Member States;
- Substantive compliance costs affecting NBs: costs to ensure their ability to perform their duties, e.g. training costs, cost of human resources, purchasing standards;
- Substantive compliance costs for economic operators: costs arising to ensure compliance with the EHSRs, purchasing of standards, costs for staff training and human resources to conduct conformity assessments, NBs' service fees in the case of involvement of a third party for assessments; and
- Administrative burden impacting economic operators: costs related to the CE marking, production of documents including the DoC, technical file, user manual and archive for the period required (i.e. 10 years).

A short list of regulatory costs is provided below.

Table 17: Regulatory costs related to the implementation of the Machinery Directive

Stakeholder	Type of cost	Description
MSA	Enforcement cost	Costs due to inspection activities
MSAs	Administrative burden	Costs due to information obligations of MS towards the EC and other MS
NB	Substantive compliance costs	Initial and recurring training expenses related to familiarisation and training
NB	Substantive compliance costs	Periodic costs of purchasing harmonised standards
Eos	Substantive compliance costs	Cost of conformity assessment (variable on the type of assessment)
Eos	Substantive compliance costs	Periodic costs of purchasing harmonised standards
Eos	Substantive compliance costs	Initial and recurring training expenses: i) familiarisation with the Directive; ii) year-on-year training
Eos	Substantive compliance costs	Other costs (e.g. equipment, re-engineering, other third-party services) that are not subject to the Directive but business as usual
Eos	Administrative burden	DoC, technical file, CE marking
NB	Administrative burden	DoC, technical file, CE marking

Source: Evaluation of the Lifts Directive

According to experts consulted, major changes in the EHSR lead to substantive one-off costs for the industry in terms of training for technical files, documentation etc. This can be mitigated by keeping the numbering as close to the current version as possible, adding new chapters for new EHSR or providing a transposition table between the revised EHSR numbering and the original, as was provided in the last revision of the Machinery Directive. A change of the wording for better legal clarity will impose some adaptation costs, though they are expected to be substantially lower. In addition, a revision of the EHSR will results in major costs for the revision of standards borne by CEN/CENELEC to ensure that the list of harmonised standards is up to date and fits the revised EHSR. This might slow down the regular revisions of the standards.

6.1. Impacts of policy option 1: Addressing new challenges posed by technological developments in digitisation

The machinery sector was mentioned in the introduction of this document; an extensive overview is provided in the Annexes. Impacts of policy Option 1: Addressing new challenges posed by technological developments in digitalisation

In general, most stakeholders of all groups participating in the 98 semi-structured interviews did not report any instances of **health and/or safety incidents resulting from the use of machinery with AI or IoT implementations**. Out of the four stakeholders that had (anecdotal) data to report, one national authority in Germany reported a fatal accident involving an industrial robot. In 2015, a technician had a fatal accident caused by an industrial robot at a Volkswagen plant when the technician (contractor) was standing inside the safety cage.[202] This was an accident not related to any AI or programme fault but due to a person being in a danger zone that was meant to be guarded to exclude personnel. On IoT, one consumer organisation noted that the scope is not very clear, and that the requirements for IoT products are not necessarily sufficient to provide the necessary levels of security, and one noted a case of an unprotected connected toy that was open to hacking due to lack of password protection[203]. Indeed, most examples mentioned in the interviews and the OPC responses referred to a lack of security in terms of connection rather than safety incidents. This might change in the future considering the expected growth in usage of new technologies (see Chapter 1).

6.1.1. Adapting the essential health and safety requirements (EHSR) of the Directive to explicitly address aspects related to digital emerging technologies

Given the development of the sector and the potential risks that might arise in relation to users of machinery with new technology applications (see section 2.2), one option considered by this revision is to adapt the existing EHSR to explicitly address these aspects.

Changes in the EHSR could have positive and negative impacts, as visualised in the table below.

[202] Financial times (2015). Worker at Volkswagen plant killed in robot accident. Available at: https://www.ft.com/content/0c8034a6-200f-11e5-aa5a-398b2169cf79

[203] This product, however, does not fall under the scope of the Machinery Directive.

Table 18: Potential impacts of policy sub-option 1.1

Policy option 1.1	Positive impacts	Negative impacts
Economic impacts	• Increased legal clarity leading to a more coherent interpretation of the scope and the definitions	• Additional costs related to the adaptation to the changes, in particular for Economic Operators, notified bodies and Market Surveillance Authorities
Social impacts	• An indirect result from the increased legal clarity could be for users to having access to products of the same levels of safety on the market	• None identified
Environmental impacts	• None identified	• None identified

The changes will also likely impact all stakeholder groups in terms of compliance costs. The degree of these costs would depend on the level of the revisions. Minor revisions in terms of complementing current EHSR are not expected to lead to substantial cost increases. In comparison, larger scale revisions would lead to more substantial costs. The main expected costs are one-off adaptation costs to the changes, their size depending on the degree of revisions. The exact costs could not reliably be quantified due to the low response rate and lack of detailed feedback on the drivers of these costs. A few manufacturers indicated in the Open Public Consultation potential one-off costs of about 8% of annual turnover on average with regards to changes in EHSR related to new technologies (e.g. collaborative robots) .[204] In terms of impacts on the workforce, interviewees indicated an increased need for IT personnel and specialists in software, safety and robot technologies. Notified bodies estimated their additional one-off costs of compliance to reach on average about 1% of annual budget. Stakeholders involved in standardisation, in particular CEN/CENELEC, indicated that any changes done in the EHSR would require a high amount of resources, especially in time, to review up to 800 standards currently applicable for machinery. This would likely particularly have an effect if more substantial changes to the EHSR are made, although only for those

[204] Results from the OPC with very low response rate (n=4). The rate is quite high, the responses did not provide further indications as to why the costs were expected to be this high. The maximum rate could be still used as best estimate considering a very extensive change or adaptation of EHSR to which the manufacturers would have to adjust, rather than punctual changes. These 8% of turnover were then quantified by using the total turnover of the machinery sector (2016) from the Eurostat structural business statistics (EUR 624,293,800,000). For costs per company, the total costs in terms of turnover has been divided by the number of enterprises in the sector (82,239). For the assessment of one-off costs for large companies and SMEs, the expected share of increase has been multiplied by the turnover of large companies (59% of the total turnover) and that of SMEs (41% of the total turnover). Recurrent costs are expected to occur for manufacturers of software that ensures a safety function and is placed independently on the market. No number of affected firms was possible to be identified, thus, no total recurrent costs could be estimated. The costs per company could reach up to EUR 75,912. This best estimate was calculated by taking the overall compliance costs of manufacturers with regards to the Machinery Directive (up to 1% of turnover). Benefits could not be quantified due to the missing data on safety incidents with regards to new technologies and the relation to the lack of coverage in the current Directive. Qualitative inputs through stakeholder consultation led to the conclusion that some indirect benefits of legal clarity could apply if the policy sub-option 1.1 is followed. This legal clarity could reach EUR 5,000 to 10,000 per instance that is on average paid for clarifying differences between Member States when machinery is traded. Given the expected increase of the use of new technologies, this indirect benefit might become more relevant in the future.

standards affected by the changes. In addition, outside of the work done by CEN/CENELEC other ISO standards governing new technologies are being developed[205].

The potential drawbacks of adding new EHSR to cover emerging technology are similar across directives. For instance, in the evaluation of the Product Liability Directive, stakeholders feared that a specification of emerging technologies in the Directive could lead to lower investment in research and innovation.[206]

Changes in the EHSRs, however, might bring benefits in terms of accounting for innovations in technology over the next years and increased safety of machinery users. An overview of the potential impacts of changes in requirements on the different stakeholders is provided below (see Table 19). Other aspects of adjusting the existing EHSR could also bring benefits to the application of the Machinery Directive. Many benefits could not be quantified in the course of the study due to the lack of granularity in accidents data or other data needed for a quantification of risks on health and safety of users with regards to connected machinery, collaborative robots or machinery with AI functions. Thus, the analysis of this policy sub-option is also based on qualitative inputs received throughout the consultation phases. A summary of the potential costs and benefits of sub-option 1.1 is shown in the table below.[207] The net effect is expected to be positive, depending on the degree of changes followed. This is largely due to the expected increase in importance and use of new technologies in the machinery sector, which increases the relevance to ensure legal certainty when complying with the Directive.

[205] Specific ISO standards are raised in the next sections, see for example 6.1.1.2 on Collaborative robots or 6.1.1.5 on Cybersecurity.

[206] European Commission (2018). Evaluation of Council Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions in the Member States concerning liability for defective products. Available at: https://op.europa.eu/en/publication-detail/-/publication/d4e3e1f5-526c-11e8-be1d-01aa75ed71a1/language-en

[207] The number of potentially affected enterprises was based on statistics from Eurostat's structural business statistics on C.28 (NACE rev.2). The number of notified bodies were taken from the list of accredited notified bodies listed on the NANDO database, 2019. The number of MSAs was taken from the list of MSAs listed on the European Commission's websites.

Table 19: Potential cost and benefits of policy sub-option 1.1

Policy option 1.1	Description	Firms			Administrations	Other organisations		Citizens/users	
Net effect (+) NV not quantifiable		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector**	**Users / consumers**
1. Number of affected stakeholders (EU-27)		**1,703**	**81,024**	**82,239[a)]**	**71 or more**	**137 or more**	**1**	**2,759,439**	**446,000,000[b)]**
2.1 Costs (total)	**One-off**	**Not reliably quantifiable** One-off costs for adaptation to changes likely	**Not reliably quantifiable** One-off costs for adaptation to changes likely	**Not reliably quantifiable** One-off costs for adaptation to changes likely	**2,361,408 €[d)]**	**Up to 1% of annual budget (no data on the budget was found)**	**Review of up to 800 standards, quantification of efforts not further possible[c)]**		**Not quantifiable, costs of changes could be pushed down the value chain**
	Recurrent (annually)	**Not quantifiable** Compliance costs for manufacturers of independent software that ensures a safety function	**Not quantifiable** Compliance costs for manufacturers of independent software that ensures a safety function	**Not quantifiable** Compliance costs for manufacturers of independent software that ensures a safety function	-	**Up to 1,370 FTE[e)]** for conformity assessments of software that ensures a safety function and is placed independently on the market	-	-	
2.2 Costs per organisation	**One-off**	**Not reliably quantifiable** One-off costs for adaptation to changes likely	**Not reliably quantifiable** One-off costs for adaptation to changes likely	**Not reliably quantifiable** One-off costs for adaptation to changes likely)	**84,336 €[d)]**	**Up to 10 FTE[e)]**	-	-	
	Recurrent (annually)	Not quantifiable as number of manufacturers developing software that ensure a safety function was not available	Not quantifiable as number of manufacturers developing software that ensure a safety function was not available	**Up to 75,912€[f)]** for manufacturers of independent software that ensures a safety function	-	**Up to 10 FTE[e)]** for additional products covered in the Machinery Directive (i.e. software that ensures a safety function and is placed independently on the market)	-	-	
3. Benefits	**Direct**	-	-	-	-	-	-	-	
	Indirect[g)]	**5,000 to 10,000 € per instance for clarifications of differences in interpretation between Member States.** Number of instances not quantifiable, legal clarity through equal requirements	**5,000 to 10,000 € per instance for clarifications of differences in interpretation between Member States.** Number of instances not quantifiable, legal clarity through equal requirements	**5,000 to 10,000 € per instance for clarifications of differences in interpretation between Member States.** Number of instances not quantifiable, legal clarity through equal requirements	-	-	-	**Not quantifiable** Users will benefit from legally coherent requirements on all products under the Machinery Directive, ensuring a coherent coverage of aspects related to new technologies and the MD effectively accounting for innovations with regards to collaborative robots	**Not quantifiable** Users will benefit from legally coherent requirements on all products under the Machinery Directive, ensuring a coherent coverage of aspects related to new technologies and the MD effectively accounting for innovations with regards to collaborative robots

Policy option 1.1	Description	Firms			Administrations	Other organisations		Citizens/users	
Net effect (+) NV not quantifiable		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector**	**Users / consumers**
		for all manufacturers on the market	for all manufacturers on the market	for all manufacturers on the market					

[a)] Due to rounding differences in the data in Eurostat, the total number of enterprises shown does not equal the sum of enterprises recorded per size class.
[b)] Proxy used: Number of inhabitants in the EU.
[c)] Likely more substantial time efforts needed with regards to larger revisions of the EHSR. The revisions would entail an evaluation of the existing portfolio of harmonised standards with regards to their applicability and in case of revised EHSR it could require adaptations.
[d)] Based on cost data from the Staff working document on the Evaluation of the Machinery Directive (p.31).
[e)] Estimates based on European Commission (2014) "Study on evaluation of the internal market legislation for industrial products" indicating up to 10 FTEs for notified bodies to assess products' conformity if all 137 Notified Bodies in the NANDO database would use 10 FTEs.
[f)] Based on up to 1% of turnover for compliance costs for additional products covered by the Directive.[g)] Some benefits might materialise quicker than others. For instance, benefits from legal clarity and digital documentation are likely to materialise quicker than benefits through changes in the requirements. Due to the differences in products covered in the Machinery Directive and the proposed changes in Policy Option 2, the life cycles of machinery could not be taken as a proxy to estimate the potential timeline for benefits.
There are instances where data are quantified based on responses to consultations or interviews. When the number of replies is too low to present an estimate, cost cannot be reliably quantified. Proxy values are used when direct information is not available.

The potential risks of new technologies are varied and therefore the potential solutions and opinions are diverse. Opinions on these different risks and whether the current MD is fit for purpose received different responses that are further explored in the next sections, as it shapes the selection of the appropriate adaptations to the Directive.

6.1.1.1 New generation machinery, wireless control, and risks of connectivity failure

The main focus of the assessment on issues related to new generation networks in this study lies on the potential risks that may result from a connectivity failure.[208] Impacts related to changing the EHSR of the Machinery Directive to account for risks related to connectivity failure were assessed qualitatively. This is mainly due to the lack of information or data available with regards to existing incidents with regards to health and safety of users resulting specifically from a communication failure of machinery. An identification of the share of connected machinery was difficult, with only around 5% of SMEs in the machine tool sector being connected (see Chapter 1). Nevertheless, with the expected increase of IoT and IIoT connections, the share of connected machinery is expected to increase rapidly. For instance, taking the number and expected growth of active IoT connections as presented in Chapter 1 and extrapolating it to the number of connected SMEs, by 2022 all SMEs would be expected to be connected. With this rapid increase in connections, the probability of incidents in relation to health and safety of users is likely to increase as well.

On the definition of new generation machinery, wireless control and risks of connectivity failure, industry associations and manufacturers consider that the current legal text and its EHSR sufficiently cover the risks. The main focus lied on the aspect of control systems. The Guide defines the control system of machinery as "the system which responds to input signals from parts of the machinery, from operators, from external control equipment or any combination of these and generates corresponding output signals to the machinery actuators, causing the machine to perform in the intended manner."[209] Products relying on complex control systems that use electrical and electronic components, software and mechanical actuators and the interaction of such systems to perform complex tasks is very common in various industries. The use of this interaction of systems had not generated a need for change in the EHSR with manufacturers, thus they would not see an advantage of a change.

In addition, the way that the EHSR are written ensures that safe products are put on the market as there is an extensive risk assessment process to ensure products remain safe throughout their life cycle. Clause 1.2.1 in Annex I on wireless control of systems was highlighted as covering most issues with connected machinery, including withstanding external influences. In particular, control systems that are using wireless technology are required to turn off or go to a safe position when the connection is missing. Clause 1.2.1 indicates that "for cable-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication". Also notified bodies that provided input to this aspect said it is comparable to control systems and that this definition must remain as general as it is currently. An added value of changing the EHSR further is uncertain.

However, one stakeholder considered it useful if additional clarifications were made on whether computers connected to and/or controlling the machines are considered as part of the machines control system. Two of the Market Surveillance Authorities (MSAs) also called for risks from temporary failures of communication channels of connected machinery to be addressed, with a focus on machinery that is not intended to stop. Here, one MSA from Slovenia indicated that in the event of a temporary connectivity failure, the machine should be stopped safely so that it does not 'fall down' directly and remains in operation if it is not intended to be stopped. A trade union suggested adding to the final sentence of Annex I, 1.2.1 "for cable-less control, an automatic stop must be activated when correct control signals are

[208] However, other aspects might be of relevance for future assessments, for example the storage of data
[209] Guide to the application of the Machinery Directive 2006/42/EC (Edition 2.2), p.181.

not received, including loss of communication" the words, "or for control that is connected to an external control device".

On networked machinery, stakeholders interviewed considered the risk assessments to be conducted in terms of assembly to be sufficient. However, a clarification of the definition of "assembly" was considered useful (see section 6.2.2.4).

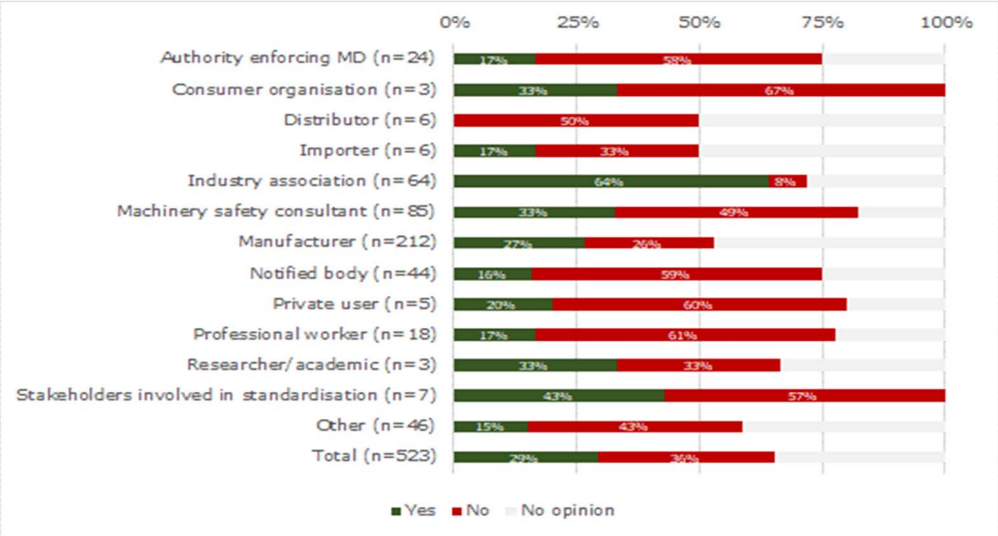
6.1.1.2 Collaborative robots

On **collaborative robots**, the sale of professional and private service robots has increased over the past few years. Given the potential risks stemming from the technological innovations regarding collaborative robots as outlined in Chapter 2 of this report, an important question is raised as to whether the requirements in the MD sufficiently cover human-robot collaboration.

Potential impacts on risks on health and safety of users related to collaborative robots and benefits of addressing collaborative robots in the EHSRs were not quantifiable due to a range of reasons. First, due to the various kinds of collaborative robots on the market, estimating the share of those that fall under the Machinery Directive in comparison to other directives was not possible. Second, the data on accidents in the databases are not granular enough to identify the number of accidents due to collaborative robots. Although data on the number of accidents with regards to industrial robots are also scarce, the data available was nevertheless reported in Chapter 2 of this study. For these reasons, the identification of impacts was conducted on a qualitative basis. The remaining risks to health and safety with regards to human-robot collaboration was outlined in Chapter 2.1.

Some information with regards to the option of adapting the EHSR to better account for risks related to human-robot collaboration was gathered through stakeholder consultation. The majority of stakeholders indicated that human-robot collaboration is not sufficiently covered by the Directive (see Figure 20). Looking into the open questions on the reasons why stakeholders did not consider the current EHSR to sufficiently cover human-robot collaboration, most industry associations and manufacturers mention the limitation of the physical separation between robots and humans as well as cybersecurity. Notified bodies, mostly address limitations in terms of force, speed and energy. Market surveillance authorities had no clear opinion as to why the EHSR do not suffice. A few mentioned that software and cybersecurity were not covered enough.

Figure 20: Does the MD sufficiently cover human-robot collaboration?

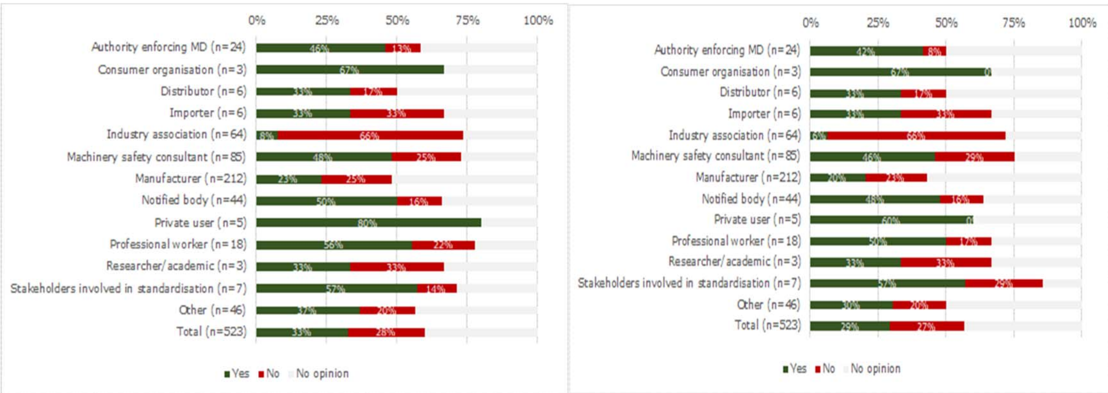


Source: Open public consultation

Of those that considered the MD to cover human-robot collaboration sufficiently, they indicated that human-robot collaboration is not new in manufacturing industries, whereas data from the US indicate that no increase in fatal accidents has resulted from an increased collaboration[210], when looking into the statistics provided by the US Department of Labour. It was indicated that the development of standards in this sector is booming in order for robots to be manufactured in a way that they take into account all the necessary measures to avoid any safety problem.[211] One of the most commonly mentioned standards in this regard is EN ISO 10218. This standard is also in the list of standards published in the OJEU on machinery. In addition, specifications on collaborative robots, such as the maximum force to be applied on a person, are said to be covered by ISO standards, albeit insufficiently. Work within the ISO/TS 15066 was mentioned to be currently underway.

On the questions whether the EHSR should be adapted or new ones should be added in order to account for human and robots in shared spaces, the responses were diverse across stakeholder groups. Generally, in favour of adapting or adding new EHSR were authorities enforcing the MD, consumer organisations, distributors, machinery safety consultants, notified bodies, private users, professional workers including trade associations, stakeholders involved in standardisation and other groups. Against were industry associations and manufacturers (see Figure 21).

Figure 21: Opinions on adapting or adding new EHSR on human-robot collaboration



With regards to what EHSR could be adapted or added, some stakeholders provided insights. The focus was mostly on impact forces. A trade union indicated that two hazards need to be accounted for: speed and crushing. For this, Annex I, 1.3.7 and 1.3.8.2 on moving parts and mechanical hazards could be adapted. In particular, the clause determining that "the moving parts of machinery must be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or must, where risks persist, be fitted with guards or protective devices" was considered limiting with regards to human-robot collaboration. The stakeholder indicated that as physical protection one could imagine a sort of effort sensing or logical protection which could identify the resistance of a human body, leading to an immediate stop and reversal to prevent damage.

Another workers' association indicated that when considering the possible developments that might occur in the next 10 to 15 years, the main problem is to limit the forces on impact or pressure on workers. Controlling the risk by separation (e.g. barriers), as used to be the most common applied method in the past, or by limiting the force of the machine is no longer possible. The reasoning behind this was that robots may need high forces for the job. Here, a new EHSR could be added on systems that limit impact and pressure forces on a worker,

[210] Collaboration in this case appears to have been used in a setting as it currently stands with most commonly physical separation of workers and industrial robots.
[211] For example, SMEs from Switzerland, UK, Italy, France, stakeholder involved in standardization from Germany

especially systems that are able to identify workers as opposed to the work item. Another aspect mentioned by a consumer organisation and some manufacturers interviewed was that the work area or environment must be taken into account with freely roaming robots especially.

One manufacturer considered it useful to pay attention to exoskeletons, as they have similar characteristics to human-robot collaboration.

Looking into other countries' approaches with regards to collaborative robots, in particular service robots, there are some examples when it comes to testing social care robots. In Japan, the Tokku approach allows the social robots to be tested in living labs where the elderly patients are taken care of. Policies are then made based on the lessons learned from the labs. One such example is Shin-tomi nursing home located in Tokyo. It utilises up to 20 different social care robots for assisting the elderly. The government of Japan sees it as a model to utilise the country's expertise in robotics to cope with the nursing requirements of an increasingly elderly population and a dwindling workforce.[212,213]

Box 3: Suggestion on additional EHSR for robots

Proposal 1 by a manufacturer: Add a potential new chapter on robotics, similar to the one for lifting of persons in Annex I, paragraph 6. "*7. Supplementary essential health and safety requirements for robots.*

7.1 General
Robots must meet all the relevant essential health and safety requirements described in this chapter.
7.1.1 Definitions
- Robot
- Robot systems
- Levels of autonomy
7.1.2 General requirements
Robots must be designed, constructed or equipped in such a way that the use of the robot in the intended environment does not engender any unacceptable risks for persons and domestic animals where relevant.
7.1.3 Controls
Robot controls must be designed to have sufficient reliability to eliminate or reduce the risks resulting from the loss of controls.
7.1.4 Override
Override by operators must be possible under all conditions. Override shall not introduce new risks.
7.1.5 Speed
Mobile robots operating at speed above 300 mm/s must be equipped with means to detect persons and capable of initiating a safety stop.
7.1.6 Detection
All equipment used or detection of persons must be sufficiently reliable, taking into account all reasonable foreseeable risks and level of autonomy.
7.1.7 Breaking
Mobile robots must be designed, constructed or equipped with sufficient breaking means
7.1.8 Power & force limiting
Robots must be designed, constructed or equipped in such a way taking into account the maximum forces (N) and energy (J) that can be applied on a person without any harm.
7.1.9 Mass inertia
Robots must be designed, constructed or equipped in such a way that mass inertia does not engender risks for persons.
7.1.10 Robot systems
Any machinery, equipment devices, external auxiliary axes or sensors supporting the robot performing its task must be taken into account in such a way that robot systems do not engender risks for persons.
7.1.11 Connectivity technology

[212] Reuters (2018). Ageing Japan: Robots' role in future of elder care. Available at: https://widerimage.reuters.com/story/ageing-japan-robots-role-in-future-of-elder-care
[213] Case study on self-driving robots; Annex II 2.2.3

Robots using any connectivity technology must be designed, taking into account all reasonable foreseeable risks resulting from connectivity failure and cybercrime."

Proposal 2 by a machinery safety consultant (UK): *"EHSR 1.3.7 need adapting. EHSR 1.4.1 may need to allow for parts of protective devices to fall off in order to provide protection; EHSR 1.4.3 might be too restrictive for co-bots; Guidance for EHSR 1.2.4.4 should make it clear that assemblies of machines also include co-bots."*

Proposal 3 by a machinery safety consultant (DE): *"The explanation of 'limiting the actuation force' from paragraph 212 of the Guide (edition 2.1) could be added to Annex I 1.3.7."*

Proposal 4 by a manufacturer (FR): *"EHSR 1.2.1 and 1.2.6 on defining the concept of unexpected start-up; EHSR 1.2.4.1 to specify the concept of control station for a robot that can be mobile; EHSR 3.6.1 to define the signals and signals necessary specifically for the robot."*

Proposal 5 by an authority enforcing MD (FR): *"Add a definition related to EHSR 1.3.7 to point 1.1.1 relating to the different work situations involving the implementation of a robotic applications, specifying that the preventive measures must be adapted to these different situations as to avoid any dangerous contact in accordance with EHSR 1.3.7. In particular focusing on i) situation of human-robot coexistence in a shared space without direct collaboration; and ii) work situation in human-robot interaction (simultaneous or alternating work on a part)."*

Proposal 6 by a researcher (IE): *"EHSR 1.3.7 risks related to moving parts should be adapted. The robots will collide with humans which is why consideration of the kinetic energy on impact is necessary. Humans will also fall over small robots if they are moving around the human area. Contact will occur between the robot and human."*

6.1.1.3 Artificial intelligence and machine learning

On **machine learning and AI in machinery**, the assessment of impacts was mainly done qualitatively. The main reason as to why benefits of addressing AI and ML in the EHSR of the Machinery Directive could not be quantified is the lack of information on safety incidents resulting from a malfunction of AI or ML in general but also more precisely in the machinery sector. The rate of application of AI and ML in the machinery sector is not well recorded, but the general (increasing) trend in the use of these solutions was presented in Chapter 1 in order to have an understanding of how the implementation is likely to develop in the future. The identified recorded risks are often in relation to security (i.e. data protection) rather than the safety and health of users. Nevertheless, potential risks are listed by authorities and given the increasing rate of uptake of these solutions, the probability of those risks leading to incidents is also likely to increase.

To receive qualitative information on AI and ML, stakeholders were consulted. Respondents' opinions varied with a number expressing some concerns about emerging technologies' effect on machinery. The majority of stakeholders had no clear opinion on the question of whether an adaptation of existing or new EHSR would be necessary and if yes, on which aspects of AI. This is likely due to the different types of AI sophistication and the limited to no application of the second and third stages of AI. Overall, most stakeholders[214] providing input on this question leaned towards minor changes to the current Directive.

Here, the risk assessment procedure is often mentioned. The current Directive states under paragraph 23: "The manufacturer or his authorised representative should also ensure that a risk assessment is carried out for the machinery which he wishes to place on the market. For this purpose, he should determine which are the essential health and safety requirements applicable to his machinery and in respect of which he must take measures." In a way similar to the industry associations, manufacturers considered the current EHSRs already covered the risk adequately due to the goal-setting way the requirements were written, leaving it to the

[214] Workshop, Exchange of ideas for the revision of the Machinery Directive with a view to new technologies, held 4 November 2019, at KAN in Sankt Augustin, Germany

relevant harmonised standards to be adapted to new or specific technologies. An industry association indicated that "manufacturer(s) (are) obliged to show the residual risk of the machinery, to apply the state of the art. If the state of the art is applied, it is possible to have residual risk but then there is the obligation to show it in the technical file and have warnings. This information is enough to carry out the risk assessment also for an AI algorithm." This is supported by manufacturers, for instance "the existing MD already covers the use and risk assessment of the potential use of these technologies"[215], or "Artificial Intelligence and IoT will not alter the risk assessment and the requirements are [sufficient]".[216] This is similar to other manufacturers, which indicated that "the Machinery Directive should remain on the level that an error in the control system shall not result in hazards. It becomes clear due to its simplicity. Like with the PED or the EMC when it becomes unclear which Directive should be followed and what requirements that apply it creates possibly unsafe machines."[217] Manufacturers and industry associations were supported by the majority of workers and employers' representations.

One manufacturer stated that "in the sense of a human-like intelligence robot [the requirements are] probably not [enough], but in the sense of a narrow definition of AI as a form of machine learning, as it is for machines only conceivable in the near future yes. (…) The basic safety and health requirements of the Machinery Directive are covering the currently realistic applications for AI".[218] This was supported by other manufacturers, as "the applications of AI that we consider realistic today (e.g. automatic learning for process improvement), is sufficiently covered by the Machinery Directive".[219] Especially on the third level of AI automation, one manufacturer providing a contrary view to the rest of the industry representatives made the point that "if the intelligent system is programmed to learn and decide independently on its own due to its own experience and its interaction with the environment, even eventually overcoming human control, whoever designs it, programmes it or builds it may not be able to predict entirely the reactions with respect to the world around it".[220]

Mainly it was suggested that it is a matter of adding to the Guide explanations of certain definitions or clarifications, but it is also necessary to explain the duties of the manufacturer with respect to machines with AI. For instance, a notified body indicated that it would be useful to provide clear definitions and limits for the terms AI, IoT, robotics, security, and misuse[221]. A workers and employers' representation underlined the statement by indicating that "some clarifications could be made either in the MD or in the Blue Guide, referring specifically to 1.2.1 of Annex 1: 'errors in the control system logic do not lead to hazardous situations', which could cover machine learning systems if they are understood as control system or its logic". One national authority from France considered that a definition of AI need not be placed in a revised machinery Directive/Regulation, but it could go into a future Guide. In particular with respect to Article 2(k) putting into service where there is a test phase (commissioning) then the machine learning will remain under the responsibility of the manufacturer and must be carried out without risk, and with respect to Safety Integration (1.1.2) to explain that the manufacturer shall provide test procedures or devices for the maintenance and adjustment of the machine using AI. On the test procedure, one workers and employers' representation specified that "with a machine with a fixed logic unit, one method of checking that the machine is operating correctly is to run tests (e.g. checking a light curtain is operating correctly on a power press using a test probe) to check it operates as expected. With AI and self-learning modules this is not possible as the outcome will vary with changes to the system due to the

[215] Manufacturer from SE
[216] Manufacturer from IT
[217] Manufacturer from SE
[218] Manufacturer from DE
[219] Manufacturer from DE
[220] Manufacturer from IT
[221] Notified body from AT and CZ

learning capability. What could be specified in the EHSR is a checking/testing method that is provided by the manufacturer for machines of this type that ensures that the "modified" operation of the machine is within specified safe limits (safe envelope)."

Some stakeholder groups indicated that the Machinery Directive does not sufficiently cover the risks of AI. Consumer organisations focused mostly on cybersecurity and personal data protection, the prior aspect being discussed in more detail in section 6.1.1.4 and the latter issue not being in the scope of the Machinery Directive. Three MSAs indicated that the risks could be addressed within the EHSR but that a separate legal act would be more useful.[222] One MSA from the UK highlighted potential issues with biased learning data, AI misinterpreting its environment and the psychological aspect of having a new kind of interaction between a machine and a person as issues potentially of interest for legislation. This is of particular relevance for robots employing AI functions, thus important for human-robot collaboration. More detail is provided in the previous section.

Most national authorities were in general in favour of adapting the EHSR to cover risks of new technologies, although no specific aspects were mentioned in most cases as to which aspects need revision. Two authorities mentioned "cybersecurity"[223], another one "the definition of the limits of responsibility to the machine's manufacturers, those responsible for the subsequent integration of software and of the users" [224]. The only national authority specifying the potential adaptation needed during the stakeholder consultation was an authority from the Netherlands, which mentioned the results of a study conducted in the Netherlands.

This study focused on health and safety requirements for machine learning suggested several additional EHSR in 1.2. of the MD. These include[225]:

- "Machines equipped with machine learning technology must be able to respond to people adequately and appropriately";
- Machines equipped with machine learning technology must indicate which actions they are about to perform and must provide details of the information on which these actions are based";
- "Machines equipped with machine learning are not permitted to make decisions or assessments in relation to injury to people or damage on the surroundings";
- "Machine learning must not cause the machine to exhibit new actions that exceed its defined task and working environment";
- "If they take incorrect decisions, machines equipped with machine learning technology must be retrospectively correctable, to prevent any future recurrences of that particular error";
- "The actions of a machine equipped with machine learning technology must be traceable in advance and retrospectively, based on transparency in the datasets used, as well as of the test environments and of the decision frameworks or assessment criteria for algorithm-based decisions";
- "The decision-making process of a machine equipped with machine learning technology must be logged and retained"; and

[222] MSAs from UK, SI and SK
[223] National authority from DK and FI
[224] National authority from PT
[225] TNO (2018). Essential H&S requirements for industrial machines equipped with machine learning. (14 September 2018). Available at: https://www.arboportaal.nl/onderwerpen/arbeidsmiddelen/nieuws/2018/10/03/reeks-onderzoeken-tno-over-opkomende-risico%E2%80%99s-voor-arbeidsveiligheid

- "The machine's control system can withstand the intended operating stresses and undesirable external influences".

A national authority from France[226] and the German Commission for Occupational Health and Safety and Standardisation (KAN)[227] had also conducted a study on the EHSR, AI and ML, reaching the conclusion that only limited adaptations to the current text were necessary (see Box 4). The approach taken in these studies was to look at what is likely to be developed in the next few decades and how risks can be controlled while allowing for machine learning to be developed.

Box 4: Findings on EHSR with regards to AI and ML

Finding 1 by a national authority (FR): Adding clarifications to EHSR 1.2.1 safety and reliability of control systems (in red). *"Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:*

- *They can withstand the intended operating stresses and external influences,*
- *A fault in the hardware, software or the logic of the control system does not lead to hazardous situation."*

Finding 2 by a national authority (FR): Adding a paragraph at the end of EHSR 1.2.1. *"The safety functions cannot change outside the limits of the manufacturer's defined scope. This scope is validated and guaranteed by the manufacturer, regardless of any modifications to the settings or rules generated either by artificial intelligence or by operators in charge of the learning phases."*

Finding 3 by KAN (DE): There are two cases considered for the assessment: *"Case 1 is when strategies are based on predefined decision models (algorithms) which contain human knowledge and experience about specific tasks, and which can be described analytically. In this case, possible actions of the machines are predictable. Case 2 is when strategies generate decision models (algorithms) on their own from processes that are too complicated to describe analytically ("learning" etc.). Here two options apply. Case 2a is when the possible effects caused by decisions made in this way can be precisely confined/controlled, meaning that the actions of the machine are also predictable. Case 2b is when the possible effects caused by decisions made in this way are not or cannot be precisely confined/controlled because no rules are used or are available for them, which means that the actions of the machine are not predictable. As long as a manufacturer is able to carry out the risk assessment for the machine, as part of the conformity assessment procedure, the essential requirements contained in Annex I of the Machinery Directive are sufficient. In this context it is understood that by the conformity assessment procedure, the whole possible learning phase needs to be covered. As a consequence, if a manufacturer is not able to carry out the conformity assessment procedure for the whole life cycle, a machine cannot be considered compliant with the Machinery Directive. A legal clarification in this sense should be added in the recitals of the new Directive and the Guidelines."*

In summary, it was suggested that machine learning could take place at different stages in the machine lifecycle. Firstly, at the manufacturer's premises prior to supply and secondly during a commissioning phase at the user's site. This type of machine learning was considered to not require any changes or additional costs for industry as it is just part of the manufacturing process (current changes to design during commissioning is already covered in the current guide to the MD). Where machine learning takes place during the use of the machine it was considered that no changes to the legal text was required and there would be no additional

[226] Machinery Directive Working Group, December 2019: paper presented by the French Ministry of Agriculture and Food - WG-2019 Proposals from the Ministry of Labour and the Ministry of Agriculture relating to Artificial Intelligence with regard to the Machinery Directive.
[227] Workshop, Exchange of ideas for the revision of the Machinery Directive with a view to new technologies, held 4 November 2019, at KAN in Sankt Augustin, Germany

recurring costs of compliance. However, this was only if the machine learning took place within set boundaries (could be physical or control based). Then provided the manufacturers risk assessment showed that the range of development by the machine within these boundaries are safe (i.e. compliant with the MD), the current MD does not need to be changed to cover this type of machine. If the operation parameters of a machine are evolved and changed under the machine's own system and the original manufacturer or notified body cannot carry out a detailed risk analysis for all the possible changes that the machine may make in its operating parameters during its use, then a solution may mean that some form of dynamic risk analysis needs to take place. A dynamic risk assessment would run during the use of the machine, enabling the detection of new risks, providing the possibility to flag stages of substantial modification.

The French study[228] considered that if "AI is used to increase the level of automation of machinery (…), this is currently just a new step in automation and, as such, AI introduces no new hazardous phenomena".

It was considered that if the machine learning does allow changes to how or where the machine operates (i.e. no fixed boundaries) the situation is different. This is because the compliance with the EHSRs (i.e. safety) of the machine during its use cannot be assessed by the manufacturer during the risk assessment. It was considered that such a machine should not be allowed into the EU market and the MD should not be modified to accommodate such situations. This suggestion was supported, but in a different format, by the French Ministry of Labour: "As per the notion of foreseeable misuse, the risk generated by foreseeable misuse shall be assessed by the manufacturer. If it cannot be managed from the design stage, self-development of the machine during use shall be avoided", where "foreseeable misuse" includes machine learning resulting in the machine operating unsafely.

In theory, it should be possible in the future to build AI-based safety systems that can adapt to control the risk as a machine's operation goes outside the original design boundary. However, taking into account the current market assessment on the implementation of AI (section 1.2.2) and the views of most of the stakeholders, such systems are not currently available with some expecting their introduction in 2040 to 2060, and no assessment of their reliance can be made since the issue of calculability for an AI algorithm requires further scientific advances. It is also unclear to what extent those systems will be available in the near to mid-term future. The French study found "that all AI presented is managed by protective systems and safety functions. At no time does the AI replace these elements for safe management. It mainly acts on the object detection features to optimise a process or gain autonomy (movement in a changing environment). The features linked to safety do not involve AI intervention and are managed conventionally. To date, no machinery with AI used to ensure safety has been defined."

If a machine that is compliant is modified later (e.g. by software changes) to now work within different boundaries, then a new risk assessment would be needed. There was no agreement among Member States as to whether such a change would require treating the machine as a new product needing conformity assessment and new CE marking or if it would be the responsibility of the user under the Use of Work Equipment Directive[229]. This is the same debate as the current situation with regards to a substantial modification that may require new Conformity Assessment and CE marking.

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[228] Machinery Directive Working Group, December 2019: paper presented by the French Ministry of Agriculture and Food - WG-2019 Proposals from the Ministry of Labour and the Ministry of Agriculture relating to Artificial Intelligence with regards to the Machinery Directive.

[229] Directive 2009/104/EC of 16 September 2009 concerning the minimum safety and health requirements for the use of work equipment by workers at work, OJ L 260, 3.10.2009, p. 5–19.

Regarding the potential **financial impact of changes in the Directive to accommodate AI,** some considerations were provided by stakeholders.

The approach taken by France[230] and the meeting held in KAN[231] makes few changes to the EHSRs and added no or minimal cost burdens on industry above what it would need to do to meet the current EHSRs to produce a safe machine. There could be a barrier to the development of autonomous machines with self-learning that can work outside the boundaries envisaged by the manufacturer, where the risk cannot be controlled by conventional (non-AI) systems. However, if AI safety systems were developed to deal with this situation such machines could be developed and placed on the market. To do this the AI safety system would need to be shown to be safe such as by meeting new harmonised standards. Then the machine manufacturer could demonstrate the machine's safety throughout its life cycle and so could be CE marked and placed on the market. It is not clear if such AI safety systems are likely to be developed and implemented in the medium term.

The suggested additions to EHSR are intended to deal with the development of autonomous machinery with self-learning that can work outside set boundaries. In this case conventional risk assessment by the original manufacturer for the life cycle of the machine is not possible, it needs a safety system that uses AI as discussed above. The suggested new EHSR to deal with this type of machine would not add greatly to costs as they would be needed to prove the AI safety system for the robot/machine was safe. However, as written, if they had to be applied to all machinery using AI and machine learning, including those that work within safe boundaries (as discussed above), this would add a significant burden to manufacturers trying to interpret these new EHSRs for machines to which they do not really apply. If these suggested EHSRs are to be adopted, then they should be modified by limiting their application to possible future autonomous machinery that can work outside set boundaries as the self-learning develops (e.g. fully autonomous robots). We do not have reliable information on the likely development time of such machinery and AI safety systems. However, the Machinery Directive takes into account the state of the art for the compliance of the essential health and safety requirements.

Looking into other countries' and sectors' approach to ensure safety of AI and machine learning, the US federal government's 15-point checklist for self-assessment of self-driving cars provides an example, though the majority of use cases focus on autonomous driving and military applications, both of which do not fall under the MD. The steps in the checklist include the following:

Table 20: Safety assessment for autonomous vehicles, US 2016[232]

Level of automation	SAE levels 3, 4, 5 (HAVs)	SAE level 2
Safety assessment letter to NHTSA required	**Yes**	**Yes**
Cross-cutting areas	**Fully**	**Partially**
C.1 Data recording and sharing: car manufacturers need to collect information and make it available so that regulators can look out for the best interests of the public by reconstructing what has gone wrong in the event of crashes and system breakdowns	Yes	Yes
C.2 Privacy: Data that is collected should be kept private	Yes	Yes
C.3 System safety: Software malfunctions would seem to be inevitable, so self-driving cars must be made with backup systems	Yes	Yes

230 Machinery Directive Working Group, December 2019: paper presented by the French Ministry of Agriculture and Food - WG-2019 Proposals from the Ministry of Labour and the Ministry of Agriculture relating to Artificial Intelligence with regards to the Machinery Directive.
231 Workshop, Exchange of ideas for the revision of the Machinery Directive with a view to new technologies, held 4 November 2019, at KAN in Sankt Augustin, Germany
232 Source: NHTSA (2016). Federal Automated Vehicles Policy: Accelerating the next revolution in roadway safety, p.34[232]

Level of automation	SAE levels 3, 4, 5 (HAVs)	SAE level 2
C.4 Vehicle cybersecurity: driverless cars should be secure and protected from "joyriding" and hacking attacks	Yes	Yes
C.5 Human machine interface: vehicles should be able to switch between autopilot and human control	Yes	Yes
C.6 Crashworthiness: driverless cars must meet national regulatory standards for crashworthiness so that occupants are protected when crashes occur	Yes	Yes
C.7 Consumer education and training: car manufacturers must ensure consumers are knowledgeable and capable of using driverless vehicles and that they understand their capabilities and limitations	Yes	Yes
C.8 Registration and certification: software that is to be used with autonomous vehicles must be approved by the National Highway Transportation Safety Administration (NHTSA)	Yes	Yes
C.9 Post-crash system behaviour: if an accident has occurred, car manufacturers must pinpoint the cause and prove their cars are safe to use again after a crash	Yes	Yes
C.10 Federal, state and local laws: driverless vehicles are required to follow state and local laws and practices related to driving, including speed limits, U-turns, right turns and red lights	Yes	Clarify to driver
C.11 Ethical considerations: human drivers must often make ethical decisions when driving. With driverless cars, what types of ethical decisions can be made by a computer?	Yes	Yes
F. Automated function	**Fully**	**Partially**
F.1 Operational design domain: manufacturers must prove their vehicles have been tested and validated to meet various driving situations and conditions including driving at night, on dirt roads etc.	Yes	No
F.2 Object and event detection and response: manufacturers must show that their cars respond properly to other cars, pedestrians, animals, falling trees, etc.	Yes	No
F.3 Fall back (minimal risk condition): when a malfunction is detected in a vehicle there should be a smooth fallback from automated driving to human control, if necessary	Yes	No
F.4 Validation methods: manufacturers must develop testing and validation criteria that account for a wide range of technologies that are expected to be used in autonomous cars and testing should include simulations, test track driving and on-road testing	Yes	Yes
G. Guidance for lower levels of automated vehicle systems	**No**	**Yes**

One further main aspect considered under the topic of AI and machine learning is **control systems, including algorithm transparency and accountability requirements**. With regards to transparency, the degree of what is meant would depend on the type and use of an algorithmic decision system, but might refer to code, logic, model, goals, decision variables and other aspects considered to provide insights into how the algorithm performs.[233]

Regarding transparency of algorithms, slightly more respondents across all stakeholder types indicated that transparency of algorithms should not be addressed in the Machinery Directive (30.2%) than those preferring a coverage of transparency (27.3%).

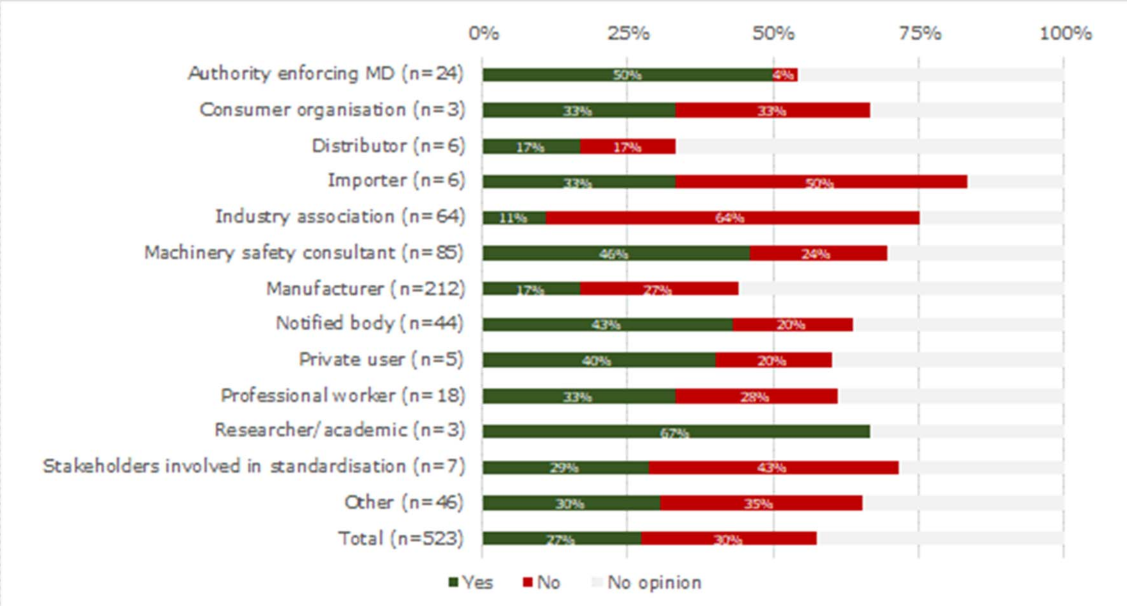
A potential conflict with the protection of know-how was raised. Manufacturers supported the claim, indicating that software is currently treated the same way as hardware, following the requirements laid out in the Directive (i.e. Annex I, 1.2.1). One further limitation expressed by industry associations was the current low level of uptake of advanced AI in the sector. It was considered useful to revise the fitness of the MD in new technologies after another 10

[233] European Parliament (2019). A governance framework for algorithmic accountability and transparency, p.4. Available at: https://www.europarl.europa.eu/RegData/etudes/STUD/2019/624262/EPRS_STU(2019)624262_EN.pdf

years. Manufacturers indicated that due to the variety of machine types in the sector, it would be very difficult to define clearly the details of software and AI systems in specific directives. Overall, this stakeholder group also considered that AI and IoT developments would not alter the risk assessments and that therefore the requirements in the current text are sufficient. Only one manufacturer indicated that for its products safety is handled by software engineers. While some standards exist, more programmed software and standards are seen as necessary, especially to ensure that the software engineers acted correctly.

As mentioned, 143 of 523 (27.3%) respondents to the OPC indicated that transparency of algorithms should be explicitly addressed in the MD. In particular, it was mostly mentioned by notified bodies, market surveillance agencies and other testing bodies to enable a full risk and conformity assessment. This was especially the case for machine learning in safety systems. It was proposed to add a description to the technical file (Annex VII-A Art. 1.(a)) that comprises "the complete and detailed description of the control logic in functional regard, including the complete software code, and in the case of machine learning systems: 1) the full state of the neural network; 2) the complete training data set that led to this state of the neural network; and 3) the algorithm that is used"[234]. In the case of commercially available software modules, the full reference to the exact version of the software module may replace the software code.

Figure 22: The MD should explicitly address transparency of algorithms and datasets



Source: Open public consultation

A study (2019) identified potential costs related to transparency of algorithmic systems, including[235]: i) sufficient staff to oversee compliance in regulatory bodies; ii) businesses and other organisations needing to create and maintain the process, code and legal oversight required by the regulatory bodies; iii) transparency that could put justifiable trade secrets at risk; iv) public access to data that could flame interest-driven controversies via the untutored or unscrupulous misuse of data; v) the requirements for transparency leading to the use of algorithms that are suboptimal for their purposes; vi) access to data that seems innocuous could lead to breaches of personal privacy (by malicious interference); and vii) increased

[234] Trade Union from Belgium

[235] European Parliament (2019). A governance framework for algorithmic accountability and transparency, p.7. Available at: https://www.europarl.europa.eu/RegData/etudes/STUD/2019/624262/EPRS_STU(2019)624262_EN.pdf

transparency of algorithms can make them easier to hack. In addition, it was the view of several consultees (verbal discussions) that a study of the full software code would not aid evaluation due to the difficulty in assessing such code written by another body.

According to a machinery expert, the requirement to list more information in the technical file (software code etc.) should not add greatly to costs provided it did not have to be in printed format and there was a proportionate approach by MSA in asking for information from the technical file (i.e. not asking for all but just the relevant parts). The main issue may be concerns about industrial confidentiality when supplying such information via a second manufacturer that markets the product under its own name, such as being required to supply it to an MSA. However, this is no different to the current situation.

Overall, these are the results of the assessment on transparency of algorithms within the temporal scope of this study. Other views or results might develop over time.

Another aspect related to transparency of algorithms comes from self-driving robots bringing forward new challenges in terms of the degree to which ethical dilemmas can be anticipated and hardwired. Should the programmer be allowed to code such dilemmas in the software of autonomous systems? Should users have control over the decision-making process of these systems in situations when a machine may be able to harm a person? AI algorithms need to ensure responsible outputs that protect the safety of people, as it is important that these algorithms are trusted by employees, companies, and customers alike. This also requires AI-enabled robots to have Human Machine Interfaces (HMIs) which provide information on the behaviour of machinery in a manner that is transparent and intelligible to the human supervisor or co-operator.[236] This level of transparency differs from making the source code transparent, as understood by many stakeholders on the topics above.

6.1.1.4 Software and software updates

Software updates were considered to fall under either maintenance or machinery substantially modified by users.[237]

Software updates falling under machinery maintenance are common updates aimed at patching and limiting shortcomings of the software. These updates are made during the lifetime of the machine and may provide difficulties for the end-user. For instance, many industrial machines last 10 years or longer with maintenance. Software and operating systems of computers that support the PLC, HMI or safety systems, however, have shorter life cycles of about one to three years.[238] Indeed, software updates are a regular procedure for machine manufacturers, with 44% of manufacturing companies running updates at least once a year (see Figure 23).[239]

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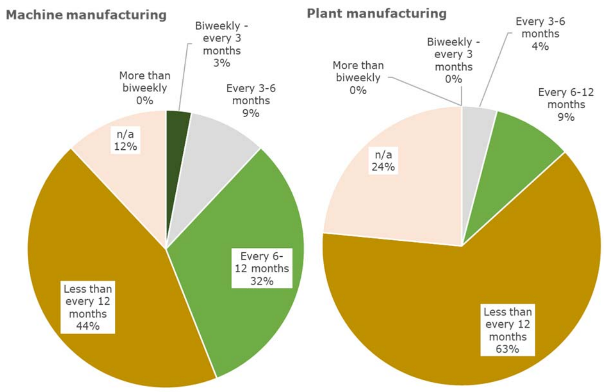
[236] Case study 3: Self-driving robots. See Annexes

[237] A similar note is provided in the European Commission's (2020). Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics. Available at: https://ec.europa.eu/info/sites/info/files/report-safety-liability-artificial-intelligence-feb2020_en_1.pdf

[238] Control design (2011). What really happens when you update software and machinery. Available at: https://www.controldesign.com/articles/2011/industrial-software-upgrades/

[239] Vogel-Heuser, B., & Ocker, F. (2018). Maintainability and evolvability of control software in machine and plant manufacturing – an industrial survey. *Control Engineering Practice, 80*(2018), 157-173.

Figure 23: Frequency of software updates



Source: Own elaboration based on Vogel-Heuser, B., & Ocker, F. (2018); Survey of 68 manufacturing companies

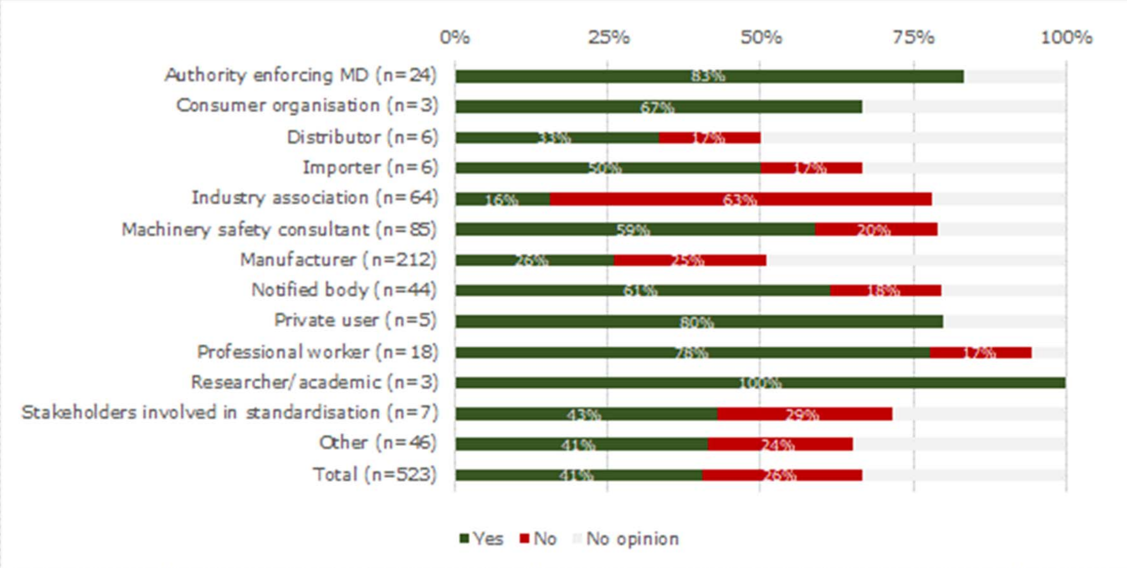
With higher connectivity among machines, the industrial control systems may require higher availability and/or safety-related capabilities. Software updates will be needed during the product life cycle, the increasing number of security-related vulnerabilities discovered on these industrial control systems and the high interconnectivity in IioT. Updates aim to fix these security weaknesses, bugs and vulnerabilities that could appear.

In manufacturing companies operating machinery in their production lines/plants, about 18% of customers receive the complete software source code, whereas 58% of machine manufacturing companies do not supply any software code. Compared to the office environment, where maintenance support activities can be carried out outside of office hours or in the background, manufacturing production is often continuous. Thus, software updates that require rebooting of a PC would interrupt the production. Another difficulty identified in a study is that there is very limited scope and time for the OEM or support organisation to test any software updates and there is little tolerance to mistakes in updates. When asked about the maintenance of software and application of security patches, only 28% of OEMs indicated that they provide updates for their own software. It is thus often the case that equipment deployed in manufacturing environments has been tailored to specific customers, making testing prior to software updates difficult.[240]

When it comes to software updates, the majority of respondents to the OPC said that they would the MD to address software updates (see Figure 24).

[240] Goh, Y. M., & Case, K. (2016). Advances in Manufacturing Technology XXX: Proceedings of the 14th international conference on manufacturing research (September 6-8 2016), Loughborough University, UK.

Figure 24: The MD should specifically address software updates



Source: Open public consultation

The way in which software updates could be addressed in the MD varies according to the level of these updates. The main difference indicated is between software updates that aim to fine-tune a product through small, frequent improvements rather than major changes, and software upgrades or a new version of the software product entirely.

Some manufacturers indicated that questions related to software updates are covered by Annex I, referring to the requirements set out in Annex I 1.1.2 and in substantial modification in the Blue Guide for software upgrades. Others reiterated that software updates open the question of responsibility after the placement of the product on the market. Assigning ownership and responsibility to the software by the OEM was considered useful by one interviewee, ideally in combination with a requirement to have a documented software release management system. The risk connected to this approach relates to the point made on accountability, i.e. it being considered a contractual aspect rather than a safety aspect and thus potentially falling outside the scope of the Directive. Notified bodies also referred to substantial modification at this point. It was related to the diagnosis of cars, namely that authorised persons are able to look into the software of the car to check the safety records and decide about the safety status.

A similar approach could be considered regarding software updates in machinery. One of the consumer organisations noted that software updates on machine learning should always be considered a substantial modification, even if the intention is not to change the product, and that the concept of putting on the market/into service should be looked at, as machine learning affects safety beyond this point, and therefore the MD approach may not be sufficient to ensure the safety of the consumer. On the other hand, among the three interviewed industry associations that provided an answer, two claimed that a software update should not be considered a substantial modification, especially considering the frequency of these updates. According to them, the point is not to protect machinery against major updates of intended behaviour, but to maintain compliance. Major updates changing intended functionality and behaviour should be possible and software updates are covered already, because they are either covered as modification or as maintenance[241]. Additionally, the majority of the interviewed manufacturers were of the opinion that software update cannot be counted as a

[241] Based on the interview conducted with the industry association.

substantial modification, given the incremental changes induced by the updates aimed at increasing performance and/or security. However, some of them claimed this holds true only if the software update does not lead to the change in the intended behaviour of the machine. Given that this aspect overlaps with the question of substantial modification, further details are provided in Section 6.2.2.4.

Another aspect relates to software that ensures a safety function and is placed independently on the market. Currently, the Machinery Directive covers software that is integrated in the machinery.[242] By contrast, software that ensures a safety function and is placed independently on the market is not. The Guide (edition 2.2) currently indicates that "safety components are considered to be physical devices (…). Software which performs a safety function, and which is placed independently on the market is not considered a 'safety component'." (p. 44)[243]

The possibility of externally uploading software to the control unit (Programmable Logic Control PLC) of machinery raises issues of cybersecurity. There are broadly two ways of performing updates – wirelessly or via physical access to the system. The user or a certified technician from the manufacturer or its authorised representative can perform the update depending on the implications of the update. However, if an unauthorised third party manages to upload code or software to a safety-critical piece of machinery, this could have severe consequence for machinery users, for example if warning systems are turned off. An update of one of the components of a piece of machinery such as the embedded system of the micro-controller can affect the rest of the components of machine as a whole. Currently, there are no specific requirements for software that ensures a safety function and is placed independently on the market. Thus, while the current MD accounts for software and updates in the case of embedded [control] applications, it does not cater for the independent software that is uploaded to the standalone machine and can control the operations of the machine.[244]

New challenges emerge during the lifetime of the machine in case the manufacturer stops the support for updates on functionality. This can include the risk of security vulnerabilities, incompatibility of new applications, compliance issues, lack of technical support and poor performance and reliability. One example for this is when Microsoft stopped the support for Windows XP while many manufacturing and calibration systems continued to rely on it. According to industry experts, the physical equipment is generally up to date, whereas underlying operating software becoming outdated is a critical issue.[245] Since it is difficult to upgrade software within complex interconnected systems of machinery, a sudden lack of security support services, such as security patches, can pose severe security risks both to business continuity and user safety. Indeed, a Verizon security study focussing on both the manufacturing and mass-market sectors, found that over 99% of exploited vulnerabilities of digital equipment are compromised more than a year after the security risk was made public,

[242] EHSR 1.2.1 Safety and reliability of control systems: "Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that: (...) a fault in the hardware or the software of the control system does not lead to hazardous situations (...)".

[243] Given this focus in the Guide, only software that ensures a safety function and is placed independently on the market was analysed in this study. Other independent software placed in the market and uploaded to the machine might have an effect on the proper safety and functioning and performance of the machine. This could be assessed in future studies.

[244] Case study 1 on digital transformation

[245] The Guardian (2014). As Windows XP support ends, are 'XPocalypse' reports overblown? Available at: https://www.theguardian.com/technology/2014/apr/14/windows-xp-support-ends-xpocalypse

meaning that lack of appropriate software updates directly leads to higher exploitation rates and compromised equipment.[246]

The majority of stakeholders (56.8%) that participated in the open public consultation agree that software which ensures a safety function and is placed independently on the market should explicitly be covered by the MD and therefore considered a safety component (Article 2(c). But 28.9% of the OPC stakeholders did not have an opinion on the question, and 14.3% of the stakeholders responded negatively. Of the stakeholder's groups participating in the OPC, the largest share (30.2%) agreeing that software should be considered as a safety component were companies/business associations.

Table 21: OPC results on whether software should be considered as a safety component

Stakeholder group	Yes	No	No opinion	Number of respondents
Authority enforcing MD (n=24)	**75%**	8.3%	16.7%	24
Consumer organisation (n=3)	33.3%	33.3%	33.3%	3
Distributor (n=6)	16.7%	16.7%	**66.7%**	6
Importer (n=6)	**66.7%**	0%	33.3%	6
Industry association (n=64)	39.1%	23.4%	37.5%	64
Machinery safety consultant (n=85)	**81.2%**	12.9%	5.9%	85
Manufacturer (n=212)	44.8%	15.1%	40.1%	212
Notified body (n=44)	**84.1%**	4.5%	11.4%	44
Private user (n=5)	40%	20%	40%	5
Professional worker (n=18)	**66.7%**	22.2%	11.1%	18
Researcher/academic (n=3)	33.3%	**66.7%**	0%	3
Stakeholders involved in standardisation (n=7)	**42.9%**	28.6%	28.6%	7
Other (n=46)	**63%**	6.5%	30.4%	46

Source: OPC results (n=523)

6.1.1.5 Cybersecurity

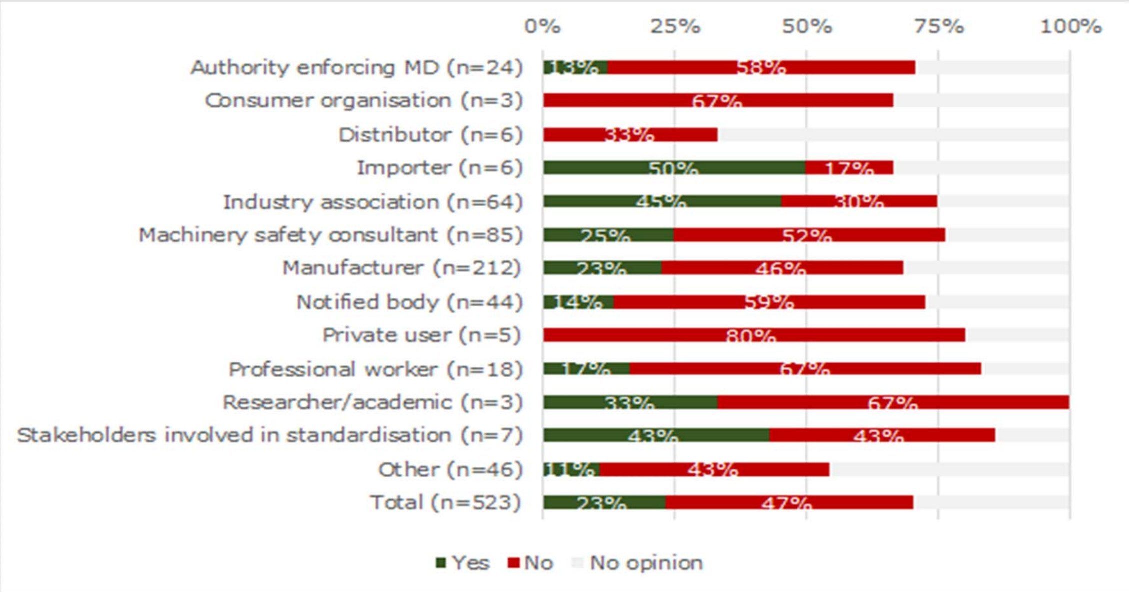
Impacts of addressing cybersecurity in the Machinery Directive were mostly assessed qualitatively. This is due to the lack of quantitative information on health and safety incidents due to a cybersecurity breach in the machinery sector. Some data in other sectors were recorded in Chapters 1 and 2 of this study, in order to have an understanding of the existing risks in general or number of incidents due to hacking. However, the impacts of these incidents were not directly linked to any harm to users' health and safety. Nevertheless, the systems contain vulnerabilities, as shown in the previous chapters. The expected increase of implementation of interconnected machinery is likely to contribute to an increase of probability of incidents that might negatively affect the health and safety of users.

Stakeholders were consulted to obtain information on the issue of cybersecurity linked to the Machinery Directive. A growing risk of malicious interfering or hacking was recognised across

[246] Verizon (2015). 2015 Data breach investigations report. Available at: https://cybersecurity.idaho.gov/wp-content/uploads/sites/87/2019/04/data-breach-investigation-report_2015.pdf

all stakeholder groups. To the question of whether the risk of cyber threats is sufficiently covered in the current MD, the majority of consultation respondents indicated that it was not.

Figure 25: OPC Results on whether MD covers cyber threats affecting health and safety (for instance, hacking and taking control of the machine/robot)



Source: OCP results (n=523)

Even though the consultation responses show that the MD is limited in its coverage of cybersecurity risks, the opinions on whether the EHSR should be adapted in order to close this gap yielded varying opinions, both across stakeholder groups and consultation activities.

The industry associations interviewed, commented that this would not fall in the scope of the Directive but should rather be dealt with elsewhere, such as the Cybersecurity Act. While the Cybersecurity Act was considered a positive initiative, it is a voluntary framework that does not provide obligatory requirements. Therefore, it was considered more beneficial for a separate horizontal legislative measure, such as a directive or regulation under the NLF, to be developed for CE-marking regulations. Manufacturers, market surveillance authorities, consumer organisations, notified bodies, and trade unions supported this position, indicating that cybersecurity is considered a broader issue that should not be specifically addressed in the MD but rather outside, and that it should link the MD to the dedicated directive or regulation. The main reasons why a change in the EHSR was not seen as beneficial were the following[247]:

- The in-service support of the manufacturer to reach resilient products against cyberattacks cannot be captured by the existing requirements, as they cover the process until the placing on the market and installation. The crucial phase of use of the product that is needed to reach resilience is not covered.
- If the existing requirements and directives or regulations for CE marking would be expanded to apply cyber requirements or requirements on resilience against cyberattacks, this would lead to further fragmentation of these requirements. Since the requirements would be changed and updated in varying intervals, changes on

[247] VDMA (2019). Cybersecurity – eine Voraussetzung für Digitalisierung (position paper). Available at: https://www.vdma.org/documents/17175809/37667271/1VDMAPosPap_Cybersecurity_190715_1563285372998.pdf/1e3cd1d6-b8fe-1544-53b1-e5e7a5f57a4f

cybersecurity requirements would need to be adapted as well, leading to a potential further fragmentation across directives. Even if efforts are made to fix these requirements on specific examples or models it would not remove the risk of a fragmentation completely. Given that manufacturers often follow multiple directives or regulations when manufacturing their products, a fragmentation of cybersecurity requirements on sectorial basis would lead to high costs and uncertainty over which to apply.

Indeed, the aspect related to the structure of the Directive focusing on ensuring the safety of machinery before it is placed on the market was often raised by industry stakeholders and manufacturers. Cybersecurity would require taking further steps once the product is on the market, especially if manufacturers consider the resilience of the product not to be sufficient. Two aspects are to be considered in this case: i) if a cyberattack happens, the product has to be resilient against it by creating a wall to protect the product; and ii) if an attack is successful and the wall overcome, then there needs to be a trigger for the control system of the machinery. In this case, the control system must be aware of the attack and its outcome. In relation to the latter case, Annex, I 1.2 requirement is cited: "if an external influence comes to the control system, the machine must go to safe position." Notified bodies interviewed referred to intended use and reasonable foreseeable misuse as well. They indicated that this is understood as physical misuse. An extension of the wording with "reasonable foreseeable abuse" was mentioned. One notified body mentioned that a reference to cyberattacks could be made within the Annex I, 1.2.1 under "external influence". Also, one of the consumer organisations interviewed gave an answer to this question, indicating knowledge of Annex I, 1.2.1 on external influences but that a more precise wording could be beneficial.

A workshop on this aspect that was run by the German Commission for Occupational Health and Safety and Standardisation (KAN) came to the same conclusion that cyberattacks are covered by Annex I, 1.2.1. The main results of the workshop indicated that[248]:

- The current Machinery Directive already requires safety, <u>even in case of cyberattacks</u> (see especially Annex I, 1.2.1 "external influences", "fault")
- In particular, and depending on the application, the <u>control system must be capable of detecting</u> the "trigger" of an attack
- The <u>ability to detect must be in relation to (dependent on) the risk</u>, understood as a function of severity and probability, caused by a potential attack

However, there was no common understanding on whether the "resilience" of the machine to withstand a cyberattack (i.e. the difficulty an attacker would have to face when trying to enter the system) should be an issue within the scope of the Machinery Directive. The only stakeholder group that provided a rather balanced position on this aspect were the national authorities interviewed. Some followed the same reasoning as the other stakeholder groups, while others indicated that some vertical requirements in the Directive could be beneficial.[249] Indeed, for many authorities enforcing the Directive, cybersecurity requirements should be addressed through cross-cutting (horizontal) legislation with specific sectoral (vertical) requirements (38%).

6.1.2. Addressing the challenges posed by innovation in digitisation through self-regulation by market participants.

Self-regulation is characterised by the development of voluntary codes of practice or standards developed by the industry, with the industry solely responsible for enforcement.

[248] KAN (2019). Presentation to the Machinery Working Group on 3 December 2019. A) Machine learning applications, B) cybersecurity, and the provisions of the Machinery Directive.
[249] National authority from the Netherlands and Bulgaria

This is in contrast to the use of harmonised standards which play a crucial role on the safety of machinery and compliance with the Directive. In particular, manufacturers can voluntarily comply with existing harmonised standards to ensure that the products conform to the relevant EHSRs. However, if they do not decide to follow a harmonised standard, they must show in their technical file that their design meets the EHSR using the state of the art, which is informed by the relevant harmonised standard.

Interview respondents also indicated that emerging technologies should be dealt with at type C level, rather than through citation of specific technologies in the EHSRs. A connection to collaborative robots was made, indicating that different risk analyses are needed for these technologies, rather than being limited by the MD. Within Machine Tool manufacturing, standards are also seen as a crucial way to address challenges related to IoT in particular. One example mentioned is the UMATI, an initiative on national level that develops universal interfaces for machine tools from different manufacturers to communicate with each other in one production line. These types of initiatives are seen as a contributor to the development of globally accepted connectivity standards.[250] International standards in relation with cybersecurity of machinery and safety of smart machinery have recently been evolving. A new ISO standard (ISO/TR22100-4[251]) to reduce the risks of cyberattacks on machinery was developed by the technical committee ISO/T 199 and published in January 2019.[252] Indeed, the standardisation efforts on IoT are considered high with tangible progress and outputs from the various IoT standards initiatives and bodies.[253]

In contrast, self-regulation in this case is seen separately from the application of harmonised standards applicable to the Machinery Directive. Stakeholders were generally not in favour of addressing challenges through self-regulation. The industry associations interviewed commented that sufficient market self-regulation should be, and in many cases already is, addressed by harmonised standards. The manufacturers were concerned about creating an unfair playing field – competitors with higher levels of safety incur higher costs, with machines becoming more expensive, and competitiveness is reduced. The national authorities interviewed were not in favour of self-regulation, considering that involvement of the notified bodies is more appropriate to ensure a high level of quality. Also, manufacturers have limited expertise to identify all the potential risks. The MSAs considered that switching to self-regulation would potentially increase the need for controls. Concerns were also raised regarding the availability and longevity of online material. Consumer organisations objected to self-regulation. It was noted that the industry can already bring their points forward through the standardisation process, and the present system is therefore quite balanced. Trade unions objected to self-regulation, one of them noting that it could potentially lead to manufacturers with a lower level of compliance dominating the market, putting the compliant ones at a disadvantage and increasing the number of accidents.

In comparison, some interviewees indicated that AI is only just emerging in their sectors and that legislation might be introduced too soon. Self-regulation was therefore considered an interesting alternative in this case. For the business-to-consumer sector, in particular, self-regulation might be especially important in terms of ethical principles too. Furthermore, industry associations could foresee the use of certification schemes for cybersecurity and adherence to certain AI ethical guidelines.

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[250] CECIMO (2019). CECIMO circular economy report (April 2019), p. 28.

[251] ISO/TR 22100-4 Safety of machinery – relationship with ISO 12100 – Part 4: Guidance to machinery manufacturers for consideration of related IT-security (cyber security) aspects

[252] ISO (2019). Smart manufacturing: new ISO guidance to reduce the risks of cyber-attacks on machinery. Available at: https://www.iso.org/news/ref2365.html

[253] European Research Cluster on the Internet of Things (2014). Internet of things. From research and innovation to market deployment. Available at: http://www.internet-of-things-research.eu/pdf/IoT-From%20Research%20and%20Innovation%20to%20Market%20Deployment_IERC_Cluster_eBook_978-87-93102-95-8_P.pdf

Table 22: Potential impacts of policy sub-option 1.2

Policy option 1.2	Positive impacts	Negative impacts
Economic impacts	• Some guidelines might not be implementable in regulation (e.g. AI ethical guidelines). Self-regulation could be a useful alternative.	• Without legal action on requirements and only following voluntary measures, a risk of market fragmentation would remain. This is because economic operators might apply different additional levels of safety requirements beyond the already existing legal requirements • This could lead to an unfair level playing field with economic operators applying additional voluntary requirements for their products having more expensive products compared to those that do not apply additional requirements
Social impacts	• Some users could benefit from higher requirements followed by some manufacturers	• Some users could be harmed by lower requirements followed by some manufacturers • There could be an indirect risk of having access to products with varying degrees of requirements implemented and could lead to increased need for market control
Environmental impacts	• None identified	• None identified

In terms of costs and benefits of sub-option 1.2, a self-regulation of the market is not expected to bring any additional costs for stakeholders, as it represents the same logic as no EU action. Similar to the baseline scenario, a continuation of self-regulation could develop towards a non-recommendable scenario, given that the negative economic and social impacts could lead to indirect costs for stakeholders (e.g. in terms of costs for legal clarifications).

6.1.3. Other findings from the consultation: Horizontal legislation and policy frameworks

One often mentioned alternative to changing the legal text of the MD or self-regulation of market participants when it comes to some risks of new technologies, is an overarching horizontal legislation.

Regarding cybersecurity, the Cybersecurity Act may represent one point of reference as an existing market initiative. It is a voluntary EU-wide certification framework for digital products, services and processes. They will be based on a comprehensive set of rules, technical requirements, standards and procedures.[254] Given the status of the framework, specificities are yet to be defined, but they will cover:

- Categories of products and services covered;
- Cybersecurity requirements (e.g. reference to standards and technical specifications);
- Type of evaluation (e.g. internal checks or third-party evaluation); and
- Intended level of assurance (e.g. basic, substantial and/or high).

[254] European Commission (2019). The EU cybersecurity certification framework. Available at: https://ec.europa.eu/digital-single-market/en/eu-cybersecurity-certification-framework

This voluntary certification framework may be followed by industry representatives. The Cybersecurity Act could have potential to cover emerging risks in relation to cybersecurity also for machinery products using new technologies to a certain extent. If taken as a basis to develop a horizontal legislation, it could also provide a first basis to a horizontal legal act. A horizontal legislation could also expand on aspects covered by sectorial legislation, for instance by referring to the relevant legislation.

Indeed, an impact assessment study carried out in parallel with this assignment and which investigated the Increased Protection of Internet-Connected Radio Equipment and Wearable Radio Equipment (RED Directive) found that "many key stakeholders, in particular from industry, noted that horizontal legislation may be a more effective regulatory approach in the medium term to ensure a level regulatory playing field between wireless products subject to the RED"[255]. This conclusion also bears relevance with regards to the Machinery Directive.

On personal data protection, France[64] considered that the manufacturer would be expected to observe the requirements of Directive 96/9/EC of 11 March 1996 on the legal protection of databases and Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data. The operator must be informed of this at least in the instruction manual. If using data from a closed, known environment, mastered by the machinery manufacturer, the usage conditions of the data shall be specified in the instructions.

6.2. Impacts of policy Option 2: Addressing the problems identified during the evaluation of the Machinery Directive

This policy option comprises several sub-options, as shown previously in this study. The overall net effect of this option is positive. However, this is dependent on the sub-options. Expected positive effects stem from an alignment to the NLF, an adaptation of the list of low-voltage products excluded, an improvement of partly completed machinery and allowing digital formats for documentation. The overall expected benefits and costs of this policy option are provided in ranges, given its interdependence between sub-options, in the table below.

[255] Whittle et al (2020) Impact Assessment on Increased Protection of Internet-Connected Radio Equipment and Wearable Radio Equipment. 716/PP/GRO/IMA/18/1133/10768 IMPLEMENTING FRAMEWORK CONTRACT 575/PP/2016/FC

Table 23: Potential costs and benefits of policy option 2

Policy option 2	Description	Firms			Administrations	Other organisations		Citizens/users	
ADDRESSING THE PROBLEMS IDENTIFIED DURING THE EVALUATION Net effect of policy sub-option (+)		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector**	**Users / consumers**
1. Number of affected stakeholders (EU-27)		**Up to 1,703**	**Up to 81,024**	**Up to 82,239**[a)]	**71 or more**	**137 or more**	**1**	**2,759,439**	**Up to 446,000,000** [b)]
2.1 Costs (total)	**One-off**	**0 to 5,233,099,943 €** Depending on the change of the Directive, one-off costs will apply. Lower ranges expected with no change, upper ranges if all changes are followed	**0 to 4,234,438,247 €** Depending on the change of the Directive, one-off costs will apply. Lower ranges expected with no change, upper ranges if all changes are followed	**0 to 10,287,191,919 €**[c)] Depending on the change of the Directive, one-off costs will apply. Lower ranges expected with no change, upper ranges if all changes are followed	**Adaptation costs to changes, not quantifiable**	**Adaptation costs to changes, not quantifiable**	**Not quantifiable** Review of up to 800 standards if changes to EHSR are made	**0.49 to 0.52**€ per manual (number of manuals for professionals not identified)	**0.49 to 0.52**€ per manual (number of manuals for professionals not identified)
	Recurrent (annually)	**0 to 685,376,947 €** Depending on the change of the Directive, recurrent costs will apply. Lower ranges expected with no change, upper ranges if all changes are followed	**0 to 523,186,820 €** Depending on the change of the Directive, recurrent costs will apply. Lower ranges expected with no change, upper ranges if all changes are followed	**0 to 1,208,277,057 €**[e)] Depending on the change of the Directive, recurrent costs will apply. Lower ranges expected with no change, upper ranges if all changes are followed	**No additional recurrent costs identified**	**No additional recurrent costs identified**	**No additional recurrent costs identified**	**Not quantifiable** Depending on the change of the Directive, recurrent costs are related to potential accidents due to a slow-speed lift malfunction	
2.2 Costs per organisation	**One-off**	**0 to 33,851,137 €** Depending on the change of the Directive, one-off costs will apply. Lower ranges expected with no change, upper ranges if all changes are followed	**0 to 514,295 €** Depending on the change of the Directive, one-off costs will apply. Lower ranges expected with no change, upper ranges if all changes are followed	**0 to 1,226,565 €** Depending on the change of the Directive, one-off costs will apply. Lower ranges expected with no change, upper ranges if all changes are followed	**No quantification possible**	**No quantification possible**	-	-	
	Recurrent (annually)	**0 to 1,903,782 €** Depending on the change of the Directive, recurrent costs will apply. Lower ranges	**0 to 41,113 €** Depending on the change of the Directive, recurrent costs will apply. Lower ranges	**0 to 67,688 €** Depending on the change of the Directive, recurrent costs will apply. Lower ranges expected with	-	-	-	-	

Policy option 2	Description	Firms			Administrations	Other organisations		Citizens/users	
		expected with no change, upper ranges if all changes are followed	expected with no change, upper ranges if all changes are followed	no change, upper ranges if all changes are followed					
3. Benefits	**Direct[d)]**	**0 to 92,843,529,319 €** Depending on the change, benefits are expected to stem from increased legal clarity and a switch to digital documentation	**0 to 64,518,384,781 €** Depending on the change, benefits are expected to stem from increased legal clarity and a switch to digital documentation	**0 to 157,361,914,100 €** Depending on the change, benefits are expected to stem from increased legal clarity and a switch to digital documentation	**Not quantifiable** Benefits are expected through a harmonisation of market surveillance processes through the alignment to the NLF and increased legal clarity	**Not quantifiable** Benefits are expected through increased legal clarity and a switch to digital documentation	-	**Not quantifiable** Harmonisation of market surveillance procedures is expected to reduce the share of non-compliant products on the market	**10,132,560,048 €** Harmonisation of market surveillance procedures is expected to reduce the share of non-compliant products on the market (especially regarding consumer products that made 88% of the alerts registered 2010-2019)
	Per organisation	**0 to 96,023,454 €**	**0 to 1,988,340 €**	**0 to 2,046,185 €**	**Not quantifiable** Benefits are expected through a harmonisation of market surveillance processes through the alignment to the NLF and increased legal clarity	**Not quantifiable** Benefits are expected through increased legal clarity and a switch to digital documentation	-	-	-
	Indirect	-	-	-	-	-	-		**Not quantifiable** Access to ICSMS communication system for pan-European market surveillance will be available to consumers as well

a) Due to rounding differences in the data in Eurostat, the total number of enterprises shown does not equal the sum of enterprises recorded per size class.
b) Proxy used: number of inhabitants living in the EU.
c) Up to 16.9% of turnover which would make the range of about 50% of the added value in the machinery sector. In order to mitigate these effects, the one-off costs can be distributed over the years of transposition of the changes, meaning that the maximum ranges of one-off costs decrease if accounting for these. In addition, other mitigating measures could be increasing the years of transposition of certain sub-options.
d) Some benefits might materialise quicker than others. For instance, benefits from legal clarity and digital documentation are likely to materialise quicker than benefits through changes in the requirements. Due to the differences in products covered in the Machinery Directive and the proposed changes in Policy Option 2, the life cycles of machinery could not be taken as a proxy to estimate the potential timeline for benefits.
e) Recurrent costs may result from maintenance of servers with regards to digital documentation, for instance.
There are instances where data are quantified based on responses to consultations or interviews. When the number of replies is too low to present an estimate, cost cannot be reliably quantified. Proxy values are used when direct information is not available.

6.2.1. Alignment to the NLF

Alignment to the New Legislative Framework received nearly universal support, despite the fact that stakeholders did not report any major problems resulting from the lack of alignment. **An alignment to the NLF would affect all stakeholder groups in the machinery sector** either positively or negatively, **in particular manufacturers and market surveillance authorities**.[256]

For the industry stakeholders that as manufacturers must apply other Directives that are aligned, more coherence would be beneficial. In particular, it was considered useful to have all Directives under one regulatory framework, as with different products, different Directives have to be complied with. National authorities considered that the alignment would lead to easier market surveillance, better explanation of certain terms and common rules between technologies. Market surveillance authorities cited clarity of responsibilities of the economic actors and focus on market surveillance. Notified bodies and machinery safety consultants on the other hand noted that the quality of the conformity assessment would increase through the alignment. As cross-sectoral products are becoming common, cross-sectoral requirements should thus be aligned where possible. See sub-chapter 2.3.1.1. in the Chapter 2 for the detailed explanation of the identified problems arising from non-alignment of the MD to the NLF.

Overall, the potential impacts are expected to be as follows:

Table 24: Expected impacts of an alignment of the MD to the NLF

Type of impact	Positive impacts	Negative impacts
Economic impacts	• Harmonised framework across technologies and products • Facilitate the movement of goods	• None identified[257], some adaptation costs (one-off) could apply
Social impacts	• Higher quality of conformity assessments and reduction of non-compliant products in the market: potentially increased safety	• None identified
Environmental impacts	• None identified	• None identified

Source: stakeholder consultation results

With regards to costs of aligning the MD to the NLF, none of the interviewed stakeholders indicated any particular costs that would result from the alignment. It was observed by some stakeholders that it would depend on what changes would be made to the legislative text as a result of the alignment. Indeed, one estimation of costs of the full alignment to the NLF was made by the UK government in 2015: GBP 540 (EUR 601[258]) one-off costs and GBP 1,350 (EUR 1,504) recurring costs per firm. The total costs of alignment (best estimate) was

[256] The number of enterprises potentially affected by change was taken from the market analysis, based on Eurostat's structural business statistics of 2016, C.28 (NACE rev.2), the number of MSAs is based on the list provided on the European Commission's website. The number of employed persons in the machinery sector is taken as best available proxy of potential users being impacted by the change. These numbers were also based on Eurostat's structural business statistics 2016, C.28 (NACE rev.2).

[257] A previous impact assessment study identified potential administrative costs borne by firms (i.e. manufacturers) due to specific administrative requirements. These, however, are not expected to apply in the case of the MD as these requirements are already in place.

[258] Converted using the European Commission's InforEuro, baseline 2015.

calculated at GBP 145.6 million (EUR 196 million[259]).[260] However, the costs were estimated based on the administrative burdens for manufacturers and importers to hold relevant information for 10 years and manufacturers' names, addresses as well as the products' identifying batches/serial numbers. This is already a requirement in the Machinery Directive; thus, these types of costs are unlikely to affect the industry in the case of an alignment of the MD to the NLF.

On the other hand, the assessment described non-monetised benefits as the better functioning of the internal market and the movement of goods, along with benefits to economic operators. In addition, the assessment indicated potential benefits to the health and safety of consumers through reducing the number of non-compliant products on the market[261] However, it was not possible to quantify the benefits in those instances. For national and market surveillance authorities, an alignment of the MD to the NLF is also not expected to have significant administrative costs, according to responses gathered from stakeholder consultation, as this has already been done for 10 Directives in the past and the relevant knowledge is therefore available.

Alignment is thus expected to not cost anything, while benefits have been identified, albeit in a qualitative manner. The net effect of policy sub-option 2.1 (full alignment to the NLF) is thus positive, as visualised in the table below. For the total expected costs of Policy Option 2, the size of the administrative and industry costs would rather depend on the other changes made to the legal text of the Directive under other policy sub-options rather than the alignment only (see sections on change of scope and definitions and revising the EHSR).

[259] Converted using the European Commission's InforEuro, baseline 2015.

[260] Government UK, Department for Business, Innovation and Skills (2015). Impact assessment on the alignment of nine Directives to the New Legislative Framework. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/450592/BIS-15-469-IA-alignment-of-nine-EU-single-market-directives-with-the-new-legislative-framework.pdf

[261] The impact assessment also included a non-quantified benefit of a reduction in the risk of environmentally unfriendly goods, but this is likely to be related to a specificity of one of the Directives that was to be aligned at the time

Table 25: Costs and benefits of an alignment to the NLF

Policy option 2.1	Description	Firms			Administrations	Other organisations		Citizens/users	
ALIGNMENT TO THE NLF Net effect of policy sub-option (+)		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector**	**Users/consumers**
1. Number of affected stakeholders (EU-27)		**1,703**	**81,024**	**82,239[a)]**	**71 or more**	**-**	**-**	**2,759,439**	**446,000,000 [b)]**
2.1 Costs (total)	**One-off**	Some adaptation costs likely but expected to be marginal by consultation participants	Some adaptation costs likely but expected to be marginal by consultation participants	Some adaptation costs likely but expected to be marginal by consultation participants	Some adaptation costs likely but expected to be marginal by consultation participants	-	-	-	-
	Recurrent	**0.00 €**	**0.00 €**	**0.00 €**	**0.00 €**	**-**	**-**	**-**	**-**
2.2 Costs per organisation	**One-off**	Some adaptation costs likely but expected to be marginal by consultation participants	Some adaptation costs likely but expected to be marginal by consultation participants	Some adaptation costs likely but expected to be marginal by consultation participants	Some adaptation costs likely but expected to be marginal by consultation participants	-	-	-	-
	Recurrent	**0.00 €**	**0.00 €**	**0.00 €**	**0.00 €**	**-**	**-**	**-**	**0.00 €**
3. Benefits	**Direct**	**Not quantifiable** Benefits are expected through a harmonisation of new-approach Directives under the same framework	**Not quantifiable** Benefits are expected through a harmonisation of new-approach Directives under the same framework	**Not quantifiable** Benefits are expected through a harmonisation of new-approach Directives under the same framework	**Not quantifiable** Access to ICSMS communication system for pan-European market surveillance is expected to facilitate the procedures	-	-	**Not quantifiable** Harmonisation of market surveillance procedures is expected to reduce the share of non-compliant products on the market (especially regarding professional products that made 12% of the alerts registered 2010-2019)	**Not quantifiable** Harmonisation of market surveillance procedures is expected to reduce the share of non-compliant products on the market (especially regarding consumer products that made 88% of the alerts registered 2010-2019)
	Indirect	-	-	**Not quantifiable** Harmonisation	-	-	-	-	**Not quantifiable** Access to ICSMS communication

Policy option 2.1	Description	Firms			Administrations	Other organisations		Citizens/users	
				of market surveillance procedures is expected to reduce the share of non-compliant products on the market (76% of products under the alert system are from third countries)					system for pan-European market surveillance will be available to consumers as well

[a)] Due to rounding differences in the data in Eurostat, the total number of enterprises shown does not equal the sum of enterprises recorded per size class.
[b)] Proxy used: number of inhabitants living in the EU.
There are instances where data are quantified based on responses to consultations or interviews. When the number of replies is too low to present an estimate, cost cannot be reliably quantified. Proxy values are used when direct information is not available.

6.2.2. Adapting the scope and definitions in the Directive

Policy option 2.4.1 covers "adapting the scope and the definitions in the Directive, e.g. assess the threshold speed for slow-speed lifts covered or adapt/ clarify the list of low-voltage products excluded and improve the definition of 'partly completed machinery'".

The issue of **clarifying scope and definitions** covers a wide range of issues. A few general observations can be made:

- Those stakeholders that in general object to opening the contents of the Directive to revision consider that unclear concepts can be clarified in the Guide.
- The concept of partly completed machinery (PCM) is considered unclear, but most stakeholders do not consider that it should be removed.
- Removing the exclusion of low-voltage machinery is not considered to bring any advantage by most respondents.
- There should be harmonised legislation for fairground equipment; the reference to "specific" in the MD is unclear.
- Concepts such as "research" and "available on the market" are somewhat unclear for the industry.
- In addition to clarification to be brought in the scope, definitions and concepts or requirements:
  - the concept of substantial modification in a machinery which leads to a new machinery requiring CE marking, should be clarified.
  - stakeholders are cautious towards changing the requirements for slow-speed lifts. The proposed increase of minimum speed is considered to cause safety hazards, particularly in combination with allowing light barrier curtains.

6.2.2.1. Adapt the list of low voltage products excluded

The assessment found that the benefits of adapting the list of low-voltage products excluded outweighs the costs of the changes. The main stakeholder groups expected to be affected by a change in the list of low-voltage products excluded are manufacturers[262] and MSAs. Users, however, could indirectly benefit from a reduction of non-compliant products on the market. Among the key positive impacts of an adaptation is an expected decrease of 26% of non-compliant products on the market.[263]

Monetisation of costs or benefits, however, are not possible to make since there are no data on costs per inspection. An added difficulty is that inspections also occur independently of suspected non-compliance cases, which weakens the relationship between the number of inspections and the number of non-compliant products.

[262] For an estimation of the potential number of manufacturers affected, the focus lied on the NACE rev.2 categories C28.23; C28.29; C28.95; C28.15.This might over- or underestimate the number of potentially affected manufacturers, as no more granulated information on the types of products manufactured could be identified. The total number of manufacturers identified was 18,005, 360 large companies and 17,645 SMEs. The statistics are based on Eurostat's structural business statistics 2016 (EU-27).

[263] A decrease of non-compliant products on the market is expected to benefit users of machinery in particular. It is not expected to be inherently related to the number of inspections conducted by authorities and therefore the costs on these inspections. To a limited extent, it might be possible that the inspections require less time if no irregularities are found. This effect could not be quantified, however.

Table 26: Expected impacts of policy sub-option 2.2.1 Adapting the list of low-voltage products

Policy option 2.2	Positive impacts	Negative impacts
Economic impacts	• Increased legal clarity of the products included and excluded from the Directive • Potential reduction of costs from clarifications with MS authorities	• Adaptation costs to the changes
Social impacts	• Reduction of non-compliant products on the market by 26%*	• None identified
Environmental impacts	• None identified	• None identified

*OPC results, n=14

Looking into the costs of changing the list of products under Art. 1.2(k), these could not be reliably quantified, though anecdotal evidence gathered through the study might serve as an indication.[264, 265] Benefits were estimated by using the expected decrease of non-compliant products on the market.[266] The table below indicates the potential costs and benefits of modifying Art. 1.2(k) of the MD.

[264] Economic operators estimated an impact of one-off costs of about 1.25% of annual turnover (n=2), while an average of 1% of annual turnover recurring costs (n=1). No further details on the reasons behind these indications could be identified. To extrapolate these costs, the turnover of the selected sub-categories of the machinery sector from Eurostat's structural business statistics 2016 (EU-27), C28 (NACE rev.2) was used. The selected sub-sectors were C28.23, C28.28, C28.95, and C28.15. These numbers might overestimate or underestimate the actual number affected by the policy change.

[265] MSAs did not indicate any expected increase in costs resulting from adapting the list of low voltage products excluded. They were recorded as EUR 0.

[266] Benefits for users were estimated by taking the expected 26% reduction of non-compliant products on the market from the average share of non-compliant products found, according to MSAs report 2013-2016 (40%) and PRODCOM statistics on production value of those machines. First the value of the total non-compliant products was estimated (40% of total production value of machinery). Then, a reduction of this value would apply to 26%, given the responses from the OPC. Five economic operators indicated the changes to bring an average decrease of 0.22% of annual turnover. These were estimated as benefits of the policy sub-option by extrapolating to the turnover of the selected sub-categories of the machinery sector from Eurostat's structural business statistics 2016 (EU-27), C28 (NACE rev.2) was used. The selected sub-sectors were C28.23, C28.28, C28.95, and C28.15. These numbers might overestimate or underestimate the actual number affected by the policy change.

Table 27: Costs and benefits of changing Art. 1.2(k)

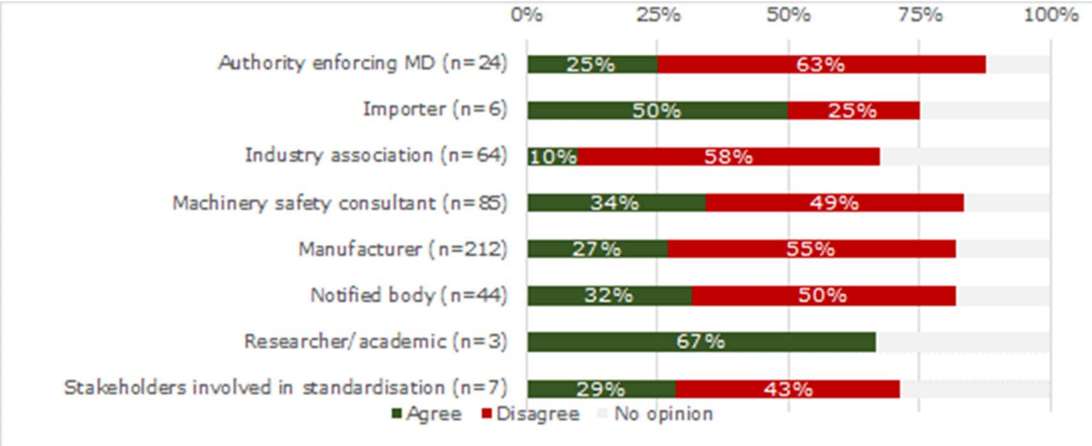
Policy option 2.2.1	Description	Firms			Administrations	Other organisations		Citizens/users	
ADAPTING THE LIST OF LOW VOLTAGE PRODUCTS EXCLUDED Net effect of policy sub-sub-option **(+)**		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector**	**Users/ consumers**
1. Number of affected stakeholders (EU-27)		360	17,645	18,005 [a)]	71 or more	-	-	884,224[c)]	191,210,900[d)]
2.1 Costs (total)	**One-off**	Some adaptation costs to changes are likely to apply but could not be reliably quantified	Some adaptation costs to changes are likely to apply but could not be reliably quantified	Some adaptation costs to changes are likely to apply but could not be reliably quantified	Some adaptation costs are likely to apply but expected to be marginal by consultation participants	-	-		-
	Recurrent (annually)	Some recurrent costs expected by a few consultation participants but could not be reliably quantified	Some recurrent costs expected by a few consultation participants but could not be reliably quantified	Some recurrent costs expected by a few consultation participants but could not be reliably quantified	0.00 €	-	-		-
2.2 Cost per organisation	**One-off**	Some adaptation costs to changes are likely to apply but could not be reliably quantified	Some adaptation costs to changes are likely to apply but could not be reliably quantified	Some adaptation costs to changes are likely to apply but could not be reliably quantified	0.00 €	-	-		-
	Recurrent (annually)	Some recurrent costs expected by a few consultation	Some recurrent costs expected by a few consultation	Some recurrent costs expected by a few consultation participants but could not be	0.00 €	-	-		-

Policy option 2.2.1	Description	Firms			Administrations	Other organisations		Citizens/users	
		participants but could not be reliably quantified	participants but could not be reliably quantified	reliably quantified					
3. Benefits	**Direct**	Some benefits are expected by a few consultation participants but could not be reliably quantified	Some benefits are expected by a few consultation participants but could not be reliably quantified	Some benefits are expected by a few consultation participants but could not be reliably quantified	Not quantifiable Expected benefits for reduction of legal unclarity	-	-		10,132,560,048 € [b)]
	Indirect	-	-	-	-	-	-	-	-

[a)] based on Eurostat structural business statistics (EU-27) 2016, C28.23, C28.29, C28.95, C28.15.
[b)] based on 26% of 40% of production value (PRODCOM proxy of products, value EUR 97,428 million).
[c)] Proxy used by looking into the home appliances industry – number of direct employees 2016, APPLiA (2017). By the numbers: The home appliance industry in Europe, 2017-2018. Available at: http://applia-europe.eu/statistical-report-2017-2018/documents/APPLiA_SR19.pdf
[d)] Proxy used: number of households in 2016 (EU-27), Eurostat [lfst_hhnhwhtc].
There are instances where data are quantified based on responses to consultations or interviews. When the number of replies is too low to present an estimate, cost cannot be reliably quantified. Proxy values are used when direct information is not available.

In comparison to this suggested change with regards to Art. 1.2(k), a removal of the exclusion of Art. 1.2(k) was not considered beneficial by the majority of all stakeholders, including manufacturers and industry associations (average of 56.3%)[267] and enforcing authorities, notified bodies, machinery safety consultants and stakeholders involved in standardisation (average of 64.3%)[268]. Manufacturers of electric products (n=133) were mostly against a removal of the exclusion (55%), though about a quarter were for the removal (23%). The main risk mentioned by several stakeholders if the exclusion was to be removed is an increase of non-compliance of electrical products on the market. Of the one third that was in favour of removing the exclusion, some argued that this would lead to all machinery falling under the scope of the MD, regardless of their type of hazard or risk – all other definitions that do not fall under the Machinery Directive in terms of electronic products (e.g. cables, installation material) would be covered under the LVD.[269]

Figure 26: Results of the OPC on removing the exclusion of Art. 1.2 (k) by stakeholder group

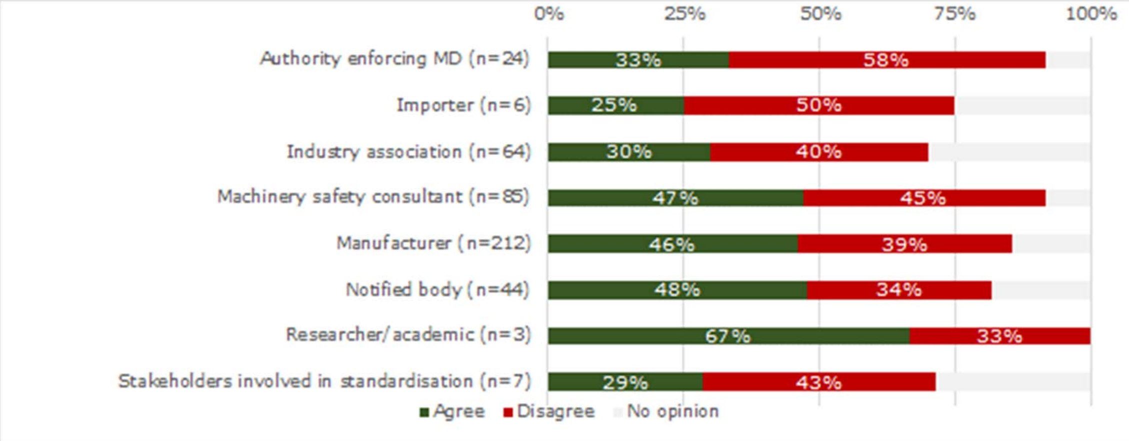


Source: OPC results (n=296)

Improving compliance through a differentiation of consumer and professional products was also not considered beneficial by most industry members (importers, industry associations) and enforcing authorities, notified bodies, machinery safety consultants and stakeholders involved in standardisation. On the other hand, manufacturers indicated it to be useful (46.1%), especially SMEs (52.4%). The distinction of commercial and consumer products was considered as not beneficial by many stakeholders due to the difficulty of drawing a line between products, considering that various types of products could be sold for either use and therefore there is no need to define every product as one or the other. The term "industrial use" of machinery, through which the product would fall under the MD was mentioned by several manufacturers to be considered. Currently, these distinctions are made punctually within the Guide (e.g. ordinary office machinery).

[267] Total of 72 respondents to the OPC
[268] Total of 92 respondents to the OPC
[269] Authority enforcing the MD in Germany

Figure 27: Results of the OPC on differentiating of consumer and professional products, per stakeholder group



Source: OPC results (n=296)

6.2.2.2. Review the threshold speed for slow-speed lifts covered

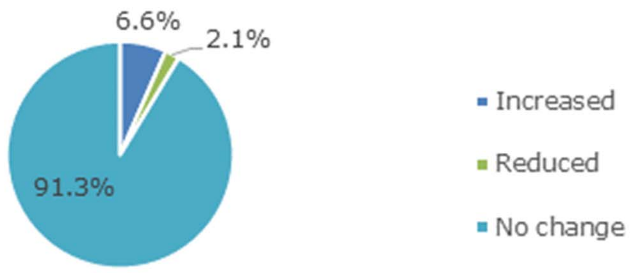
Any changes regarding slow-speed lifts will affect all manufacturers of these lifts due to familiarisation to the process, compliance costs and potential new conformity assessments. To provide an estimate, the potentially affected enterprises are the 7,699 recorded enterprises manufacturing lifting and handling equipment in the EU-28 (NACE 2 – C2822) in 2016. Other costs could arise for Market Surveillance Authorities and notified bodies.

Table 28: Types of costs related to changes to speed thresholds of slow-speed lifts

Stakeholder	Type of cost	Description
MSAs, Eos, NB	Substantive compliance costs	Familiarisation and training to the changes of the regulation
Eos	Substantive compliance costs	Potential changes of conformity assessment and type of assessment
Eos, NB	Substantive compliance costs	Potential purchase of new harmonised standards necessary
Stakeholders involved in standardisation	Substantive compliance costs	Potential need for new harmonised standards to adjust for changes

Overall, large majority of respondents to OPC claimed that potential speed limit increase for lifts would not result in the change of the organisational costs (91.3%). Lifts manufacturers (n=47) indicated similar expected effects with about 66% expecting no changes, 28% increased costs and 6% decreased costs.

Figure 28: OPC Results on increasing/decreasing of the costs as a result of a speed limit increase for lifts (n=288)



Increasing the maximum speed limits for slow-speed lifts was considered to bring increased safety risks and therefore not to be beneficial for the protection of health and safety of users by most respondents to the consultation activities. Machinery safety consultants and manufacturers of lifts, in particular, shared this concern, indicating that person lifts especially should be assessed by third parties as is done under the Lifts Directive.[270] A change of the threshold speed for slow-speed lifts could thus negatively impact users of these lifts, both professional and consumer groups.[271]

Table 29: Group of stakeholders' responses to the OPC on increased safety concerns of increasing the speed threshold for slow-speed lifts

Results / Stakeholder	Increased safety concerns	No increased safety concerns	No opinion
Authority enforcing MD (n=24)	**66.7%**	12.5%	20.8%
Consumer organisation (n=3)	33.3%	33.3%	33.3%
Distributor (n=6)	33.3%	16.7%	**50%**
Importer (n=6)	16.7%	16.7%	**66.7%**
Industry association (n=64)	15.6%	4.7%	**79.7%**
Machinery safety consultant (n=85)	**45.9%**	24.7%	29.4%
Manufacturer (n=212)	25.9%	11.3%	**62.7%**
Manufacturer of lifts or lifting appliances (n=47)	**78.7%**	10.6%	10.6%
Notified body (n=44)	**77.3%**	9.1%	13.6%
Private user (n=5)	**60%**	0%	40%
Professional worker (n=18)	**61.10%**	11.10%	27.8%
Researcher/academic (n=3)	**66.70%**	33.30%	0%
Stakeholders involved in standardisation (n=7)	28.60%	14.30%	**57.1%**
Other (n=46)	**50%**	6.50%	43.5%
Total	**38%**	**12.40%**	**49.5%**

The main reason indicated for this increased safety concern is the relationship between speed and the gravity of accidents, as higher speed carries higher risks. An increase of velocity increases the dynamism factors, increasing the effort needed to start and stop the movement. In addition, the reaction time of people using the lifts would decrease with higher speeds of the lifts, irrespective of whether persons experience a dangerous situation or when goods move or fall over. More specifically, the possibility of avoidance/limitation of the risk by reaction (according to the PL of ISO 13849-1). While a speed of 0.25 m/s would still provide a threshold

[270] Based on interviews and public consultation responses.
[271] In order to have a rough estimation of the potential number of users affected, Eurostat's 2012 disability statistics was used. About 5 million wheelchair users are estimated. This number might be over- or underestimated, given that other users might access those types of lifts or not all these users might be accessing these types of lifts.

to react to approaching hazards, an increased speed to 0.5 m/s might result in a loss of that possibility.[272] Notified bodies indicated that safety of lifts under the MD are already much lower than under the Lifts Directive. If an increase of speed limits were to be followed by the revision of the MD, the risks would increase, and the safety levels would decrease. This could imply negative impacts on users of lifts, in particular of those for lifting of persons.

Table 30: Impacts of reviewing the threshold speed for slow-speed lifts in the MD

Type of impact	Positive impact	Negative impact
Economic	• Reduction of costs for third-party conformity assessments through increase of lift products covered by the MD	• Increased costs for compliance through familiarisation to changes, training and new conformity assessments • Costs related to adaptation of harmonised standards to changes • Potential reduction of coherence between the Lifts Directive and the Machinery Directive
Social	• None identified	• Risk of increased safety hazards

Source: responses to stakeholder consultation

Potential impacts of increasing the threshold speed for slow-speed lifts are related to categories of lifts potentially falling under the MD rather than the Lifts Directive (LD) after the revision. One of the main differences between lifts under both Directives is the conformity assessment procedure. Lifts as per the LD are required to be assessed by a third party, while lifts under the MD are largely assessed through internal checks processes. Exceptions are product groups under Annex IV, namely under 8 "Monitoring devices for loading and movement control in lifting machinery", and 17 "Components of machinery designed for lifting and/or lowering persons between different landings and included in the list of: a) devices for locking landing doors; b) devices to prevent the load-carrying unit from falling or unchecked upwards movement; c) overspeed limitation devices; d) energy-accumulating shock absorbers, non-linear, or with damping in the return of movement; e) energy-dissipating shock absorbers; f) safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls; and g) electric safety devices in the form of safety switches containing electronic components".[273] These products may still be assessed through internal checks if complying with the relevant harmonised standards. Following a joint action market surveillance on vehicle lifts, 62% of EU manufacturers followed the internal-checks approach under Annex IV.[274] The potential cost[275] and benefits[276] of a change regarding an increase of thresholds for slow-speed lifts are provided in the table below.

[272] Large German manufacturer of machines
[273] Machinery Directive Annex IV
[274] Prosafe (2018). Joint action on machinery 2014: Chainsaws, vehicle lifts. Joint market surveillance action co-funded by the European Union under Grant agreement No. S12.718616.
[275] Economic operators indicated a potential increase of one-off costs of about 8.9% of annual turnover, compared to a decrease of costs of 0.33% of annual turnover (estimated as benefit of a change). Costs for users could only be roughly estimated given the lack of granular data. For this, the average annual number of wheelchair users' injuries due to a defective lift given by the US Department of Transport in 1995 (https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/97850) was extrapolated using the UK's HSE Appraisal values or 'unit costs' in terms of financial costs of injuries (https://www.hse.gov.uk/economics/eauappraisal.htm).
[276] Potential benefits could result from differences in compliance costs between the Lifts Directive and the Machinery Directive. According the Evaluation of the Lifts Directive, compliance costs reach 0-0.74% of annual turnover, whereas for the Machinery Directive, no share of annual turnover was indicated. Referring to the European Commission (2014) Evaluation of the internal market legislation for industrial products, the compliance costs can reach up to 1% of annual turnover. The average annual compliance costs per organisation in both Directives show very differing results, with the Lifts Evaluation indicating an average of EUR 71,500 per annum, compared to the Machinery Directive's average (if a market with equal distribution is considered) of EUR 9,924 per annum.

Table 31: Costs and benefits of increasing the speed limits of slow-speed lifts in the Machinery Directive

Policy option 2.2.2	Description	Firms			Administrations	Other organisations		Citizens/users	
ADAPTING THE SPEED LIMITS OF SLOW-SPEED LIFTS Net effect of policy sub-sub-option (-)		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector**	**Users / consumers**
1. Number of affected stakeholders (EU-27)		154	7,545	7,699[a)]	71 or more	137 or more	1	2,759,439	5,000,000[d)]
2.1 Costs (total)	**One-off**	195,681,561 € to 2,964,872,130 €[b)]	135,982,101 € to 2,060,334,870 €[b)]	331,663,662 € to 5,025,207,000 €[b)]	Adaptation costs to changes, not quantifiable but expected to be marginal by consultation participants	Adaptation costs to changes, not quantifiable but expected to be marginal by consultation participants	Review of standards affected by the changes		-
	Recurrent	No additional recurrent costs expected	No additional recurrent costs expected	No additional recurrent costs expected	No additional recurrent costs expected	No additional recurrent costs expected	-	**Not quantifiable** Increased safety concerns expected by consultation participants	**Not quantifiable** Increased safety concerns expected by consultation participants (8 out of 11 lifts in the RAPEX 2010-2019 are consumer products)
2.2 Costs per organisation	**One-off**	1,270,825 € to 19,254,917 €[b)]	18,023 € to 273,072 €[b)]	43,079 € to 652,709 €[b)]	Adaptation costs to changes, not quantifiable but expected to be marginal by consultation participants	Adaptation costs to changes, not quantifiable but expected to be marginal by consultation participants	-		-
	Recurrent	No additional recurrent costs expected	No additional recurrent costs expected	No additional recurrent costs expected	No additional recurrent costs expected	No additional recurrent costs expected	-		-
3. Benefits	**Direct**	109,933,461 €[c)]	76,394,439 €[c)]	186,327,900 €[c)]	-	-	-		-
	Indirect	**-**	**-**	**-**	**-**	**-**	**-**		**-**

[a)] Based on Eurostat structural business statistics 2016 (EU-27), C28.22 lifting and handling equipment.
[b)] Based on 8.9% of turnover, ranges are from 6.6% that indicated expected cost increase to full 100% (=0.59% of turnover). Turnover estimated on Eurostat 2016 (EU-27): EUR 56,463 million total sector; EUR 33,313 million all large manufacturers (EUR 216 million per company); EUR 23,150 million all SMEs (EUR 3 million per SME). Adaptation costs include adjustments to the changes in order to ensure compliance, in particular related to the coherence of the Directives and applying the correct EHSR to the products after the revisions.
[c)] Based on 0.33% of turnover. If lifts would move from the Lifts Directive to the Machinery Directive, lower compliance costs are expected.
[d)] Proxy used: Persons with impaired mobility in the EU (2012) – Eurostat disability statistics; total potential affected users would be 7,759,439.
There are instances where data are quantified based on responses to consultations or interviews. When the number of replies is too low to present an estimate, cost cannot be reliably quantified. Proxy values are used when direct information is not available.

6.2.2.3. Improve the definition of 'partly completed machinery'

The OPC results show that the majority of respondents to the public consultation (52.4%) support the change of definition of **partly completed machinery** (PCM) and believe that further clarification would be beneficial.

Even though there are unclarities about the definition of PCM, the majority of stakeholders interviewed were not in favour of removing the concept from the MD. Stakeholders mentioned that there is value in the concept, among others through the declaration of incorporation, since the boundaries as to who is responsible to address which requirements of the Directive are set out.[277] A removal of this concept was expected to lead to additional costs, including costs for negotiating the current PCM requirements for each delivery contract individually, for filing these individual contracts and linking them to the technical file, for court cases and for clarifications with market surveillance authorities.[278]

The value of keeping the concept of PCM was thus recognised by the stakeholders, but more clarification is welcomed. One suggested solution is to distinguish between "ready-to-install drives" that can be installed in compliance with the general conditions defined by the system manufacturer and for which the manufacturer has already conducted a conformity assessment, and "non-ready-to install drives" for which the conformity assessment must be carried out by the assembler. This relates to another suggestion on specifying that a (complete) machine should be able to operate safely by means of no other machine or machine parts once it is connected to its energy source. A further specification of PCM could be done by introducing the relative differences between partly completed machinery and interchangeable equipment. Another aspect set out was that partly completed machinery should receive a CE marking as well, as the requirements are fulfilled. In many cases partly completed machinery does already get a CE marking due to other directives, e.g. the EMC. Without this CE marking, partly completed machinery is put on the same level as unsafe machinery even though very often only a few aspects remain open that must be assessed by the assembler.

A clearer demarcation between partly completed machinery and components could also be beneficial. One respondent said that "in contrast to components, partly completed machinery is an essential part of the machinery. This means that 'partly completed machinery' can be: i) a drive system; ii) the assembly/assemblies driven by the drive system; iii) a unit of such an assembly; or iv) the combination of the drive system and one or more but not all units of the assembly/assemblies driven by the drive system." In contrast to that, a "component" can be: i) a component of the machinery not having any moving parts or not moving at all; ii) a component of the drive system; iii) a components (of a unit) of the assembly/assemblies driven by the drive system; iv) a component of the machinery not being part of the machinery's movement mechanism; or v) another component of the machinery that is not essential for the machinery to operate or move, respectively." Further clarifications could be made through examples of partly completed machinery or guidelines.

Box 5: Suggested definitions for partly completed machinery

<u>Proposal 1 by a machinery safety consultant:</u> *"A combination of two or more elements, at least one of which is mobile, assembled but which must be integrated with a machine, with other partially completed machinery, or with a functioning logic in order to have a well-defined purpose."*

<u>Proposal 2 by an industry association:</u> *"Partly completed machinery means an assembly which is almost completed or fully functioning machinery which is only lacking some elements to perform its specific application or which is ready to be fitted to specific*

[277] Example from one manufacturer from the Netherlands
[278] One manufacturer from Germany, no figures were provided

machinery that is subject to this Directive and because of this incomplete status cannot comply fully with the essential health and safety requirements set out in Annex I."

Indeed, the positive impacts of a provision of further clarifications of this concept is expected to outweigh the costs of adaptation. Given that no manufacturers of partly completed machinery could be found, the impacts were estimated for the whole machinery sector.

Table 32: Potential impacts of improving the definition of PCM

Policy option 2.2.3 ADAPTING THE DEFINITION OF PARTLY COMPLETED MACHINERY	Positive impacts	Negative impacts
Economic impacts	• Manufacturers could decrease costs for clarifications on Partly Completed Machinery	• No major impacts have been identified
Social impacts	• No major impacts have been identified	• No major impacts have been identified
Environmental impacts	-	-

In the case of improving the definition of PCM, the costs and benefits[279] could not be quantified. Thus, qualitative inputs of the impacts outlined above have been used to assess this policy sub-option, as shown in the table below (see Table 33).

[279] Some indication for the potential benefits come from the consultation results that indicated costs arising from clarification procedures (EUR 5,000 to 10,000 per instance) and 37% of respondents indicating that they have encountered a problem of wrong classification

Table 33: Potential costs and benefits of improving the definition of PCM

Policy option 2.2.3	Description	Firms			Administrations	Other organisations		Citizens/users
CHANGING THE DEFINITION OF PARTLY COMPLETED MACHINERY Net effect of policy sub-sub-option (+)		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector/users or consumers**
1. Number of affected stakeholders (EU-27)		**1,703**	**81,024**	**82,239[a)]**	**71 or more**	**137 or more**	**-**	**-**
2.1 Costs (total)	**One-off**	Adaptation costs to changes, not quantifiable but expected to be marginal by consultation participants	Adaptation costs to changes, not quantifiable but expected to be marginal by consultation participants	Adaptation costs to changes, not quantifiable but expected to be marginal by consultation participants	Adaptation costs to changes, not quantifiable but expected to be marginal by consultation participants	Adaptation costs to changes, not quantifiable but expected to be marginal by consultation participants	-	-
	Recurrent	No costs were identified	No costs were identified	No costs were identified	No costs were identified	No costs were identified	-	-
2.2 Costs per organisation	**One-off**	Adaptation costs to changes, not quantifiable but expected to be marginal by consultation participants	Adaptation costs to changes, not quantifiable but expected to be marginal by consultation participants	Adaptation costs to changes, not quantifiable but expected to be marginal by consultation participants	Adaptation costs to changes, not quantifiable but expected to be marginal by consultation participants	Adaptation costs to changes, not quantifiable but expected to be marginal by consultation participants	-	-
	Recurrent	No costs were identified	No costs were identified	No costs were identified	No costs were identified	No costs were identified	-	-
3. Benefits	**Direct**	-	-	Cost savings of about EUR 5,000 to 10,000 per instance (Number of instances was not identified)	Not quantifiable. Expected benefits include increased legal clarity	Not quantifiable. Some cost savings could stem from decreased efforts in solving problems of unclarity	-	-
	Indirect	-	-	-	-	-	-	-

[a)] Due to rounding differences in the data in Eurostat, the total number of enterprises shown does not equal the sum of enterprises recorded per size class.
There are instances where data are quantified based on responses to consultations or interviews. When the number of replies is too low to present an estimate, cost cannot be reliably quantified. Proxy values are used when direct information is not available.

6.2.2.4. Other recommendations identified

Throughout the consultation of stakeholders, other aspects were raised and discussed. These are summarised in this section.

Assembly

The results of the OPC show that the majority of participant stakeholders do not think that the definition of "assembly" should be revised. However, one-fifth of respondents expressed no opinion, making the overall assessment of this question more nuanced. Less than half (42.8%) of stakeholders in total that participated in the OPC responded the question negatively. In comparison, most machinery safety consultants, private users and professional workers said that the definition of "assembly" should be revised. About a third of the manufacturers indicated a preference for change. For detailed share of responses per stakeholder type, see the table below (Table 34).

Table 34: OPC responses on revising the definition of "assembly"

Stakeholder group	Yes	No	No opinion
Authority enforcing MD (n=24)	33.3%	**41.7%**	25%
Consumer organisation (n=3)	0%	33.3%	**66.7%**
Distributor (n=6)	33.3%	**50%**	16.7%
Importer (n=6)	33.3%	**50%**	16.7%
Industry association (n=64)	17.2%	**64.1%**	18.8%
Machinery safety consultant (n=85)	**61.2%**	29.4%	9.4%
Manufacturer (n=212)	30.7%	**48.1%**	21.2%
Notified body (n=44)	36.4%	**43.2%**	20.5%
Private user (n=5)	**80%**	0%	20%
Professional worker (n=18)	**50%**	22.2%	27.8%
Researcher/academic (n=3)	33.3%	**66.7%**	0%
Stakeholders involved in standardisation (n=7)	42.9%	42.9%	14.3%
Other (n=46)	**41.3%**	23.9%	34.8%
Total (n=523)	36.7%	**42.8%**	20.5%

Source: OPC results (n=523)

Even though the majority of the stakeholders were not in favour of changing the definition of "assembly", some mentioned that the definition of the word is complicated to understand. For example, one machinery safety consultant asked about the difference between the assembled machinery and machine, apart from the manual recovery of the parts[280]. According to one company from UK, it is very difficult to decide where to place the scope of individual component machines with an assembly of machines like a production line or a process plant. According to one business association/company, assembly of machines is counted as a whole/complete machinery only if several machines are safety-related. Therefore, an event that occurs in one component of the system can lead to a risk to another component.

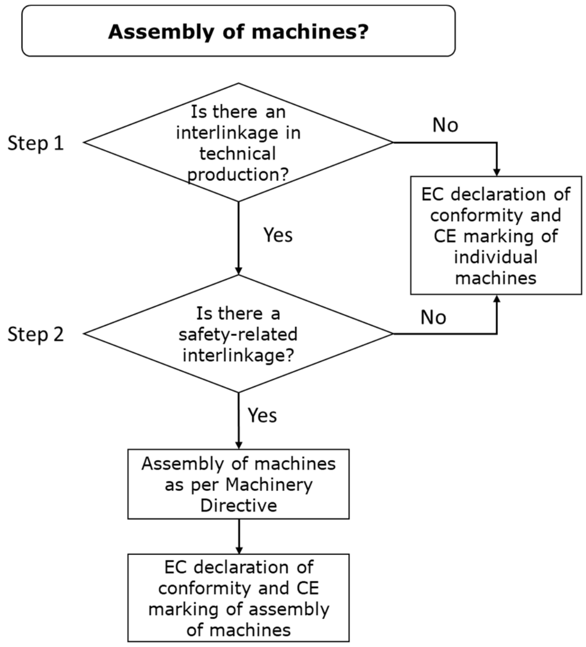
It was mentioned by some machinery safety consultants from Germany that the subject of "totality of machines" is still controversial in at least certain industries (chemistry, power plants) in Germany. According to the machinery safety consultants, it should be made clear that a totality consists not only of machinery and partly completed machinery, but also other components, such as low voltage equipment (switches, cables, electric motors, etc.), ATEX components, pressure equipment, simple pressure vessels, etc. The "whole" is not a whole within the meaning of the Machinery Directive due to the integration of such components. That is self-evident, but this discussion has been alive in Germany since the beginning of the

[280] According to one machinery safety consultant from France.

Machinery Directive. As a result, such companies buy only incomplete machines with CE and compel "dependent" manufacturers to violate applicable law[281].

Some notified bodies from Germany also warned that there is an erroneous translation. In German, the Directive uses the word "*Gesamtheit*", which is translated as "wholeness/entirety", when in fact it refers to "assembling" (e.g. installation, montage). Additionally, a stakeholder involved in standardisation from Germany mentioned that "assembly" is nationally defined, whereas it should apply the same across the EU. The referred to aspect is visualised below.

Figure 29: Workflow on assembly of machines



Source: German Ministry of Labour (2011), translated from German

One manufacturer suggested that the following elements should be taken into account: i) integrated manufacturing system (IMS) as per ISO 11161; ii) single integrated line; and iii) complete (or complex) industrial plant. According to the manufacturer, for each of these types, the Directive should state under what conditions it should be considered as one assembly subject to conformity assessment. The considerations under indent 38 in the Guide were considered very relevant, to an extent that it could be integrated into the legal text itself. For some of the proposals on the clarification of the definition of assembly see the box below.

[281] Based on responses of the consultation activities.

Box 6: Proposals on the clarification of the definition of assembly[282]

Proposal from machinery safety consultant (IT): *"Assembly of machinery should specify if it applies also to the temporary installation of machinery and control systems, potentially interchangeable and if – in this case – a specific DoC of the assembly of machinery is required for every possible configuration. An example of this are hundreds of chain hoists combined with controllers, integrated for rigging installations and controlled with a unique control device."*

Proposal from a machinery safety consultant (NL): *"Assembly: a unit consisting of components that have been fitted together to perform a specific function, and that can be disassembled without destruction."*

Proposal from a machinery safety consultant (NL): *"Please define the common control system of an assembly. Lots of assemblies are connected by 24V I/O signalling. It is not clear if that is to be defined as a common control system."*

Proposal from a manufacturer (DE): *"As soon as any machinery are interlinked as a unit from a safety point of view, it should be considered as an 'assembly of machinery'. This assembly of machinery is to be considered as a new machine placed on the market. However, if several machine items with individual functions on a handling process are installed and can be used independently, they are rather to be considered as a 'group of machinery'. If an emergency stop affects this machinery when activated, and this is not required from a safety viewpoint, it is not an 'assembly of machinery' but a group of machinery."*

Proposal from a manufacturer (NL): *"Responsibility about assembly should be clear, and make clear who must do the risk assessment in this case."*

Proposal from a notified body (DE): *"Assembly of machinery/equipment linked in connection with incomplete equipment should be defined according to the interpretation document of the BMAS on the assembly of machinery, see* https://www.bmas.de/DE/Themen/Arbeitsschutz/interpretationspapier-gesamtheit-von-maschinen.html*"*

Proposal from an industry association (DE): *"Article 2(a), fourth indent should be deleted. This part of the definition has led to numerous discussions in practice, to claims, to conformity assessments of complex industrial plans and to a CE mark for the complete system to install. In Germany, the ministry responsible had published the BMAS interpretative paper. Already in the first indent it becomes clear that a machine is an entity of interconnected parts or devices and this includes both individual parts of a machine, as well as the assembly composed of several machines, if they are linked together in terms of safety."*

Proposal from a professional worker (DE): *"The 'assembly instructions' should be renamed. As a suggestion, the instructions could be called 'integration instructions', as many manufacturers of incomplete machines make the assembly of the machine itself, and therefore argue that no assembly instructions are necessary."*

[282] Based on responses of the consultation activities.

Existing machinery modified substantially that leads to new machinery, requiring CE mark (hereafter 'substantial modification'[283])

The aspect of substantial modification was raised with regards to software upgrades and also within the Open Public Consultation.

Overall, the aspects that relate to machinery modified are Art. 2(h) placing on the market and Art. 2(k) putting into service. More specifically, it relates to changes made to the product that are so substantial that a new CE marking is required. Within the Guide to the application of the MD (ed. 2.2), paragraph 82 introduces the aspect. Here, it refers to "some cases [whereby] machinery is sold to an importer or a distributor who then modifies machinery at the request of a customer before the machinery is put into service (…). If the modifications were foreseen or agreed by the manufacturer and covered by the (…) risk assessment, technical documentation and EC Declaration of Conformity, the original manufacturer's CE marking remains valid. (…) If the modification is substantial (for example, a change of function and/or performance of the machinery) are not foreseen or agreed by the manufacturer, the original (…) CE marking becomes invalid and has to be renewed (…)".[284] Paragraph 86 provides more insight: "The Machinery Directive applies to machinery when it is placed on the market and/or put into service. Machinery that is placed on the market in the EU is put into service when it is used in the EU for the first time. This applies to new machines that are completed and tested at the user's site (may be referred to as 'in-situ' manufacturing), including both machines the user has built himself or have been built for him by another. Existing machinery originally first put into service outside the EU and moved by the user to his own site in the EU is also subject to the Machinery Directive as it is now being put into service for the first time in the EU. However, 'putting into service' does not apply to existing machinery (which was originally been put into service or placed on the market in the EU) that has had modifications carried out, unless they are so extensive that the machine is considered as new (…). In such cases, the obligations of the manufacturer with respect to the placing on the market and the putting into service of the machinery are the same (…)." Paragraph 72 gives insight into new and second-hand machinery. It specifies that "in general, the Machinery Directive does not apply to the placing on the market of used or second-hand machinery.[285] (…) The question arises as to when a transformation of machinery is considered as construction of new machinery subject to the Machinery Directive."

As indicated, the OPC also asked stakeholders about the potential issues resulting from substantially modifying machines. Just over a half (53.1%) of the stakeholders mentioned they had modified their machine, of which 36.5% were companies. The large majority of the respondents (78.3%) claimed to have not encountered any problems after performing the modification. Despite not many problems encountered, the majority of the OPC respondents (61.2%) claimed that the MD should define criteria for modifying machinery substantially.

The most mentioned aspects within the open question of the OPC on what would be appropriate criteria to define substantial modification were any modification made to the machinery that changes its intended use, leads to the increase of the existing risks or introduces new risks and thus changes the safety features of the machine. If criteria on substantial modification of the machinery are to be better clarified, the majority of the OPC respondents (70.8%) believe that the change would not bring any changes to the organisational costs, with slightly more expecting a decrease of costs (15.6%) than increasing costs (13.5%).

[283] Guide to application of the Machinery Directive ed. 2.2, p. 74
[284] Guide to application of the Machinery Directive ed. 2.2, p.71.
[285] There is one exception to this general rule. The Machinery Directive applies to used or second-hand machinery that was first made available with a view to distribution or use outside the EU when it is subsequently placed on the market or put into service for the first time in the EU.

Table 35: OPC responses on defining criteria for machinery modified substantially

Stakeholder group	Yes	No	No opinion
Authority enforcing MD (n=24)	**58.3%**	37.5%	4.2%
Consumer organisation (n=3)	**66.7%**	0%	33.3%
Distributor (n=6)	**50%**	16.7%	33.3%
Importer (n=6)	**50%**	0%	**50%**
Industry association (n=64)	**43.8%**	29.7%	26.6%
Machinery safety consultant (n=85)	**82.4%**	10.6%	7.1%
Manufacturer (n=212)	**58%**	17%	25%
Notified body (n=44)	**68.2%**	13.6%	18.2%
Private user (n=5)	**80%**	0%	20%
Professional worker (n=18)	**66.7%**	22.2%	11.1%
Researcher/academic (n=3)	**66.7%**	33.3%	0%
Stakeholders involved in standardisation (n=7)	**57.1%**	14.3%	28.6%
Other (n=46)	**54.3%**	7.5%	12.7%
Total (n=523)	**61.2%**	17.8%	21%

Source: OPC results

On the question what constitutes a substantial modification of the machine, consulted stakeholders provided different opinions or proposals for clarifications. The most commonly mentioned references within the OPC regarding substantial modification were the Blue Guide on the implementation of the EU regulation on products 2016 (section 2.1, pp. C272/16 to 17) and the flowchart developed by the German Labour Ministry and the clarifications provided by the French Labour Ministry. To date, four Member States have an interpretation paper or leaflet describing how to deal with modifications to machinery (France, Germany, the Netherlands and Sweden).[286]

Several respondents indicated that these criteria are well defined based on the risk assessment factor. The Blue Guide specifies the need for a new conformity assessment "if the risk assessment leads to the conclusion that the nature of the [safety] hazard has changed, or the level of risk has increased"[287]. Furthermore, the Blue Guide of the OJEU is cited (p.c272/16): "The definition provided in the Blue Guide, p. C272/16 of the OJ of the EU, is appropriate: "A product, which has been subject to important changes or overhaul aiming to modify its original performance, purpose or type after it has been put into service, having a significant impact on its compliance with Union harmonisation legislation, must be considered as a new product." This type of specification of criteria is also available under the Guide to application of the Lifts Directive page 39. Such a clarification or description included in the Machinery Guide was considered as useful by the majority of respondents. Most respondents agree on keeping the risk-based definition, specifying that the criteria relevant to substantial modification shall comprise:

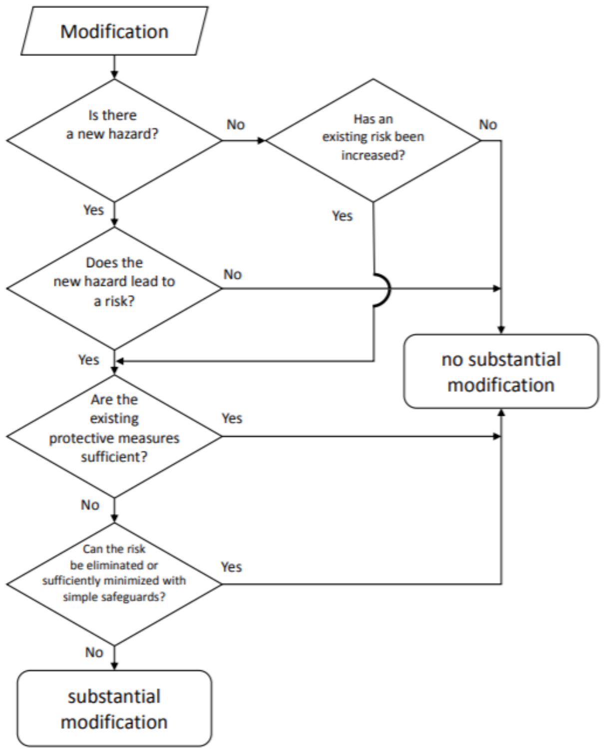
- Different risks after modification;
- New risks after modification;
- Higher risk levels or hazards after modification; and
- Enhanced performance, new functions or fundamental changes in function (e.g. power increases).

[286] MACHEX SUB-WG (n/d). Modifications to CE and non-CE machinery in use. Available at: https://www.ispettorato.gov.it/it-it/Attivita/Documents/Attivita-internazionale/Informative-paper-Modifications-to-CE-and-non-CE-marked-machinery-in-use.pdf

[287] European Commission (2016). Blue Guide on the implementation of EU products (2016/C 272/01), pp. 16. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726(02)&from=BG

In addition, the visualisation of this risk assessment after modification made by the German Federal Ministry of Labour is given as best practice by several respondents of various countries (see Figure 30).

Figure 30: Decision steps for the substantial modification of machinery



Source: German Federal Ministry of Labour and Social Affairs (2015)[288]

Respondents have also indicated that it would be useful to have a valid EU-wide interpretation of substantial modification as the current national interpretive papers, such as those of Germany or France, are not automatically used throughout the whole EU. Indeed, national authorities for example emphasised that there are no criteria on substantial modification.

One shortcoming related to the unequivocal definition is said to bring too much flexibility to modification without reassessment of risks. In particular, the following definition within the Guide (Edition 2.1) was flagged: "Where a change is made with the introduction of a specific application change, it will be considered as a new machine and is subject to the Machinery Directive." The notion of defined application is considered very broad. Examples of explicit entries to counter this shortcoming include:

- "A change in the safety function on the machine should require a reassessment of the risk and proof that the Performance Level[289] achieved is of the same value or higher";
- "Replacement of worn equipment should require proof that the machine's parameters have not changed"; and

[288] Available at: https://www.bmas.de/SharedDocs/Downloads/DE/Thema-Arbeitsschutz/en-interpretation-paper-substantial-modification-to-machinery.pdf;jsessionid=9ABA14919A0962CC5CEB2A556218990E?__blob=publicationFile&v=1

[289] As defined in harmonised standard EN ISO 13849-1:2015: Safety of machinery – Safety-related parts of control systems - Part 1: General principles for design

- "The changes carried out require a risk assessment process and demonstration that the machine does not pose additional risks after modification".

Another suggestion provided is to give a list of different European interpretations in all languages under one official webpage. Furthermore, it was specified that the person conducting the modification should be considered the manufacturer after substantial modification as this is often carried out by another party than the original manufacturer. One industry association mentioned that they had faced cases where the reconstruction of equipment has not been done by the original manufacturer, which modified the results of the initial risk analysis, namely surface treatment that generates an ATEX risk.

Several respondents have also indicated that providing specific examples of substantial modifications in the Blue Guide or the Machinery Guide could be useful and provided suggestions on how the definition could be improved (see Box 7).

Box 7: Proposals for criteria and clarifications on the definition of substantial modification[290]

Proposal 1 by a national authority: *"A 'substantial modification' should be considered a modification that could lead to a change in the machinery functions as well as to its safety. In case of such a modification the one that has made it would be required to carry out a conformity assessment of the new/modified machinery, to carry out the required tests, to draw up the EU DoC, to place a new plate on the machinery that indicates its name and address and affix the CE marking."*[291]

Proposal 2 by a manufacturer: *"A change that introduces new or higher risk, such as a change in functionality, capacity, technology or use. A modification of any safety function, or a modification of a structural (load bearing) part which would fail in a critical manner is also considered a substantial modification."*

Proposal 3 by an industry association: *"Substantial modification leading to considering the machine as a new machine should only be subject to very significant changes, such as a change of use taking the machinery outside its originally intended use (e.g. a goods-only lift being modified to carry persons) (…)."*

Proposal 4 by an industry association: *"A modification is substantial when it involves variations in the performances and/or in the purposes, and/or in the technologies used, and/or in the functions of the machine such as to introduce new dangers or increase the existing risk levels. Changes aimed only at improving safety do not constitute a substantial change."*

Proposal 5 by a machinery safety consultancy: *"A substantial modification is a change of the specific application of the machinery."*

Looking into the examples within specific product sector, substantial modification was considered very important for the home appliance sector because appliances can be applied in different situations. According to a stakeholder, "the concept of substantial modification could be/should be/must be clarified, not necessarily in the Machinery Directive, but could also be clarified in the Blue Guide (preferably section 2.1.). The clarification should consider investigating the concept of substantial modification with: i) circular economy (what happens when you recycle, repair the machine etc., should it be regarded as substantial modification or not?); and ii) digital transformation: at which point would you consider that you have a substantial modification after an update. At which point do you have a new product? This is

[290] Based on responses of the consultation activities
[291] Based on the interview conducted with the representative of national authority.

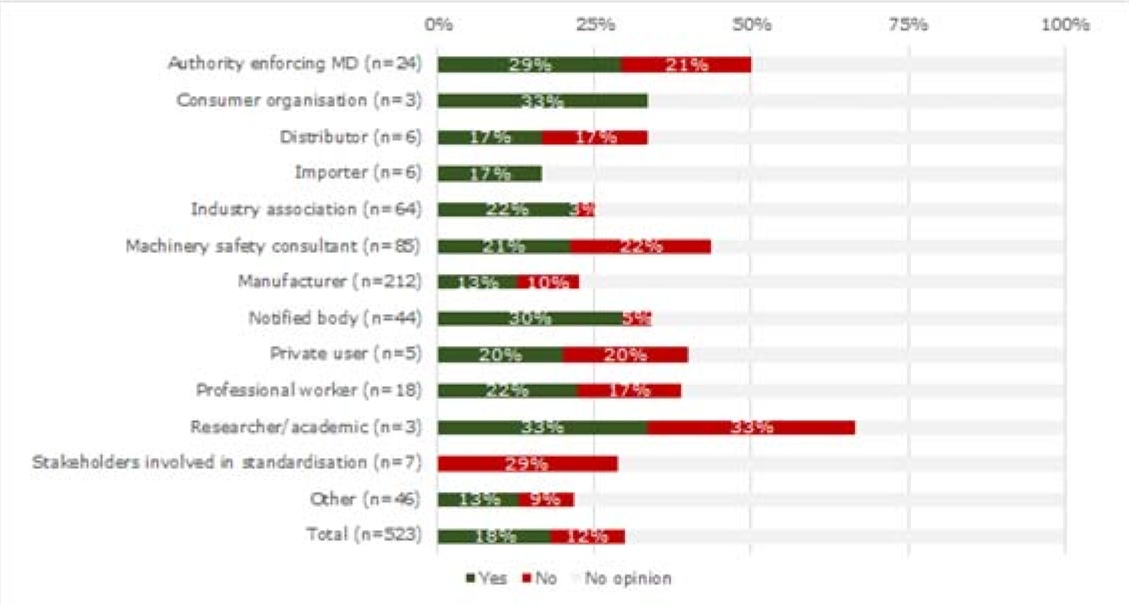
also not clear and should be clarified." For lifts, lifting platforms and escalators, when an existing machinery is completely replaced or only some minor components remain (e.g. guide rails in lifts), it must be considered a new machinery and the conformity assessment shall be applied.

Machinery for nuclear purposes

The current MD under Art. 1.2(c) excludes "machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity".[292]

One of the questions asked during the consultation is whether the exclusion shall apply solely to machinery that in the event of failure may result directly in an emission of radioactivity. The majority of the consulted stakeholders did not provide any specific opinion on this question. This was similar to the stakeholders interviewed, with most manufacturers for instance indicating that they have no direct experience with machinery designed for nuclear purposes. From those that provided an opinion, most agreed with the exclusion (see Figure 31). One MSA specified that the nuclear safety legislation does not necessarily contain occupational safety but only radiation safety. In particular, for the machinery for hoisting and handling of nuclear fuel and other loads, the legislation of integration of occupational and nuclear safety is said to be confusing at present. Manufacturers of nuclear machinery that responded to the OPC (n=8), in majority were against a revision (n=5) rather than for a change (n=2).

Figure 31: OPC results on whether the criteria for nuclear purposes should be revised



Source: OPC, n=523

Given the responses there is reason to believe that stakeholders may have misunderstood the question, indicating that they are against a reduction of the exclusion and that "all periphery machinery has to be safe"[293], "that it should not be excluded overall when it is a machine/safety component"[294], and that "many 'normal' devices are used in nuclear power plants and it is

[292] The number of enterprises affected by change could not be identified
[293] Professional/worker from Germany
[294] Private user from Austria

unreasonable to exempt them from meeting the requirements of the MD"[295]. Similar reasoning is provided by those in favour of limiting the exclusion, mentioning for example that "a failure of a pump could indirectly also lead to an emission of radioactivity; an exemption of a pump from the MD would decrease the safety of this pump"[296].

Respondents who were against a change of exclusion raised the concern that "it would create a gap enabling lower requirements to be followed. Nuclear emissions are extremely dangerous as they are not visible to bystanders"[297]; "nuclear machinery and equipment should have their own strict directive because the risk and danger are enormous"[298]; "the use of nuclear energy requires the assessment of very specific aspects, therefore, the exclusion is justified by the development of Directives on the use of nuclear energy"[299]; and "the machine is not the problem [in this case, but] the contamination of any equipment when in contact with radioactivity; machinery going into a reactor needs to comply with the reactor safety regulation"[300]. Another risk raised by a notified body regarding a change of the exclusion was that "direct" and "indirect" would be terms that are very difficult to define. This could lead to new unclarities rather than an improvement of the existing MD. One proposition by a national authority was to rephrase the Art. 1.2(c) from "machinery specially designed or put into service for nuclear purposes (…)" to "machinery specially designed or put into service for nuclear installations". It was indicated that the current exclusion matches with that of other Directives, such as the PED (Art. 1.2(h)) "items specifically designed for nuclear use, failure of which may cause an emission of radioactivity"[301].

Specific equipment for amusement parks/fairgrounds

The current MD excludes "specific equipment for use in fairgrounds and/or amusement parks" (Art. 1.2(b)). The majority of interviewed stakeholders agreed that the specific equipment for use in fairgrounds and/or amusement parks and its use require clarification. For all stakeholder types (national authorities, notified bodies, manufacturers, consumer organisations, workers associations and market surveillance authorities), most agreed that the exclusion on specific equipment for use in fairgrounds and/or amusement parks should be removed. For consumer organisations this remains an important issue, since currently there is no EU legislative framework covering this type of equipment, and each year millions of consumers are going to amusement parks and using this equipment, especially when being on holiday abroad. It would still be important to have EU legislation as serious accidents are still happening[302]. According to one notified body, it is possible to shift the amusement rides into the MD under the condition that a special safety sector (G Forces etc.) is clearly defined[303]. National authorities[304] raised the concern that if the exclusion was to be agreed in the revised Directive, national provisions as they are currently present should be considered in the refined text, providing at least the minimum requirements that are currently set out. To have a proxy of the potential number of companies affected by change, NACE R93 "sports activities and amusement and recreation activities" was used. In 2017 (EU-27) 108,684 enterprises were recorded.[305]

[295] Machinery safety consultant form Poland
[296] Manufacturer from Italy
[297] Manufacturer from Germany
[298] Authority enforcing the MD from Portugal
[299] Machinery safety consultant form Italy
[300] Machinery safety consultant from Germany
[301] Directive 2014/68/EU on Pressure Equipment
[302] Based on the interview conducted with the consumer organisation
[303] Based on the interview with the notified body
[304] For example, authorities from AT, DK and IE
[305] The number of potential firms affected could not be identified. NACE R93.2 Amusement and recreation activities was investigated to access a proxy. However, a lack of data on this activity was encountered. For R93, Cyprus, Malta, Poland and Sweden did not provide any numbers

Machinery on seagoing vessels

Art. 1.2(f) of the MD currently excludes seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units. Some Member States raised the concern that machinery on board of those vessels that are not crucial for safety of persons on sea, such as machinery for handling and processing fishing products, are therefore excluded from the MD. This could potentially lead to safety hazards of workers using those types of machinery on board, which is why the study posed the question whether the exclusion in Art. 1.2(f) should be limited to machinery on board of those vessels that is crucial for safety of persons on sea.

The large majority of interviewed stakeholders, however, believe that there is no need for more precise exclusion on seagoing vessels and mobile offshore units and machinery installed on board of such vessels and/or units. More than a third of the consulted stakeholders (37.5%), which answered the specific question[306] on the machinery on seagoing vessels, believe that there is no need for making any changes to the Directive, while 12.5% of them (only business associations) said that the machinery on seagoing vessels should be covered within MD. An exact estimation of the potential number of actors that would be affected by greater precision of the exclusion is not possible due to the lack of data on manufacturers of machinery that is installed on seagoing vessels. To have a proxy of the number of actors in the sector in general, NACE C30.1 building of ships and boats and NACE C33.15 repair and maintenance of ships and boats is used. In 2018 (EU-27), about 7,745 companies were recorded in the activity "building of ships and boats" and in 2017 (EU-27) 15,870 in "repair and maintenance of ships and boats". This would make a total of 23,615 companies.[307]

However, it must be noted that 50% of the respondents to the question responded with "no opinion", as they did not have the appropriate involvement and knowledge on the topic. Of those respondents that agreed with the current exclusion on the seagoing vessels and mobile offshore units, most said that the exclusion is acceptable if the seagoing vessels and offshore industry are covered by the rigid legislation on their own. According to one market surveillance authority, this type of equipment is sufficiently covered by the Marine Equipment Directive (MED). According to one respondent that agreed that seagoing vessels and offshore equipment to be covered within MD, equipment like hoists and winches should also be covered by the MD (equal to the situation with vehicles whereby machinery installed on vehicles also remains under the scope of the MD). This approach would be cost-neutral or even save cost as otherwise all machinery on a vessel will fall under the classification system of the concerned vessel[308].

Role of an installer

Some of the interviewed stakeholders agreed that the role of an installer can be added similarly as it is arranged in the Lifts Directive. This idea was supported by some notified bodies, workers and employers' associations and market surveillance authorities. Manufacturers, on the other hand, gave a divided response. Around a fifth (20.8%)[309] of the participant manufacturers in the interview session believed that there is no need to make additional clarifications to the role of an installer. According to some, the MD already covers the activity of an installer in two clauses (§36 Machinery supplied without connection components and §264 Assembly, installation and connection). On the other hand, 16.6% of manufacturers agreed that the role of an installer should be clarified and covered in MD as it is done in the Lifts Directive. Similarly, national authorities gave a divided response. When one national authority agreed on adding the role of an installer, the other one opposed the idea, saying that there is a difference

[306] In total 16 stakeholders responded to the question.
[307] Eurostat [sbs_na_ind_r2]
[308] Based on the interview conducted with the manufacturer.
[309] Out of total 24 manufacturers interviewed.

between lifts and machines, and in the case of machines the installer has a different function. See main responses of each stakeholder group in the box below.

Box 8: Proposals for clarification on the definition of the role of installer[310]

Proposal from a market surveillance authority: *"The role of installer is unclear. The reality is that the installer role already exists. Brands have a technical official service, which is not clear to what extent it needs to be regulated, if it were to be regulated. In the case of lifts, there is a national regulation."*

Proposal from workers and employers' representatives: *"We would support this for some limited cases, i.e. not just for an installer who only places a complete machine on a floor and may just bolt it down. But where the installation is critical for safety then this would make sense, e.g. for platform lifts. At present such situations can be covered by the final installer being a manufacturer of an assembly, but this is not a good solution. In general, we consider this is only needed for a small sub-set of machinery such as platform lifts."*

Proposal from a manufacturer: *"No, an installer would have to follow the instruction of the OEM and all required instructions are sufficiently covered by the current MD. Special roles for an installer leads to splitting of responsibility and finally to confusion. One additional remark to this question: Full adoption of the New Legislative Framework will help the alignment of definitions."*

The role of installer was mentioned as a suggestion for possible revision of definition also by some stakeholders participating in OPC. According to an industry association from UK, MD does not recognise the role of an installer for specific machinery, such as lifting appliances. A lifting appliance is placed on the market only after its installation, like lifts, when they can be inspected and CE marked. According to the industry association, the MD should recognise the role of the installer similar to the Lifts Directive for specific machinery, such as lifting appliances that can be considered as ready machinery only after its installation, when they must be inspected and CE marked before taking into use[311]. This view was shared by some other stakeholders participating in the OPC, such as notified body (NL), manufacturer (UK, AT) and authority for enforcing MD (NL). One option that was presented by the manufacturer includes moving all appliances for lifting persons from the MD to the Lift Directive, in order to ensure for all lifting appliances the same safety level and to make the work easier for all in the process chain involved stakeholders (producer, installer, tester and authority). To estimate the potential number of affected firms by a change to the role of an installer, NACE C33.2 "installation of industrial machinery and equipment" was used. In 2018 (EU-27), around 40,000 companies were registered.[312]

Pressure Equipment Category I

The current Pressure Equipment Directive (PED) (2014/68/EC) excludes equipment classified as no higher than category I as defined by PED and falling in the scope of one of the directives as listed in article 1, paragraph 3.6, e.g. for low voltage or machinery.[313]

The majority of the interviewed stakeholders agreed that the current exclusion of the Pressure Equipment of Category 1 from the Pressure Equipment Directive (PED) does not cause

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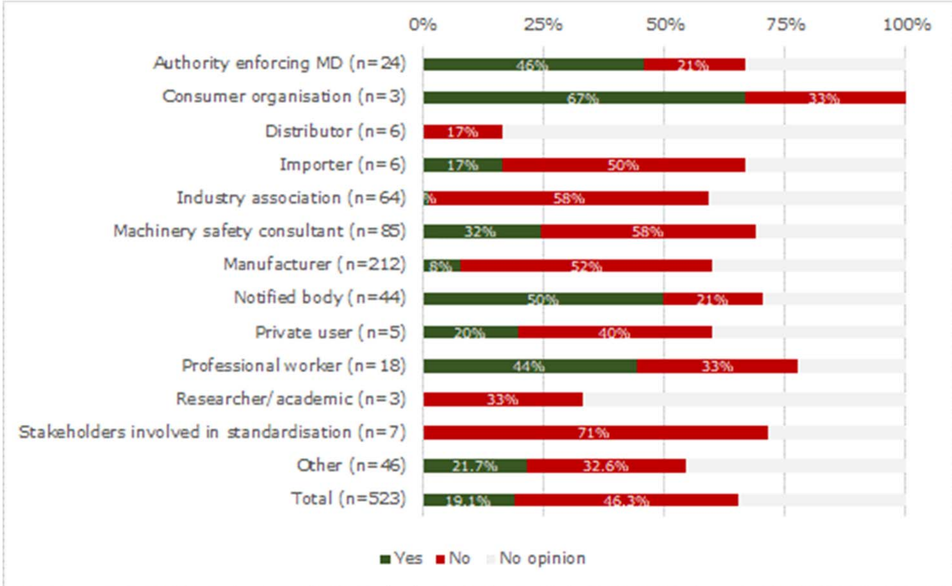
[310] Based on the interviews conducted.
[311] Based on the OPC conclusions.
[312] Eurostat [sbs_na_ind_r2]
[313] Pressure Equipment Directive (2014/68/EU). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0068&from=EN

interpretation problems or leads to increased safety concerns.[314] The view was shared by all stakeholder groups included in the interview exercise (manufacturers, national authorities, notified bodies, market surveillance authorities and workers/employer's association). The results for national authorities differed from the interviews to the responses in the OPC, where 46% of authorities indicated safety concerns.

Figure 32: OPC results on whether the exclusion of PED Cat. I leads to safety concerns



Source: Open Public Consultation

The large majority of manufacturers said there is no need for making any changes, but they also added that an inclusion of the Pressure Equipment Cat. 1 in the PED would not result in any major changes for them. Most respondents to the OPC did not expect any changes in terms of costs to their organisation were the approach be adapted (70%). Almost all remaining respondents expected their costs to increase (28%) rather than reduce (2%). Increased costs are expected by manufacturers of pressure equipment (61% of respondents) and nuclear machinery (88% of respondents). Some manufacturers also added that covering the pressure equipment Cat. 1 within the MD is beneficial from the cost point of view, as it allows them to perform internal checks which would not be possible if the equipment were to be covered by the PED. Similarly, interviewed market surveillance authorities agreed that the equipment with low pressure can be considered within the MD. Market surveillance authorities also emphasised that the PED covers hazards related to pressure, and the MD is thus necessary for ensuring additional safety requirements. However, it was also mentioned that there is some unclarity with certain products, such as valves that can be powered. Their legal status is unclair as they can sometimes fall under the definition of partly completed machinery in the MD and sometimes under pressure equipment. It is thus necessary to explain the status of these components. All interviewed national authorities agreed there is no problem with the current arrangement of the pressure equipment Cat. 1, compared to 21% of answers in the OPC. The explanation shared by the national authorities is that equipment with low pressure or equipment with no risk of explosion should be covered by the MD, whereas equipment with higher pressure can be covered by PED. Notified bodies agreed that there is no difference in safety if the pressure equipment Cat. 1 is covered by the MD or by the PED. They did, however, emphasise that if the equipment is covered by the MD, the costs of conformity assessment shall be borne by the machine manufacturer. Workers and employers' association on the other

[314] The number of potential firms affected by change could not be identified

hand expressed the support for including the pressure equipment Cat.1 in the PED. However, according to them, the inclusion should be restricted to items such as motorised valves. The benefit is to place such items as motorised valves in a Directive that covers the hazard: in almost all such valves the mechanical risk is almost nil as the moving parts are internal in the valve. Besides workers' associations, only one national authority (SK) and two notified bodies (CZ, FI) also expressed support for the inclusion of the equipment in PED. According to the notified bodies, MD or its harmonised standards do not relate to pressure equipment. One must use harmonised standards under the PED, and as this equipment is not in the scope of the PED, the manufacturers do not use them. This creates a safety concern. OPC results did not reveal any issues regarding the exclusion of the pressure equipment Cat. 1 from the PED.

Risks during maintenance

A few manufacturers and notified bodies that participated in the OPC mentioned that MD revision should improve the maintenance aspects to be performed on a machine, as during maintenance operations injuries may also occur. Only manufacturers and notified bodies provided a comment on the matter. Notified bodies, for example, mentioned that maintenance requirements should be better explained in the manual. Often the main process is safe enough, but servicing, cleaning and maintenance are dangerous due to missing safety features[315].

Updating the EHSR in relation to seating (EHSR 3.2.2)

Interviewed stakeholders were asked the question of whether the essential safety requirements related to seating (EHSR 3.2.2.) should be updated in order to allow innovation to mitigate the risk of ejection. All stakeholder groups (national authorities, notified bodies, market surveillance authorities, workers representatives), except for manufacturers, agreed that the health and safety requirements related to seating should be revised and/or updated.[316] According to these stakeholder groups, the safety requirements/standards do not cover worker's seating. Machines should be constructed in such a way as to prevent the worker from being unattached. According to the workers' association, which agreed with the update, the current regulation prescribes the need of a restraint system attached directly to the driver's seat. Such a requirement may limit innovation as there are other technological solutions on the market, such as restraint systems that keep operators within the framework of the protective structure, e.g. doors or door-bar systems.

Manufacturers on the other hand (five out of a total of six respondents to the question) rejected the update. Some manufacturers mentioned that seating requirements are already covered by requiring Open Platform Communication (OPC) systems for the seat, and there may be certain operating conditions (e.g. on flat ground) where being forced to use the restraint could be a severe burden and might encourage users to look for ways to defeat the system. Another manufacturer warned that seating could cause other hazards. For example, in the case of the underground mines, all machines must be possible to move in the case of an evacuation of the mine. A machine that blocks a tunnel just because the seat belt switch has failed would not be accepted. Another manufacturer mentioned that depending on the type of mobile machinery, product type specific harmonised standards are a very good tool to add such or similar requirements, when they become state of the art for this/these type(s) of machinery[317]. Compared to the interviewed stakeholders, the stakeholders that took part in the study's OPC on the other hand did not report any issues regarding the update of the EHSR in relation to seating (EHSR 3.2.2).

[315] Based on the OPC conclusions.
[316] The number of potential affected firms could not be identified
[317] Based on the interviews conducted.

Protection against hazardous substances

Interviewed stakeholders were asked the question whether the MD should address the protection against exposure of workers to hazardous substances since the initial design phase (through principles of safety integration). Workers' associations and market surveillance authorities supported the idea, whereas consumer organisations and manufacturers opposed it. According to the majority of the manufacturers (9 out of 11 respondents to the question), safety of workers is handled by Directive 89/391/EEC[318] and is mainly the responsibility of the employer. Safety integration cannot be addressed by one manufacturer only, as the employer often selects machinery from multiple manufacturers for its final application. If hazardous substances are within the intended use of the machinery, it is already a mandatory part of the risk analysis performed by the manufacturer according to ISO 12100. Consumer organisations responded similarly, saying there is other legislation in place that ensures the protection. Workers associations, on the other hand, unanimously supported the idea. According to workers associations, the exposure should be assessed during safety assessment and should be mitigated. For example, dust is generated by many machines and is considered very harmful for lungs, same as fine dust or metal micro parts. Concerns relate to emissions from engines especially (although this is not regulated in the MD but in other pieces of law)[319].

Overhead power lines

According to the national authorities interviewed, two of the respondents that provided an insight indicated that the risk of contact with overhead power lines should be foreseen in the MD requirements. One industry association provided an answer to the question, indicating that the requirements are set out under the intended use, meaning that if a manufacturer produces a product that is applicable in all Member States, the differences, such as the height of power lines, have to be taken into account during the design stage. The rest of the stakeholder groups did not make a reference to the matter[320].

[318] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, OJ L 183, 29.6.1989, p. 1–8.
[319] Based on the interviews conducted.
[320] Based on the interviews conducted.

6.2.3. Adapting the EHSR: Redefinition of the requirements for completely enclosed carrier or control of movements for slow-speed lifts to permit innovative technologies to be used for achieving a carrier completely enclosed

The policy sub-option discussed is specifically regarding slow-speed lifts. Any changes regarding slow-speed lifts will affect all manufacturers of these lifts as indicated in section 6.2.2.2 above in this report.

One of the example technologies mentioned for revising the requirements of completely enclosed carriers for slow-speed lifts is "light barrier curtains". Given this technological specification in the consultation phase, many stakeholders indicated that no technological solutions should be specifically mentioned in the Directive as to not hinder innovation.

A change would especially impact manufacturers of slow-speed lifts, as it would generate one-off costs of familiarisation with the new approach. If the requirements were to be changed, the impacts would depend on whether internal checks of risks were to be allowed or whether third-party risk assessment is made obligatory. In case of conformity assessment through internal checks, the risk could be higher safety concerns in particular for persons using these lifts to some extent, as the level of safety of innovative solutions depends on the product (see section 6.2.2.2 for safety risks of internal checks in relation to lifts).

In the case of third-party assessment, a change would impact the costs of compliance of companies as the assessment would need to be externalised under fees (see Section 6.3 for more information on notified bodies). Notified bodies and other accredited organisations would also be impacted by a larger product portfolio to assess.

As already indicated, one of the potential risks of changing the EHSR regarding the carrier requirements in slow-speed lifts is higher safety hazards, in particular those related to falling objects or persons. In the years 2009 to 2019, the RAPEX alert system recorded 12 cases of non-compliant lifts under the Machinery Directive. Of these 12, 10 were vehicle lifts, one a stairlift and one a platform for lifting of persons. In particular, manufacturers of lifts indicated that any change related to lifts would lead to lower safety levels. They also indicated that the current provisions under the MD do not hinder innovation in the sector.

Table 36: Impacts of redefinition of requirements for slow-speed lifts

Policy option 2.2.2 REVIEWING THE SPEED LIMITS OF SLOW-SPEED LIFTS	Positive impacts	Negative impacts
Economic impacts	• Manufacturers could use alternative technologies with regards to slow-speed lifts	• One-off cost of adaptation to changes
Social impacts	• No major impacts have been identified	• Special caution should be given to lifts intended for consumers, lifts intended for the lifting of persons, including vulnerable consumers. A missing physical barrier to those lifts is likely to decrease the possibility of mitigateing the risk of falling of persons and/or objects
Environmental impacts	-	-

Nevertheless, most stakeholders indicated that alternative solutions should be allowed if they do provide similar or higher levels of safety and protection, which should be based on risk assessments. This is because it would depend on the type of product. For instance, light barrier curtains were estimated to not provide protection against the falling of persons or objects from lifting platforms; in these cases the risk levels would be higher.

Manufacturers indicated that light barrier curtains could provide the same level of safety, given that the risks must be assessed. Many indicated that both light barrier curtains and hold-to-run buttons can be tampered with, either with tape or other disturbances (e.g. dirt in the case of light barrier curtains).

An alternative solution mentioned by a machinery expert would be to allow alternative solutions but to conduct third-party conformity assessments to identify the suitability of the technological solution to the level of safety required. In addition, adding the description of light barrier curtain as a safety component under Annex V was considered useful. Here again, the respondents stressed that the safety of new applications has to be of at least the same level, if not higher, as state-of-the art solutions, and that this would depend on the type of product and that it must be ensured by a reliable conformity assessment.

One manufacturer from Germany specified that both solutions are not comparable, as the safety from hold-to-run devices depends on the person's actions, while light barrier curtains may experience technological failures. Instead, both solutions could complement each other. The equality of technologies must be considered, according to many manufacturers. For example, if the lifting platform stops running due to an ergonomic failure of the user (e.g. a cramp in the finger), the platform would need to also stop automatically in the case of failure of the light barrier curtain.

Notified bodies further stressed that the use of alternative solutions to the fully enclosed carrier would have to keep in mind products for professional use (e.g. goods lifts) in comparison to ascenders with up to 0.15 m/s velocity, which are usually used by the general public, including the elderly, children and animals.[321] Indeed, "light barrier curtains do not allow the device to start when their light sensing field is disturbed and safely stops when the light field is interrupted, but they do not prevent the material from falling out of the open lift platform, nor do they protect persons from falling off a platform"[322]. One French notified body indicated that it would be possible to integrate these technologies, but that light barrier curtains would fall under a safety component according to Annex V.

National authorities expressed similar concerns as notified bodies. In relation to the lifting of persons, in particular, the main goal in the EHSR is to avoid a people falling, which is considered most effective through the building of fences or physical restraints for users.

Another potential negative impact of changing the EHSR, especially under Annex I, as indicated by CEN/CENELEC during the consultation activities, is the need to control harmonised standards in relation to the safety of machinery for the lifting of persons and their applicability to the changes. A transition period of a minimum of three years is required. However, a standardisation expert indicated that the changes made regarding the LVD exclusion within the first revision of the Directive had led to very high adaptation costs. Familiarisation and full revision of the standards were said to be not yet finalised about 10 years after the last changes.

A potential change of this option yielded opposite results, dependent on the type of product and change. Many slow-speed lifts are used by (vulnerable) consumers (i.e. elderly, children, people with restricted mobility). Many stakeholders consulted, especially manufacturers of lifts, indicated that risks related from falling from slow-speed lifts are less likely addressed by other

[321] Notified body from Italy, response to the open public consultation
[322] Notified body from Slovakia

solutions than a physical barrier, such as completely enclosed carriers, while hold-to-run controls obligate an operator of a lift to stay in one place, limiting the risk of injuries or incidents caused by moving of the operator. Some stakeholders considered that for other products, the flexibility of using alternative solutions that provide the same or higher level of safety could benefit manufacturers. With regards to this option, it is important to keep in mind the expected increase of the use of slow-speed lifts for the lifting of persons in the future and the products appearing more often in the alert system compared to other lifts, most of them targeting consumer use. There are also expected one-off costs in terms of adaptation or resources spent for familiarisation with the changed requirements. The main potential costs and benefits identified in the consultation activities are shown in the table below.

Table 37: Potential costs and benefits of adapting the EHSR on fully enclosed carriers in slow-speed lifts

Policy option 2.3	Description	Firms			Administrations	Other organisations		Citizens/users	
CHANGING THE REQUIREMENTS FOR CARRIERS OF SLOW-SPEED LIFTS		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector**	**Users/ consumers**
1. Number of affected stakeholders (EU-27)		154	7,545	7,699[a)]	71 or more	137 or more	1	2,759,439	5,000,000[d)]
2.1 Costs (total)	**One-off**	5,981,713 to 2,231,982,390 €[b)]	4,156,783 to 1,551,038,610 €[b)]	10,138,496 to 3,783,021,000 €[b)]	Not quantifiable One-off costs to the changes will likely apply	Not quantifiable One-off costs for adaptation to the changes will likely apply	Not quantifiable Review of a number of standards due to changes in EHSR will likely apply		-
	Recurrent	-	-	-	-	-	-		**Not quantifiable** Increased safety concerns especially for slow-speed lifts intended for the lifting of persons
2.2 Costs per organisation	**One-off**	38,847 to 14,495,275 € [b)]	551 to 205,571 € [b)]	1,317 to 491,365 € [b)]	-	-	-		-
	Recurrent	-	-	-	-	-	-		-
3. Benefits	**Direct**	499,697,550 €[e)]	347,247,450 € [e)]	846,945,000 € [e)]	-	-	-		-
	Indirect	-	-	For some manufacturers, the use of alternative technologies providing the same level of safety as the current requirements could lead to lower costs	-	-	-		-

[a)] Based on Eurostat structural business statistics 2016 (EU-27), C28.22 lifting and handling equipment. This makes about 7,699 enterprises; 7,545 SMEs and 154 large manufacturers.
[b)] Based on 6.7% of turnover. Turnover estimated on Eurostat 2016 (EU-27): EUR 56,463 million total sector; EUR 33,313 million all large manufacturers (EUR 216 million per company); EUR 23,150 million all SMEs (EUR 3 million per SME). In order to account for the potential costs per year at minimum scale, the 25 years are taken for the lower ranges, reaching 0.268% of turnover.
[c)] Based on 1.5% of turnover.
[d)] Proxy used: Persons with impaired mobility in the EU (2012) – Eurostat disability statistics; Total potential affected users would be 7,759,439.
[e)] Based on 1.5% of turnover.
There are instances where data are quantified based on responses to consultations or interviews. When the number of replies is too low to present an estimate, cost cannot be reliably quantified. Proxy values are used when direct information is not available.

6.2.4. Allowing digital formats for documentation

One of the identified results of the evaluation is the option to provide digital formats for documentation rather than the provision of user manuals in paper format as it is currently indicated in the Guide. While this policy option would not require a change of the legal text in the Machinery Directive directly, since changing the wording in the Guide might suffice, a specification in the EHSR could provide further legal certainty. Allowing digital documentation could have the following wider impacts, as indicated by various stakeholder groups in the consultation activities:

Table 38: Impacts of digital documentation

	Key positive impacts	Key negative impacts
Economic impacts	• Manufacturers and otherwise authorised representatives might be able to save a share of the printing, paper and shipping costs • Potential for research and innovation in digital tools	• SMEs might face higher costs in developing and maintaining the database for online manuals • Potential liability issues in third countries through missing information in paper
Social impacts	• Opportunity to access the manuals at any point of time • Shorter manuals enhancing readability for users • Easier search for information possible • Access to other languages online • Blind and partially sighted persons might have easier access to the information (e.g. through reading out options of digital user manuals)	• Workers in certain environments might not be able to access digital tools • For certain types of machinery, it might not be possible to access manuals through digital tools (e.g. transportable machinery) • Availability of online manuals unsure in cases of bankruptcy • Changes or updates of the manual in the future might not match their own version of a product anymore • Certain group of users or users from some countries with less internet connectivity could have more difficulties in accessing the user manuals (e.g. those less digitally savvy) • Increased barrier or threshold for consumers to read the manuals which might lead to less consumers accessing and reading the manual, and thus higher safety risks
Environmental impacts	• Saving of paper and decrease of carbon footprint (Saving of costs of emission 32,595,273 €)*	

Sources: OPC results, stakeholder consultation; *The saving of costs of emissions were calculated by taking the CO_2 costs of emissions of printing all user manuals minus the costs of emissions of servers and the share of printed parts of manuals individually. Calculation further explained in the footnote below.[323]

[323] This was estimated taking the benefits of cost of emission (CO_2) saved from the printing of manuals subtracted by the cost of emission of having additional servers to manage digital manuals. The total emission of CO_2 for the machinery sector with regards to ICT was estimated using the European Environment Agency (2019) total greenhouse gas emission estimates of the European industry (877 million tons CO_2), taking 10% of the share of machinery of the total sold production in the industry according to Eurostat 2019 (88 million tons CO_2) and then the 2% of ICT share on carbon emissions from Climatecare.org (1.8 million tons CO_2). The costs of one ton of CO_2 on average in 2019 was of EUR 22. Adding these costs to the potential additional costs from those economic operators that do not yet use digital formats (18%) and that would add to the environmental costs

This sub-option of Policy Option 2 is expected to directly impact manufacturers in particular, along with authorised representatives in charge of providing user manuals with their products and users of these products and manuals, given the requirements to deliver documentation with the product. The potential impacts on the different stakeholder groups is shown in the table below.

Table 39: Impacts of switching to digital documentation by affected group

Groups		Key negative impacts	Key positive impacts
Consumers, workers and employees		• Time and additional action to access digital tools for reading the manuals • Adapting costs to changes • Difficulty of access without internet	• Access to manuals at any time • Easier search for information • Increased readability through easier adaptation of text
Businesses	Manufacturers	• Increased costs of development and maintenance of the database for manuals	• Shorter time to update information • Cost savings related to printing, paper and shipping
	Users	• Time and higher threshold to access digital tools for reading the manuals • Increased printing and paper costs related to printing the manual	• Access to manuals at any time • Easier search for information • Increased readability through more possibilities to adapt text
	SMEs	• Increased costs of development and maintenance of database for manuals	• Shorter time to update information • Saving printing, paper and shipping costs
Member States and public authorities		• Increased costs of adaptation to new procedure • Time to identify the correct manual and documentation	• Easier search for information
Notified bodies		• Increased costs of adaptation to new procedure	• Access to manuals at any time • Less storage costs for printed manuals

of servers (EUR 6.9 million EUR) would make the total cost of emission of digital manuals of about EUR 45,550. In order to account for the effects of having digital manuals, such as the emissions generated by printing the translation only or only printing the relevant parts of the manuals, the OPC shares were taken into the calculation of additional CO_2 costs of digital user manuals. The first step was identifying the CO_2 emissions (in tons) of one user manual of 300 pages. Using VTT's carbon footprint of a hardback book (about 0.0012 tons of CO_2 per manual of 300 pages), the emissions of one page could be estimated to about 0.000004 tons. In order to understand the potential CO_2 emissions of printing the translation only, the 0.0012 tons of CO_2 per manual were multiplied by 1/23 (one of 23 official EU languages), reaching 0.00005 tons of CO_2 per manual. This was then multiplied by the number of manuals based on one manual per sold machinery (3.1 billion), by the share that would print the translation only (22.9/96.1) and by the cost of one ton (22 EUR). This would make an additional EUR 832,257 cost of emission of digital manuals. To account for those costs of emission that would arise from people printing the relevant parts in their languages only, 50% of the manual in their language is taken as estimate of what would be printed. The estimated CO_2 tons of printing the relevant parts of translations are at about 0.00003. To calculate the CO_2 costs, these were multiplied by 45% indicating they would print relevant parts only (43.6/96.1), by the total number of manuals in the machinery sector times the cost of one ton (22 EUR). This led to additional CO_2 costs of digital manual of about EUR 780,241. Taking all the CO_2 costs of digital manuals accounting for the reaction of people with regards to printing on their own, the total CO_2 costs were estimated to be about EUR 47,162,687 (EUR 45,550 + 832,257 + 780,241). To estimate the benefits-to-cost ratio, the total benefits in terms of CO_2 costs of printing all the manuals fully is taken as benefit. Based on 0.0012 tons of CO_2 per manual times 3.1 billion manuals times 22 EUR for one ton of CO_2, the total costs of emissions for printing manuals are about EUR 79,757,960. The benefit-to-cost ratio is thus EUR 32,595,273 (EUR 79,757,960-47,162,687).

In order to estimate the potential additional costs and cost savings for manufacturers through a switch to digital documentation, the following inputs have been assessed. A change to the use of digital documentation could imply one-off costs for economic operators of purchasing and setting up a server[324], while recurring costs of maintaining this database and the information up to date[325]. In addition, while manufacturers might save these types of costs, there are new costs that might arise with the development of the database for the user manuals or the provision of other digital tools (e.g. CD-ROMs or USB sticks). The purchasing and setup costs of a server can be estimated from about USD 1,000 to 3,000 (average of EUR 1,845)[326] for small companies to purchase servers and an average of USD 125 (EUR 115) per month recurring costs to maintain the server.[327] Some manufacturers or large companies might already possess a website including such a database due to e-commerce activities, which would affect these costs less than for other companies that would have to start from the beginning. Within the machinery sector, 81.8% of the manufacturers already use digital formats for documentation and/or manuals.[328] Thus, the costs will apply to the remaining 18%, in particular.

Printing costs for user manuals have been estimated by different businesses associations and companies.[329] The ranges for printing costs were indicated to be between EUR 0.04 to 1 per page. Manuals can range from 10 to 900 pages, with the upper limit reached by extensive manuals that contain all languages or complete data packages, for example. However, the most mentioned manual size is between 100 and 400 pages. The total weighted average of pages per manual reaches about 300 pages. The number of manuals printed per year depends on the type of product manufactured and the company size. Respondents reported printing between 30 to 3.2 million manuals each year. The results of the open public consultation indicate an average number of manuals of 197,127 per company per year. This would be higher than the amount of machinery sold, according to PRODCOM statistics (3.1 billion). Thus, to ensure coherence with the data above, the number of user manuals printed per year in the machinery sector is taken as one per machinery, thus about 3.1 billion manuals per year. Depending on the size of the manual and the number of products manufactured, the printing costs per year are reported to reach 1-4% of turnover per year. A full switch to digital documentation could therefore save manufacturers and authorised representatives paper, printing and shipping costs. A visualisation of the cost-benefit estimates of switching to digital documentation is provided in the table below, with details of the calculations provided under the table (see Table 40).

[324] Average of USD 2,000 (EUR 1,845) for small businesses. This average is taken for all equally, though costs for large manufacturers might be lower. Setup costs were indicated to be on average about USD 125 (EUR 115). Cost estimates taken from https://www.servermania.com/kb/articles/how-much-does-a-server-cost-for-a-small-business/#Maintenance_Costs

[325] Estimated at USD 295 (EUR 272) per month for systems with very high requirements. Costs taken from Servermania (https://www.servermania.com/kb/articles/how-much-does-a-server-cost-for-a-small-business/#Maintenance_Costs)

[326] Converted using European Commission's InforEuro, baseline 2019

[327] CostOwl.com (2019). How much does a database design service cost? Available at: https://www.costowl.com/b2b/design-services-database-cost.html

[328] Results from the online survey, n=22

[329] The information taken for the assessment of costs and benefits as well as potential impacts of the policy option are based on the input received through desk research and stakeholder consultation.

Table 40: Potential costs and benefits of switching to digital documentation

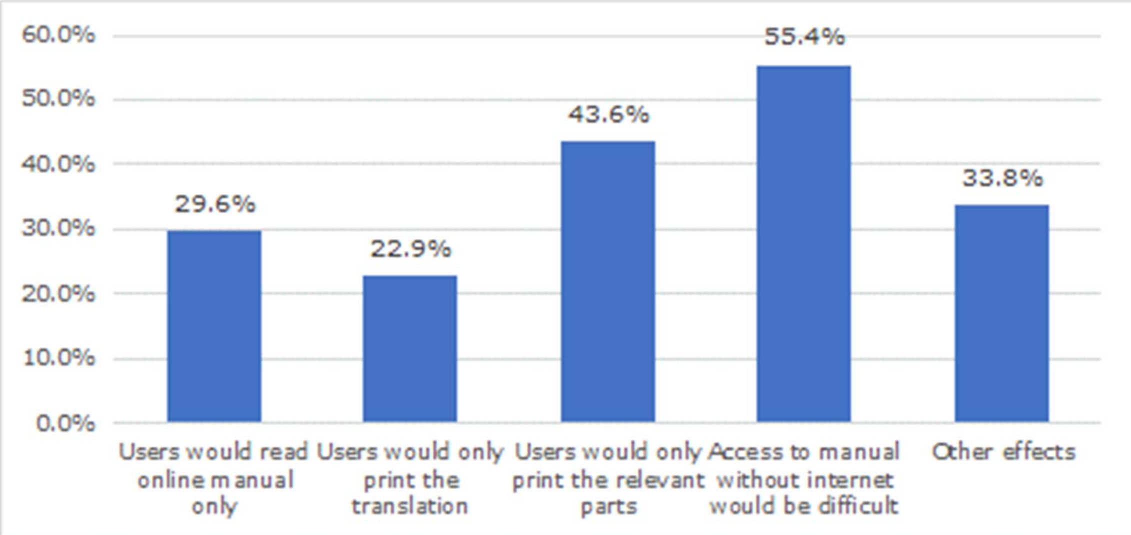
Policy option 2.4	Description	Firms			Administrations	Other organisations		Citizens/users	
ALLOWING DIGITAL FORMATS FOR DOCUMENTATION Net effect of policy sub-sub-option (+)		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector**	**Consumers**
1. Number of affected stakeholders (EU-27)		**1,703**	**81,024**	**82,239**[a)]	**71 or more**	**137 or more**	-	**2,759,439**	191,210,900[f)]
2.1 Costs (total)	**One-off**	600,818 €[b)]	28,585,267 €[b)]	29,013,919 €[b)]	**Not quantifiable One-off costs for adaptation to change expected**	**Not quantifiable One-off costs for adaptation to change expected**	-		
	Recurrent	1,000,547 €[e)] (annually)	47,603,220 €[e)] (annually)	48,317,057 €[e)] (annually)	-	-	-	**0.49**[k)] **to 0.52€**[j)] per manual (number of manuals for professionals not identified)	**0.49**[k)] **to 0.52€**[j)] per manual (number of manuals for consumers not identified)
2.2 Costs per organisation	**One-off**	1,960 €[c)] [c)]	1,960 €[c)] [c)]	1,960 €[c)]	**Not quantifiable One-off costs for adaptation to change expected**	**Not quantifiable One-off costs for adaptation to change expected**	-	-	
	Recurrent	3,264 €[d)] (annually)	3,264 €[d)] (annually)	3,264 €[d)] (annually)	-	-	-	-	
3. Benefits	**Direct**	Up to 92,083,335,500 € (91,646,183 € per organisation) printing costs saved with online manuals only Up to 91,469,446,597 € (53,710,773 € per organisation) printing costs saved with digital manuals and QSG	Up to 63,990,114,500 € (1,926,262 € per organisation) printing costs saved with online manuals only Up to 63,563,513,737 € (784,502 € per organisation) printing costs saved with digital manuals and QSG Up to 52,309,379,313 € (645,604 € per organisation) printing costs saved with digital	Up to 156,073,450,000 € (1,897,803 € per organisation) printing costs saved with online manuals only[g)] Up to 155,032,960,333 € (1,885,151 € per organisation) printing costs saved with digital manuals and QSG[h)] Up to 127,583,851,984 € (1,551,379 € per organisation) printing costs saved with digital	-	**Not quantifiable** Some notified bodies might benefit from decreased storage costs for documentation	-	**Not quantifiable** Some users might benefit from digital documentation (e.g. Increased readability)	**Not quantifiable** Some users might benefit from digital documentation (e.g. Increased readability)

Policy option 2.4	Description	Firms			Administrations	Other organisations		Citizens/users	
		Up to 75,274,472,671 € (44,201,100 € per organisation) printing costs saved with digital manuals and printed manuals on demand	manuals and printed manuals on demand	manuals and printed manuals on demand[i]					
	Indirect	-	-	-	-	-	-	-	-

[a] Due to rounding differences in the data in Eurostat, the total number of enterprises shown does not equal the sum of enterprises recorded per size class.
[b] Based on average costs of purchasing and setting up a server for small business (it is likely that costs for large manufacturers are lower) for 18% of enterprises not yet using digital formats in the sector times the number of companies in the sector. These one-off costs are expected to be the same irrespective of the sub-option as servers would need to be purchased and set up in all sub-options.
[c] Based on average of EUR 1,845 for purchasing a server plus average of EUR 115 to set up a server (EUR 1,960 per organisation).
[d] Based on average of EUR 272 per month (EUR 3,246 per year) costs of maintaining the server at maximum complexity of the system for small businesses. Costs for large manufacturers are likely to be lower. These are expected to be the same across sub-options.
[e] Based on the yearly costs of maintaining a server times the number of enterprises, large manufacturers and SMEs and the 18% of enterprises not yet using digital formats.
[f] Proxy used: number of households Eurostat EU-27, 2016.
[g] Estimates based on the total printing costs of user manuals (2.5% of turnover – turnover in machinery sector EU-27, 2016 at EUR 624,293 million) that would be saved with the option of only having digital manuals.
[h] Based on the difference between the total printing costs saved by having digital manuals only (=total printing costs) and printing costs of a QSG of two pages. The costs of two pages were calculated as follows: Printing costs of one manual by dividing the total printing costs (2.5% of turnover) by the total number of manuals (one per machinery at 3.1 billion machines) = EUR 50 per manual (this cost is very likely overestimating the real cost of one manual as it does not account for economies of scale but it has been used to ensure the coherence of data used for calculations. This would make EUR 0.17 per page and 0.33 for two pages (the QSG). Therefore, the total difference in printing costs saved with regards to QSG would be EUR 156,073,450,000 minus EUR 1,040,489,667 = EUR 155,032,960,333.
[i] Based on the difference between the total printing costs saved by having digital manuals only and printed manuals on demand. The costs of printing on demand was estimated by taking OPC answers on the preferences of the form of documentation, whereby 30% would prefer to have it always printed; 20.7% to have it printed on demand and 62.7% would like to have it always digital. To account for the multiple answers of these percentages, the share of printed on demand was calculated by dividing 20.7 by the total number => 20.7/(30+20.7+62.7) => 18%. This share was used to estimate the printing costs of the total printing costs that would apply with printing on demand (EUR 28,489,598,016). The difference was then estimated to achieve the potential printing costs saved of having digital manuals with a printing on demand option (EUR 156,073,450,000 minus EUR 28,489,598,016).
[j] Based on the estimation of costs of one manual at EUR 50 (caveats on this number explained above under h)). The cost of printing translation only was estimated by taking 1/23 of a manual based on the assumption that this manual contains all 23 EU languages times the EUR 50. This would likely apply to the 22.9/96.1 of OPC respondents expecting only the translations to be printed. With both assumptions, costs of printing translations only would reach about EUR 0.52 per manual. No difference could be made on the number of manuals used by professional users in comparison to consumers.
[k] Based on similar estimates as j) with the difference that 43.6 of 96.1 expected only relevant parts to be printed (about 50% of the manual in their language 1/23). This would lead to printing costs of about EUR 0.49 for printing the relevant parts of their language per manual. No difference could be made on the number of manuals used by professional users in comparison to consumers.
There are instances where data are quantified based on responses to consultations or interviews. When the number of replies is too low to present an estimate, cost cannot be reliably quantified. Proxy values are used when direct information is not available.

For private users and workers, a change to digital documentation could provide additional burden to access the information. There is the risk that this threshold would lead to less reading of the manuals and thus increase the safety risks. On the other hand, users might access the manuals more often given the increased readability. The expected effects of having digital manuals only according to the OPC results are shown in the graph below (see Figure 33).

Figure 33: Potential impacts of switching solely to online manuals



Source: Open Public Consultation (n=523; multiple answers possible)

Looking into the share of individuals that have used the internet to have a proxy on the use of digital tools, 87% of individuals (in EU-28) used the internet at least once in three months in 2019. Taking the average yearly growth rate, this share would reach 100% by 2024 (or by 2033 at conservative estimates).[330] At the same time, certain groups such as less digitally savvy users or workers without internet access in certain environments could face increased difficulty to access the manuals. Allowing printed user manuals on demand would also cover the risks of certain consumer groups, such as less digitally savvy ones and users in specific working environments, of not being able to access the full manual when there is no internet connection. At the same time, digital versions of the manual might be easier to read, such as through the search function or the manufacturer's possibility to enhance the format or provide additional information. Consumers and users could have access to the main health and safety, installation information on the spot when receiving the product through a Quick Start Guide (QSG), for example, while providing the option to access additional information digitally in a potentially more readable format, at any time and in the desired language.

Switching to digital user manuals could be implemented in different ways, such as:

- No change – always paper documentation;
- Full switch to digital documentation;
- Digital documentation accompanied with a printed QSG; and
- Digital documentation with paper formats on demand.

The different options of degree of digitalisation of user manuals are expected to have several costs and benefits, the range depending on the form of implementation. These differences have been accounted for in the calculations of potential costs and benefits (cost savings) of

[330] Eurostat (2020). Internet use by individuals [tin00028]; average yearly growth: 3% (conservative estimates 1%)

switching to digital manuals and in combination with QSG or printed on demand are considered in the cost and benefit table before.

When digital documentation is selected, a clarification of which kind of documentation may be digital and which in paper form (e.g. basic safety information) should be clarified, as it is currently not harmoniously understood in the market and applied loosely, particularly regarding partly completed machinery.[331] Another potential barrier in the adoption of digital documentation is the risk that users may not have access to online connectivity when putting the machine in use. Considering that handbooks for machinery can be very technical for users to use, a potential alternative is to provide a paper format Quick Start Guide in combination with additional information online. To counter the risk of no access to online connectivity, a printed version of the full handbook could be requested free of charge.

In the case of digital documentation in combination with a printed Quick Start Guide (QSG), the paper, printing and shipping cost savings would be lower than with a full switch[332]. They would also be lower than printed manuals on demand.[333]

Given the potential impacts along with the costs and benefits quantified and the further non-quantifiable impacts of a switch, the most preferable option in the provision of digital documentation is to allow a form of digital manual combined with a printed Quick Start Guide, ideally with allowing printed user manuals on demand. Indeed, according to the cost-benefit estimation it would be beneficial to allow the flexibility of providing documentation digitally or on paper while following the minimum requirements when opting for the digital manual. This choice is explained by the following reasons.

Manufacturers and other authorised representatives – the stakeholders responsible for providing user manuals – would have lower paper, printing and shipping costs in relation to the user manuals. Other costs related to user manuals, such as translation costs, would not change and still apply. Nevertheless, the benefits of this flexibility and the increased facility to update manuals when necessary are expected to be higher than no change of the current approach. Indeed, the majority of the respondents to the inception impact assessment and the stakeholder consultation activities carried out during the study also indicated a preference for digital documentation, partly due to the positive environmental impact, the reduced burden and costs and the facility to provide instruction updates.[334] The main risk remaining in relation to providing information in a digital way is the effect on the availability of the online manual should the manufacturer cease to exist during the lifetime of the machinery.

However, some stakeholder groups oppose the option of allowing digital documentation, as shown in the results of the Open Public Consultation, with 30% always preferring printed manuals. This applies especially to authorities enforcing the Directive, which mostly opted for having manuals printed always (58.3%).

[331] Stakeholder from Germany, 28/02/2019
[332] About EUR 85,596,864 lower for total machinery sector
[333] About EUR 107,659,456 lower for total machinery sector
[334] DG GROW C3 (2019). Feedback on the inception impact assessment for a potential revision of the Machinery Directive 2006/42/EC.

6.3. Impacts of policy Option 3: Modifying Annex IV

The study's OPC shows that the consulted stakeholders are not unanimous about whether the internal checks option in Annex IV of the MD leads to safety concerns or not. Around 40% of the OPC respondents indicated that it does and 39% indicated it does not. In particular, the majority of authorities, consumer organisations, distributors and importers, notified bodies, private users and professional workers believe that the internal checks option represents safety concerns. On the other hand, most industry associations, machinery safety consultants, manufacturers, researchers, and stakeholders involved in standardisation negated higher safety concerns due to internal checks. See sub-chapter 2.3.3 in the Chapter 2 of the study to learn more about the problems associated with the internal checks option of the Annex IV machinery.

6.3.1. Costs related to internal checks and third-party involvement

There are different types of costs that arise through compliance with the MD and the conformity assessment of the machinery. In order to assess the costs and benefits to modifying Annex IV, it is relevant to understand which costs apply to which procedure and by whom these are borne. Given the procedures for conformity assessment of relevance to this revision, the main actors involved in the conformity assessment, and thus affected by a change are manufacturers and accredited bodies (notified bodies).

On cost data related to conformity assessment through internal checks and third-party assessment, case studies conducted under the evaluation of the Internal Market Legislation of Industrial Products in 2014 provide useful insights.[335] Administrative and compliance costs for manufacturers and firms are related to four steps:

- Preparatory actions and familiarisation with the applicable legislation and administrative obligations;
- Substantive compliance: introduction of processes or changes to product design and production processes to ensure compliance;
- Conformity assessment procedures and preparation of documentation; and
- Declaration of conformity or other statement of compliance and CE marking.

The costs assessed by the evaluation of the internal market regulation for industrial products were as follows[336]:

Table 41: Costs of compliance and conformity assessment

Type of costs	One-off costs	Recurring costs
Administrative costs	• Familiarisation with legislation and standards • Notified bodies fees for legislation and mandatory testing	• Development and updating of technical files • Production of DoC and CE marking • Conformity assessment: preparation of technical files together with testing

[335] European Commission (2014). Commission Staff Working Document part 1: Evaluation of the internal market legislation for industrial products (SWD/2014/023 final). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52014SC0023&from=SK&lang3=choose&lang2=choose&lang1=EN

[336] European Commission (2014). Commission Staff Working Document part 1: Evaluation of the internal market legislation for industrial products (SWD/2014/023 final), p.92. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:6da8f15b-8438-11e3-9b7d-01aa75ed71a1.0001.01/DOC_1&format=PDF

Type of costs	One-off costs	Recurring costs
Substantive compliance costs	• Modifications to product design • Modifications to product design once they have been placed on the market • Costs of temporarily or permanently withdrawing products from the market	• Conformity assessment: preparation of technical files in parallel with testing activities with applicable modules defined in legislation

Source: Evaluation of the Lifts Directive

The overall compliance costs with the Directive were estimated to not exceed 1% of annual turnover. For the purpose of this revision, the focus lies on the third type of costs of the overall compliance costs: conformity assessment procedures and preparation of documentation. Of this share of total compliance costs, about 20-25% (average 23%) are estimated to be used for a conformity assessment procedure with internal checks, whereas 55% for a third-party conformity assessment. Taking these indications to calculate the costs of the total turnover in the machinery sector in the EU, the results are as follows: Following the evaluation of the Machinery Directive in 2018, EC-type examinations are used in 8% of all the cases, followed by 2% for full quality assurance; internal checks of Annex IV products are carried out in 10% of all the assessments.[337] To assess the compliance costs with regards to the machinery sector, these shares are used.

Table 42: Estimation of affected amount of machinery if Annex IV is modified

Type of conformity assessment	Share of type of conformity assessment of all assessments
Internal checks of non-Annex IV machinery	80%
Internal checks of Annex IV machinery	10%
EC-type of examination	8%
Full quality assurance	2%

Thus, the likely total compliance costs for manufacturers resulting from the different conformity assessment procedures for the machinery sector are as shown in the table below.[338]

Table 43: Costs of conformity assessment procedures in the machinery sector

	Description	Firms		
Costs for conformity assessment		**Large companies**	**SMEs**	**All**
2.1 Costs (total)	**Internal checks**	745,875,018 €	518,319,927 €	1,264,194,945 €
	Third-party assessment	202,583,338 €	140,778,252 €	343,361,590 €
2.2 Costs per organisation	**Internal checks**	437,977 €	6,397 €	15,372 €
	Third-party assessment	118,957 €	1,737 €	4,175 €

The compliance costs and other aspects related to the conformity assessment borne by manufacturers are aggregated through different sources. These include, among others, costs for CE marking, staff costs, costs for testing facilities, fees for notified bodies (third-party

[337] European Commission (2018). Evaluation of the Machinery Directive.

[338] These are based on the estimation of 1% of turnover for conformity assessments. Out of these, 23% are for internal checks for 90% of all assessment procedures and 55% are for third-party conformity assessment for 10% of all assessment procedures.

assessment), costs for translations of the Declaration of Conformity, and costs for purchasing harmonised standards. In order to allow for a concise study, the details on these costs are not further elaborated.[339]

The other main actors involved in the conformity assessment procedure are notified bodies. A survey with **notified bodies** found that most do not occupy more than 10 full-time equivalent (FTE) in conformity assessment services and 13% occupy more than 50 FTE. In the EU-27, a total of 137 accredited notified bodies can be found that are assigned to sector machinery.[340] Nevertheless, along with conformity assessments, notified bodies provide other services to firms. For instance, some notified bodies also participate in notified bodies groups (NBG), which adds operation costs of a few thousand to more than EUR 100,000 per year. Other annual fees of participation, such as in the Medical Devices Directive NBG was estimated to about EUR 2,330 to 4,500 plus extra costs for the most active members travelling to the meetings.[341]

Table 44: Cost of compliance for notified bodies

Step of compliance	Description	Value
Direct costs: Costs of compliance related to human resources	FTEs	Up to 10 FTE
Direct costs: Costs of compliance related to purchasing harmonised standards	Costs per harmonised standard	EUR 50 to 250*
Number of affected bodies	Notified bodies in the EEA	179

*based on the evaluation of the Lifts Directive, given that all products covered by the Lifts Directive are subject to third-party conformity assessment compared to selective Annex IV machinery under the MD, this data is likely to be over-estimating the compliance costs for products under the MD in the current application.; Sources: European Commission (2014) study on evaluation of the internal market legislation for industrial products, the evaluation of the Lifts Directive and NANDO database

Finally, Market Surveillance Authorities test products on the market for their compliance. Thus, they are not directly affected during the conformity assessment procedure but only when the products are placed on the market. For **national authorities**, it wasn't possible to quantify costs.

6.3.2. Impacts of modifying Annex IV

The three main sub-options to consider under a modification of Annex IV are: i) removal of conformity assessment through internal checks of Annex IV machinery; ii) adapting the list of products in the Annex; and iii) removing the Annex IV. The first two sub-options might be implemented at the same time, while the last sub-option is mutually exclusive to the previous two. Thus, an overarching assessment of policy option 3 is not recommendable. A modification of Annex IV machinery would at least affect the share of machinery in the scope of Annex IV

339 European Commission (2014). Commission Staff Working Document part 1: Evaluation of the internal market legislation for industrial products (SWD/2014/023 final). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52014SC0023&from=SK&lang3=choose&lang2=choose&lang1=EN provides insights into costs related to conformity assessments. These include costs due to familiarisation and preparatory work for internal checks. Here, firm costs are given by 15-20% of time of total human resources, three to four FTE for large companies and under one FTE for SMEs. The purchase of harmonised standards could range from under EUR 1,000 to 2,000 for specific product groups and EUR 50 to 200 for each standard. There are also costs related to test labs, whereby SMEs tend to use external labs costing about EUR 1,000 per model family and the setting up of labs up to EUR 200,000 and 1-2 FTE for personnel.

340 NANDO database (2019). Available at: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=131881. Last accessed: 15/11/2019; 179 for the whole EEA

341 European Commission (2014). Commission Staff Working Document part 1: Evaluation of the internal market legislation for industrial products (SWD/2014/023 final). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52014SC0023&from=SK&lang3=choose&lang2=choose&lang1=EN

that is currently assessed through internal checks, EC-type of assessment or full quality assurance, however.

For the first sub-option, **removing the option for internal checks for conformity assessments of Annex IV machinery**, the following potential impacts might apply.

Table 45: Potential impacts of removing the option for internal checks of Annex IV machinery

Type	Positive impact	Negative impacts
Economic	• The effectiveness of the Directive to facilitate the functioning of the internal market could increase based on a common approach to all Annex IV machinery	• Time and costs for familiarisation with new legal text (one-off) • Increased costs for third parties hired for the conformity assessment (recurring)
Social	• Increased safety of (new) high-risk products	• Potential increased costs of products if additional costs are moved down the value chain

With regards on the costs of this option, they are estimated by taking the difference between the compliance costs for manufacturers for both types of conformity assessments.[342] Removing the option for internal checks would affect 10% of all conformity assessments currently carried out. If the option of conformity assessments with internal checks of machinery under Annex IV were to be removed, manufacturers expected one-off costs of about 6% of annual turnover on average.[343] Additional recurring costs, as already indicated, would stem from the cost differences between conformity assessments carried out through internal checks, and those done by third parties for the 10% of assessments currently carried out through internal checks. However, removing the option for internal checks might lead to a higher degree of safety of the machinery. To assess the potential benefits of removing the option for internal checks the evaluation of the Machinery Directive is taken for a proxy. Here, the estimation of the MD being effective to very effective in ensuring the protection of health and safety of users in the market when Annex IV machinery is assessed through internal checks is 83%, compared to 94% when an EC-type examination is followed. Thus, removing the option of internal checks of Annex IV machinery has the potential to increase the effectiveness of the MD to ensure the protection of health and safety by 13% for the 10% of assessments currently carried out through internal checks.

The total potential costs and benefits related to the removal of the internal checks option under Annex IV are summarised in the table below (see Table 46).

[342] The differences in costs result from the previous 23% of total conformity assessment costs related to internal checks, compared to 55% related to third party assessments

[343] Results from the Open Public Consultation.

Table 46: Costs and benefits of removing the internal checks option for Annex IV machinery

Policy option 3	Description	Firms			Administrations	Other organisations		Citizens/users	
SUB-OPTION 3.1 REMOVING THE OPTION FOR INTERNAL CHECKS FOR ANNEX IV MACHINERY NET EFFECT (+)		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector**	**Users / consumers**
1. Number of affected stakeholders (EU-27)		**1,703**	**81,024**	**82,239[a)]**	**-**	**137 or more**	**-**	**2,759,439**	**446,000,000[b)]**
2.1 Costs (total)	**One-off**	Some adaptation costs expected but could not be reliably quantified	Some adaptation costs expected but could not be reliably quantified	Some adaptation costs expected but could not be reliably quantified	-	**Not quantifiable** One-off costs in adaptation expected	-	Not quantifiable, costs of changes could be pushed down the value chain	Not quantifiable, costs of changes could be pushed down the value chain
	Recurrent (annually)	Not quantifiable	Not quantifiable	**202,895,485 €[c)]**	-	-	-	-	
2.2 Costs per organisation	**One-off**	Some adaptation costs expected but could not be reliably quantified	Some adaptation costs expected but could not be reliably quantified	Some adaptation costs expected but could not be reliably quantified	-	**Not quantifiable** One-off costs in adaptation expected for average of 10 FTEs[e)]	-	-	
	Recurrent (annually)	Not quantifiable	Not quantifiable	**2,467 € [c)]**	-	-	-	-	
3. Benefits	**Direct**	Some benefits through changes expected by a few consultation participants but could not be reliably quantified	Some benefits through changes expected by a few consultation participants but could not be reliably quantified	Some benefits through changes expected by a few consultation participants but could not be reliably quantified	-	-	-	**Not quantifiable** Effectiveness of Directive to protect health and safety of users expected to increase 13%[d)] for 10% of the machinery currently following internal checks	**Not quantifiable** Effectiveness of Directive to protect health and safety of users expected to increase 13% for 10%[d)] of the machinery currently following internal checks

Policy option 3	Description	Firms			Administrations	Other organisations		Citizens/users	
SUB-OPTION 3.1 REMOVING THE OPTION FOR INTERNAL CHECKS FOR ANNEX IV MACHINERY NET EFFECT (+)		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector**	**Users / consumers**
	Indirect	**Not quantifiable** Effectiveness of Directive to facilitate the functioning of the internal market expected to increase 1%[f)]	**Not quantifiable** Effectiveness of Directive to facilitate the functioning of the internal market expected to increase 1%[f)]	**Not quantifiable** Effectiveness of Directive to facilitate the functioning of the internal market expected to increase 1%[f)]	-	Increased product portfolio of 10% of machinery under Annex IV currently assessed through internal checks	-	-	

[a)] Due to rounding differences in the data in Eurostat, the total number of enterprises shown does not equal the sum of enterprises recorded per size class.
[b)] Proxy used: Number of inhabitants in the EU.
[c)] Based on the difference in cost for conformity assessment of third-party assessments compared to internal checks for the 10% of products that currently fall under internal checks under Annex IV.
[d)] Based on the 2018 Evaluation of the Machinery Directive and the difference in effectiveness of the Machinery Directive to ensure the health and safety of users by type of conformity assessment.
[e)] Estimates based on European Commission (2014) "Study on evaluation of the internal market legislation for industrial products" indicating up to 10 FTEs for notified bodies to assess products' conformity.
[f)] Based on the 2018 Evaluation of the Machinery Directive and the difference in effectiveness of the Machinery Directive to facilitate the functioning of the internal market by type of conformity assessment.
There are instances where data are quantified based on responses to consultations or interviews. When the number of replies is too low to present an estimate, cost cannot be reliably quantified. Proxy values are used when direct information is not available.

Regarding the updating of Annex IV through the inclusion of other high-risk categories, a split of opinions is found in the consultation responses. Importers, machinery safety consultants, notified bodies, professional workers and stakeholders involved in standardisation were generally in favour of adding further categories. In comparison, industry associations were against new categories. Results also indicate that several stakeholders from different groups are in favour of regular updates to the Annex, especially C-standards for Annex IV, to keep up to date with new equipment in old equipment families.

Taking into account the types of compliance costs related to the conformity assessment and results from the data collection and stakeholder consultation activities, the following impacts of modifying Annex IV may apply.

Table 47: Potential impacts of adapting the list of products under Annex IV

Type	Positive impact	Negative impacts
Economic	• Reduction of costs related to time for specialisation with conformity assessment procedure (for manufacturers) • Increased business opportunities for additional conformity assessment procedures for notified bodies	• Time and costs for familiarisation with new legal text (one-off) • Increased costs for third parties hired for the conformity assessment (recurring)
Social	• Increased safety of (new) high-risk products	• Potential increased costs of products if additional costs are moved down the value chain

The additional one-off costs estimated by manufacturers of machines, if the Annex were to be adapted, was about 4.3% of annual turnover. Recurring costs would apply to machinery that would move into the Annex IV. An exact share of impacted assessments could not be identified, however. These items of machinery could also be assessed through internal checks within the Annex IV, if the first sub-option is not implemented. Thus, the potential costs and benefits are given at maximum ranges. An overview of the potential impacts of modifying Annex IV is listed below (see Table 48).

Table 48: Impacts of modifying the list of products under Annex IV

Policy option 3	Description	Firms			Administrations	Other organisations		Citizens/users	
SUB-OPTION 3.1 REMOVING THE OPTION FOR INTERNAL CHECKS FOR ANNEX IV MACHINERY NET EFFECT (0 to +)		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector**	**Users / consumers**
1. Number of affected stakeholders (EU-27)		**1,703**	**81,024**	**82,239**[a)]	**-**	**137 or more**	**-**	**2,759,439**	**446,000,000**[b)]
2.1 Costs (total)	**One-off**	**Not quantifiable** One-off costs in adaptation expected	**Not quantifiable** One-off costs in adaptation expected	**Not quantifiable** One-off costs in adaptation expected	-	**Not quantifiable** One-off costs in adaptation expected	-	Not quantifiable, costs of changes could be pushed down the value chain	Not quantifiable, costs of changes could be pushed down the value chain
	Recurrent	**Not quantifiable** Increased costs of compliance for third-party assessment procedures for products that are currently assessed through internal checks	**Not quantifiable** Increased costs of compliance for third-party assessment procedures for products that are currently assessed through internal checks	**Not quantifiable** Increased costs of compliance for third-party assessment procedures for products that are currently assessed through internal checks	-	-	-	-	-
2.2 Costs per organisation	**One-off**	**Not quantifiable** One-off costs in adaptation expected	**Not quantifiable** One-off costs in adaptation expected	**Not quantifiable** One-off costs in adaptation expected	-	**Not quantifiable** One-off costs in adaptation expected for average of 10 FTEs[c)]	-	-	-
	Recurrent	**Not quantifiable**	**Not quantifiable**	**Not quantifiable**	-	-	-	-	-

Policy option 3	Description	Firms			Administrations	Other organisations		Citizens/users	
SUB-OPTION 3.1 REMOVING THE OPTION FOR INTERNAL CHECKS FOR ANNEX IV MACHINERY NET EFFECT (0 to +)		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector**	**Users / consumers**
		Increased costs of compliance for third-party assessment procedures for products that are currently assessed through internal checks	Increased costs of compliance for third-party assessment procedures for products that are currently assessed through internal checks	Increased costs of compliance for third-party assessment procedures for products that are currently assessed through internal checks					
3. Benefits	**Direct**	-	-	-	-	-	-	**Non quantifiable** The effectiveness of the Directive in protecting the health and safety of users could increase 5-13% for products moved to the Annex IV[d)]	**Non quantifiable** The effectiveness of the Directive in protecting the health and safety of users could increase 5-13% for products moved to the Annex IV [d)]
	Indirect	-	-	-	-	-	-	-	-

[a)] Due to rounding differences in the data in Eurostat, the total number of enterprises shown does not equal the sum of enterprises recorded per size class.
[b)] Proxy used: Number of inhabitants in the EU.
[c)] Estimates based on European Commission (2014) "Study on evaluation of the internal market legislation for industrial products" indicating up to 10 FTEs for notified bodies to assess products' conformity.
[d)] Based on the 2018 Evaluation of the Machinery Directive and the difference in effectiveness of the Machinery Directive to ensure the health and safety of users by type of conformity assessment.
There are instances where data are quantified based on responses to consultations or interviews. When the number of replies is too low to present an estimate, cost cannot be reliably quantified. Proxy values are used when direct information is not available.

When it comes to **removing Annex IV** (policy option 3.3), the potential impacts that may apply are visualised in the table below.

Table 49: Potential impacts of removing Annex IV

Type	Positive impact	Negative impacts
Economic	• Reduction of costs related to third-party conformity assessment	• Time loss and costs for familiarisation with new legal text (one-off)
Social	-	• Decrease of the Directive's effectiveness to ensure the health and safety of users

The potential costs and benefits of the sub-option are calculated by assessing the differences between current total compliance costs of third-party assessment and internal checks, the current number of products under third-party or full QA conformity assessment procedures and the differences of effectiveness of the MD in protecting health and safety of users. The assumption is made that notified bodies would no longer be involved in the conformity assessment, thus decreasing the costs of compliance for them within the machinery sector. An overview of the potential impacts is outlined in the following table.

Table 50: Impacts of removing Annex IV

Policy option 3	Description	Firms			Administrations	Other organisations		Citizens/users	
SUB-OPTION 3.3 REMOVING ANNEX IV NET EFFECT (-)		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector**	**Users / consumers**
1. Number of affected stakeholders (EU-27)		**1,703**	**81,024**	**82,239a)**	**-**	**137 or more**	**-**	**2,759,439**	**446,000,000b)**
2.1 Costs (total)	**One-off**	**Not quantifiable** One-off costs in adaptation expected	**Not quantifiable** One-off costs in adaptation expected	**Not quantifiable** One-off costs in adaptation expected	**-**	**Not quantifiable** One-off costs in adaptation expected	**-**	**-**	**-**
	Recurrent	-	-	**-**	**-**	**-**	**-**	**Non quantifiable** The effectiveness of the Directive in protecting the health and safety of users could decrease 9% for the 10% of assessments currently done by third parties c)	**Non quantifiable** The effectiveness of the Directive in protecting the health and safety of users could decrease 9% for the 10% of assessments currently done by third parties c)
2.2 Costs per organisation	**One-off**	**Not quantifiable** One-off costs in adaptation expected	**Not quantifiable** One-off costs in adaptation expected	**Not quantifiable** One-off costs in adaptation expected	**-**	**Not quantifiable** One-off costs in adaptation expected for average of 10 FTEs d)	**-**	**-**	
	Recurrent	-	-	**-**	**-**	**-**	**-**	**-**	

Policy option 3	Description	Firms			Administrations	Other organisations		Citizens/users	
3. Benefits	**Direct**	**-**	**-**	**Up to EUR 202,895,485**[e)] If all 10% of assessments done by third parties move to internal checks	**-**	**-**	**-**	**-**	
	Indirect	**-**	**-**	**-**	**-**	-	**-**	**-**	

[a)] Due to rounding differences in the data in Eurostat, the total number of enterprises shown does not equal the sum of enterprises recorded per size class.
[b)] Proxy used: Number of inhabitants in the EU.
[c)] Based on the 2018 Evaluation of the Machinery Directive and the difference in effectiveness of the Machinery Directive to ensure the health and safety of users by type of conformity assessment.
[d)] Estimates based on European Commission (2014) "Study on evaluation of the internal market legislation for industrial products" indicating up to 10 FTEs for notified bodies to assess products' conformity.
[e)] Based on the difference in costs for conformity assessment between internal checks and third-party assessment.
There are instances where data are quantified based on responses to consultations or interviews. When the number of replies is too low to present an estimate, cost cannot be reliably quantified. Proxy values are used when direct information is not available.

6.4. Impacts of policy Option 4: Conversion of the Directive into a Regulation

The majority of the stakeholders were in favour of policy option 4 (79% of OPC respondents). Indeed, the positive impacts are expected to outweigh the negative impacts, as shown in the table below.

Policy option 4	Positive impacts	Negative impacts
Economic impacts	• Increased facilitation of trade through equal application of the Regulation across Member States • Decrease of costs stemming from clarifications between manufacturer and MS authorities	• Some one-off costs resulting from the adaptation will likely apply
Social impacts	None identified	None identified
Environmental impacts	None identified	None identified

The benefits included more uniform implementation, no transposition-related problems and improved legal certainty. Some industry representatives reported that they faced issues when exporting to countries like Turkey and Switzerland. These were mostly related to different interpretations of the MD. When exporting, differences can also arise due to translation, with words used to describe products being more broadly used than originally intended. The associated costs of resolving differences (e.g. writing letters, printing) could amount to between EUR 100 to 500. See chapter 2.3.4 for detailed explanation of the problems arising from differences in the implementation and interpretation of the MD. Economic operators were therefore in favour of conversion due to a regulation providing higher legal security and imposing the same legal requirements for all actors across the countries, facilitating trade. Authorities, notified bodies, and machinery safety consultants noted similar benefits that ensure uniform implementation across Member States. No significant costs are foreseen.

The main costs and benefits identified throughout the consultation activities are shown in the table below, monetised where possible.

Table 51: Potential costs and benefits of a conversion of Directive to a Regulation

Policy option 4	Description	Firms			Administrations	Other organisations		Citizens/users	
CONVERTING THE DIRECTIVE INTO A REGULATION Net effect of policy sub-option (+)		**Large companies**	**SMEs**	**All**	**Market Surveillance Authorities / Member States**	**Notified bodies**	**Standardisation bodies**	**People employed in machinery sector**	**Users / consumers**
1. Number of affected stakeholders (EU-27)		**1,703**	**81,024**	**82,239[a)]**	**27 EU Member States to 71 MSAs or more**	**137 or more**	-	-	-
2.1 Costs (total)	**One-off**	Some adaptation costs likely but expected to be marginal by consultation participants	Some adaptation costs likely but expected to be marginal by consultation participants	Some adaptation costs likely but expected to be marginal by consultation participants	Some adaptation costs likely but expected to be marginal by consultation participants	Some adaptation costs likely but expected to be marginal by consultation participants	-	-	-
	Recurrent	**No expected costs**	**No expected costs**	**No expected costs**	**No expected costs**	**No expected costs**	-	-	-
2.2 Costs per organisation	**One-off**	Some adaptation costs likely but expected to be marginal by consultation participants	Some adaptation costs likely but expected to be marginal by consultation participants	Some adaptation costs likely but expected to be marginal by consultation participants	Some adaptation costs likely but expected to be marginal by consultation participants	Some adaptation costs likely but expected to be marginal by consultation participants	-	-	-
	Recurrent	**No expected costs**	**No expected costs**	**No expected costs**	**No expected costs**	**No expected costs**	-	-	-
3. Benefits-	**Direct**	**Not quantifiable** Benefits expected through equal interpretation of Regulation across Member States	**Not quantifiable** Benefits expected through equal interpretation of Regulation across Member States	**EUR 100 to 500 per instance** Cost savings in terms of clarification procedures between manufacturer and Member State authorities. Number of instances could not be estimated	**Up to EUR 531,900,000[b]** Benefits expected from missing transposition costs of the Directive	**Not quantifiable** Benefits expected through equal interpretation of Regulation across Member States	-	-	-
	Indirect	-	-	-	-	-	-	-	-

[a)] Due to rounding differences in the data in Eurostat, the total number of enterprises shown does not equal the sum of enterprises recorded per size class.
[b)] Based on a proxy in UK Government (2008). Explanatory memorandum to supply of machinery (safety) regulations 2008.
There are instances where data are quantified based on responses to consultations or interviews. When the number of replies is too low to present an estimate, cost cannot be reliably quantified. Proxy values are used when direct information is not available.

7. HOW DO THE OPTIONS COMPARE?

This chapter provides an overview of the effectiveness and efficiency of the policy options with regards to the objectives and the different groups affected. Given that one of the objectives of this revision is to "ensure coherent interpretation of the scope", no separate analysis of the impacts of the changes on coherence is provided in this chapter. The results are quantified where possible, otherwise impacts are shown in a qualitative manner. Given the size of the revisions, the effectiveness and efficiency criteria are shown in separate tables.

The table below shows a comparison of all policy options against the effectiveness criterion.

Table 52: Comparison of policy options against the effectiveness criterion

Policy option	Effectiveness					Net effect
	Cover new risks brought by new digital technology, AI, IoT, robotics	Ensure the clarity of the scope	Full alignment to the New Legislative Framework	Allow innovative technologies	Reduction of administrative requirements related to documentation	
Baseline	**(0)** Considering a dynamic baseline scenario, certain aspects of new technologies are sufficiently covered by the current MD, while others are not.	**(0)** Considering a dynamic baseline scenario, shortcomings in clarity of scope and definitions and differences in transposition would not be resolved if the baseline scenario were to be followed.	**(0)** Considering a dynamic baseline scenario, the MD is not aligned to the NLF and would not be aligned if no revisions were applied.	**(0)** No impacts are expected with a dynamic baseline scenario given the technology-neutral approach of the Directive.	**(0)** Considering a dynamic baseline scenario, a change in the Directive would have no impact on the administrative requirements related to documentation. The differences would apply with a change in the Guide.	**(0)**
Policy option 1: Addressing new challenges posed by technological developments in digitalisation	**(+)** Dependent on the subject to which these changes are applied. An adaptation of EHSR (1.3.7 and 1.3.8.2) would reduce risks in relation to human-robot collaboration. If a software that ensures a safety function is placed independently on the market and is covered by the MD would enable covering risks related to these software programmes in the machinery sector.	**(-/+)** Dependent on the subject to which these changes are applied. Providing adaptation of EHSR or new EHSR on human-robot collaboration would increase coherence across MS and provide equal requirements for all manufacturers. Other subjects that apply horizontally across sectors, i.e. Cybersecurity would increase the risk for fragmentation in the internal market. Other aspects (e.g. failure of connectivity, software updates) are said to be already sufficiently covered in the existing EHSR, mostly by industry. A change of these would increase the risk for unclarities. On the other hand, following self-regulation of the market in this regard could create an unlevel playing field through different implementation approaches by manufacturers.	**(0)**	**(0)**	**(0)**	**(+)**
Policy option 2: Addressing the problems identified during the evaluation of	**(0)**	**(-/+)** Dependent on the aspect that is revised, the changes could improve or risk reducing the coherence. An alignment of the MD to the NLF is expected to increase the clarity through a	**(+)** This objective is met if the MD is aligned to the NLF	**(+)** The MD in general is technology-neutral and allows for innovative technologies. If the requirements for fully enclosed carriers in slow-speed lifts is adapted, the implementation of	**(+)** This policy option includes the sub-option of allowing digital formats for documentation. This is expected to reduce	**(++)**

Policy option	Effectiveness					Net effect
	Cover new risks brought by new digital technology, AI, IoT, robotics	Ensure the clarity of the scope	Full alignment to the New Legislative Framework	Allow innovative technologies	Reduction of administrative requirements related to documentation	
the Machinery Directive		harmonisation of market surveillance procedures. Adapting the list of low-voltage products is also expected to improve the coherent interpretation of the scope. Improving the definition of partly completed machinery is expected to improve the coherence of interpretation. Reviewing the threshold speed of slow-speed lifts on the other hand is expected to decrease the coherence with regards to the Lifts Directive in particular.		other alternative technological solutions could be implemented. One should keep in mind that reaching this objective does not interfere with the main objective of the MD to ensure safety and health of machinery users (especially persons using slow-speed lifts in this case).	administrative burden related to documentation.	
Policy option 3: Modifying Annex IV	**(0)**	**(+)** The removal of conformity assessment with internal checks from Annex IV products has the potential of establishing the application of equal conformity assessment procedures across Annex IV products and manufacturers.	**(0)**	**(0)**	**(0)**	**(+)**
Policy option 4: Conversion of Directive to a Regulation	**(0)**	**(+)** A conversion of the Directive to a Regulation is expected to decrease differences in interpretation across Member States.	**(0)**	**(+)** Harmonised enforcement procedures	**(+)** A conversion to a regulation is expected to reduce administrative burden for economic operators related to documentation needed for clarifications or unclarities of differences across Member States.	**(+)**

In order to provide more granular insights, the effectiveness criterion is also compared per sub-option of all policy options *vis-à-vis* the baseline scenario. In order to facilitate visibility, each policy option will be shown in separate tables.

Table 53: Comparison of policy option 1 against the effectiveness criterion

Policy option	Effectiveness					Net effect
	Cover new risks brought by new digital technology, AI, IoT, robotics	Ensure the clarity of the scope	Full alignment to the New Legislative Framework	Allow innovative technologies	Reduction of administrative requirements related to documentation	
Baseline	**(0)** Considering a dynamic baseline scenario, certain aspects of new technologies are sufficiently covered by the current MD, while others are not.	**(0)** Considering a dynamic baseline scenario, shortcomings in clarity of scope and definitions and differences in transposition would not be resolved if the baseline scenario were to be followed.	**(0)** Considering a dynamic baseline scenario, the MD is not aligned to the NLF and would not be aligned if no revisions were applied.	**(0)** No impacts are expected with a dynamic baseline scenario given the technology-neutral approach of the Directive.	**(0)** Considering a dynamic baseline scenario, a change in the Directive would have no impact on the administrative requirements related to documentation. The differences would apply with a change in the Guide.	**(0)**
Policy option 1.1: Adapting the essential health and safety requirements (EHSR) of the Directive to explicitly address aspects related to digital emerging technologies.	**(+)** Dependent on the subject to which these changes are applied to. An adaptation of EHSR (1.3.7 and 1.3.8.2) would reduce risks in relation to human-robot collaboration. If a software that ensures a safety function is placed independently on the market and falls under the MD, it would enable covering risks related to these software programmes in the machinery sector.	**(-/+)** Dependent on the subject to which these changes are applied to. Providing adaptation of EHSR or new EHSR on human-robot collaboration would increase coherence across MS and provide equal requirements for all manufacturers. Other subjects that apply horizontally across sectors, i.e. specifying cybersecurity requirements in every sectoral Directive could increase the risk for fragmentation in the internal market (e.g. different requirements in different Directives, additionally being revised at varying speeds). Other aspects (e.g. failure of connectivity, software updates) are said to be already sufficiently covered in the existing EHSR. A change of these would increase the risk of unclarities. On the other hand, following self-regulation of the market in this regard is expected to create an unlevel playing field through different implementation approaches by manufacturers.	**(0)**	**(0)**	**(0)**	**(+)**
Policy option 1.2: Addressing the challenges posed by innovation in digitisation through self-regulation of the market	**(-)** A self-regulation of the market in relation to covering new risks brought by emerging technologies will hinder meeting the objective in specific aspects.	**(-)** A self-regulation of the market in specific areas will increase the risk of different levels of applications across economic operators and thus generate an unlevel playing field.	**(0)**	**(0)**	**(0)**	**(-)**

Table 54: Comparison of policy option 2 against the effectiveness criterion

Sub-options			Effectiveness					
Sub-option 1	Sub-option 2	Sub-option 3	Cover new risks brought by new digital technology, AI, IoT, robotics	Ensure the clarity of the scope	Full alignment to the New Legislative Framework	Allow innovative technologies	Reduction of administrative requirements related to documentation	Net effect
Baseline			**(0)** Considering a dynamic baseline scenario, certain aspects of new technologies are sufficiently covered by the current MD, while others are not.	**(0)** Considering a dynamic baseline scenario, shortcomings in clarity of scope and definitions and differences in transposition would not be resolved if the baseline scenario were to be followed.	**(0)** Considering a dynamic baseline scenario, the MD is not aligned to the NLF and would not be aligned if no revisions were applied.	**(0)** No impacts are expected with a dynamic baseline scenario given the technology-neutral approach of the Directive.	**(0)** Considering a dynamic baseline scenario, a change in the Directive would have no impact on the administrative requirements related to documentation. The differences would apply with a change in the Guide.	**(0)**
2.1 **Alignment to the New Legislative Framework**, without any change in the substantial content of the current legal act (scope, definitions, essential health and safety requirements).	2.1.2 **Allowing digital formats for documentation** by modifying the Guide to application of the Machinery Directive.		**(0)**	**(+/-)** An alignment to the NLF would increase a harmonisation of market surveillance procedures across Member States and increase the clarity with other new-approach Directives currently under the NLF. With regards to 2.1.2., one potential limitation in the scope is that a change in the Guide does not provide a legal obligation, thus differences in the provision of documentation across manufacturers and Member States could be followed,	**(+)** This objective is met through a full alignment to the NLF.	**(0)** The MD is technology neutral and has not posed challenges for innovation. No change in the legal act would mean no impact on this.	**(+)** The NLF does not impose a format for the instructions.	**(+)**

Sub-options			Effectiveness					
Sub-option 1	Sub-option 2	Sub-option 3	Cover new risks brought by new digital technology, AI, IoT, robotics	Ensure the clarity of the scope	Full alignment to the New Legislative Framework	Allow innovative technologies	Reduction of administrative requirements related to documentation	Net effect
				risking a fragmentation of the approach, limiting the clarity in scope and definitions.				
2.2 **Allowing digital formats** for documentation by modifying the Guide to application of the Machinery Directive, without alignment to the NLF.			**(0)**	**(0/-)** No alignment to the NLF would not lead to direct costs but would hinder capturing the benefits of harmonising market surveillance procedures and the integration of the MD in the same legal framework as other new-approach Directives. One potential limitation in the scope is that a change in the Guide does not provide a legal obligation, thus differences in the provision of documentation across manufacturers and Member States could be followed, risking a fragmentation of the approach.	**(-)** This policy sub-option would hinder meeting the objective of a full alignment to the NLF.	**(0)** The MD is technology neutral and has not posed challenges for innovation. No change in the legal act would mean no impact on this.	**(+)** Allowing digital formats for documentation within the Guide is expected to decrease administrative burden in relation to documentation.	**(-)**
2.3 **Alignment to the New Legislative Framework**, with changes in the substantial content of the current legal act.	2.3.1 **Adapting the scope and the definitions** in the Directive, e.g. assess the threshold speed for slow-speed lifts covered or adapt the list of low-voltage products excluded and improve the definition of 'partly completed machinery'.		**(0)**	**(-/+)** Dependent on the changes made in the legal act, the clarity of scope could be increased, others could increase the risk of fragmentation (e.g. reviewing the threshold speed for slow speed lifts could	**(+)** This objective is met through a full alignment to the NLF.	**(0)** The MD is technology neutral and has not posed challenges for innovation. No change in the legal act would mean no impact on this.	**(0)** Given that the legal act does not prescribe the way in which documentation is to be provided, a change in other areas would	**(0)**

Sub-options			Effectiveness					
Sub-option 1	Sub-option 2	Sub-option 3	Cover new risks brought by new digital technology, AI, IoT, robotics	Ensure the clarity of the scope	Full alignment to the New Legislative Framework	Allow innovative technologies	Reduction of administrative requirements related to documentation	Net effect
				increase coherence problems with the Lifts Directive).			have no impact on this objective.	
	2.3.2 **Adapting the essential health and safety requirements** (EHSR).	2.3.2.1 **Allowing digital formats for documentation** by modifying the EHSR.	**(0)**	**(-/+)** Dependent on the changes made in the legal act, the clarity of scope could be increased, others could increase the risk of fragmentation.	**(+)** This objective is met through a full alignment to the NLF.	**(0)** The MD is technology neutral and has not posed challenges for innovation. No change in the legal act would mean no impact on this.	**(+)** Allowing digital formats for documentation within the EHSR is expected to decrease administrative burden in relation to documentation, if the Guide is adapted accordingly as well.	**(++)**
		2.3.2.3 **Redefinition of the requirements for completely enclosed carrier** or **control of movements for slow speed lifts** to permit innovative technologies to be used for achieving a carrier completely enclosed.	**(0)**	**(0/-)** Dependent on the changes made in the requirements, it could increase the risk for fragmentation through differences in application and overlap with other Directives (i.e. Lifts Directive).	**(+)** This objective is met through a full alignment to the NLF.	**(+)** While the MD is technology neutral, an adaptation of the requirements for completely enclosed carrier or control of movements for slow speed lifts would allow the use of alternative solutions. It is important to keep in mind that this objective does not interfere with the general objective of the MD to ensure health and safety of users (i.e. persons using lifts).	**(0)** Given that the legal act does not prescribe the way in which documentation is to be provided, a change in other areas would have no impact on this objective.	**(0/+)**
2.4 **Changes in the substantial contents** of the current legal act without	2.4.1 **Adapting the scope and the definitions** in the Directive, e.g. review the threshold speed for slow-speed lifts covered or adapt the list of low-voltage products excluded, and improve the		**(0)**	**(-/+)** Dependent on the changes made in the legal act, the clarity of scope could be increased, others	**(-)** This policy sub-option would hinder meeting the	**(0)** The MD is technology neutral and has not posed challenges for innovation. No	**(0)** Given that the legal act does not prescribe the way in which	**(-)**

Sub-options			Effectiveness					
Sub-option 1	Sub-option 2	Sub-option 3	Cover new risks brought by new digital technology, AI, IoT, robotics	Ensure the clarity of the scope	Full alignment to the New Legislative Framework	Allow innovative technologies	Reduction of administrative requirements related to documentation	Net effect
alignment to the NLF.	definition of machinery'.	'partly completed		could increase the risk of fragmentation (e.g. reviewing the threshold speed for slow-speed lifts could increase coherence problems with the Lifts Directive).	objective of a full alignment to the NLF.	change in the legal act would mean no impact on this.	documentation is to be provided, a change in other areas would have no impact on this objective.	
	2.4.2 **Adapting the essential health and safety requirements** (EHSR).	2.4.2.1 **Allowing digital formats for documentation** by modifying the EHSR.	**(0)**	**(-/+)** Dependent on the changes made in the legal act, the clarity of scope could be increased, others could increase the risk of fragmentation.	**(-)** This policy sub-option would hinder meeting the objective of a full alignment to the NLF.	**(0)** The MD is technology neutral and has not posed challenges for innovation. No change in the legal act would mean no impact on this.	**(+)** Allowing digital formats for documentation within the EHSR is expected to decrease administrative burden in relation to documentation, if the Guide is adapted accordingly as well.	**(0)**
		2.4.2.3 **Redefinition of the requirements for completely enclosed carrier** or **control of movements for slow speed lifts** to permit innovative technologies to be used for achieving a carrier completely enclosed.	**(0)**	**(0/-)** Dependent on the changes made in the requirements, it could increase the risk for fragmentation through differences in application and overlap with other Directives (i.e. Lifts Directive).	**(-)** This policy sub-option would hinder meeting the objective of a full alignment to the NLF.	**(+)** While the MD is technology neutral, an adaptation of the requirements for completely enclosed carrier or control of movements for slow-speed lifts would allow the use of alternative solutions. It is important to keep in mind that this objective does not interfere with the general objective of the MD to ensure the health and safety of users (i.e. persons using lifts).	**(0)** Given that the legal act does not prescribe the way in which documentation is to be provided, a change in other areas would have no impact on this objective.	**(0/-)**

Table 55: Comparison of policy option 3 against the effectiveness criterion

Policy option	Effectiveness					Net effect
	Cover new risks brought by new digital technology, AI, IoT, robotics	Ensure the clarity of the scope	Full alignment to the New Legislative Framework	Allow innovative technologies	Reduction of administrative requirements related to documentation	
Baseline	**(0)** Considering a dynamic baseline scenario, certain aspects of new technologies are sufficiently covered by the current MD, while others are not.	**(0)** Considering a dynamic baseline scenario, shortcomings in clarity of scope and definitions and differences in transposition would not be resolved if the baseline scenario were to be followed.	**(0)** Considering a dynamic baseline scenario, the MD is not aligned to the NLF and would not be aligned if no revisions were applied.	**(0)** No impacts are expected with a dynamic baseline scenario given the technology-neutral approach of the Directive.	**(0)** Considering a dynamic baseline scenario, a change in the Directive would have no impact on the administrative requirements related to documentation. The differences would apply with a change in the Guide.	**(0)**
Policy option 3.1: Removing the internal check option from Annex IV products when the product is manufactured in accordance with harmonised standards.	**(0)** This policy-option alone follows the same logic as the baseline scenario.	**(+)** By removing the conformity assessment option with internal checks for Annex IV products, the same assessment procedure will be applied to the same category of products rather than based on company decisions.	**(-)** This policy-option alone follows the same logic as the baseline scenario.	**(0)** This policy-option alone follows the same logic as the baseline scenario.	**(0)** This policy-option alone follows the same logic as the baseline scenario.	**(0)**
Policy option 3.2: Updating Annex IV.	**(0)** This policy-option alone follows the same logic as the baseline scenario.	**(+/-)** Dependent on whether products are included or removed from the Annex IV and whether the conformity assessment through internal checks is removed. If it is not removed and additional products added, there is a risk for increased fragmentation in type of conformity assessment applied to the new products included in the Annex.	**(-)** This policy-option alone follows the same logic as the baseline scenario.	**(0)** This policy-option alone follows the same logic as the baseline scenario.	**(0)** This policy-option alone follows the same logic as the baseline scenario.	**(0/-)**
Policy option 3.3: Removing Annex IV.	**(0)** This policy-option alone follows the same logic as the baseline scenario.	**(+)** By removing the Annex IV, the conformity of all products will likely be assessed through internal checks. It is important to keep in mind that this objective does not interfere	**(-)** This policy-option alone follows the same logic as the baseline scenario.	**(0)** This policy-option alone follows the same logic as the baseline scenario.	**(+)** This policy-option alone follows the same logic as the baseline scenario.	**(0)**

Policy option	Effectiveness					Net effect
	Cover new risks brought by new digital technology, AI, IoT, robotics	Ensure the clarity of the scope	Full alignment to the New Legislative Framework	Allow innovative technologies	Reduction of administrative requirements related to documentation	
		with the main objective of the MD to ensure the health and safety of machinery users. While a removal of Annex IV might increase the clarity of scope, it could lead to increased safety risks.				

Table 56: Comparison of policy option 4 against the effectiveness criterion

Policy option	Effectiveness					Net effect
	Cover new risks brought by new digital technology, AI, IoT, robotics	Ensure coherent interpretation of the scope	Full alignment to the New Legislative Framework	Allow innovative technologies	Reduction of administrative requirements related to documentation	
Baseline	**(0)** Considering a dynamic baseline scenario, certain aspects of new technologies are sufficiently covered by the current MD, while others are not.	**(0)** Considering a dynamic baseline scenario, shortcomings in clarity of scope and definitions and differences in transposition would not be resolved if the baseline scenario were to be followed.	**(0)** Considering a dynamic baseline scenario, the MD is not aligned to the NLF and would not be aligned if no revisions were applied.	**(0)** No impacts are expected with a dynamic baseline scenario given the technology-neutral approach of the Directive.	**(0)** Considering a dynamic baseline scenario, a change in the Directive would have no impact on the administrative requirements related to documentation. The differences would apply with a change in the Guide.	**(0)**
Policy option 4: Conversion of Directive to a Regulation.	**(0)** This policy-option alone follows the same logic as the baseline scenario.	**(+)** By converting the Directive to a Regulations differences in interpretations across Member States would be removed. This would increase the clarity of the scope.	**(-)** This policy-option alone follows the same logic as the baseline scenario.	**(0)** This policy-option alone follows the same logic as the baseline scenario.	**(+)** A conversion to a regulation is expected to reduce administrative burden for economic operators related to documentation needed for clarifications or unclarities of differences across Member States.	**(+)**

The other aspect against which the policy options is compared is for the efficiency criterion, namely the cost and benefit assessment. These are quantified where possible.

Table 57: Comparison of the impact of policy options against the efficiency criterion

Policy option	Efficiency
Baseline	**Net effect (0)** No change will not generate additional costs for stakeholders. However, certain aspects that could reduce administrative burden or additional costs for compliance through unclarities in the scope would not be exploited.
Policy option 1: Addressing new challenges posed by technological developments in digitalisation	**Net effect (+)** **Benefits (↑):** Dependent on the changes applied – the potential benefits are: • An adaptation of EHSR (1.3.7 and 1.3.8.2) would enhance legal clarity in relation to human-robot collaboration. If a software that ensures a safety function is placed independently on the market and is covered by the MD, it would enable risks related to these software programmes in the machinery sector to be covered. • Increased legal clarity regarding requirements for new technologies **Costs (↑):** Dependent on the changes applied – the potential costs are: • One-off costs related to adaptation to new legal framework: Up to EUR 50 billion for total machinery sector (EUR 29.6 billion all large companies, EUR 20.4 billion all SMEs); up to EUR 0.6 million per organisation, EUR 17 million per large company and EUR 0.25 million per SME. Given that minor revisions are envisaged, the costs are not expected to be substantial.

Policy option 2: Addressing the problems identified during the evaluation of the Machinery Directive	**Net effect (+)**
	Benefits (↑): Dependent on the changes applied – the potential benefits are:
	• Alignment to the NLF: harmonised framework across technologies and goods – facilitation of the movements of goods, higher quality of conformity assessments and reduction of non-compliant products in the market
	• Adapting the scope and definitions with regards to low-voltage products excluded from the MD and improving the definition of partly completed machinery: reduction of additional costs resulting from clarification procedures (EUR 5,000 to 10,000 per instance) to up to EUR 10 billion reduction of non-compliant products
	• Allowing digital formats for documentation: Reduction of environmental impacts resulting from printing of user manuals and reduction of costs for economic operators (up to EUR 3 billion for the machinery sector)
	Costs (↑): Dependent on the changes applied – the potential costs are:
	• Alignment to the NLF: Some adaptation costs to the changes are likely to affect manufacturers and MSAs but are expected to be marginal by consultation participants (0)
	• Adapting the scope and definitions:
	  ○ One-off costs related to adaptation to new legal framework: Up to EUR 10 billion for total machinery sector (EUR 5 billion large manufacturers, EUR 4 billion SMEs); up to EUR 1 million per organisation, EUR 32 million per large manufacturer and 0.5 million for SMEs;
	  ○ Recurring costs: Up to EUR 1 billion total machinery sector (EUR 0.6 billion large manufacturers, 0.5 billion SMEs), up to EUR 0.07 million per organisation, EUR 1.9 million per large company and EUR 0.5 million per SME

Policy option 3: Modifying Annex IV	**Net effect: (0); (+) if combined with alignment to the NLF and/or policy option 4** **Benefits (↑):** Dependent on the changes applied – the potential benefits are: • Updating Annex IV: ensuring an updated list of products that represent the development of the market • Removing the conformity assessment through internal checks of Annex IV products: increased effectiveness of the Directive in ensuring safety of the products through third-party assessment and increased effectiveness of Directive in facilitating the functioning of the internal market **Costs (↑):** Dependent on the changes applied – the potential costs are: • One-off costs to adaptations: Up to EUR 35 billion for the whole machinery sector (EUR 20.6 billion large manufacturers, EUR 14 billion SMEs); up to EUR 0.4 million per organisation, EUR 12 million per large company and EUR 0.177 million per SME • Recurring costs of removing the option for internal checks: Increased costs of up to EUR 203 million for the whole machinery sector; up to EUR 2,467 per company • Recurrent costs of adding new products to Annex IV in terms of costs for third-party assessment of currently non-Annex IV products that are assessed through internal checks
Policy option 4: Conversion of Directive to a Regulation	**Net effect: (+)** **Benefits (↑):** coherent interpretation of the regulation across Member States; up to EUR 500 per clarification case and up to EUR 531 million resulting from missing transposition costs (if changes to Directive are made) **Costs (0):** Some adaptation costs (one-off) for all stakeholder groups (manufacturers, MSAs, notified bodies) likely but expected to be marginal by consultation participants

The most effective policy options may also have different impacts on stakeholders. The table below provides an overview of these impacts, quantified where possible.

Table 58: Comparison of impacts on stakeholder groups

Policy option	Firms	Notified bodies	Standardisation bodies	EU institutions	Member States	Citizens/users	
Number of affected stakeholders	**Up to 82,239 (EU-27) or more** Up to 81,024 SMEs (EU-27) or more Up to 1,703 large companies (EU-27) or more	**137 or more**	**In particular CEN/CENELEC**		**71 MSAs or more 27 EU Member States** or more considering EEA (in particular for policy option 4)	**2,759,439 persons employed in the sector (EU-27)** or more users of machinery	**Up to 446,000,000 inhabitants in the European Union**
Baseline	**(0)** Considering a dynamic baseline scenario, additional costs related to unclarities or administrative burden related to documentation are not decreased.	**(0)**	**(0)**	**(0)** Considering a dynamic baseline scenario, the costs related to transposition procedures are not reduced (policy option 4).	**(0)** Considering a dynamic baseline scenario, differences of interpretation or unclarities with scope and definitions might create additional costs for MSAs.	**(0)** Considering a dynamic baseline scenario, risks to health and safety might increase if nothing is changed.	**(0)** Considering a dynamic baseline scenario, risks to health and safety might increase if nothing is changed.
Policy option 1: Addressing new challenges posed by technological developments in digitalisation.	**(+/-)** Dependent on the changes: **Policy option 1.1** **(+)** Level playing field for manufacturers if EHSR are adapted and legal clarity **(-)** additional costs of compliance related to the changes of EHSR. These costs can be mitigated if the numbering of the EHSR are kept as close as possible to the current numbering and adding a new chapter or section for new EHSR. **Costs:** One-off costs of up to EUR 251,000 for SMEs to 17 million for large companies and up to 1% of turnover recurring costs for manufacturers of independent software that ensures a safety function, if changes are followed.	**(+/0)** Dependent on the changes **Policy option 1.1** **Costs**: One-off costs in terms of adaptation to changes will likely apply (up to 1% of turnover). **Benefits:** Legal clarity of requirements for new technologies.	**(-/0)** Dependent on the changes **Policy option 1.1** **Costs**: One-off costs in terms of reviewing the existing standards.	**(0)** No substantial impacts identified. EUR 0 or negligible.	**(+/0)** dependent on the changes **Policy option 1.1** **Costs**: One-off costs in terms of adaptation to changes will likely apply. **Benefits:** Legal clarity of requirements for new technologies.	**(+/-)** dependent on the changes **Policy option 1.1** (+) Users are likely to benefit from legally coherent requirements under the Directive if EHSR are adapted.	**(+/-)** dependent on the changes **Policy option 1.1** (+) Users are likely to benefit from legally coherent requirements under the Directive if EHSR are adapted.

Policy option	Firms	Notified bodies	Standardisation bodies	EU institutions	Member States	Citizens/users	
	Benefits: Legal clarity of requirements for new technologies						
Policy option 2: Addressing the problems identified during the evaluation of the Machinery Directive	**(+)** Alignment of the NLF and improvement of scope and definitions and allowing digital formats are expected to benefit manufacturers through reduction of additional costs of compliance. Clarifications in the EHSR are also expected to benefit in terms of reduction of additional costs borne by manufacturers related to process of clarifying aspects. Changes in EHSR will affect manufacturers' one-off costs related to training and adaptations. However, these costs can be mitigated if the numbering of the revised EHSR are kept as close to the current numbering as possible. **Costs:** One-off costs of up to EUR 34 million for large manufacturers to 653,000. **Benefits**: EUR 34 million for large manufacturers to 43,000.	**(0/+)** Dependent on the changes **Costs:** Some one-off costs due to adaptation to the changes are likely but expected to be marginal by consultation participants. **Benefits:** Adaptation of cope and definitions is expected to bring increased legal clarity and some cost savings could be achieved by allowing digital documentation.	**(0/-)** Dependent on the changes **Costs:** One-off costs would apply if EHSR are adapted in order to review the existing standards.	**(0)** No substantial impacts identified. EUR 0 or negligible	**(0/+)** Dependent on the changes **Costs**: One-off costs for legal implementation and preparing market surveillance, but these are not expected to be substantial costs (estimation of 0.25 person-hours) **Benefits:** Access to ICSMS communication for pan-European market surveillance and a more harmonised market surveillance approach through an alignment to the NLF is expected to bring benefits through a facilitation of the procedures. A clarification of the scope and definitions might also facilitate enforcement.	**(+)** Potential reduction of non-compliant products from the market through alignment to NLF and adaptations to the scope. **Benefits:** Decrease of up to 26% of non-compliant products.	**(+)** Potential reduction of non-compliant products from the market through alignment to NLF and adaptations to the scope. **Benefits:** Decrease of up to 26% of non-compliant products.
Policy option 3: Modifying Annex IV	**(-)** Third-party conformity assessment is expected to generate higher costs than internal checks. **Costs:** One-off costs of up to EUR 12 million for large companies and up to EUR 0.177 million for SMEs. These costs could be mitigated by notified bodies reviewing the standards applied by the manufacturer of Annex IV machinery rather than	**(+)** **Costs:** Some one-off costs are likely to apply to adapt to the changes but are expected to be marginal by consultation participants. **Benefits:** Potential for increased product	**(0)**	**(0)** No substantial impacts identified. EUR 0 or negligible.	**(0)** No substantial impacts identified. EUR 0 or negligible	**(+)** Potential increase of safety of users through expected increase of effectiveness of the Directive in ensuring the health and safety of users through a removal of	**(+)** Potential increase of safety of users through expected increase of effectiveness of the Directive in ensuring the health and safety of users through a removal of

Policy option	Firms	Notified bodies	Standardisation bodies	EU institutions	Member States	Citizens/users	
	conducting the full conformity assessment. **Benefits:** Indirect benefits could apply through an increased effectiveness of the Directive in facilitating the functioning of the internal market. A few manufacturers indicated a potential for reduction of compliance cost.	portfolio for assessments.				the option for internal checks (Annex IV machinery).	the option for internal checks (Annex IV machinery).
Policy option 4: Conversion of Directive to a Regulation	**(+)** Harmonised interpretation of the Regulation across Member States facilitates the trading and decreases costs in relation to current differences. **Costs:** Some one-off costs for adaptation to the changes are likely but not expected to be substantial by consultation participants. **Benefits:** Reduction of additional costs borne by procedure to resolve differences of interpretation of up to EUR 500 per case.	**(+)** **Costs:** Some one-off costs in terms of adapting to the changes are likely to apply but considered to be marginal by consultation participants. **Benefits:** Some benefits through an equal interpretation of Regulation across Member States are likely to apply.	**(0)**	**(+)** Positive impact as a Regulation is applied directly in all Member States and EU institutions do not have to check whether Member States have correctly transposed the legal text.	**(+)** **Costs:** No substantial costs identified through direct application of EU regulation to national law **Benefits:** A regulation could bring benefits in terms of low to no transposition costs applying with a change. A regulation could harmonise interpretation across Member States and facilitate the market surveillance procedures.	**(0)** No direct impacts identified. Indirect impacts or benefits could result from a harmonisation of the products in the market.	**(0)** No direct impacts identified. Indirect impacts or benefits could result from a harmonisation of the products in the market.

8. PREFERRED POLICY OPTIONS

Overall, this impact assessment study has identified that the current Machinery Directive (2006/42/EC) is predominantly fit for purpose for ensuring the health and safety of machinery users, and overall fit for purpose for ensuring the well-functioning of the internal market. Nevertheless, suggested revisions and the application of several preferred policy options would further improve the effectiveness and efficiency of the Directive.

Given that the policy options assessed in this revision are not mutually exclusive, the preferred policy options follow from the comparison made in the previous chapter. Within each policy option there are specific aspects that could benefit from an adaptation in the form of more legal certainty and improvement of safety for users.

- **Policy Option 1: Addressing new challenges posed by technological developments by adapting the EHSR** is preferred over the option of self-regulation of the market due to the risks of generating an unfair level playing field through different adaptation rates of economic operators under self-regulation. For the revisions or adaptations of the EHSR, there are different degrees to which aspects and which EHSR could benefit from a revision. These follow the topics of relevance outlined in the previous chapters:
    - **Networked machinery and risks from connectivity failure**: Information was collected qualitatively through a consultation of relevant stakeholder. Many, in particular from the industry, often referred to clause 1.2.1 under Annex I "for cable-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication" is considered to cover the risk of connectivity failure as well. A potential added value of a further adaptation or clarification was not identified by them. This was mainly based on qualitative inputs due to the lack of existing evidence on health and safety incidents resulting from a connectivity failure, partly as accident statistics are not recorded at a sufficiently granular level.
    - **Collaborative robots**: many relevant stakeholders found that the current EHSR could benefit from an adaptation. The most often referred to clauses with regards to collaborative robots are under Annex I, namely section 1.3.7 "the moving parts of machinery must be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or must, where risks persist, be fitted with guards or protective devices" and section 1.3.8.2. These aspects are currently not considered sufficient with regards to collaborative robots whereby close collaboration between users and machine is a core concept. This stands in contrast to industrial robots, in which case the currently most commonly used protective device or guards are fences that physically separate users from the machine. Other aspects related to collaborative robots, such as limitation of speed or force, are likely to benefit from further development of harmonised standards. In addition to risks of physical harm, case study findings suggest the need to define obligations for OEMs of collaborative robots to mitigate mental health risks for human collaborators, including also the need to regulate relevant aspects of data privacy of social robotics in cases where this may have an impact on users' safety and mental health.
    - **Artificial Intelligence and Machine Learning**: The current penetration rate of AI and ML in machinery covered by the Machinery Directive is low. However, following the expected general trend of AI software revenue growth, the use of AI and ML could increase 1,170% from 2018 to 2025. Due to the low penetration rate within the temporal scope of this study, quantitative evidence on health and safety incidents that resulted from a fault in the ML or AI logic within the machinery sector and especially regarding machinery covered by the MD was not identified. In order to receive information qualitatively,

relevant stakeholders were consulted. The opinions on this matter varied across and between stakeholder groups, limiting the potential for this study to provide a clear recommendation of action. With regards to the stakeholders that indicated that the MD as it stands does account for ML, the clause most commonly referred to is under Annex I, EHSR 1.2.1 safety and reliability of control systems. In particular the aspects of "a fault in the hardware or the software of the control system does not lead to hazardous situations" and "errors in the control system logic do not lead to hazardous situations" are the main requirements identified to link to the logic of a machine-learning algorithm as well. Another requirement that was linked to the safety of machinery with machine learning applications is the risk assessment conducted by the manufacturer or authorised representative. Here, the main aspect raised is on the risk assessment covering the full learning process before the product is placed on the market. The potential of the risk assessment to cover all the ML phases before the product is put on the market, is likely to depend on the level of sophistication of AI, according to many relevant stakeholders across groups. While ML in Narrow AI could be fully risk assessed, General AI at the highest sophistication level and autonomy might not, and relevant stakeholders indicated that this could mean that the product would not comply with the Directive. There is a high level of uncertainty to predict whether and if yes, when, this sophisticated level of AI might be reached. Some national authorities, in comparison, provided some suggestions for adaptations to the EHSR to better account for health and safety risks resulting from AI and ML. These included a specification within this EHSR, namely "a fault in the hardware, software *or the logic* of the control system does not lead to hazardous situations". On transparency of algorithms, the potential of an added value of covering this aspect in the Machinery Directive was not clear. This is due to the difficulty of estimating the benefits a transparency of algorithm vis-a-vis the costs for adaptation and a potential conflict with the protection of know-how, the status quo and expected development of the technology, the costs associated with a transparency of algorithms and the level of complexity in understanding the algorithms from outside for assessment.

- **Software and software updates**: With regards to software updates, two distinctions are referred to most commonly. The first category of updates is common, small and frequent updates that aim to fix bugs, security weaknesses or other vulnerabilities that appear. For these, Annex I section 1.6 maintenance, in particular clause 1.6.1, was most commonly referred to by relevant stakeholders consulted as the applicable requirements in the current Directive. The second category of updates relate to software upgrades that may lead to substantial changes in the product, with machinery substantially modified. The study investigated whether existing requirements in the MD suffice in order to account for potential health and safety risks generated by software upgrades. Stakeholder consultation results indicated that defining criteria as to what constitutes 'machinery substantially modified' has the potential to provide added value through increased clarity. A distinction between common software updates and major upgrades of software leading to machinery substantially modified is expected to mitigate the impact on manufacturers, given the vital role that updates play in the maintenance and ensuring of the safety of machinery. Case study findings furthermore suggest the need to make it mandatory for OEMs to provide safety-critical software updates throughout the entire lifetime of machinery, so as to ensure the development and deployment of security and bug fixes for the Operating System as long as the machinery is in use. Another aspect that was covered in the stakeholder consultation phase related to independent software that ensures a safety function and is put independently on the market. This software is currently not within the scope of the Machinery Directive. However, taking into account the wide share and increasing rate of uploading independent software in machinery, many stakeholders emphasised the importance of this kind of software being covered in the Directive in the future.

  - **Cybersecurity**: The risks of cybersecurity were acknowledged by all stakeholder groups. Here again, it was referred to the Annex I, EHSR 1.2.1 on control systems, namely the clause "control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that (…) they can withstand the intended operating stresses and external influences (…)". A provision of clarity that external influences include cyberattacks, could provide added value. With regards to other aspects of cybersecurity, given that it is not machinery-specific only but it also applies to other sectors and directives, a horizontal legislation under the NLF framework was often mentioned as a potential complement. Another often mentioned initiative is the Cybersecurity Act, albeit as a good starting point for further development, if ever its requirements become mandatory.

- **Policy Option 2: Addressing the problems identified during the evaluation of the Machinery Directive**. The preferred revisions depend on several aspects. The overall impact assessment comprising all the sub-options of policy option 2 showed a positive expected benefits-to-cost ratio. The aspects or sub-options that were identified to likely bring the highest positive impact across effectiveness and efficiency criteria through a revision are shown below in chronological order following the previous chapters.
  - **Alignment to the NLF**: This sub-option is expected to bring high benefits compared to the expected minor costs for adaptation to the changes It is also preferred by the majority of stakeholders across groups consulted. Indeed, no major costs have been identified that would arise through an alignment. The main benefit expected from an alignment is the harmonisation of market surveillance processes under the NLF.
  - **Adapting/ clarifying the list of low voltage products excluded**: With regards to Art. 1.2(k) on the exclusion of low-voltage products, which was identified as a source of confusion within the evaluation, among the main sources of confusion raised by stakeholders were in particular low-voltage gear, electric motors, ordinary office machinery and household appliances intended for domestic use. An adaptation of the list is expected to bring benefits to many stakeholder groups, including increased legal clarity resulting in a decrease of costs related to clarifications for industry and an expected reduction of non-compliant products on the market which would benefit users. Qualitative inputs from the stakeholder consultation supported the cost-benefit analysis, while the results showed that removing the exclusion was not preferred by most stakeholders. Many stakeholders also said that with new legislation, such as the RED, certain products are now excluded from the LVD but included in the RED or related to products covered by the ATEX. More precision of the scope of exclusions to other Directives could therefore bring additional benefits in terms of clarifications.
  - **Improving the definition of partly completed machinery**: Currently, the definition of PCM leads to some uncertainties with regards to the classification of the product and the CE marking. By improving the definition and hence providing more legal certainty on PCM, especially manufacturers are expected to benefit from a reduction of costs related to solving unclarities through additional agreements. Many stakeholders consulted, in particular from the industry, indicated that a removal of the concept is not expected to lead to higher benefits as costs would arise and the existing benefits of the concept would not be exploited. Among the costs that would arise are costs to negotiate the requirements for each delivery contract individually, filing the contracts,

linking them to the technical file, costs for court cases or clarifications with market surveillance authorities.

- **Redefinition of the requirements for completely enclosed carrier or control of movements for slow-speed lifts to permit innovative technologies to be used for achieving a carrier completely enclosed**: A potential change of this option yielded opposite results, dependent on the type of product and change. Many slow-speed lifts are used by (vulnerable) consumers (i.e. elderly, children, people with restricted mobility). Many stakeholders consulted, in particular manufacturers of lifts, indicated that risks related to falling from slow-speed lifts are less likely addressed by other solutions than a physical barrier, such as completely enclosed carriers, while hold-to-run controls obligate an operator of a lift to stay in one place, limiting the risk of injuries or incidents caused by the operator moving. Some stakeholders considered that for other products, the flexibility of using alternative solutions that provide the same or higher level of safety could benefit manufacturers. With regards to this option, it is important to keep in mind the expected increase of the use of slow-speed lifts for the lifting of persons in the future and the products appearing more often in the alert system compared to other lifts, most of them targeting consumers' use. However, it must be taken into account that the Machinery Directive is technology neutral and manufacturers choose the technical solution as far as it complies with the EHSRs of the Directive.
- **Allowing digital formats for documentation**: The results of the impact assessment have shown higher benefits of allowing digital documentation than costs related to the change. The benefits expected in terms of reduced costs of emissions (environmental costs) and printing costs saved are higher than the costs from switching to digital documentation across the options of having only digital documentation, a combination of digital documentation combined with Quick Start Guides (QSG) or digital documentation and printing on demand. In order to mitigate potential risks and costs arising from users not having access to digital tools, which could restrict their ability to access the documentation or costs through printing their own relevant parts if only digital documentation is provided, the combinations might overall provide higher benefits to cost comparisons. Indeed, printed Quick Start Guides and the possibility of requesting a printed manual without additional costs could provide an alternative solution to complete digital documentations. If digital documentation was to be allowed, specific requirements should be developed and set out in terms of minimum required information to be provided within the QSG. In the case of a change to allow digital formats for documentation, a revision within the EHSR would provide higher legal clarity than changing the Guide alone.

- **Policy Option 3: Modifying Annex IV.**
  - One of the options within this policy option is the removal of internal checks of Annex IV products. The results of the study have shown that a removal of the internal check option is expected to lead to higher compliance costs for manufacturers of high-risk machinery, as fees for third parties such as notified bodies would apply for every product on the list. Recurring costs, therefore, would be higher as third-party conformity assessment would be required for the 10% of products currently under Annex IV and being assessed through internal checks. However, the effectiveness of the MD to ensure the health and safety of users is expected to increase by a removal of internal checks for Annex IV machinery, which will overall benefit the users of machinery. Indeed, most stakeholder groups consulted consider internal checks to lead to safety concerns. This was mostly related to the lack of technical knowledge of all the safety requirements or all the available standards to be applied.

    - A modification of the list of products under Annex IV could be beneficial to adapt the list to potential developments of the market. Costs of compliance or recurring costs would increase for those items of machinery that are moved into the Annex IV and are assessed by third parties. Similar benefits in terms of increased effectiveness of the Directive to ensure health and safety of users is expected from conformity assessments of products under Annex IV compared to non-Annex IV products. A regular update of the list could benefit a more proactive adaptation to technological developments on the market, though bearing in mind not generating unclarities relating to which products are covered by the Annex.

- **Policy Option 4: Converting the Directive to a regulation**. The assessment of this policy option led to the conclusion that a conversion would be beneficial, decreasing delays in transposition and differences in interpretation across Member States and therefore decreasing costs resulting from these aspects.

9. HOW WOULD ACTUAL IMPACTS BE MONITORED AND EVALUATED?

The successful implementation of the revised Machinery Directive, or regulation, depends on several factors. This chapter proposes several indicators to monitor and evaluate the implementation of the changes.

Monitoring and evaluation indicators ought to be designed and agreed before implementation in order to ensure that any progress and ex post studies undertaken can robustly measure changes before and after the implementation.

First, a set on indicators should be identified to monitor progress on the driving goal of the MD: safety of machinery itself all along its life cycle. The starting point are data on accidents at work examined in chapter 2 and in Annex III, although some key data limitations should be considered. In fact, availability of data differs depending on the variable. The main characteristics of the accident and of the employer, so called 'Phase I' and 'Phase II' variables of ESAW, are based on compulsory data provided by individual companies and reported by countries with a more or less coherent method. Variables on causes and circumstances, so called ESAW 'Phase III' variables, are the most interesting for an in-depth analysis due to their level of detail. However, reporting is not compulsory for all Phase III variables by Member State authorities; as such, availability and reliability varies strongly between countries. In this case, an improvement of data reliability and completeness, for instance by making it mandatory for companies and countries to record and report all relevant cases of occupational accidents and diseases, could contribute to a higher quality of evaluation. Safety incidents on a consumer level are not recorded. This could pose a challenge for the evaluation in terms of effectiveness across product groups. The same counts for incidences with consumer products. Currently, the granularity of the data available does not allow for a detailed identification of the products under the scope of the Machinery Directive that are used by non-professional users. There is a lack of data on the number of incidences of consumers with such products. This caveat might affect the accuracy of the evaluation of the Directive.

Second, the revised Directive or then regulation will be directly applicable in all Member States. In the case that the MD remains a Directive, Member States are required to transpose the changes into national law within the set deadline, send the Commission the text of the national implementing measures that incorporate the new provisions. The European Commission would need to verify that the Member States correctly align with the changes. Here, the indicator for a successful implementation would be the absence of infringement cases for violation of the new provisions or non-communication. In the case of a conversion to a regulation, a successful implementation could be measured by an absence of a formal infringement procedure. The European Commission already provides annual reports on monitoring the application of EU law, reviewing EU countries' performance on key aspects.

Indicators of success for policy option 1, especially when adapting the legal text of the current Directive, would be the ability to take into account and deal with new innovations and new technologies. This should be evaluated five to seven years after the implementation of the revision. The Commission could consult competent authorities and stakeholders for evaluation. In the case that the legal text is not changed, but a stronger emphasis on new harmonised standards is put, CEN/CENELEC could facilitate the monitoring of the development through data generation as currently followed and presented in the Working Group meetings. Some of the changes under policy option 1 might face limitations when being evaluated. New technologies such as robots, for instance, are not covered separately in one NACE class. Only certain products are listed within other sub-classifications. Data on new technologies within the machinery sector are very scarce and very often only accessible through purchase. An adaptation or a higher granularity in product classifications and easier access to data will likely benefit the robustness of the evaluation. Information and data on new technologies could be accessed in a general context to have a rough estimate. A potential source for evaluation of the development in the area of AI may provide the AI Watch's KnowledgeBase.[344] Another option to support the collection of data for the evaluation of the Machinery Directive could be leveraging the use of new technologies and their automatic generation of data.

The expected objectives and impacts of policy option 2 are to improve the functioning of the internal market by removing current uncertainties and unclarities in the application of the Directive. The effects and a successful implementation would lead to a reduction in compliance costs, especially regarding the administrative burden related to additional paperwork for clarifications and paper documentation. An indicator for monitoring would be effectiveness and efficiency of the revised areas of application, for which an evaluation after five to seven years could provide information through stakeholder consultations. One potential limitation to an in-depth evaluation is the categorisation of the machinery sector in the structural business statistics. Here, the NACE codes do not allow the market sector and potential affected or involved actors to be identified to a high degree of accuracy. This is the case, for example, with the product group slow-speed lifts or low-voltage products. With regards to the effectiveness of the Machinery Directive, an alignment to the NLF would bring the ICSMS system for market surveillance to the MD. The ICSMS system is the internet-supported Information and Communication System for the pan-European Market Surveillance.[345]

For policy option 3, indicators of success would be the higher safety of high-risk products, given that the preferred option is to remove internal check option and to keep Annex IV and update the list at regular intervals. This could be monitored and evaluated five to seven years after implementation of the revisions, including covering information on the costs of compliance involving a third party (i.e. Notified Bodies) and the effectiveness of the revision to ensure health and safety of users of high-risk machinery. Relevant stakeholders could be consulted to evaluate the impact of the revision. Other data on the compliance of those products whose conformity was assessed through a third party, after the change of the Machinery Directive. This rate could be compared to the past. Here as well, a lack of data and granularity might pose a challenge to a successful evaluation of the effectiveness of the Machinery Directive with regards to high-risk machinery.

[344] European Commission (n.d.). AI Watch: KnowledgeBase. Available at: ec.europa.eu/knowledge4policy/ai-watch_en

[345] https://webgate.ec.europa.eu/icsms/

ANNEX I: EXECUTIVE SUMMARY

The Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC was implemented in 2009. It is the core legislation regulating products of the mechanical engineering industries and has the objective of ensuring a high level of safety and protection for machinery users and other exposed persons and of securing the free movement of machinery in the internal market.

Problem definition

In 2018, the Directive was evaluated to analyse the performance and its ability to meet those objectives effectively, efficiently and coherently. This evaluation identified potential for improvements of the current legal text.

One of the concerns relates to the developments in the use of new technologies, in particular autonomous machines, artificial intelligence, collaborative robots and the Internet of Things. Unintended or unaccounted risks that are not currently covered by the Directive may arise from the implementation and growing adoption of these technologies within machinery, potentially giving rise to health and safety concerns for users of these machines. For example, to cover the risks related to cybersecurity of these cyber-physical machines.

Another identified shortcoming of the current Directive relates to overlap of framework and Directives. This includes the lack of alignment of the Machinery Directive to the New Legislative Framework, compared to the majority of other new approach Directives. This leads to differences in market surveillance processes across Member States, among others. A lack of clarity in scope and definitions was also identified, especially related to Art. 1.2(k) on the exclusion of low voltage products and the definition of partly completed machinery. These unclarities risk increasing compliance and enforcement costs for economic operators, notified bodies and market surveillance authorities. Furthermore, differences in implementation of the Directive across Member States might hinder reaching the full potential of a well-functioning internal market.

One further risk flagged was related to innovation in slow-speed lifts. The Machinery Directive covers lifts of up to 0.15 m/s in speed. The current requirement for hold-to-run controls of those lifts in Annex I EHSR 6.2 indicates that "the control devices for [upward and downward] movements must be of the hold-to-run type except where the carrier itself is completely enclosed". This requirement might hinder innovation preventing the implementation of other run control systems when there is no fully enclosed carrier, or vice versa the use of other safety systems than a fully enclosed carrier.

The Machinery Directive does not indicate explicitly the form in which documentation should accompany the products. As such, and despite the developments of digitalisation worldwide but also in the machinery sector, the Guide to the Application of the Machinery Directive indicates that documentation (Declaration of Conformity, technical file, health and safety instructions) should be provided in paper. This indication is reasoned by the inability to assume that a "user has access to the means of reading instructions supplied in electronic form or made available on an Internet site." Since the implementation of the Machinery Directive in 2009, the uptake and use of electronic means and digital tools has steeply increased, while the indications to provide paper documentation leads to administrative burden borne by economic operators in terms of printing and shipping costs. It also risks conflicting with the environmental objectives to reduce paper waste and other environmental impacts.

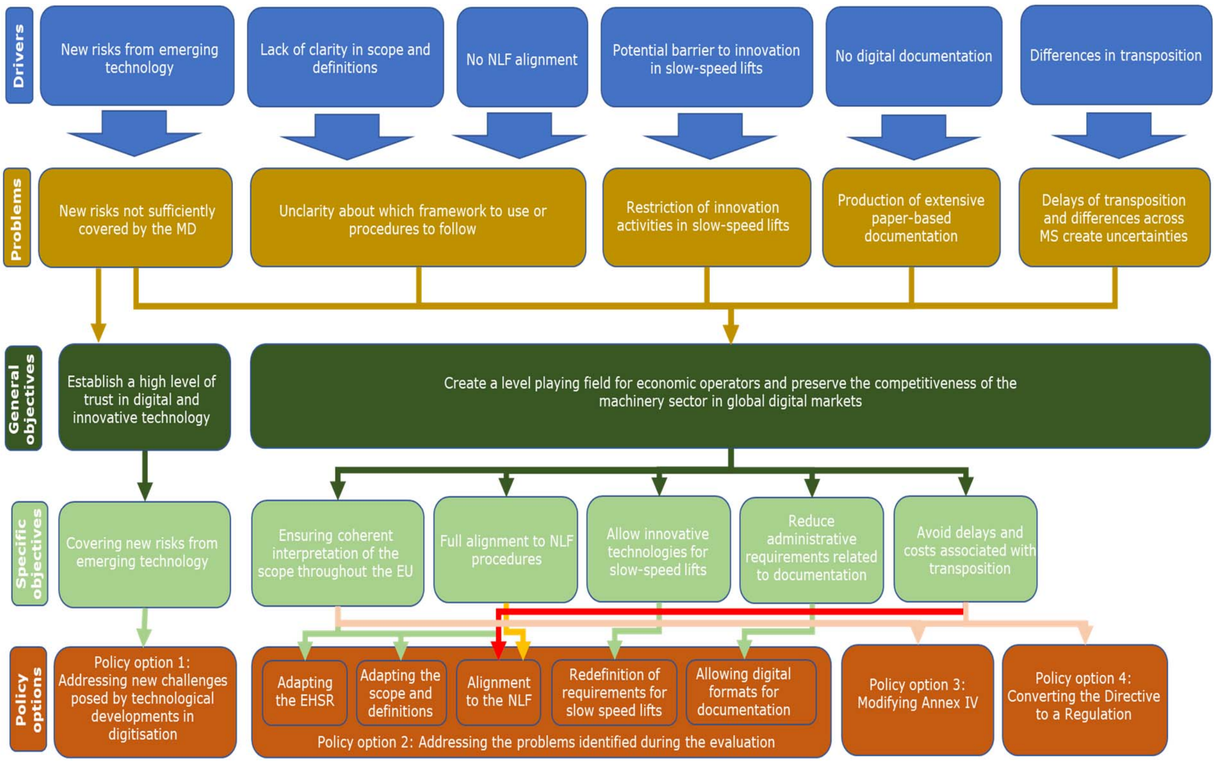
Finally, Annex IV of the Machinery Directive lists high-risk machinery that is subject to self-conformity assessment by the manufacturer only when existing harmonised standards are complied with. In the case of non-existing standards or not fully meeting those that are existing, a third-party conformity assessment must be conducted. Given that many products within the list of high-risk machinery are used by consumers as well (e.g. saws, chainsaws, person lifts (i.e. stairlifts)) and that these are among most of identified non-compliant products in the Rapid Alert System (RAPEX) system, the question arises as to whether the internal checks option within Annex IV leads to safety concerns. At the same time, the list of products within Annex IV might no longer represent the state of the art in the market.

On the basis of these recommendations coming from the evaluation, including the identified gaps or shortcomings of the Directive, four policy options were considered for this revision study.

Policy options

The different policy options to address the objectives pursued by the revision of the MD are presented below:

Figure 34: Problem tree



<u>Baseline: No EU action</u>

The baseline scenario of the revision consists in no EU action, meaning no change to the current regulatory framework. This option can be discarded from the general outset because of the European Commission's commitment to aligning, where appropriate, existing legislation to the NLF. A baseline following no EU action would also mean that the problems outlined above would remain, which would hamper the objective of contributing to a well-functioning single market and trade of goods in the EU and the EEA as a whole.

In addition, no action would likely lead to Member States taking action at national level, which would further undermine the functioning of the internal market and potentially the level of safety and health of machinery users and others exposed to machines.

Nevertheless, the baseline scenario is taken to measure the potential impacts of the policy options vis-à-vis the current state. The assessment of policy options is illustrated with "+" for positive, "-" for negative and "0" for neutral impacts and compares the benefits and disadvantages in comparison to the baseline. In most instances, the impacts of the baseline would not be neutral but rather negative in terms of meeting the general objectives of this revision.

Policy Option 1: Addressing new challenges posed by technological developments in digitisation

Option 1 addresses specifically the issue of new risks through emerging technologies in machinery not being explicitly covered by the Machinery Directive. There are two potential approaches to addressing these new risks:

- Policy option 1.1 – Adapting the essential health and safety requirements (EHSR) of the Directive to explicitly address aspects related to digital emerging technologies; or

- Policy option 1.2 – Addressing the challenges posed by innovation in digitisation through self-regulation by market participants.

Adapting the EHSR under policy option 1.1 could entail various potential changes, including adding new EHSR on robots or cybersecurity, redefining General Principles (Annex I) to address autonomous behaviour of machines or the iterative process of risk assessment and risk reduction measures.

Since the Machinery Directive is one of the first pieces of product safety sectorial legislation being assessed vis-à-vis the adaptation to new technologies, it may as such be serving as a reference point for other sectorial modifications. It is therefore important to note that there are aspects covered only briefly in this study that need to be further assessed in future investigations in particular with regards to ESHR and AI.

Policy Option 2: Addressing the problems identified during the evaluation of the Machinery Directive

According to the evaluation of the Machinery Directive, the main recommendations for potential adaptations are focused in five sections:

- Alignment to the NLF;
- Allowing digital formats for documentation;
- Adapting the scope and the definitions;
- Adapting the essential health and safety requirements (EHSR); and
- Redefinition of the requirements for completely enclosed carrier or control of movements for slow-speed lifts.

Option 2 is divided into several sub-options, which can be applied regardless of the NLF alignment. These sub-options are not mutually exclusive, neither is option 2 mutually exclusive with other options. All sub-options under Option 2 are outlined below:

Table 59: Sub-options of Policy Option 2

Option	Sub-option		
Option 2 – Addressing the problems identified during the evaluation of the Machinery Directive	2.1 **Alignment to the New Legislative Framework**, without any change in the substantial content of the current legal act (scope, definitions, essential health and safety requirements)	2.1.2 **Allowing digital formats for documentation** by modifying the Guide to application of the Machinery Directive	
	2.2 **Allowing digital formats** for documentation by modifying the Guide to application of the Machinery Directive, without alignment to the NLF		
	2.3 **Alignment to the New Legislative Framework**, with changes in the substantial contents of the current legal act	2.3.1 **Adapting the scope and the definitions** in the Directive, e.g. review the threshold speed for slow-speed lifts covered or adapt the list of low-voltage products excluded, and improve the definition of 'partly completed machinery'	
		2.3.2 **Adapting the essential health and safety requirements** (EHSR)	2.3.2.1 **Allowing digital formats for documentation** by modifying the EHSR
			2.3.2.3 **Redefinition of the requirements for completely enclosed carrier** or **control of movements for slow-speed lifts** to permit innovative technologies to be used for achieving a carrier that is completely enclosed
	2.4 **Changes in the substantial contents** of the current legal act without alignment to the NLF	2.4.1 **Adapting the scope and the definitions** in the Directive, e.g. review the threshold speed for slow-speed lifts covered or adapt the list of low-voltage products excluded, and improve the definition of 'partly completed machinery'	
		2.4.2 **Adapting the essential health and safety requirements** (EHSR)	2.4.2.1 **Allowing digital formats for documentation** by modifying the EHSR
			2.4.2.3 **Redefinition of the requirements for completely enclosed carrier** or **control of movements for slow-speed lifts** to permit innovative technologies to be used for achieving a carrier completely enclosed

Policy Option 3: Modifying Annex IV

In the majority of cases, safety of machinery can be assessed by manufacturers internally (internal checks). They may voluntarily comply with harmonised standards to meet the EHSR. The exception is high risk machinery listed in Annex IV of the current MD, which includes types of high-risk machinery that are permitted to be assessed through internal checks, only if the machinery is manufactured in full accordance with harmonised standards. If the standards are not fully complied with or in the case of non-existing standards, manufacturers of these high-risk machines are required to involve a third party, e.g. notified bodies, for the conformity assessment.

One of the questions in this revision of the Directive is whether the internal checks option of high-risk machinery provides sufficient levels of safety and whether the list of product categories in the Annex is up to date with the market. In case Annex IV is modified, this would mean potential inclusion of further types of machines that might be assessed for conformity through internal checks or the exclusion of others currently listed in Annex IV. Removing Annex IV would mean that all risk categories of machinery are subject to internal checks. On the other hand, if the internal checks option for Annex IV machinery is removed, there is a need for conformity assessments run by third parties (e.g. notified bodies).

The summary of policy option 3 and its sub-options is provided in the following table.

Table 60: Overview of sub-options of policy option 3

Option 3 – Modifying Annex IV	3.1 Removing the internal checks option when the product is manufactured in accordance with harmonised standards
	3.2 Updating Annex IV
	3.3 Removing Annex IV

The assessment of the status of Annex IV is relevant to contribute to the achievement of general objective 1, ensure the highest safety of machinery users and persons exposed to machines.

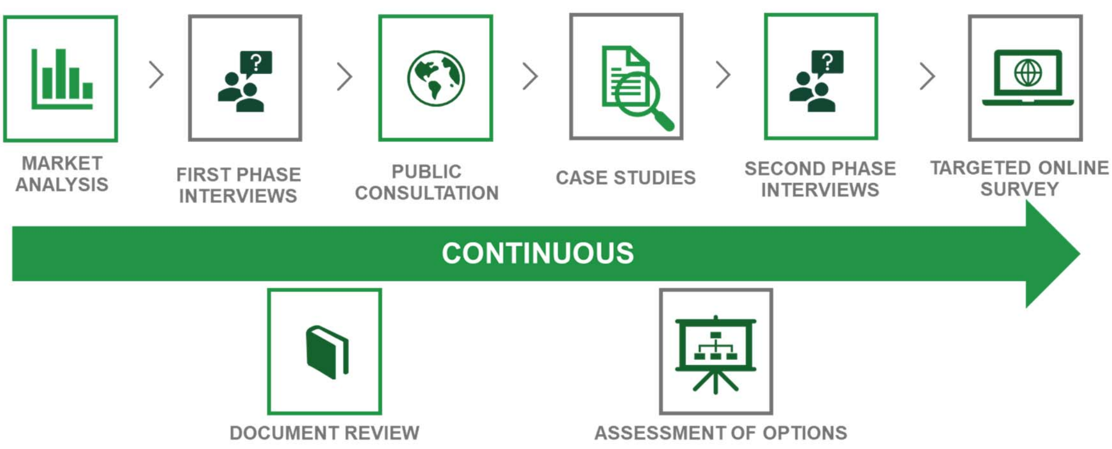
Policy Option 4: Conversion of the Directive into a Regulation

Option 4 addresses the legal instrument of the chosen policy option. It is therefore not mutually exclusive with either option 1, option 2 or option 3. Under option 4, the Machinery Directive would be converted to a regulation, becoming immediately applicable and enforceable by law in all Member States. This option would allow any present or future transposition infringements or differences to be avoided.

Evidence underpinning the study

The impact assessment study was carried out through a range of data collection methods, summarised in the Figure below:

Figure 35: Study data collection tools overview



Key existing documentation and information were reviewed in a **desk research exercise and literature review** with the objective of providing an accurate description of the state of play regarding the current market developments and characteristics.

In addition, an assessment of the likely impacts of the policy options for the main target groups (consumers, businesses, Member States, notified bodies, and standardisation organisations) has been conducted. For that purpose, several assessment tools were employed: firstly, **desk**

research and literature review gathered all data and information available from statistical databases, reports and studies.

Subsequently, a **stakeholder consultation** comprising semi-structured interviews (68 interviews) was organised to refine the assessment and gather input on potential impacts regarding the effectiveness and efficiency of the policy options.

An **open public consultation** targeting a wider range of stakeholders was organised to complement the inputs received from the interviews. In total, the OPC received 528 replies. 15 responses were handed in with delay, which due to the format in which they were made available hindered the possibility of including them into the full dataset. These were analysed separately and included to the full results where relevant. More than 70% were companies/businesses and their organisations. Over half of the respondents were companies (57%), of which 39% are SMEs.

Following these consultation tools, **follow-up interviews** (30) were conducted to close the data and information gaps identified. Following the same incentive, an online survey was conducted, targeting those stakeholders that provided the least amount of input in the previous consultation phases.

Three **use cases** were also developed, based on desk research and interviews. The topics covered new technologies – digital transformation, product optimisation and self-driving robots.

The results and input from the data collection tools were assessed using a multi-criteria analysis consisting of a quantitative assessment based on available data, and a qualitative dimension based on the interviews with relevant stakeholders. Lastly, public consultation and survey results were used to assess benefits of stakeholders that cannot be monetised.

The diversity of methodologies used to collect data described above ensures a broad coverage of different sources of information. In order to ensure the robustness of the results of this impact assessment, the key method of triangulation of findings was employed during the data analysis phase to verify the findings increasing the validity of the overall study.

Conclusions and impacts

The first policy option under consideration aimed to address the risks arising from new technologies in machinery and was split by two sub-options: i) Adapting the essential health and safety requirements (EHSR) to explicitly address aspects related to digital emerging technologies; and ii) addressing challenges posed by innovation in digitisation through self-regulation by market participants. The study results show that certain adaptations to the EHSR are more beneficial with regards to effectiveness of achieving the objectives of the study and efficiency. In addition, addressing challenges through self-regulation of market participants could lead to an increased risk of a development of an unlevel playing field with some industry actors implementing more stringent requirements for their products in comparison to others. Furthermore, the expected growth trend of the implementation of new technologies worldwide but also within the machinery sector indicate a need for some revisions of the Machinery Directive to be fit for purpose in accounting for innovations on the market.

The largest growth of new technologies is expected to be driven by an uptake of connected consumer goods (e.g. lawnmowers) and the deployment of sensors (e.g. in smart robotics). The use of Artificial Intelligence and specifically Machine Learning within machinery covered by the Directive is currently fairly low, but it is expected to grow in the nearer future. When following the general expected growth of AI software revenues and expected cost decreases in manufacturing using AI, the penetration rate could increase 1,170% from 2018 to 2025. With regards to robotics, for instance, the global production value growth of agricultural robots is expected to have a compound average growth rate of 22.8% from 2020 to 2025[346] and the production value of construction robots is expected to grow at a compound average growth rate of about 10.1% from 2017 to 2023.[347]

An adaptation of the EHSR to address aspects related to digital emerging technologies (sub-option 1.1) is expected to impact market participants, in particular manufacturers, notified bodies and stakeholders involved in standardisation. Additional compliance costs are likely to arise from familiarisation to the new legal text and workforce need for specialised personnel. For stakeholders involved in standardisation, a change of the EHSR would require the reviewing of the existing relevant standards to ensure their applicability to the changes. There are various aspects to be considered with regards to potential risks posed by new technologies and the benefits that a revision of the Directive could bring. Among the expected shared benefits of a revision is the equal requirements and therefore legal clarity for all industry actors. Ensuring legal certainty with regards to the requirements for new technologies will also become more relevant considering the expected increase of use of these technologies in the machinery sector. In addition, equal requirements are expected to bring indirect benefits in terms of equal quality of products for machinery users. This benefit has the potential to be particularly exploited if combined with a harmonisation of market surveillance procedures that could be achieved by an alignment to the NLF under policy option 2. Nuances into the various aspects and potential risks arising from new technologies were explored mainly qualitatively through consultation of relevant stakeholders. All in all, as most of the challenges stemming from the new technologies are already covered in a non-explicit way by the Directive, an adaptation of EHSRs should not imply significant costs per se.

First, risks related to and health and safety incidents resulting from connectivity failure of new generation machinery and wireless controls are not widely documented. The information gathered through stakeholder consultation resulted in leaning towards connectivity failures being covered under the current EHSR of the Directive. Clause 1.2.1 of Annex I was often referred to by stakeholders, which indicates that that "for cable-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication". Many stakeholders could therefore not identify the potential added value of revising the EHSR to further account for health and safety risks related to loss of communication. As highlighted by the case studies, the integration of machinery in IoT networks makes the assessment of the previously standalone machinery far more complex to assess. A revision of the MD could therefore include physically or logically connected entities in the definition of control or communication systems, so as to require an assessment of a new 'whole' of the interconnected system. Due to the continuously evolving nature of IoT systems, it was found not to be feasible to conduct a comprehensive reassessment following each evolution of the network, also due to the difficulty of specifying a generally applicable threshold for an IoT network evolution following which a new risk assessment would be required. However, it was found that a revised MD could specify EHSRs for communication processes for IoT-embedded machinery to ensure stable and secure communication. Another potential issue that could be further explored due to the dynamic nature of IoT devices is related to a dynamic risk assessment procedure to ensure that products may be monitored once placed on the market.

Second, risks of Artificial Intelligence (AI) and especially Machine Learning (ML) and algorithmic systems are often not quantified with regards to health and safety incidents

[346] MarketsandMarkets (n.d.) Agricultural Robots Market by Offering, Type (UAVs, Milking Robots, Driverless Tractors, Automated Harvesting Systems), Farming Environment, Farm Produce, Application (Harvest Management, Field Farming), Geography - Global Forecast to 2025. Available at: https://www.marketsandmarkets.com/Market-Reports/agricultural-robot-market-173601759.html

[347] MarketWatch (2019). Construction Robots Market 2019 Global Industry Size, Share, Business Growth, Revenue, Trends, Global Market Demand Penetration and Forecast to 2024| 360 Market updates. Available at: https://www.marketwatch.com/press-release/construction-robots-market-2019-global-industry-size-share-business-growth-revenue-trends-global-market-demand-penetration-and-forecast-to-2024-360-market-updates-2019-10-16

resulting from a failure of these systems. To some extent, the lack of data might be due to the low penetration rate of sophisticated AI and ML systems within machinery covered by the Directive. The general expected growth of AI software revenue suggests that the penetration rate will increase steeply in the future, with the revenue of the AI software market in Europe expected to increase by 1,170% from 2018 to 2025. It is therefore likely that the penetration rate will also greatly increase for the machinery in the scope of the Directive. Uncertainties in the development of the level of sophistication and autonomy of AI and ML make it difficult to predict the future, especially the next 10 years. This uncertainty was reflected in the responses by stakeholders in the consultation. The responses yielded no clear opinion on the question whether an adaptation of existing or new EHSR would be necessary and if yes, on which aspects of AI. This is likely due to the different types of AI sophistication within the existing Narrow AI and the limited to no application of the second stage of General AI (and in some classifications the third stage of AI, Super AI). Overall, most stakeholders[348] providing input on this question leaned towards minor changes to the current Directive. Here, the risk assessment procedure required by the Directive is often mentioned. This refers to the obligation to conduct a full risk assessment before placing an item on the market. Stakeholders expected that it was feasible to conduct a full risk assessment, especially when ML is based on pre-defined decision models (and are thus predictable) or when autonomous learning is precisely confined and controlled. In cases where ongoing ML is not blocked, the machinery will continue to evolve and hence require continuous or dynamic risk assessment and tracing of operations over time. As highlighted by the case studies, the incorporation of software as a safety or control component should hence be considered independently of the MD. Relevant stakeholders indicated that if a manufacturer is not able to carry out the conformity and risk assessment procedure for the whole possible learning phase before it is placed on the market, the product would not be compliant with the Machinery Directive. Those systems, however, are not currently available on the market and the timeline of their introduction into the sector is unsure. The adapting of EHSR with regards to Artificial Intelligence and specifically Machine Learning could therefore come in too soon, according to some industry respondents. Those stakeholders propose that clarifications on what is meant by AI and IoT within the Guide could provide clearer guidelines. On the other hand, there are also arguments for regulatory action brought by some Member States. Besides, this problem might also affect other machinery not in the scope of this Directive, thus developing a horizontal regulatory AI framework may also provide the EU with an early regulatory advantage, while being coherent with the sectorial legislation.

Third, risks with regards to software and software updates might arise. Quantified evidence on health and safety incidents resulting from failures in software updates is scarce, particularly for the machinery covered by the Directive. Many stakeholders consulted differentiated between recurrent and minor updates that are run to close patches and increase security of the systems and major updates or upgrades that would lead to performance increases or changes of the machine. With regards to software updates, many stakeholders from different groups referred to the current requirements in Annex I 1.6.1 on maintenance. Results from case studies conducted indicate that a provision or specification of requirements that need to be in place to ensure that software updates are safe could be beneficial. With regards to upgrades, many referred to the concept of a machinery substantially modified that would require a new conformity assessment. The results of the consultation also showed that criteria on substantial modification could be improved and provided at least in the Guide to increase the clarity of the concept, also with relation to major software updates. When it comes to software that ensures a safety function and is placed on the market independently from the machinery product, the conclusions show that it should be covered by the Directive and be considered as a safety component. While integrated software is already covered in the Directive, software that is independently placed on the market is not. Given the increase of use and upload of this independent software on the machinery products, including this product

[348] Workshop, Exchange of ideas for the revision of the Machinery Directive with a view to new technologies, held 4 November 2019, at KAN in Sankt Augustin, Germany

in the scope of the Directive could bring safety benefits to users and an improved level playing field on the market.

Fourth, cybersecurity was flagged as a risk of connected machinery, although not being specific to the sector. Many stakeholders found that the text of the Machinery Directive should make it clear to whether "external influences" under Annex I 1.2 requirement covers cyberattacks or not. Further specifications and frameworks on cybersecurity were found that may be more suitable covered in a horizontal legislation across sectors.

Finally, the trends on the increased use of industrial robots and of collaborative robots indicate that these products and the potential risks that might arise from them (e.g. smart co-bots and the risk of collision with workers) might need to be covered more extensively in the Machinery Directive. Health and safety incidents in relation to industrial or collaborative robots are not well documented. Many stakeholders consulted indicated that the current Directive does not sufficiently address collaborative robots and refer to EHSR 1.3.7 "the moving parts of machinery must be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or must, where risks persist, be fitted with guards or protective devices". The currently most widely used solution to comply with this requirement is the placing of fences or gates separating industrial robots from persons. Stakeholders raised the limitations of this requirement with regards to collaborative robots, as their intended use is to work in close proximity to humans rather than in physically separated cages. Therefore, an adaptation of the existing EHSR, in particular 1.3.7, to better account for human-robot collaboration could be beneficial, keeping in mind the trends and developments of collaborative and free-roaming robots. Other relevant aspects with regards to collaborative robots were raised throughout the study which could be explored more in depth in the future: i) The mental health risks for human collaborators with co-bots; ii) relevant aspects of data privacy of social robotics, which often capture and process voice, visual and other data that can include potentially personal or other sensitive information, and the potential cases where this may have an impact on safety and mental health; and iii) conditions under which specific safety, or trust-relevant information on robotic behaviour, should be made visible to operators on the Human-Machine Interface system.

With regards to policy option 2, namely addressing the problems identified during the evaluation of the Machinery Directive, the potential impacts vary across sub-options. On the alignment of the Directive to the New Legislative Framework, costs of compliance for economic operators are not expected to increase due to the fact that the same administrative requirements exist under the NLF. In turn, a full alignment would benefit the harmonisation of market surveillance procedures, thus leading to a decrease of non-compliant products on the market.

On the adaptation of the list of low-voltage products excluded from the Directive, a modification is expected to benefit machinery users through an estimated decrease of 26% of non-compliant products on the market. A change of the scope would affect manufacturers of machinery of those categories, in particular, as well as those producing electrical equipment currently falling under the Low Voltage Directive (LVD). Adaptation costs to the changes would apply but an adaptation of the list is also expected to bring benefits in terms of increased legal clarity and therefore reduced costs of clarification procedures due to the current uncertainties. Many stakeholders consulted indicated that clarifications would be particularly useful in the product categories of ordinary office machinery, and household or consumer appliances. During the course of the study, the description on ordinary office machinery and printers was adapted in the new version of the Guide to the application of the Machinery Directive (edition 2.2). The differentiation between household or consumer appliances and those for commercial purposes was not considered to be beneficial by stakeholders, given that many products might be sold for either purpose, with an expected trend of more products falling into either category in the future. A removal of the exclusion of Art. 1.2(k) from the Directive is also not recommended by stakeholders, but rather further references of exclusion to other Directives should be considered (e.g. the Radio Equipment Directive).

An increase of the threshold speed for low-speed lifts from 0.15 m/s to potentially 0.5 m/s was flagged as leading to increased safety concerns. A change of this threshold speed would particularly affect manufacturers of lifting devices and equipment, both of which fall either under the scope of the Machinery Directive or the Lifts Directive (LD). The increased safety concerns of slow speed lifts as per Machinery Directive were reasoned by the Directive allowing a conformity assessment procedure with internal checks, while lifts under the Lifts Directive are obliged to be assessed by a third party. Similar concerns were raised about the differences in installation procedures of lifts under the MD compared to the LD. In addition, an increase of speed limits might decrease the external coherence between both Directives.

The final concept under consideration for revision is that of partly completed machinery. A clarification on this matter was considered to benefit economic operators in terms of decreasing costs through resources spent on contractual agreements or solving unclarities with suppliers.

The assessment on the option of adapting the requirements for completely enclosed carrier or control of movements for slow-speed lifts to permit innovative technologies to be used for achieving a carrier completely enclosed led to the conclusion that new technologies should be allowed if they provide the same or higher level or safety than the current applications. However, given that the lifting appliances under the scope of the Machinery Directive also include lifts used by the general public and vulnerable users (e.g. the elderly, children, persons with impaired mobility), a potential distinction between professionally used lifts (e.g. goods lifts) and person lifts might be necessary to ensure the effectiveness of the Directive to protect the health and safety of users. According to stakeholders, alternative solutions to physical walls of an enclosed carrier are unlikely to limit the risk of a fall from the lift, and the hold-to-run controls ensures that the person controlling the carrier remains at a specific location in the carrier rather than moving and thus risking a contact with the moving walls or a fall.

The option of allowing digital formats for documentation was also assessed in this revision study. Removing the requirements for printed documentation is expected to lead to large cost savings for economic operators especially those related to printing. In addition, given that manuals tend to have many pages, especially when translated into multiple languages, the environmental impacts could be decreased. The cost savings of moving from paper documentation to electronic formats are expected to be higher than the one-off and recurring costs of developing and maintaining the databases or servers hosting the documentation. Other potential benefits of digital documentation, as indicated by many stakeholders, is the increased readability of digital formats among others. However, allowing solely digital formats carries the risk of shifting printing costs to users, as 24% of stakeholders expected that users would print the translation and 45% expected that users would print the relevant parts in their own languages. One potential alternative is to combine the option for digital documentation with the main information on safety and health risks and handling information based on minimum requirements on a printed Quick Start Guide (QSG) and the provision of a (free of charge to the user) printed version of the full documentation upon request. This could mitigate risks whereby users might not be able to access digital tools, for example in specific surroundings (e.g. ATEX environments).

The assessment of policy option 3 on the modification of Annex IV leads to the conclusion that removing the internal checks option for Annex IV machinery would lead to higher safety of high-risk machinery due to an expected increase of effectiveness of the Directive to protect the health and safety of users. Many stakeholders consulted also indicated that there would be increased safety risks related to conformity assessments of Annex IV machinery through internal checks. However, these would be modified by an increase in compliance costs for manufacturers. Nevertheless, the Evaluation of the Machinery Directive estimated that about 10% of all products are Annex IV and currently assessed through internal checks. Many stakeholders also indicated that providing regular updates of the list of products under the Annex are likely to be beneficial to better account for the developments and changes on the market.

Finally, a conversion of the Directive to a Regulation (policy option 4) is not considered to bring additional costs to stakeholder groups, in particular national authorities. It is rather expected to benefit authorities given that transposition costs would no longer arise. A conversion would benefit economic operators by decreasing transposition differences across Member States and therefore expected reduced costs resulting from clarification procedures.

ANNEX II: METHODOLOGY

1. METHODOLOGICAL FRAMEWORK

This section presents a general overview of the methodological approach taken during this study. Section 2.1.1 presents the key concepts that form the backbone of this methodological framework based on the Better Regulation Guidelines. Section 2.1.2 presents all individual assessment tools and methods that have been carried out throughout the course of the study. Lastly, section 2.1.3 presents the strategy taken to ensure the robustness of the results presented in the study, in particular the triangulation approach.

1.1. Methodological approach

The overarching goal of this study is to assess potential impacts of the selected policy options considered for the revision of the Machinery Directive.

The study has considered three key assessment criteria, which are understood as follows:

- **Effectiveness:** the impacts of policy options for achieving the general and specific objectives of the revision initiative;
- **Efficiency:** the likely costs and benefits of the revisions and policy options on different sectors and stakeholders; and to some extent
- **Coherence:** the fit between the goals of the study, the adopted methodology, and its implementation.

An intervention logic forms the basis of this methodological approach illustrating the causality between the problems that need to be tackled, the pursued objectives and results and the long-term impact of the policy options considered.

1.1.1. Overview of the assessment tools and methods

In order to provide an exhaustive and systematic answer to all evaluation questions, the project team collected data and information from a wide range of sources.

Firstly, key existing documentation and information were reviewed in a **desk research exercise and literature review** with the objective of providing an accurate description of the state of play regarding the current market developments and characteristics. See Section 2.2 for a more detailed explanation of the desk research strategy.

In addition, an assessment of the likely impacts of the policy options for the main target groups (consumers, businesses, Member States, notified bodies, and standardisation organisations) has been conducted. For that purpose, several assessment tools were employed: firstly, **desk research and literature review** gathered all data and information available from statistical databases, reports and studies. Subsequently, a **stakeholder consultation** comprising semi-structured interviews was organised to refine the assessment and gather input on potential impacts regarding the effectiveness and efficiency of the policy options. See Section 1.3 for a more detailed explanation of the interview strategy. Moreover, an **open public consultation** targeting a wider range of stakeholders has been organised to complement the inputs received from the interviews. Following these consultation tools, **follow-up interviews** were conducted to close the data and information gaps identified. Lastly, following the same incentive, an online survey targeted at those stakeholders that provided the fewest input in the previous consultation phases was conducted.

The results and input from the data collection tools have been assessed using a multi-criteria analysis consisting of a quantitative assessment based on available data, and a qualitative dimension based on the interviews with relevant stakeholders. Lastly, public consultation and survey results have been used to assess benefits of stakeholders that cannot be monetised.

1.1.2. Robustness of the results

The diversity of methodologies used to collect data described above ensures a broad coverage of different sources of information. In order to ensure the robustness of the results of this impact assessment, the key method of triangulation of findings has been employed during the data analysis phase to verify the findings increasing the validity of the overall study.

Triangulation of findings means cross-checking and validating information collected through one method by comparing it with the information collected through other methods. In this way, it tests the consistency of findings collected across the different methods and enables to assess some of the threats influencing analysis results. By doing so, some of the biases that come with the different data collection tools can be mitigated. For instance, this is case with the statistical biases that come with quantitative targeted consultations such as the surveys that have been conducted for this study (sampling bias, non-response bias and response bias).

Triangulation is also useful to combine quantitative and qualitative data and to ensure the overall coherence of the analysis. This approach, using multi-level and multi-stakeholder dimension in the data collection, ensured the robustness and reliability of the data and information used to draw up conclusions in this study.

1.2. Desk research strategy

The aim of the desk research exercise was to review the existing evidence and to collect relevant market data. An extensive desk research exercise was carried out, making use of all data and information available from public databases, reports and other supporting sources.

As a first step, we have identified known public databases that are relevant to understand the machinery sector in Europe and its developments. In the progress of the study and following remarks on the inception phase of the study and the progress reports, the following data sources have been used:

- Eurostat: Structural Business Statistics, National Accounts;
- International Organisations: OECD Stan Industrial Database, UNIDO Industrial Database, UN Comtrade, World Input-Output Database (WIOD, OECD TiVA, etc.);
- Other: EU KLEMS, potentially national databases, Statista.

Following the approach of previous studies, the statistical classification of economic activities in the European Community (NACE rev.2) division C28 'Machinery and equipment n.e.c.' is used for the market overview.

A second step of this exercise was to identify additional, previously unknown, sources by actively searching literature using the websites of the EC, of stakeholder organisations and other websites like Google (Scholar). This approach allowed to gather circumstantial evidence on specific sectors of focus in the study.

In the third step the collected desk research material was reviewed. The sources compiled in the previous two steps were reviewed for relevant information helping us to answer the assessment questions.

After the document review the findings were summarised and presented as the input for the first progress report. The First Progress Report presented the preliminary results of the desk research carried out.

1.3. Targeted interviews' strategy

1.3.1. Overview

The objective of the targeted interviews was to obtain data and information from various groups of stakeholders in order to gain insights on the potential impacts of the policy options in terms of effectiveness and efficiency. The targeted stakeholder consultation focused on semi-structured interviews with up to **98 stakeholders**. These interviews were split in two phases, a first round of interviews with 68 stakeholders and a second round with 30 additional ones. Due to a change in the methodological approach, the CATI survey originally planned was taken out from the selection of consultation tools in accordance with the Steering Group and replaced with 16 additional focused interviews.

Semi-structured interviews targeted the following stakeholders:

- Workers' and employers' representatives;
- Consumer associations;
- CEN-CENELEC;
- Market surveillance authorities;
- Notified bodies;
- National authorities;
- Businesses/Companies;
- Industry associations; and
- AI High Level Expert Group.

Targeted stakeholders relevant for the online survey strategy were identified through the exercise of **stakeholders mapping**.

Stakeholder mapping

As a relevant stakeholder has been identified anyone that has to implement, follow, comply with, enforce compliance or be otherwise impacted by the Machinery Directive.

The first step of the stakeholder mapping consisted of desk research based on existing experience on previous assessments and similar studies conducted. This collection of potential interviewees was expanded by approaching industry associations and their members. In addition, the preliminary list of stakeholders was presented to the Steering Group, which provided the study team with additional contacts.

Implementation of the interviews

The semi-structured interviews implementation was prepared in the following way:

- **Developing the draft questionnaire.** Based on the ToR, desk research and scoping-interviews the first version of the questionnaires were developed based on the identification of relevant questions and topics to the different stakeholder groups;
- **Piloting the draft questionnaires**. The project team tested the draft questionnaires in the inception phase. In total six companies, one market surveillance authority, two national authorities and one notified body were interviewed to test the complexity and understandability of the questions;

- **Finalisation of the questionnaires.** During the inception phase in consultation with DG GROW, we finalised the draft questionnaire. Where necessary, different routes were developed for different target groups using selected questions;
- **Conducting of the interviews.** The finalised questionnaires were sent in advance to the selected stakeholders mapped in the stakeholder mapping exercise. In-depth interviews were conducted via phone or face-to-face consultations following the relevant guides. The responses were typed during the consultation and the interview minutes saved;
- **Finalisation of the interviews**. Due to the timing of the study, the first round of semi-structured interviews ran well into September, while most of the second round was completed by the beginning of December. A **total of 98 interviews** was conducted. When the interviews were conducted, the minutes were sent to the respective interviewees for validation and once accepted they were transferred into a statistical program for further analysis.

In the interest of the respondents, VVA is obliged not to share the identity of the respondents with the Commission, national authorities or any other third parties, and the raw data will not be published.

1.3.2. Results of the interviews

In the first round, **68 interviews** were conducted. A combination of face-to-face and telephone/Skype interviews has been used depending on the location and availability of the interviewees. The interviews were conducted from June to September 2019.

The table below represents the stakeholder's split of the first round. The first column of the table depicts the planned stakeholder split (as indicated in the proposal) and the second column depicts the actual stakeholder split and the number of interviews conducted with the stakeholders. While interviews with EU institutions were suggested in the proposal, the relevance had changed in the course of the study and were thus not further pursued in accordance with the Commission.

Table 61: Planned and actual stakeholder split and the number of interviews conducted

Stakeholder type	Initial split	Interviewed
Workers' and employers' representatives	4	6
Consumer associations	2	2
Stakeholders involved in standardisation	5	1
Market surveillance authorities	2	8
Notified bodies	5	4
National authorities	13	7
Companies	30	25
Industry associations	4	13
Members of High-Level Expert Groups	2	2
EU institutions	3	-
Total	**70**	**68**

As it can be observed from the table, for half of the stakeholder groups the planned target of interviews was reached. The interviews with workers and employers' representatives, market surveillance authorities and industry associations exceeded the initial planned target number.

1.3.3. Follow-up interviews

During the second phase, **30 interviews** were conducted, mostly between October and November. The targeted interviews' strategy focused on the reaching out to those stakeholders, for which the target number of interviews had not yet been reached. This included:

- CEN-CENELEC;
- National authorities;
- Companies; and
- Experts.

Implementation of the follow-up interviews

The follow-up interviews were conducted in a similar way as the first round. In addition, given the change of strategy within the stakeholder consultation approach – namely the replacement of CATI with additional semi-structured interviews – the following interview targets are set (see Table 62). The identified data gaps were dealt with by sticking to specific questionnaires developed for each stakeholder type.

Table 62: Follow-up interviews

Stakeholder type	Interviewed	CATI replacement
Workers' and employers' representatives	0	No indication
Consumer associations	0	No indication
Stakeholders involved in standardisation	2	No indication
Market surveillance authorities	1	8
Notified bodies	2	5
National authorities	0	No indication
Companies	19	No indication
Industry associations	3	No indication
Members of High-Level Expert Groups	0	No indication
EU institutions	-	-
Expert authorities and persons	3	3 Cybersecurity authorities; rest no indication
Total	**30**	**40-45**

Results

As the table shows, the original target number of interviews established to replace the CATI was partially reached. In fact, the low response rate from market surveillance authorities and notified bodies only allowed for a partial achievement, while the number of expert authorities and persons reached is in line with the initial planned target number. In addition, the number of new companies reached was particularly significant.

Overall, the total number of interviews conducted was 98 (see Table 63).

Table 63: Total number of interviews conducted

Stakeholder group	Number of interviews
AI expert; High-level expert group	5
CEN/CENELEC representatives; other stakeholders involved in standardisation	3
Company/manufacturer	44
Consumer association	2
Industry association	16
Market Surveillance Authority	9
National authority	7
Notified body	6
Workers/professionals association	6
Grand Total	**98**

1.4. Open public consultation

1.4.1. Description of the OPC

The aim of the open public questionnaire was to target wider range of stakeholders, which could complement the impact assessment, notably with comparable and quantifiable data.

The questionnaire for public consultation was prepared in line with the requirements of the Better Regulation Guidelines. Public consultation was opened in June 2019 for a period of minimum 12 weeks. The consultation was closed at the end of August 2019.

There were no major issues encountered during this activity. Certain limitations that are inherent to the design of the open public consultation questionnaire do however exist. For example, the category "other" under the question on the type of stakeholder included responses such as "Ministry of Labour" that were thus not recorded under the right stakeholder type (national authorities). Similarly, the question on the "organisational size" applies to all respondents except citizens. 46% of the respondents claimed to have been "large companies" (250 employees or more), however this category applies not just to actual companies, but as well to associations/organisations, public administrations, universities etc. From the results of the open public questionnaire it is therefore not possible to know how many companies actually participated in the consultation. In order to account for this, an additional value was created to encode company size for those respondents that are enterprises. The profile of the responding organisations was in general very similar to the target sample, guaranteeing statistical representativeness.

1.4.2. Robustness of the results

The open public consultation received in total 528 replies. 15 responses were handed in with delay, which due to the format in which they were made available hindered the possibility of including them into the full dataset. These were analysed separately and included to the full results where relevant. More than 70% were companies/businesses and their organisations. Over half of the respondents were companies (57%), of which 39% are SMEs.

Figure 36: Classification of legal entities

Source: Open Public Consultation (n=523)

Table 64: Public consultation respondents

Stakeholder type	Total
Academic/research institution	4
Business association	70
Company/business organisation	302
Consumer organisation	2
EU citizen	68
Non-EU citizen	2
Non-governmental organisation (NGO)	11
Other	29
Public authority	35
Trade union	5
Grand Total	528

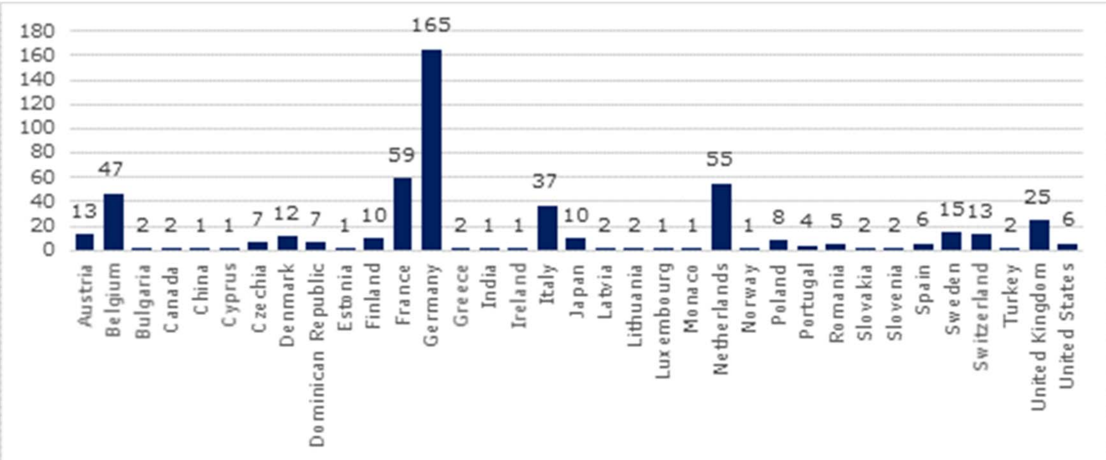
Respondents were mostly from Germany (around 31%) followed by France (around 11%), Netherlands (10%) and Belgium (9%). The vast majority of consultation respondents are from the EU (92%), non-EU participants originating from:

- China (1),
- the Dominican Republic (7),
- India (1), Japan (10),
- Monaco (1),
- Norway (1),
- Switzerland (13),
- Turkey (2), and
- United States (6).

Table 65: Country of origin of open public consultation responses

Country of origin	Total	Country of origin	Total
Austria	13	Latvia	2
Belgium	47	Lithuania	2
Bulgaria	2	Luxembourg	1
Canada	2	Monaco	1
China	1	Netherlands	55
Cyprus	1	Norway	1
Czechia	7	Poland	8
Denmark	12	Portugal	4
Dominican Republic	7	Romania	5
Estonia	1	Slovakia	2
Finland	10	Slovenia	2
France	59	Spain	6
Germany	165	Sweden	15
Greece	2	Switzerland	13
India	1	Turkey	2
Ireland	1	United Kingdom	25
Italy	37	United States	6
Japan	10		
Grand Total			**528**

Figure 37: Country of origin of the open public consultation participants

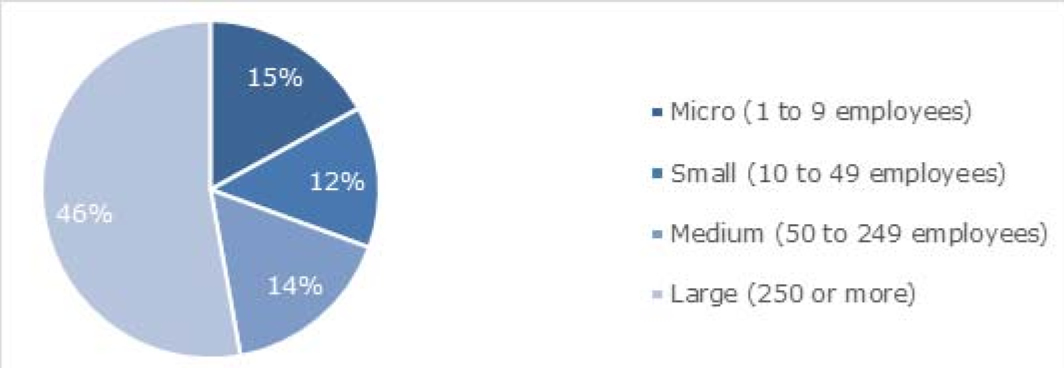


Source: Open Public Consultation (n=528)

The distribution of respondents by country follows the general specificities of the machinery sector. In terms of turnover in the machinery and equipment sector (2017), Germany recorded the highest number, with Italy, France and the Netherlands following.

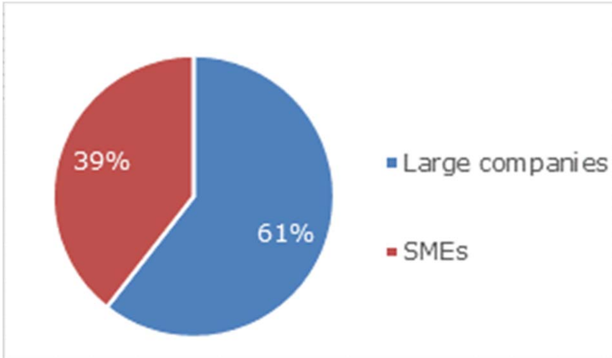
Of all the respondents, 458 are organisations. Overall, the distribution of organisation size is fairly equal, with about 53% being large organisations (250 or more employees) and 47% being micro-, small, or medium-sized organisations (see Figure 38). Looking into the respondents that indicated to answer as a business organisation or company, the distribution of SMEs and large companies is not representative of the market structure. In the machinery and equipment sector, over 90% are SMEs (see Annex III) – compared to 39% of the companies that participated in the consultation being SMEs (see Figure 39).

Figure 38: Organisation size



Source: Open Public Consultation (n=459)

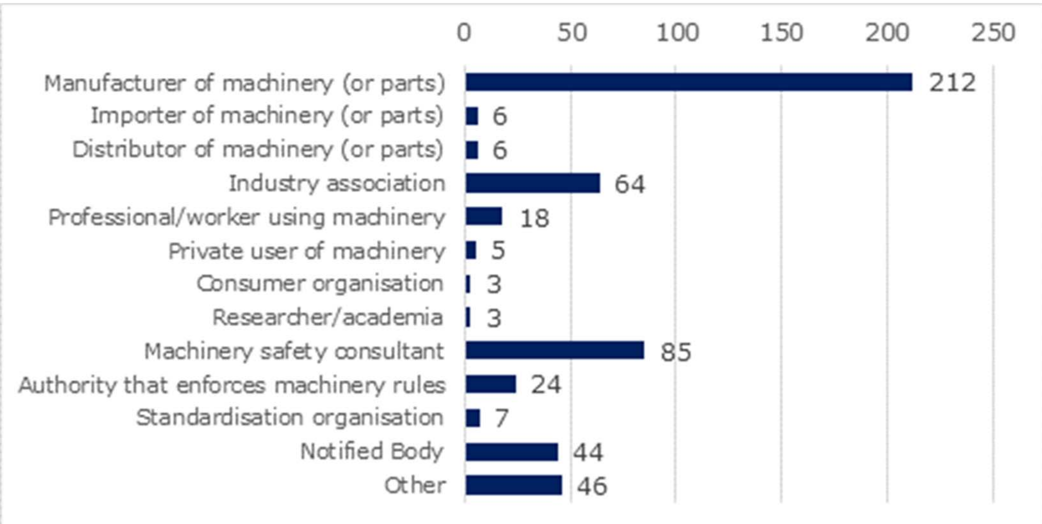
Figure 39: Company size



Source: Open public consultation (n=302)

To the question of what type of stakeholder or organisation the respondents represented, most answered "manufacturers of machinery" (40%). This is followed by machinery safety consultants (16%), industry associations (12%) and notified bodies (8%).

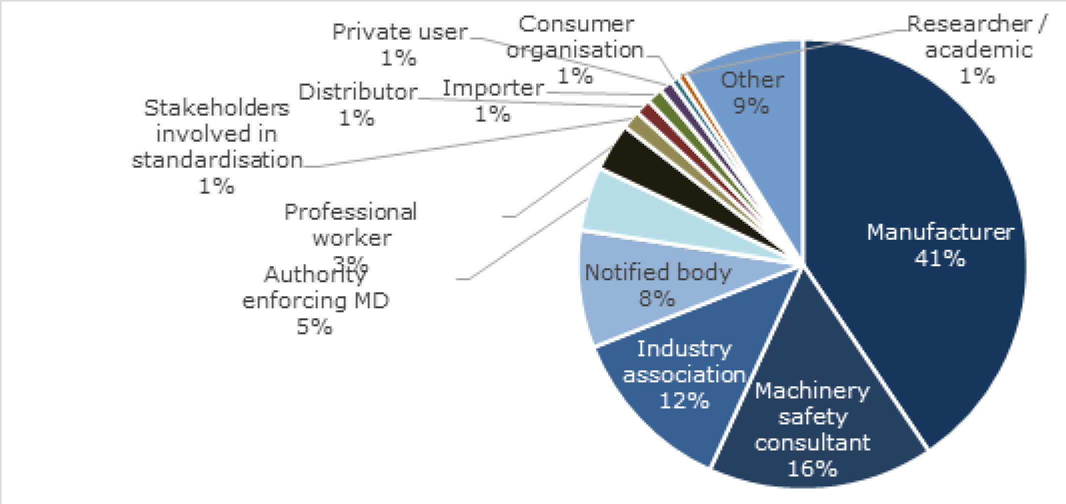
Figure 40: Type of organisation represented by respondents



Source: Open Public Consultation (n=528)

To gain a better view of the stakeholder groups that responded to the consultation, one further identification question was asked, namely which type of stakeholder group they represent. The majority of respondents were manufacturers, followed by machinery safety consultants and industry associations (see Figure 41).

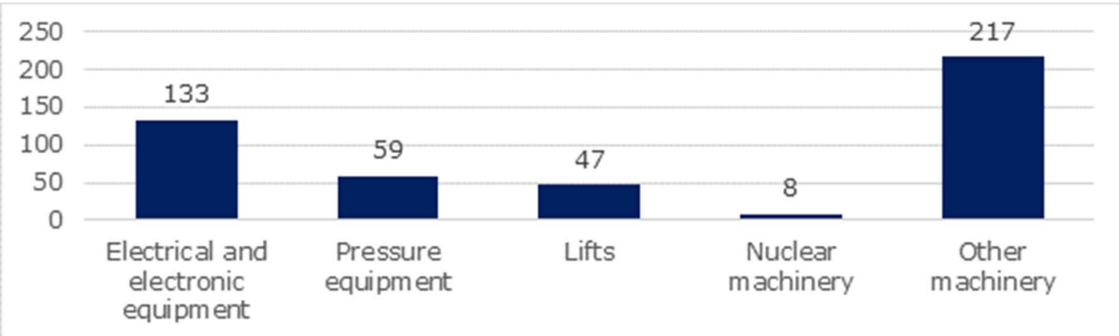
Figure 41: Stakeholder types – are you or do you represent:



Source: Open public consultation (n=523)

Given the topical focus of this study on clarity and potential change of the scope and definitions in relation to specific machinery, the consultation asked the participants whether they manufacture, import or distribute electrical and electronic equipment, pressure equipment, lifts, or nuclear machinery. Most mentioned to focus on other machinery (217 mentions). Electrical and electronic equipment was mentioned on second place (133).

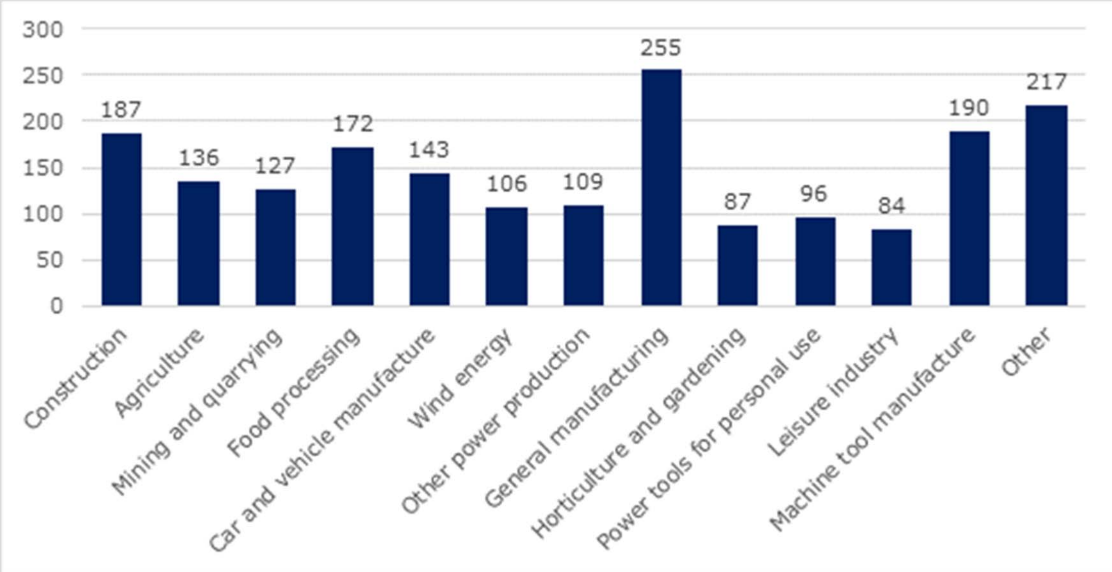
Figure 42: Are you a manufacturer, importer or distributor of:



Source: Open public consultation, multiple answers possible

The respondents indicated that among the most relevant machinery products for their organisation or institution are within the general manufacturing sector (255), followed by machine tool manufacture (190) and construction (187).

Figure 43: Relevant kind of machinery for organisation or institution



Source: Open public consultation, multiple answers possible

Of the seven standardisation organisations that participated in the consultation, four operate on national level and three on European level. The majority of the notified bodies that provided answers to the consultation (36 of 44) are involved in EC type-examinations and eight in Quality Assurance.

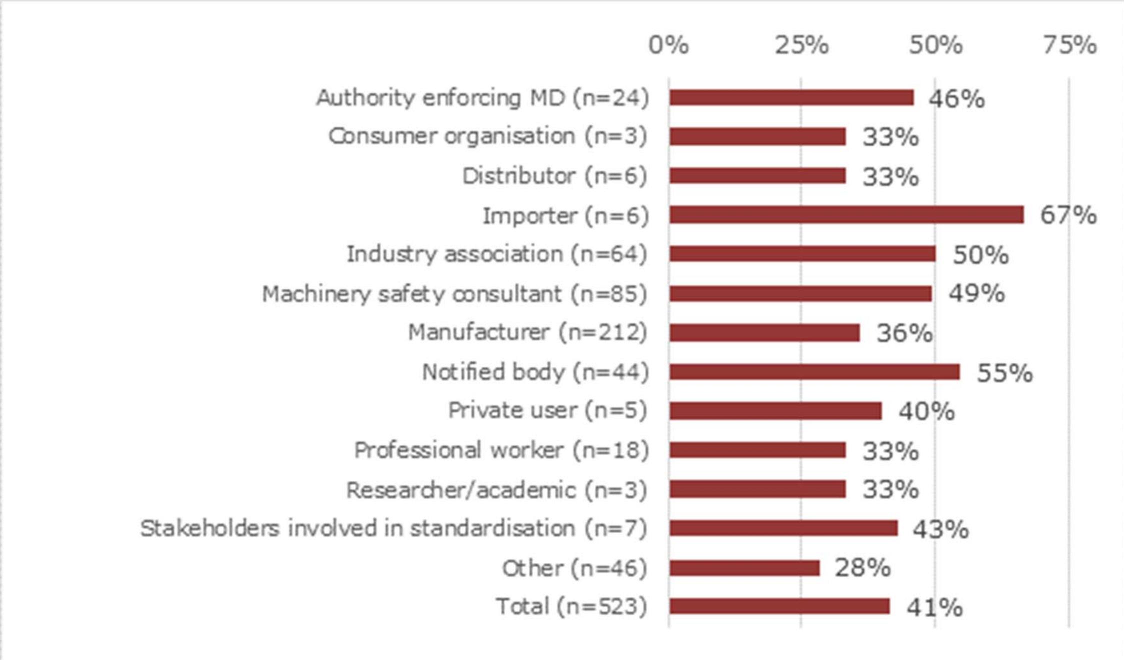
Most respondents either had detailed knowledge on the Machinery Directive its objectives, the limits and the requirements/obligations that it imposes across all industry sectors (43%) or on specific sectors (47%). Fewer respondents had limited knowledge (9%) and five respondents indicated not really knowing the Directive.

1.4.3. Results of the OPC

Experienced issues or problems with machinery

When it comes to the trading of machinery and problems reported, most respondents (41%) had heard or experienced issues when buying or selling machinery from or to the EU, EFTA, Switzerland or Turkey. Across stakeholder groups, in particular importers have had difficulties (67%), followed by notified bodies (55%) and industry associations (50%). Large companies indicated more often to having had experienced difficulties (43%) than SMEs (35%).

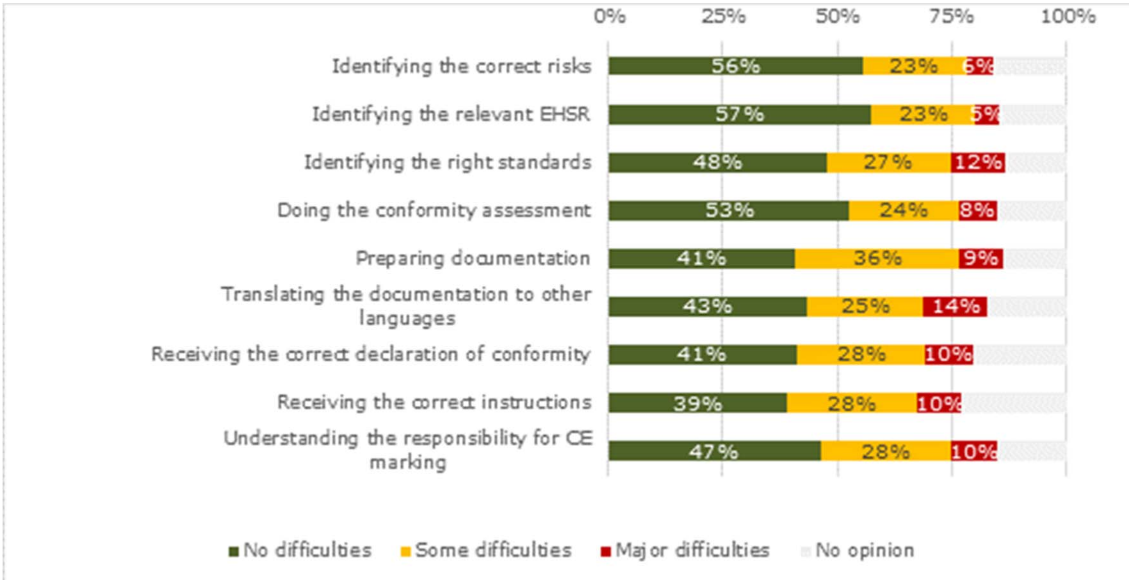
Figure 44: Difficulties in buying/selling machinery from/to EU/EFTA/CH/TK



Source: Open public consultation, n=523

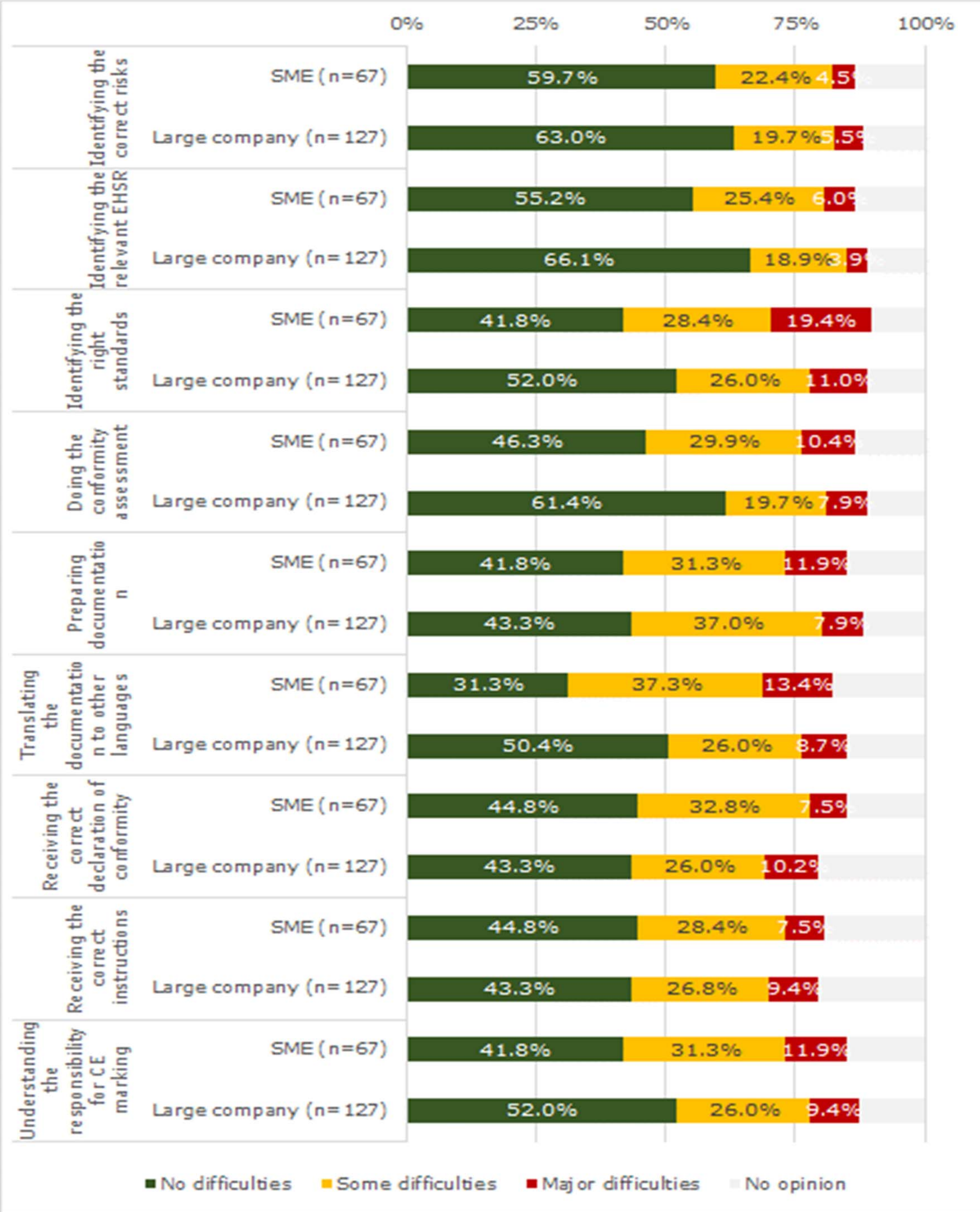
To the question "has any of the following aspects caused difficulties", 288 provided input – namely distributors, importers, industry associations and manufacturers. While the overall results show that all aspects did not generate many major difficulties to the respondents (see Figure 45), there are differences across stakeholder groups. On average, SMEs experienced somewhat more difficulties than large companies, albeit the majority of SMEs still indicating no difficulties across aspects.

Figure 45: Has any of the following aspects caused difficulties?



Source: Open Public Consultation (n=288)

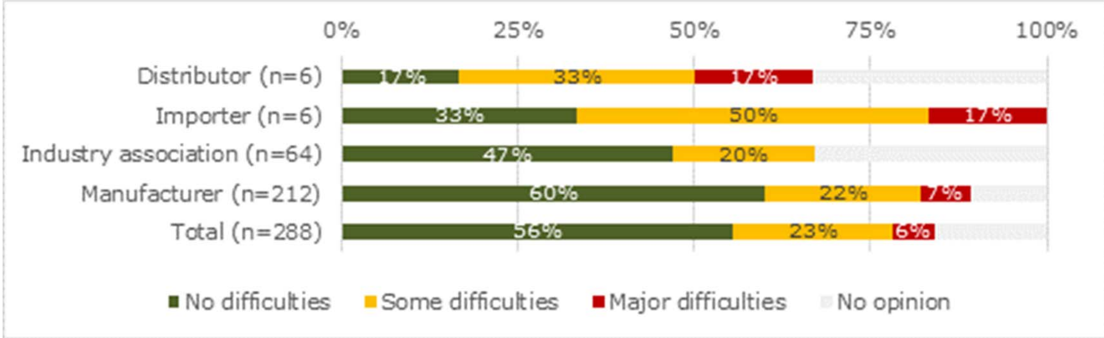
Figure 46: Difficulties experienced, SMEs and large companies



Source: Open public consultation, n=194

On the question whether the respondents had experienced any difficulties in identifying risks, most manufacturers and the majority of industry associations did not indicate having had any difficulties, while over half of the importers that participated to the consultation mentioned that they did. Most distributors had also experienced at least some difficulties (see Figure 47). Most of SMEs (59.7%) and large companies (63%) did also not experience any difficulties in identifying the risks.

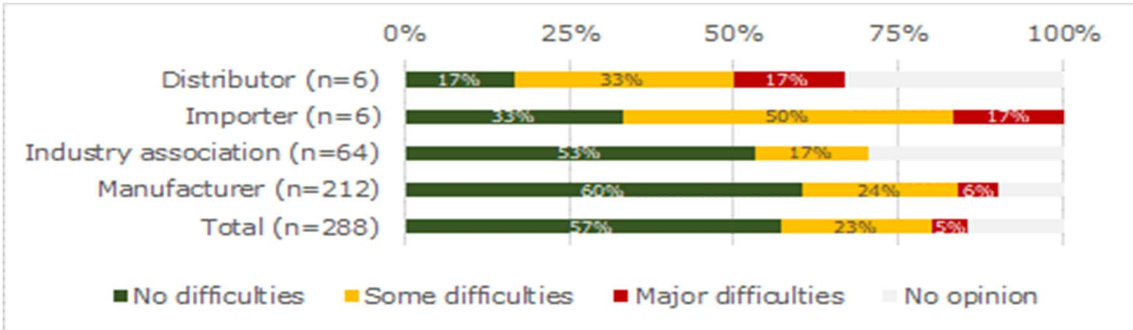
Figure 47: Difficulty – identifying risks



Source: Open Public Consultation (n=288)

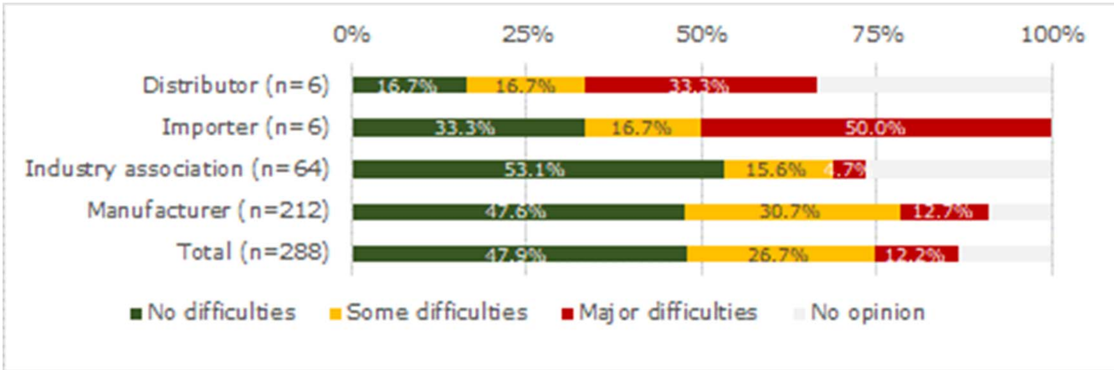
A similar tendency is visible for difficulties in relation to identifying the correct EHSRs and finding the right standards, where most industry associations indicated not having experienced any difficulties, while especially the importers mentioned having had at least some difficulties. Most manufacturers answered that they did not experience any difficulties in identifying the right EHSRs but were closely split when it came to identifying the right standards (see Figure 48 and Figure 49).

Figure 48: Difficulty - identifying the right EHSRs



Source: Open Public Consultation (n=288)

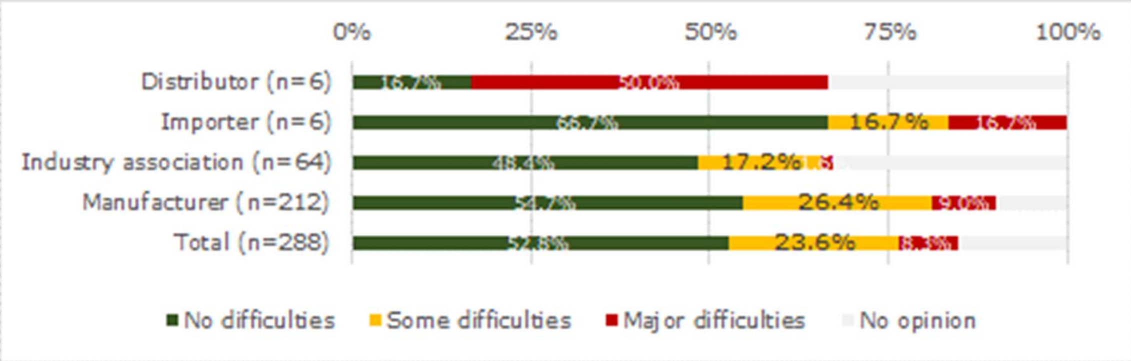
Figure 49: Difficulty - finding the right standards



Source: Open Public Consultation (n=288)

According to the answers in the consultation, doing the conformity assessment did not cause difficulties with most importers, industry associations or manufacturers. Half of the respondents under the distributor category, however, mentioned having experienced major difficulties with the conformity assessment. When it comes to receiving the correct declaration of conformity, the answers are split within each stakeholder group. Even though 46% of the manufacturers indicated not having had encountered difficulties with this, 40% answered they did at least to some extent. About 36% of industry associations did not have had any difficulties, 39% had no clear opinion. Only most of the respondents under the importer category answered having had experienced at least some difficulties.

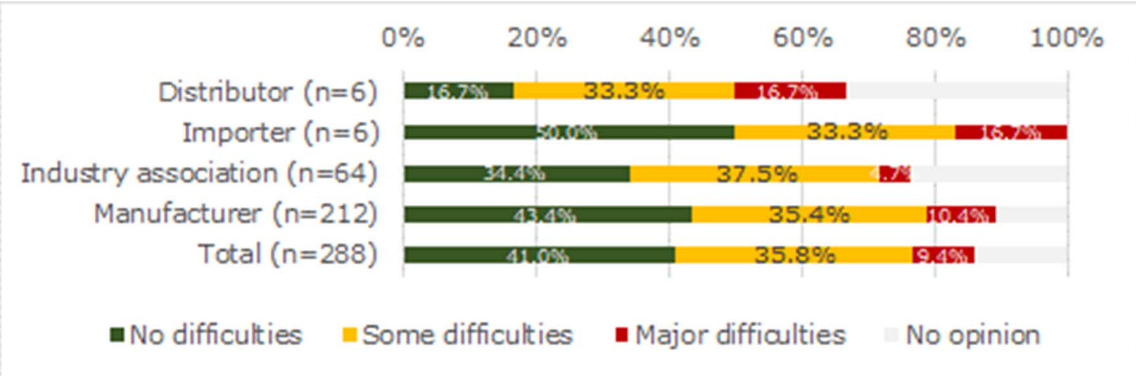
Figure 50: Difficulties with the conformity assessment



Source: Open public consultation

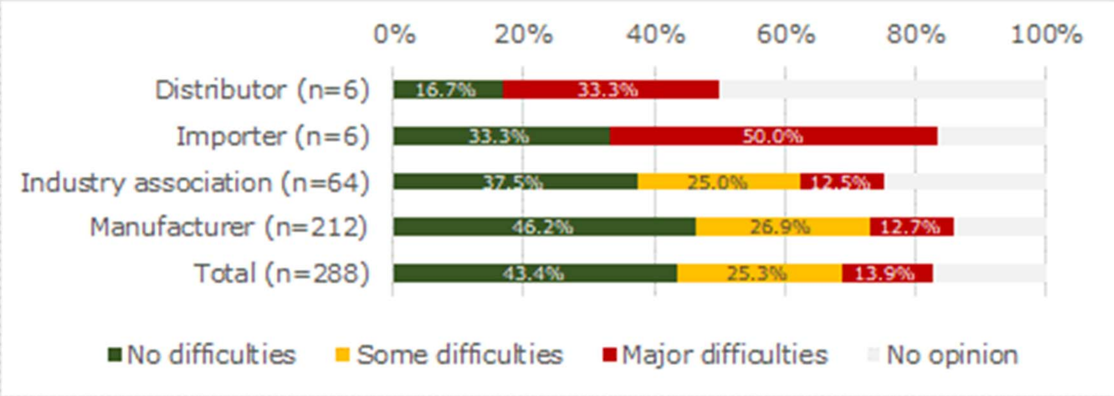
Regarding difficulties with the documentation, most respondents indicated having had at least some difficulties with both the preparation of documentation and translation in other EU languages, especially distributors and industry associations. Importers and manufacturers' opinions are relatively evenly split.

Figure 51: Difficulties regarding preparing the documentation



Source: Open public consultation

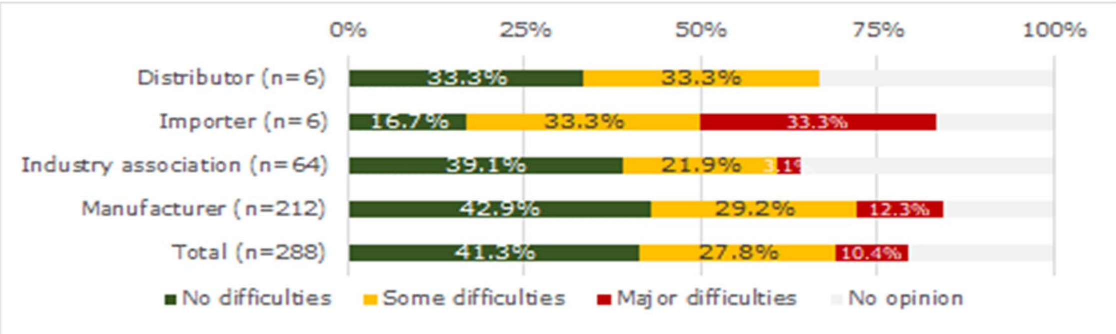
Figure 52: Difficulty - translating documentation in other EU languages



Source: Open Public Consultation (n=288)

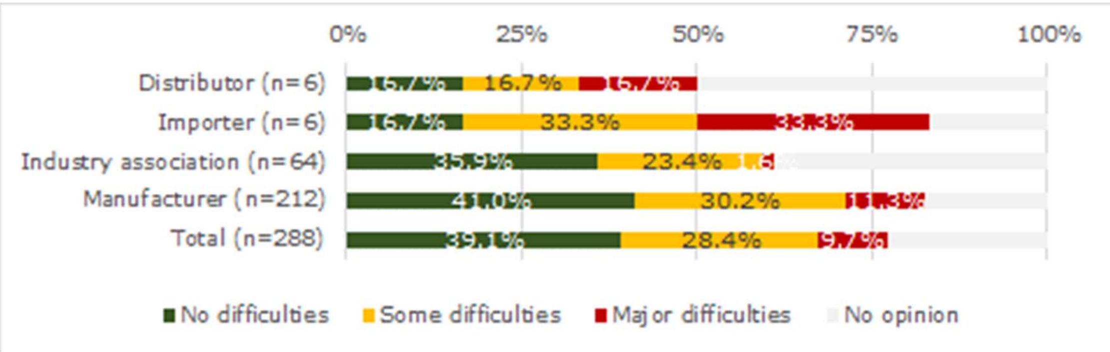
Receiving the correct DoC, receiving the correct instructions or understanding the responsibility for CE marking did not seem to have caused major difficulties either.

Figure 53: Difficulties - receiving the correct DoC



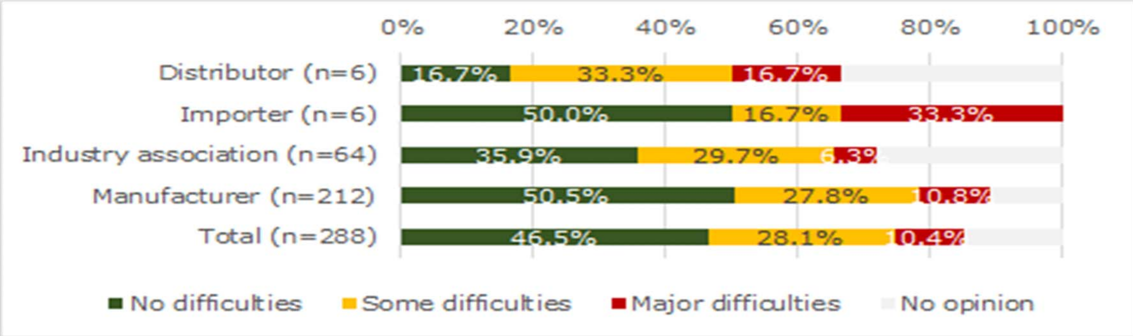
Source: Open public consultation (n=288)

Figure 54: Difficulties - receiving the correct instructions



Source: Open public consultation

Figure 55: Difficulties with understanding the responsibility for CE marking

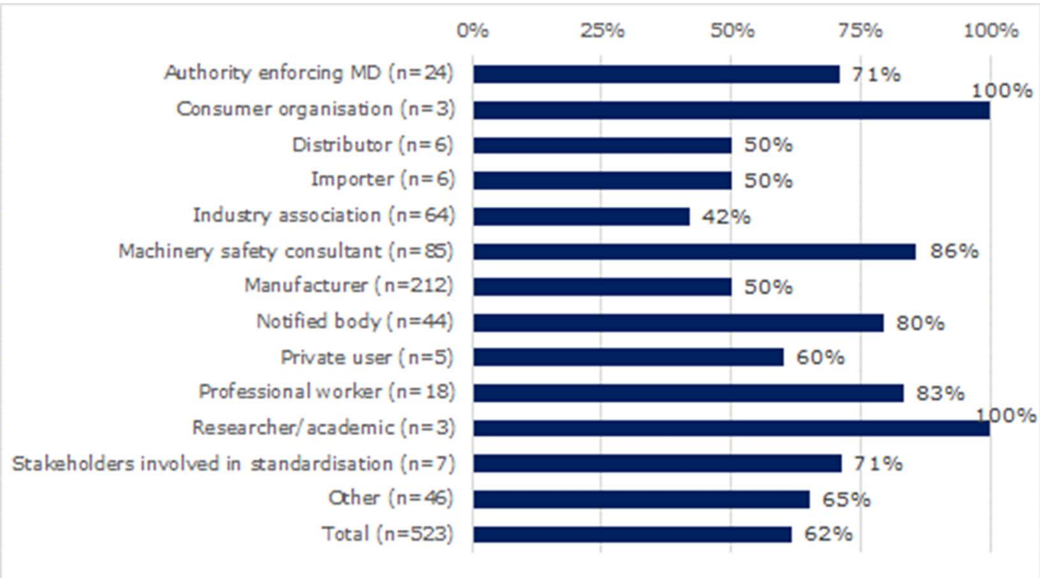


Source: Open public consultation

One source of confusion related to documentation is related to those definitions and criteria that are explained on less detail (see sections 5.2.4 and 5.2.5). For instance, according to a large company from the Netherlands, the overlapping of different incremental lists of harmonized standards makes it sometimes complex to comply in full. In addition, some companies find that a few minor improvements could be made, e.g. with an exhaustive list of which Directives need to be mentions in the 'EC Declaration of Conformity' or a clearer division of compliance responsibility between suppliers, distributors and costumers.

The majority of respondents to the question (Q23) whether there were situations in which the safety of users (or domestic animals or property) was at risk when using machinery indicated that they had indeed heard or encountered such situations (62%). 23% had not experienced such situation. On the question whether the machinery that caused the problem was purchased form a company in the EU, EFTA, Switzerland or Turkey (Q25), 75% (of total n=323) indicated that it was.

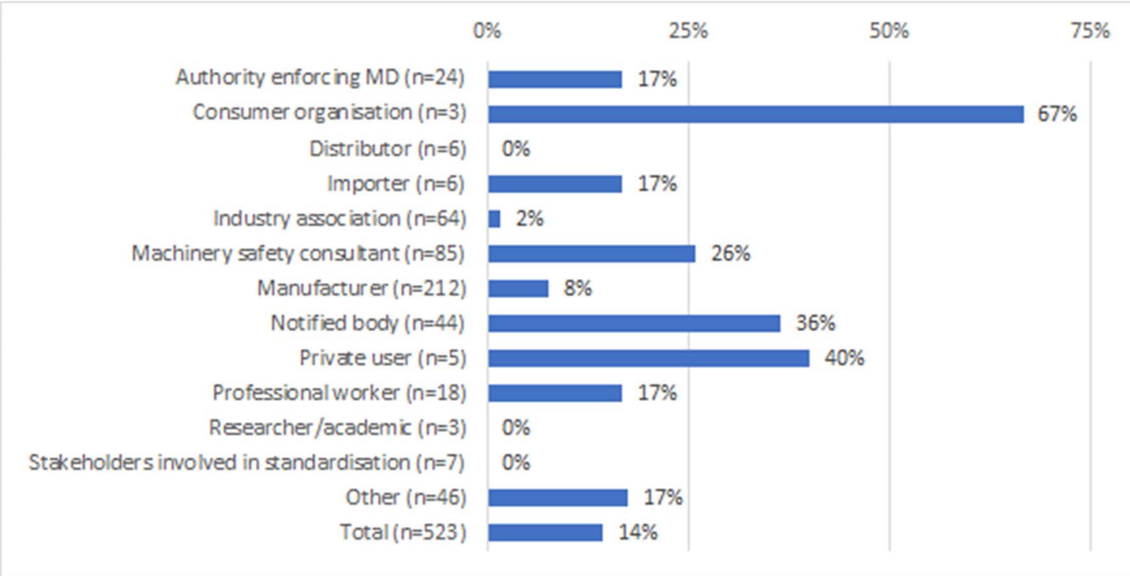
Figure 56: Respondent has heard or encountered situations in which the safety of users was at risk



Source: Open public consultation

Comparing to the question whether there have been situations in which the safety of users (or domestic animals or property) was at risk as a result of the internet connection of the machinery (Q26), 371 respondents (71%) negated having heard or encountered such situations. One exemption represents the answers from consumer organisations, of which the majority did indicate having encountered such risk situations in result of a machinery with internet connection. Of the 75 respondents that said they did encounter such situations, 68% indicated that the machinery causing the problem had been purchased from a company in the EU, EFTA, Switzerland or Turkey (Q28).

Figure 57: Respondent has heard or encountered situations in which the safety of users was at risk (due to the internet connection of a machine)

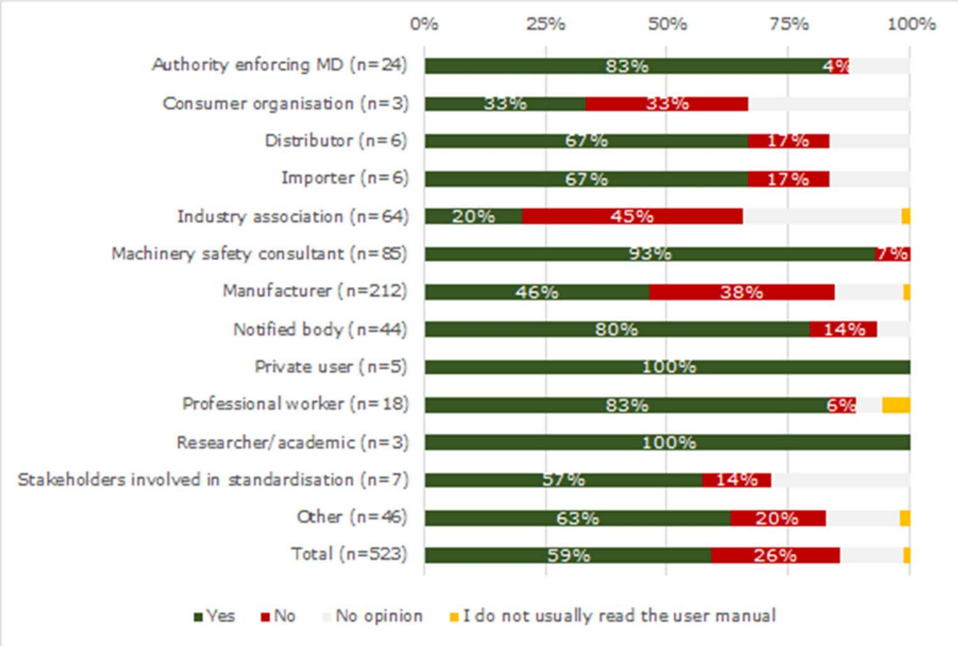


Source: Open public consultation

User manuals

Regarding the user manuals, the majority of respondents did experience difficulties in understanding or finding the information on them (59%). In particular private users, machinery safety consultants, professional workers and authorities enforcing the Directive have had difficulties to understand the manual. SMEs indicated more often to have encountered difficulties (61%) than large companies (51%).

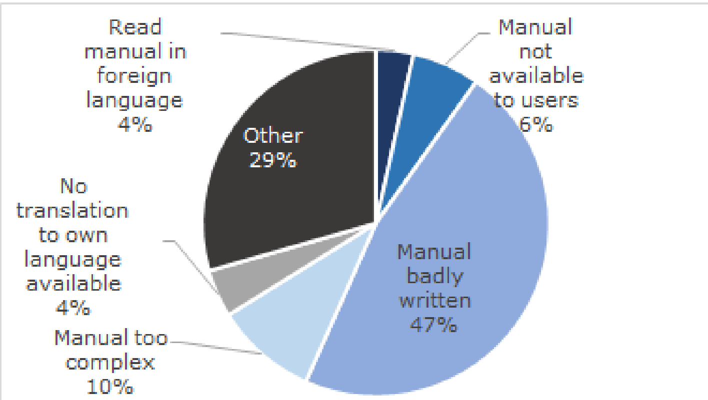
Figure 58: Difficulty to understand the user manual



Source: Open public consultation

The most mentioned reason for these difficulties was the fact that the manual was badly written or badly translated to the respondents' language (47%), followed by the manual being too complex or technical (10%).

Figure 59: Reasons for difficulties to understand the user manual



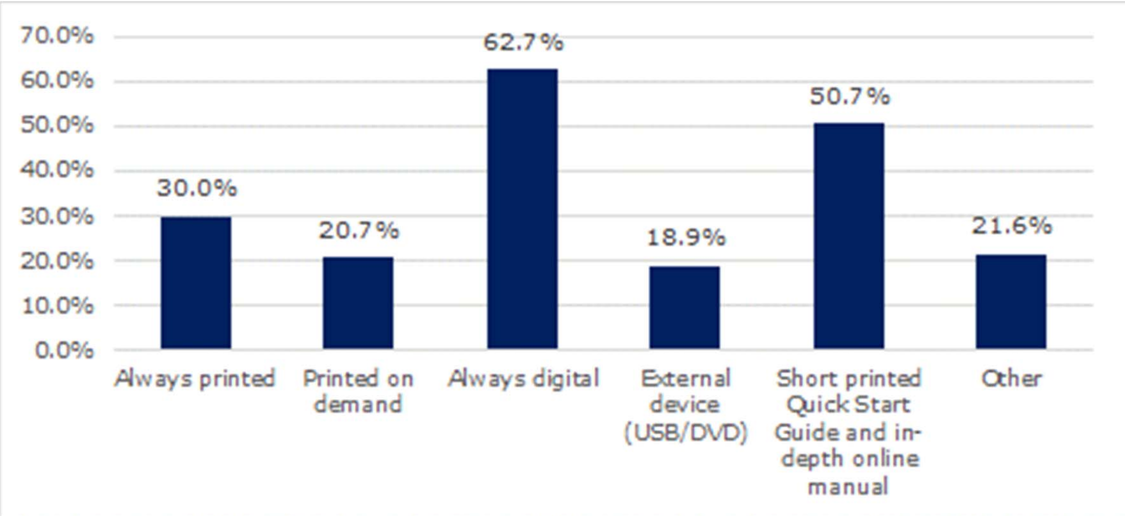
Source: Open public consultation (n=316)

Several respondents stressed that the structure of the manuals does not follow operational needs, thus forcing users to navigate repeatedly across different sections in order to retrieve information. Other respondents underlined that manuals do not always refer to a single machine but rather to multiple ones or even a different model, which leads to fewer specific information being included and longer time to retrieve them. For instance, several respondents pointed out that information on residual risks and safety functions are often absent or not detailed enough. A large company from Switzerland reasoned this with the fact that information typically reserved for the 'Technical File' is omitted from the user manual, which makes it difficult to verify compliance to EHSR before an incident occurs and market surveillance authorities have to intervene.

The vast majority of respondents to the question whether they had to update manuals (Q42, n=288) – namely distributors, importers, industry associations and manufacturers - indicated that they have had the need to do so (87%). Almost all of the respondents to this question indicated that it would have been easier with electronic manuals (98%). On the different cost savings options, the most often named option that would lead to expected savings was online manuals only (31%). Fever respondents chose expected cost savings by using online manuals in combination with a Quick Start Guide (24%), followed by online manuals in combination with on-demand printouts (22%).

When it comes to the question how the machinery manuals should be delivered to the users, over half of the respondents indicated that it should be accessible through a digital user manual (online or displayed by the product) (63%), followed by a short printed Quick-Start Guide combined with an access to a more in-depth online user manual (51%) (see Figure 60).

Figure 60: Preferences on the provision of user manuals



Source: Open Public Consultation (n=523, Multiple answers possible)

The main differences comparing the different groups of stakeholders show that:

- Printing a Quick-Start Guide was less chosen by SMEs (45%) than large companies (56%) or other respondents (50%);
- The option of always having a printed user manual was chosen by the majority of authorities enforcing the Directive (58.3%) though a combination with a QSG could provide a potential alternative (46%);
- Most distributors would prefer user manuals to be either printed on demand or in combination with a QSG (both mentioned by 67%);
- Having only online manuals was the most often chosen option by importers (67%), industry associations (63%), machinery safety consultants (57%), notified bodies (55%), private users (all), professional workers (72%) and other respondents (67%); and
- Consumer organisations' most chosen option is the combination with a QSG (67%).

Most stakeholder groups that most often indicated the option of having an online manual only chose the option to combine the manual with a QSG as second option – which could provide an alternative to the first choice (see Table 66).

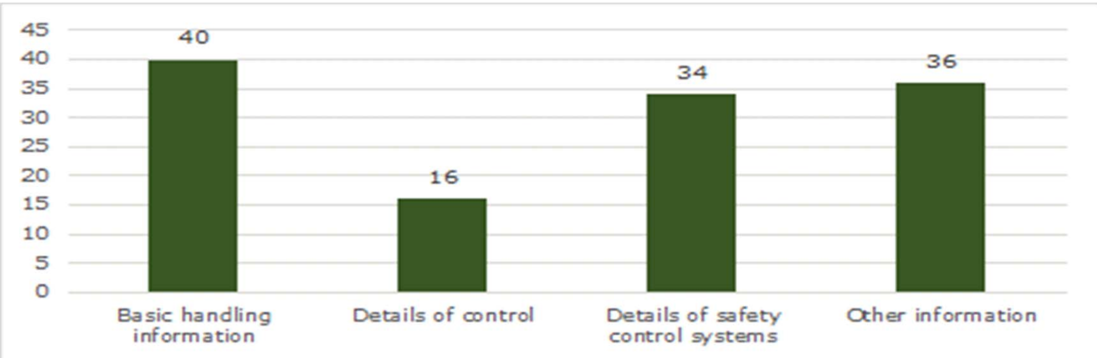
Table 66: Preferences on the delivery of user manuals by stakeholder group

	Q32.1: Delivery user manual - always printed	Q32.2: Delivery user manual - printed on demand	Q32.3: Delivery user manual - digital	Q32.4: Delivery user manual - external device (DVD/USB)	Q32.5: Delivery user manual - QSG	Q32.6: Delivery user manual - other
Authority enforcing MD	58.3%	12.5%	33.3%	20.8%	45.8%	25.0%
Consumer organisation	0.0%	0.0%	33.3%	0.0%	66.7%	33.3%
Distributor	16.7%	66.7%	33.3%	16.7%	66.7%	0.0%
Importer	16.7%	16.7%	66.7%	16.7%	16.7%	16.7%
Industry association	12.5%	25.0%	62.5%	14.1%	57.8%	51.6%
Machinery safety consultant	45.9%	16.5%	56.5%	22.4%	50.6%	12.9%
Manufacturer	19.3%	27.4%	69.3%	21.7%	49.5%	13.2%
Notified body	38.6%	11.4%	54.5%	15.9%	52.3%	31.8%
Private user	40.0%	20.0%	100.0%	20.0%	60.0%	0.0%
Professional worker	50.0%	22.2%	72.2%	11.1%	44.4%	11.1%
Researcher/academic	0.0%	0.0%	33.3%	33.3%	33.3%	33.3%
Stakeholders involved in standardisation	14.3%	14.3%	57.1%	0.0%	71.4%	28.6%
Other	52.2%	2.2%	67.4%	15.2%	47.8%	30.4%

Source: Open Public Consultation (n=523)

Given that the Quick Start Guide is one of the preferred options, the next question targeted on the content to be provided in such Guides. Most respondents indicated it should contain basic handling information and details of safety related control systems (182 and 178 mentions respectively) (see Figure 61).

Figure 61: Preferred content in Quick Start Guides

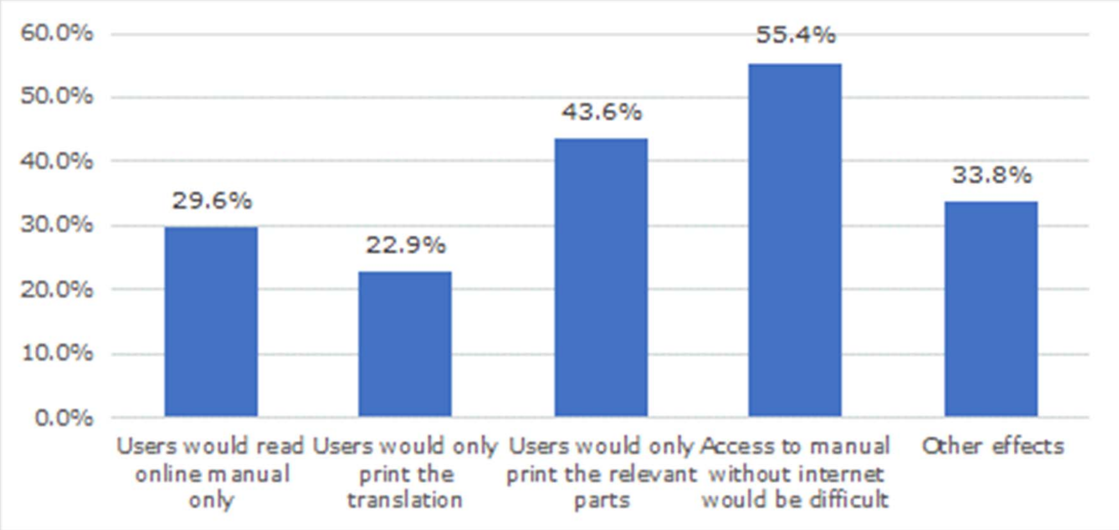


Source: Open Public Consultation (n=523; multiple answers possible)

Looking into the responses given under "other", the provision and inclusion of the main safety hazards and risks was mentioned in 49 of 78 cases.

On the potential effects if the switch to online manuals only would be followed, most respondents indicated that for those persons without internet access it would be more difficult to access them (55%). However, another likely result according to the respondents is that users would only print the relevant parts of the manual, which might be beneficial for the environment through minimising paper waste (see Figure 62).

Figure 62: Potential impacts of switching solely to online manuals

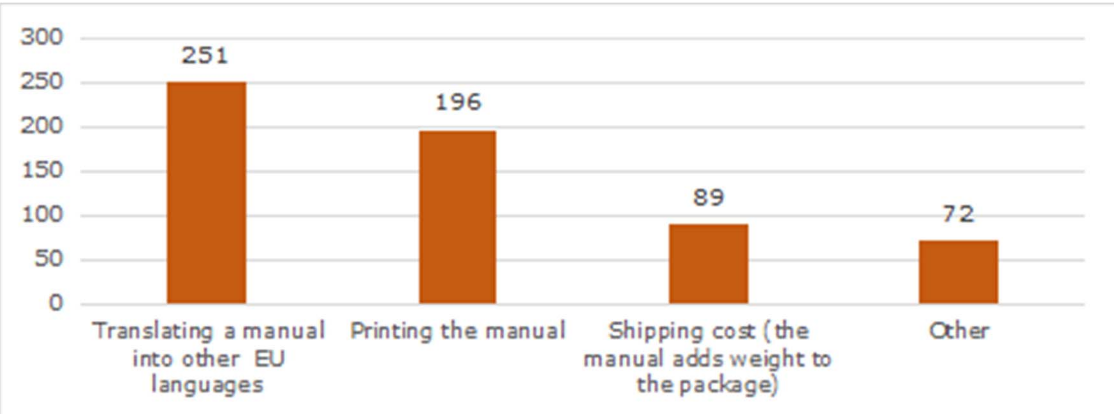


Source: Open Public Consultation (n=523; multiple answers possible)

Private users and researchers/academics chose the option that users would print only the relevant parts most often. Stakeholders involved in standardisation chose the options that only the translations would be printed and that the access without internet would be more difficult equally often (43%). While the latter potential impact of a switch to digital manuals was chosen by most companies, SMEs mentioned it more often (61%) than large companies (53%).

Currently, the manuals are provided in paper form. To assess the potential cost-savings of switching to online manuals only the participants were asked what the current costs are in relation to preparing the manuals. Most costs are related to the translation of the manuals to the EU languages where the product is placed on the market (48%). Printing the material was mentioned by 37% of the respondents as well.

Figure 63: Current costs related to the preparation of the manuals



Source: Open Public Consultation (n=62; multiple answers possible)

When looking into printing volumes, the data indicated by companies had caveats due to differences in reporting types and specificities on the machinery developed that needs accompanying user manuals. Of the responses, the average indicated number of sheets of paper per year is 31 million for large companies and almost 2 million for SMEs. Regarding the cost savings of switching to online manuals, most respondents indicated that they would apply to the printing and paper costs only, as other costs such as translation fees would still occur. The indicated share of cost savings applies also for the option of having only online manuals.

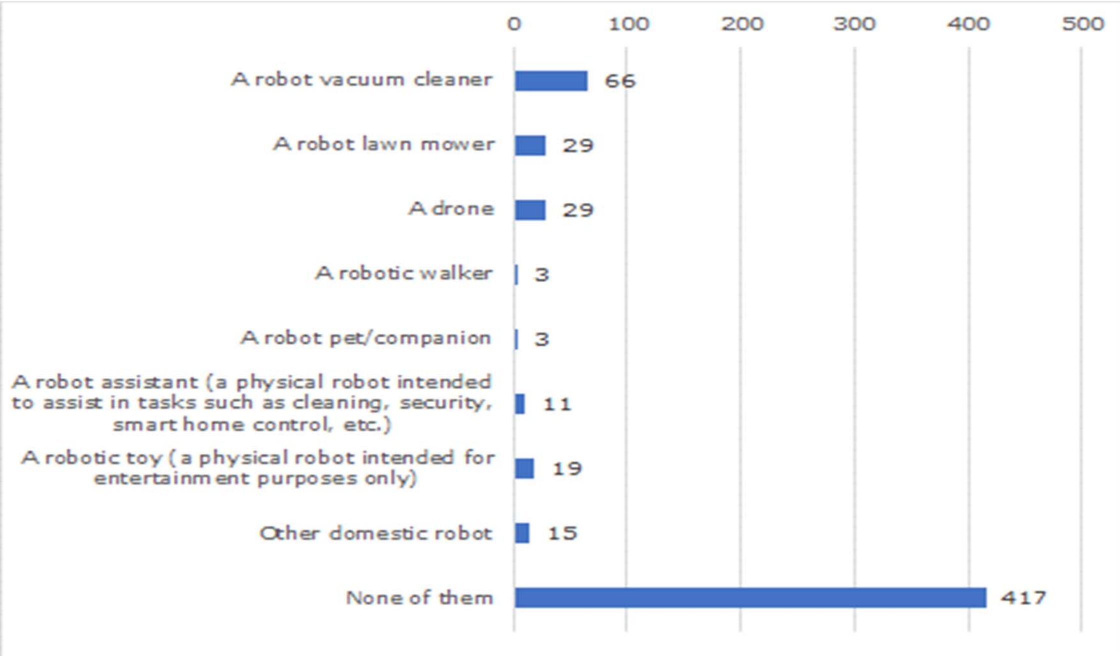
Some of the benefits indicated by respondents irrespectively of the quantitative savings are environmental as less sheets of paper would be needed, technical advantages (e.g. for updates or quick search for information) and knowing that the manuals would not be lost. However, a number of respondents also indicated that the development and maintenance of the database would generate initial costs to recurring costs with a switch to digital documentation.

New technologies

IoT, robots and new technology in machinery

To date, the vast majority of respondents do not own any domestic robot (79%). Those that indicated having at least one mentioned owning a robot vacuum cleaner (66 mentions). Owning a robot lawn mower and a drone were mentioned 29 times (see Figure 64).

Figure 64: Current or previous ownership of autonomous domestic robots



Source: Open Public Consultation (n=155; multiple answers possible)

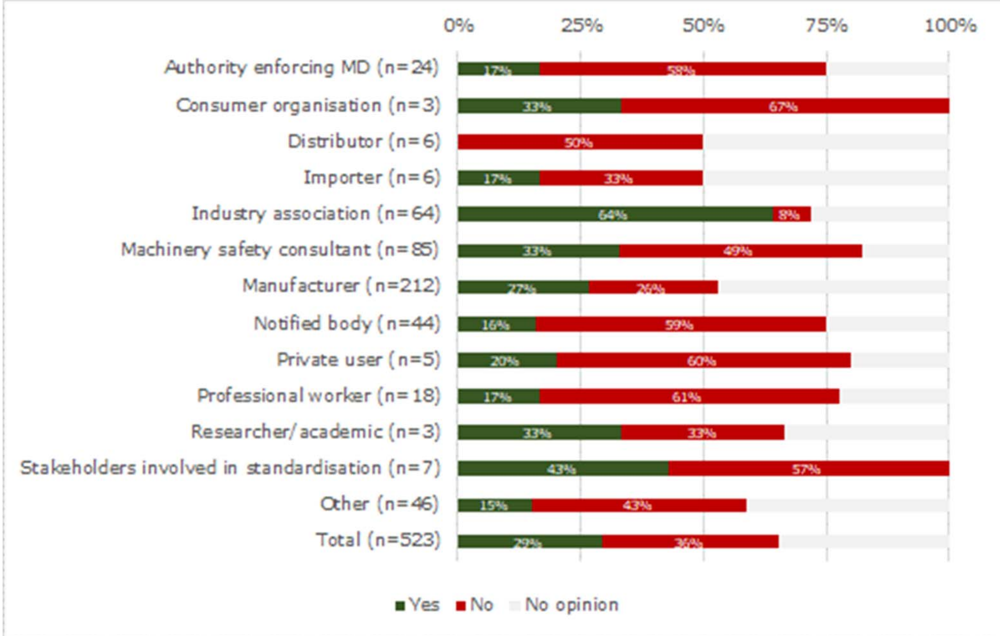
Of those respondents that own a domestic robot, about 80% had purchased them in the EU, EFTA, Switzerland or Turkey (Q49). However, most of the domestic robots are not connected to the internet (59%), compared to about one-third possessing an internet connection (30%).

Most respondents (81%) indicated that they had also not encountered situations in which their safety or that of someone else was at risk (Q51). However, 12% mentioned that they did experience such situations. The exception are consumer organisations (67%) and professional workers (75%), which indicated the opposite. Of those 14 respondents, 13 indicated that the machinery that caused the problem had been purchased in the EU, EFTA, Switzerland or Turkey.

When it comes to safety, security or privacy concerns regarding house appliances with internet connection, over one-third of the respondents indicated to not buy such appliances (38%). This is followed by respondents using the internet connection only when necessary or by taking other measures (e.g. covering the camera or disabling the microphone) (19%) or using the internet connection regardless of having such concerns (17%).

Regarding human-robot collaboration, more respondents indicated that the safety is not sufficiently covered by the current MD (36%) than those indicating it does (29%). The exception are industry associations, for which 64% indicated that it is sufficiently covered by the Directive.

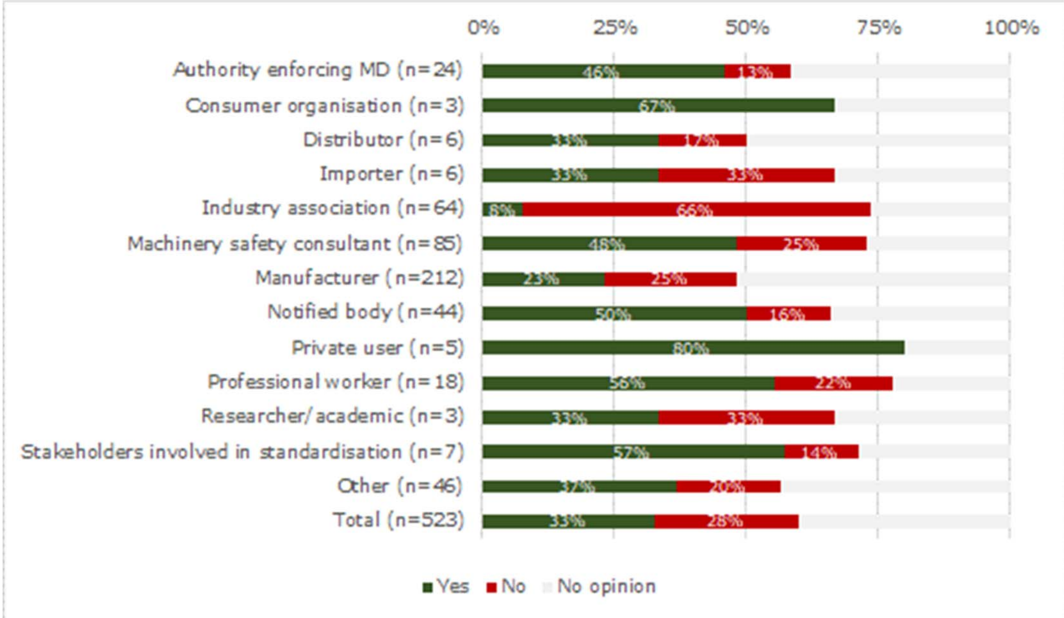
Figure 65: The Machinery Directive sufficiently covers human-robot collaboration



Source: Open public consultation

The majority of respondents had no clear preference on whether the EHSR should be adapted to take into account humans and robots sharing a space (40%). However, more SMEs and other respondents indicated this option positively than negatively. Only large companies were slightly more against the option (32%) than for it (31%). Here, only industry associations strongly opposed the option of adapting the EHSRs (66%).

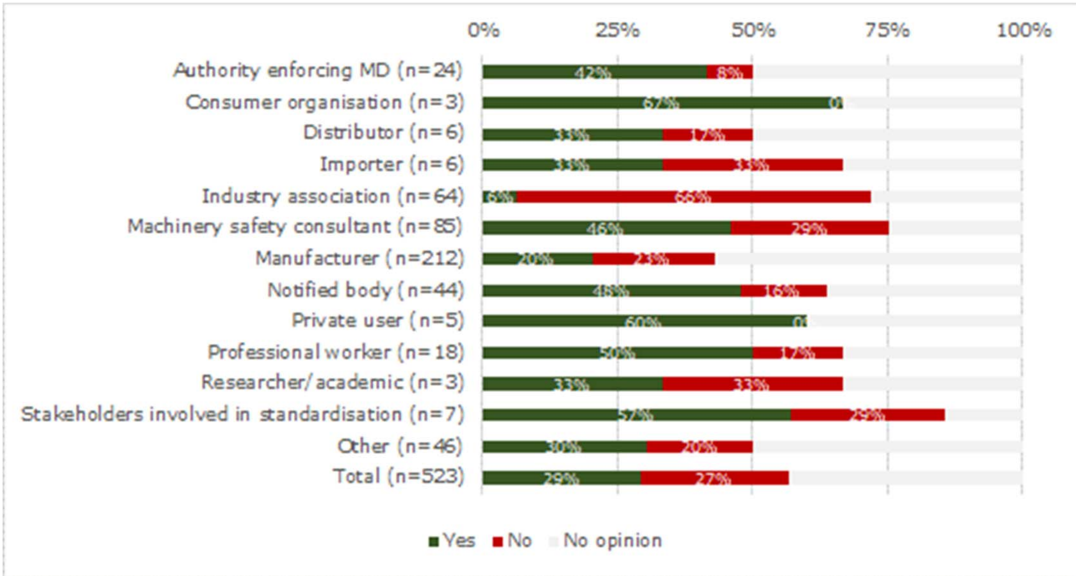
Figure 66: The EHSR should be adapted to account for human and robots sharing space



Source: Open public consultation

Similar responses were given on the question whether new EHSR should be included in order to take into account the human-robot collaboration (43% of respondents indicated no preference). However, SMEs, large companies and other respondents indicated a slight preference to add new standards rather than not. Again, of all the stakeholder groups, only industry associations were strongly against this option (66%).

Figure 67: New EHSR should be added to account for humans and robots sharing a space



Source: Open public consultation

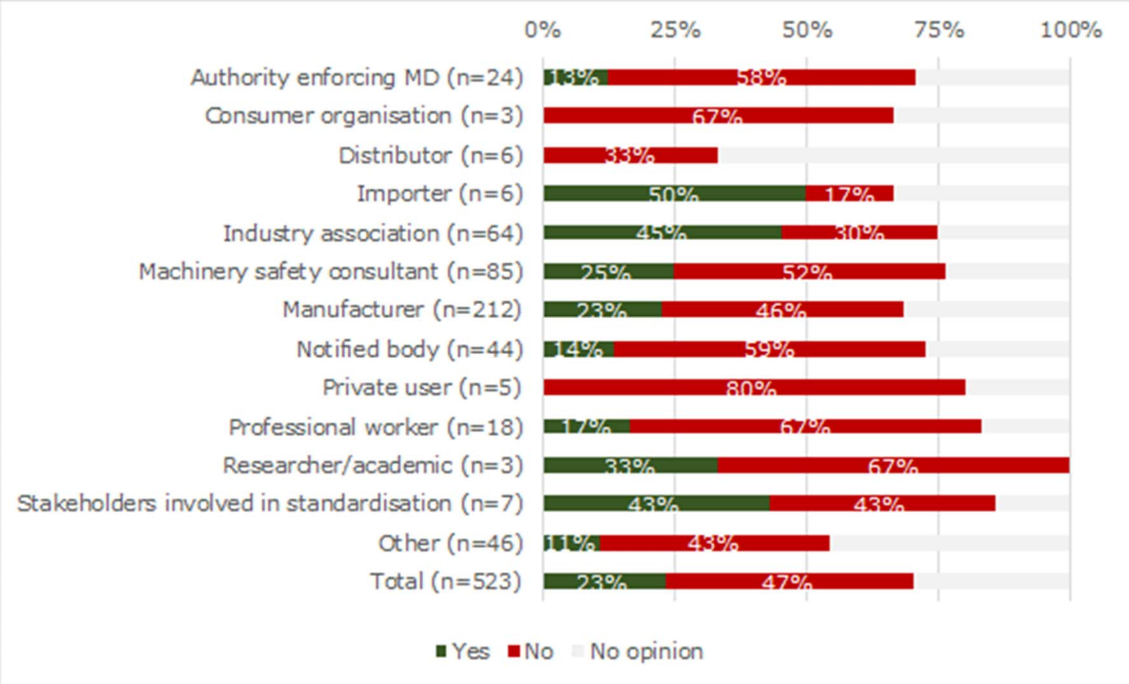
Apart from humans and robot sharing a space and human-robot collaboration, some of the respondents mentioned additional fields that, according to them, might require adapting the

EHSR. Among these, are robots moving freely in the workspace (risk of accidental collision and mandatory distances, applied force and contact surfaces), IT connections of between work equipment, risks during maintenance, scope and limitation of AI and IoT, and failure of safety related control software and components.

By contrast, other respondents believe that specific provisions should be left outside the ESHR, as additional technology requirements can be specified more effectively in harmonised standards in coordination with notified bodies and companies. Moreover, several respondents mention a number of existing harmonised standards for robots which are not under review and could provide effective examples.

Cybersecurity was another topic covered by the consultation. On the question whether the MD covers cyber threats affecting health and safety (e.g. through hacking and taking control of robots), most respondents said it is not (47%), followed by no opinion (30%). The exception are importers and industry associations, which rather indicated that it is sufficiently covered (50% and 45% respectively).

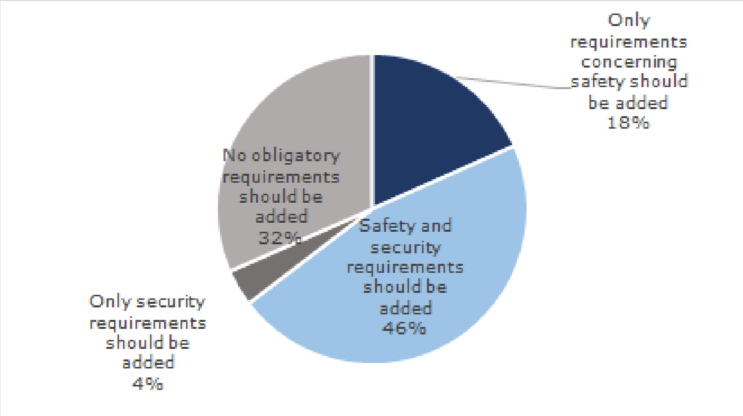
Figure 68: Does the Directive cover cybersecurity sufficiently?



Source: Open public consultation

According to the respondents, rather only safety and security requirements should be added, if it was to be covered by the MD (see Figure 69). While most stakeholder groups supported this option, the majority of industry association and distributors answered that no obligatory requirements should be added (67%).

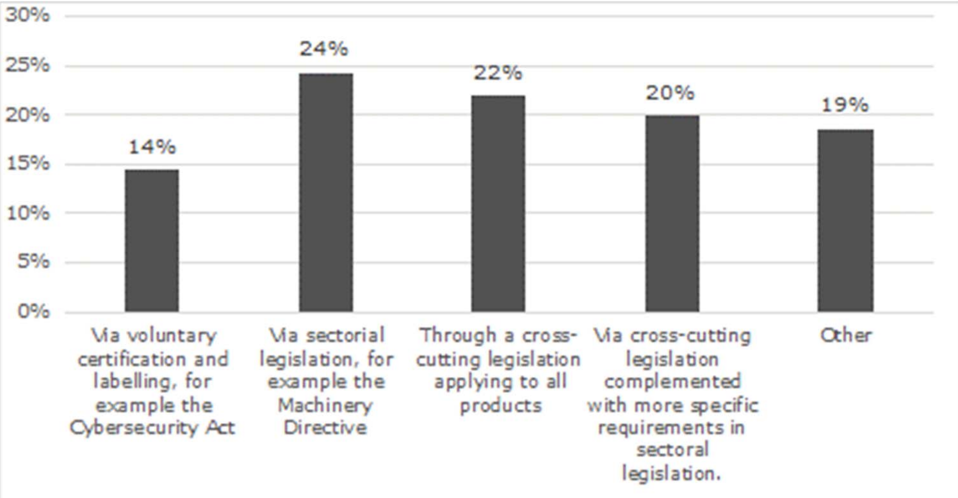
Figure 69: What requirements on cybersecurity, if any, should be added?



Source: Open Public Consultation (n=523)

If cybersecurity requirements for manufacturers was to be implemented by the EU as a whole, there were little differences in preferences between a sectorial legislation such as within the MD (25%), a cross-cutting legislation across products (22%) and a cross-cutting legislation with specific requirements (20%) (see Figure 70). This tendency is also present within the responses recorded by each stakeholder group.

Figure 70: How should cybersecurity requirements for manufacturers of machinery be implemented in the EU?



Source: Open Public Consultation (n=523)

Differences in stakeholder groups are shown in the table below.

Table 67: How should cybersecurity requirements for manufacturers of machinery be implemented in the EU, by stakeholder group

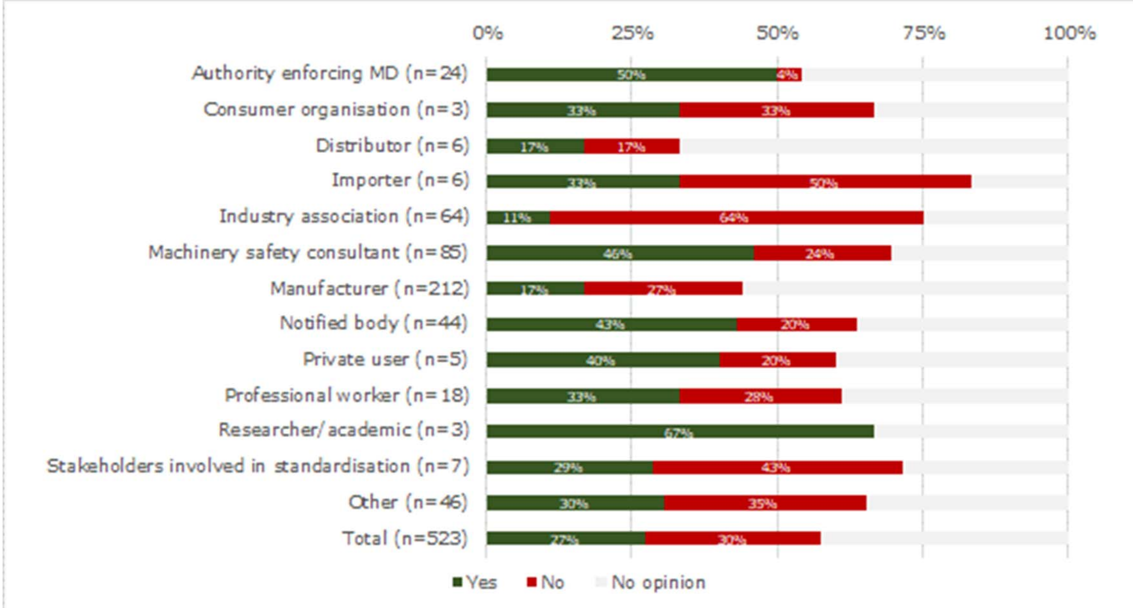
	Via voluntary certification and labelling, e.g. the Cybersecurity Act	Via sectoral legislation, e.g. the Machinery Directive	Through a cross-cutting legislation applying to all products	Via cross-cutting legislation complemented with more specific requirements in sectoral legislation	Other
Authority enforcing MD (n=24)	4.2%	20.8%	25%	37.5%	12.5%
Consumer organisation (n=3)	0%	66.7%	0%	33.3%	0%
Distributor (n=6)	16.7%	0%	0%	33.3%	50%
Importer (n=6)	33.3%	16.7%	16.7%	16.7%	16.7%
Industry association (n=64)	15.6%	17.2%	18.8%	10.9%	37.5%
Machinery safety consultant (n=85)	12.9%	29.4%	28.2%	23.5%	5.9%
Manufacturer (n=212)	17%	28.8%	22.6%	16.5%	15.1%
Notified body (n=44)	15.9%	15.9%	18.2%	18.2%	31.8%
Private user (n=5)	0%	20%	0%	60%	20%
Professional worker (n=18)	5.6%	33.3%	22.2%	38.9%	0%
Researcher/academic (n=3)	0%	33.3%	33.3%	33.3%	0%
Stakeholders involved in standardisation (n=7)	14.3%	14.3%	42.9%	14.3%	14.3%
Other (n=46)	13%	15.2%	19.6%	21.7%	30.4%
Total (n=523)	**14.5%**	**24.5%**	**22.2%**	**20.1%**	**18.7%**

Source: Open public consultation

Artificial intelligence and machine learning

Many respondents did not have any preference on whether the **MD should explicitly address transparency of algorithms and datasets** (42%), followed by 30% negating that it should. Large companies were rather against addressing transparency of algorithms in the Directive (22% "yes", 36% "no") in contrast to SMEs which were slightly more in favour than against (24% "yes", 22% "no"). There are differences between manufacturers of special machinery. Most strongly opposing the transparency of algorithms were manufacturers of nuclear machinery (75%), followed by pressure equipment (59%) and electrical equipment (51%). No preference or opinion was indicated by manufacturers of lifts (68%).

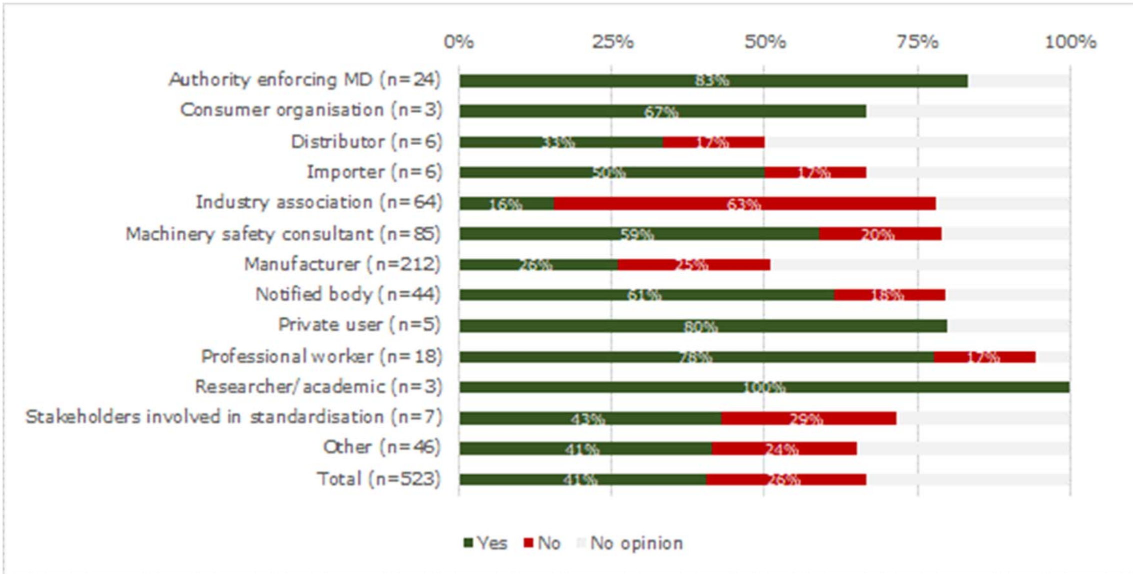
Figure 71: The MD should explicitly address transparency of algorithms and datasets



Source: Open public consultation

When it comes to whether the MD should explicitly address software updates, most respondents answered that it should (41%). In comparison, only 26% indicated it should not. Only the majority of the industry associations answered that it should not be addressed (63%). No preference was given by distributors and manufacturers. Large companies showed a slight preference for the Directive addressing software updates (36%) while SMEs showed no strong opinion (45% "no opinion").

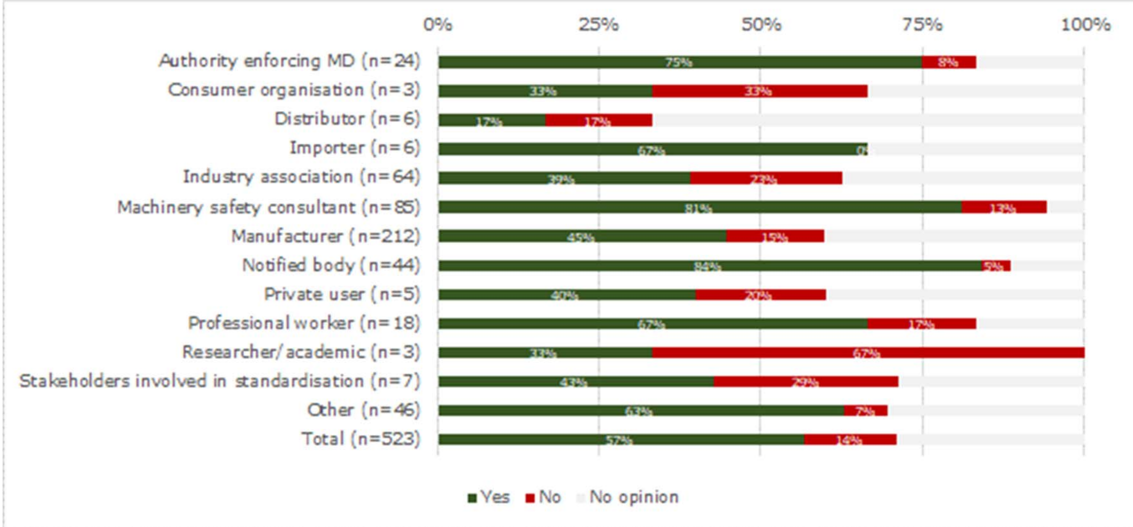
Figure 72: The MD should specifically address software updates



Source: Open public consultation

In addition, the majority of respondents think that software which ensures a safety function and is placed independently on the market should be explicitly covered by the MD and be considered a safety component (Art. 2(c) (57%). SMEs showed stronger preference for this option (61%) than large companies (48%). Comparing stakeholder groups, especially notified bodies showed preference towards this option (84%), followed by machinery safety consultants (81%) and authorities enforcing the Directive (75%).

Figure 73: The MD should cover independent software as safety component



Source: Open public consultation

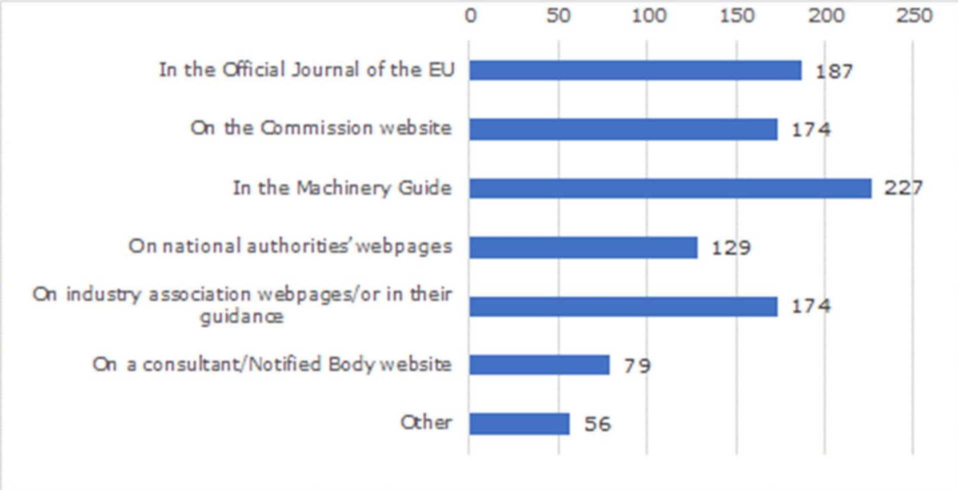
The concept of placing on the market is considered still relevant when software updates are added later on to the machinery by the majority of respondents (58%). This is the same for the concept of foreseeable misuse as defined in the MD (65%).

Clarity of information and framework to use, changing scope and definitions and other criteria

Identifying the right legislation

When producing, importing or distributing machinery, organisations have different sources they can access for information. Most of the different options are mentioned more or less equally frequent (33-43%). Amongst the most mentioned sources is the Machinery Guide, the Official Journal of the EU, the Commission website and the industry association webpages and guidance. Many of the respondents, however, did not provide any indication of a source (45%).

Figure 74: Source of information when producing, importing or distributing machinery

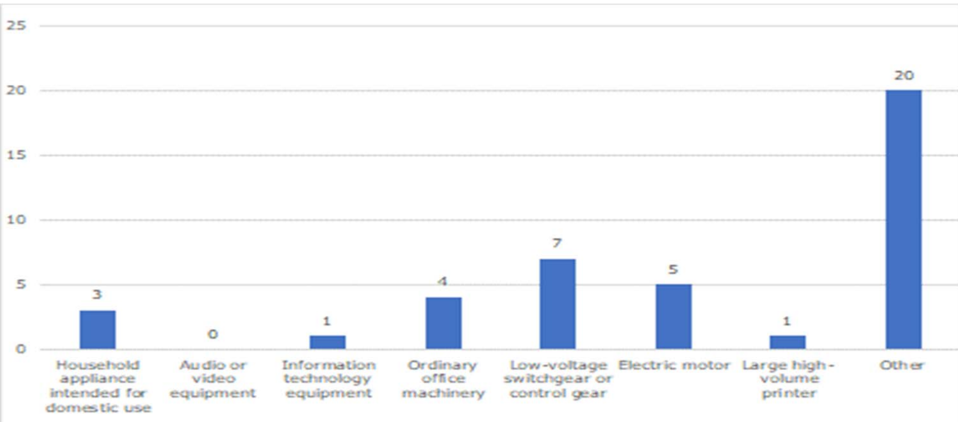


Source: Open Public Consultation (n=288, multiple answers possible)

The Machinery Guide as source for information was chosen by 87% of large companies and 64% of SMEs, followed by the Official Journal of the EU. Large companies indicated more often to use other options as well, e.g. the Commission website (65%) or industry association websites (61%).

The question whether there were any difficulties to identify the right legislation to obtain CE marking was answered by importers, industry associations and manufacturers. Most of those respondents did not encounter such difficulties (65%). About one in three respondents on the other hand still found it difficult (31%). The appliances that caused the difficulty of understanding were mostly other products not listed in the questionnaire (49%). Of those listed, the low-voltage switchgear or control gear was mentioned to cause some difficulties by 17% of the respondents, followed by electric motors (12%), ordinary office machinery (10%) or household appliances intended for domestic use (7%) (see Figure 75).

Figure 75: Type of machinery that caused difficulty of understanding the right piece of legislation to use (Q60)



Source: Open Public Consultation (n=41; multiple answers possible)

SMEs mentioned difficulties with housing appliances, ordinary office machinery, electric motors and other products, while large companies also experienced some difficulties in relation with low-voltage gear and large printers. The respondents also indicated that they had encountered problems in ensuring compliance with their product (71%). In about half of the cases, national authorities have questioned the respondents' decision on which directive or national rules to apply (44%). The exception are industry associations, which indicated more often that they have had national authorities questioning their compliance (9 out of 11).

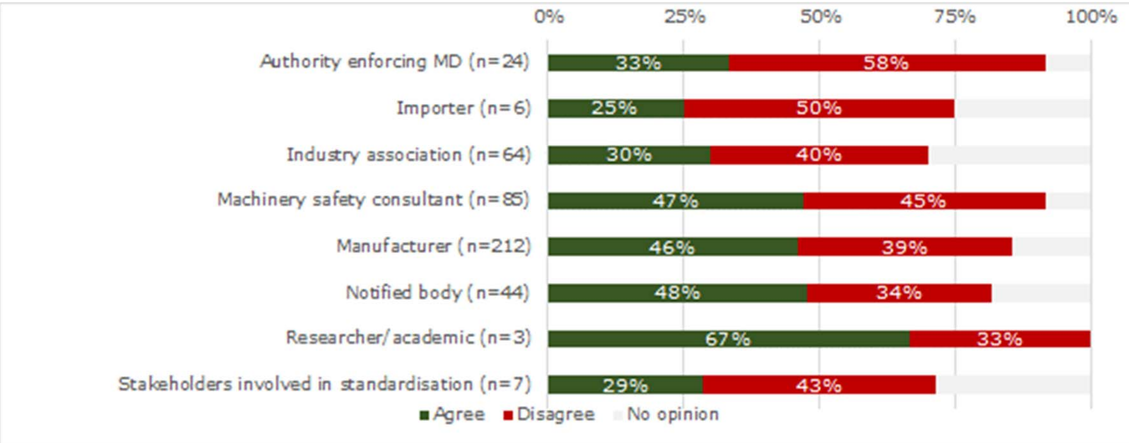
Low voltage machinery

When it comes to the question whether the exclusions of certain low voltage machinery from the scope of the Machinery Directive (Art. 1.2(k)) had caused any problems, over half of the respondents indicated that this was not the case (58%). About 19% had encountered problems due to the exclusion of these types of machinery. The question whether there had been enforcement or standardisation problems due to the exclusion of certain low voltage machinery was answered by authorities enforcing the Directive, machinery safety consultants, notified bodies, researchers/academics, and stakeholders involved in standardisation. The majority of those answered that they had not (57%) experience any problems, compared to 17% who indicated that they had. Not much difference between the different types of stakeholders was identified.

Stakeholders were provided with different alternative solutions to prevent future confusions or improve compliance, but none of the alternative options were preferred by a majority of respondents. However, there are some differences in preferences across the stakeholder groups that answered these questions.

Manufacturers, machinery safety consultants, notified bodies and researchers, for instance, were rather in favour of differentiating the products. Those respondents manufacturing electrical equipment were slightly more for the differentiation of consumer and professional products (41%) than against (40%). Thus, no clear preference can be derived from this result. Manufacturers of lifts were more strongly opposed (73%) while manufacturers of nuclear machinery agreed with the alternative solution (75%). Most authorities enforcing the Machinery Directive opposed the option of differentiating between consumer and professional products (58%) and most stakeholders involved in standardisation rather disagreed than agreed to this alternative. Notified bodies were, in comparison, more approving of the solution (48%) than disapproving (34%).

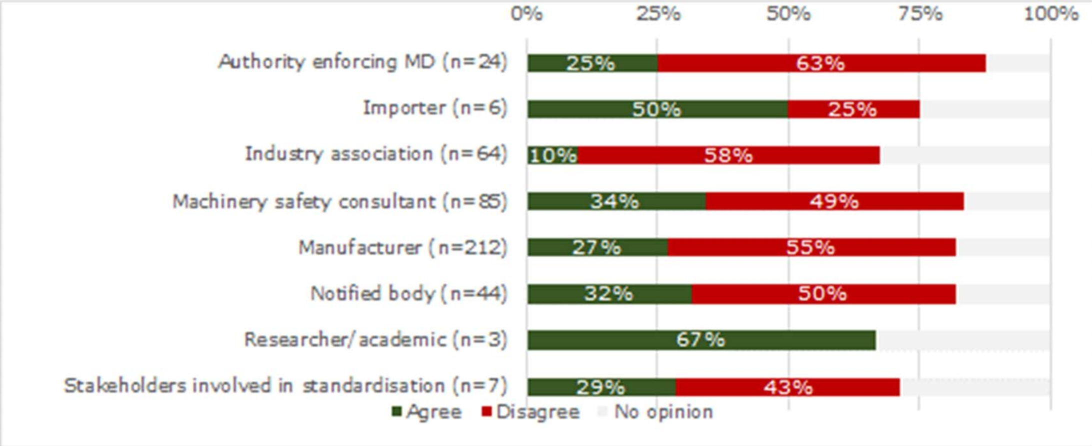
Figure 76: Respondents' opinion on differentiating between consumer and professional products for Art. 1.2(k), by stakeholder group



Source: Open public consultation (n=296)

Another proposed solution was to remove the exclusion of the low voltage products in Art. 1.2(k). The majority of stakeholder groups rather opposed this option, such as authorities enforcing the Directive (63%), industry associations (58%), machinery safety consultants (49%), manufacturers (55%), notified bodies (50%) and stakeholders involved in standardisation (43%).

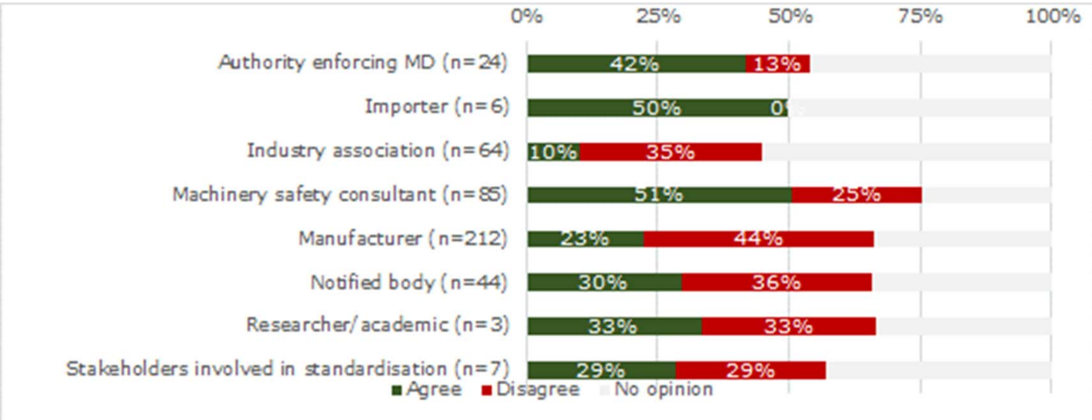
Figure 77: Respondents' opinion on removing the exclusion of low voltage products in Art. 1.2(k), by stakeholder group



Source: Open public consultation (n=296)

Finally, on the question whether more harmonised standards could benefit the application of the Directives and the respective exclusions, the responses were varied. Authorities, importers, and machinery safety consultants were rather in favour. In comparison, industry associations, manufacturers and notified bodies were rather opposed.

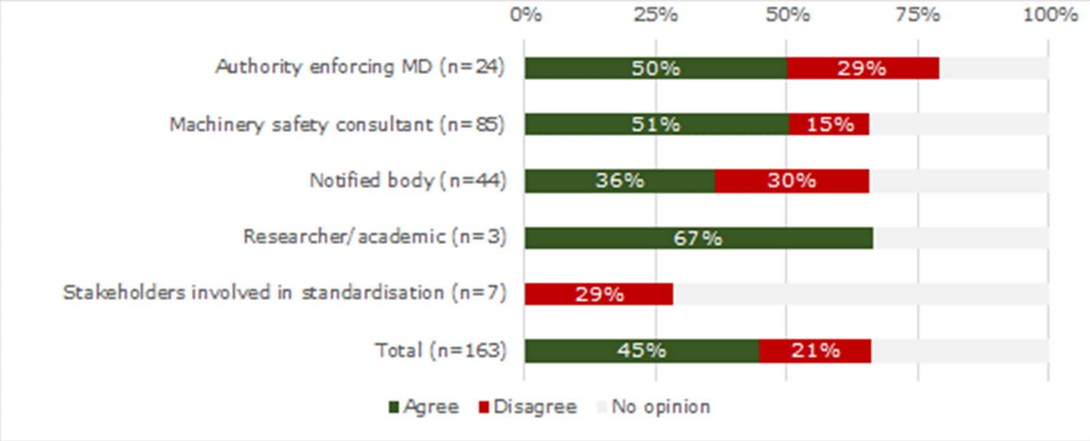
Figure 78: Respondents' opinion on more standards facilitating the compliance or enforcement of Art. 1.2(k), by stakeholder group



Source: Open public consultation (n=296)

More respondents, however, indicated that the changes in general would facilitate the enforcement of the Machinery Directive process (45%) rather than not being beneficial (21%). Stakeholders involved in standardisation do, however, not expect the suggested changes to facilitate the standardisation process.

Figure 79: Respondents' opinion on the suggested solutions' impact on facilitating enforcement or standardisation, by stakeholder group

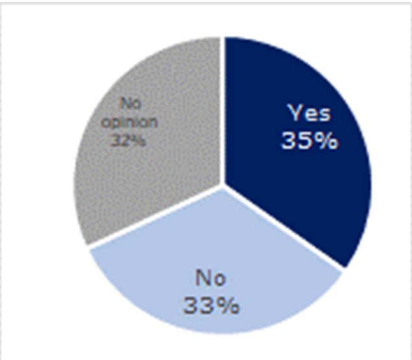


Source: Open public consultation

The changes were not expected to result in additional cost for the respondents' administrations (52%). Increased costs were expected by 5% of the respondents. 12 of 27 respondents (44%) indicated that the changes would impact the annual costs for enforcement and/or standard setting.

The respondents from the industry were not in line regarding whether some one-off investments (e.g. staff training, new equipment) would be required if any of the alternative options or changes were to be pursued (Q68) (see Figure 80).

Figure 80: Would the changes require one-off investments?

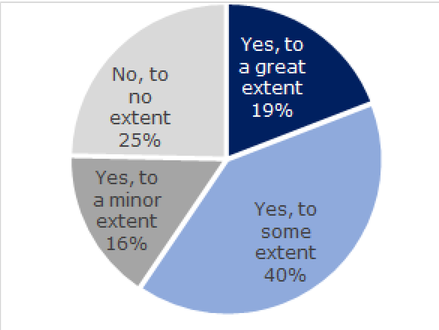


Source: Open Public Consultation (n=133)

SMEs indicated more that they would expect the changes to require one-off investments (43%) than large companies (29%). Of the respondents indicating that some one-off cost investments as necessary, over half indicated that they would not consider them as significant (56%). Most SMEs, however, indicated the initial costs of changes as significant (56%). Overall, most respondents (65%) estimated that their recurrent annual costs of compliance with the Directive requirements would not change if any of the alternative options on the exclusion of certain low voltage machinery were to be applied. About 20% indicated that there would be increased costs. Considering the respondents that indicated an effect on the costs of compliance, over half of them considered them as significant (55%).

Regarding the coherence of the EHSR 1.5.8 on noise with the requirements of the Outdoor Noise Directive (2001/14/EC), the majority of respondents indicated that there is – either to a great extent or some extent (59%) (see Figure 81).

Figure 81: Are the EHSR 1.5.8 on noise coherent with the requirements of the Outdoor Noise Directive?

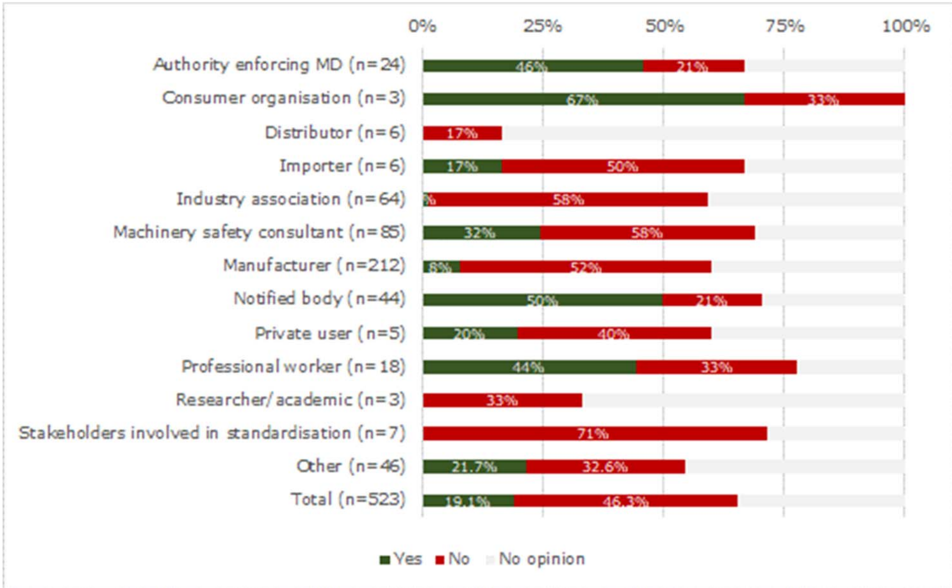


Source: Open Public Consultation (n=523)

Pressure equipment category I

Regarding the exclusion of pressure equipment category I from the Pressure Equipment Directive 2014/68/EU (Q86) and whether it leads to increased safety concerns, most respondents indicated that it does not lead to safety concerns (46%), compared to 19% of respondents indicating that it does. The opinions differentiated between stakeholder groups. Here, half of the notified bodies indicated that the exclusion of pressure equipment category I from the PED does lead to safety concerns (50%). About 71% of stakeholders involved in standardisation indicated that it does not. Most manufacturers focusing on different types of machinery indicated no safety concerns from the exclusion.

Figure 82: PED exclusion increases safety concerns



Source: Open Public Consultation (n=523)

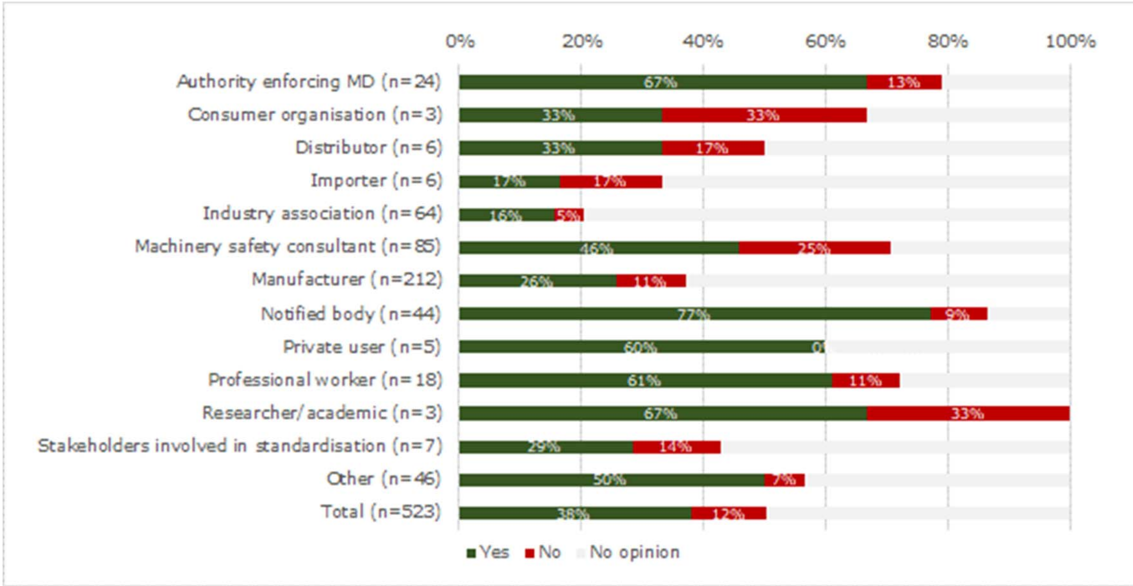
Whether it would be beneficial to apply the Pressure Equipment Directive in addition to the Machinery Directive when it comes to pressure equipment category I did not yield clear results. About the same share of respondents indicated that it would not be beneficial (39%) as those that did not have an opinion (38%). In comparison, 24% answered that it would have a benefit. Some stakeholder groups indicated more preference towards applying the PED and the MD in parallel, namely authorities enforcing the Machinery Directive (58%), notified bodies (50%), private users and professional workers (44%). Importers and industry associations mostly opposed this option (67% and 52% respectively).

Most respondents, however, did not expect any changes in terms of costs to their organisation, would the approach be adapted (70%). Almost all remaining respondents expected their costs to increase (28%) rather than being reduced (2%). Increased costs are expected by manufacturers of pressure equipment (61% of respondents) and nuclear machinery (88% of respondents).

Slow speed lifts

In terms of low speed lifts being covered by the Machinery Directive, the question whether an increase of the maximum speed from 0.15 m/s to 0.50 m/s would create safety problems appeared to be too technical for the respondents, with 50% providing no opinion. 38% indicated that it would create safety problems, compared to 12% who answered it would not. Most notified bodies (77%) expect safety problems to arise with an increase of speed limits, followed by authorities enforcing the Directive (67%). Especially manufacturers of lifts see a potential increase of the speed limits of slow-speed lifts leading to safety concerns (78%).

Figure 83: Increase of threshold speed for slow-speed lifts leads to safety concerns

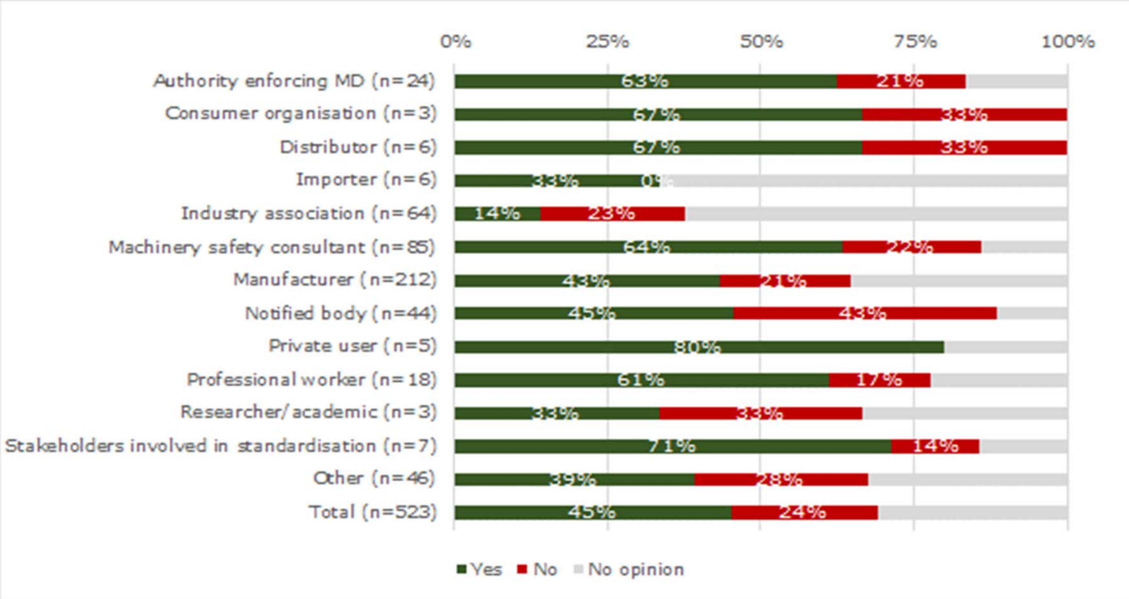


Source: Open public consultation

If the speed limit was to be increased, the vast majority of respondents would not expect the costs for their organisations to change (91%). Related to this question is the topic of lifting platforms without completely enclosed carriers needing to include a hold-to-run button. To the question whether this safety requirements should be revised to allow innovative technologies to be used (e.g. light barrier curtains), 45% of the respondents indicated “yes” and 24% “no”. If the safety requirements were to be changed, the large majority of respondents would not expect a change in the costs for their organisation (78%).

Related to the question of changing requirements on carrier and run-control for low-speed lifts is question 118, to revise safety requirements to allow for innovative technologies such as light barrier curtains. Manufacturers had generally no clear preference on this question with the exception of lift manufacturers, of which 64% negated that it should be revised.

Figure 84: The requirements for carriers or run-controls for slow-speed lifts should be revised



Source: Open public consultation

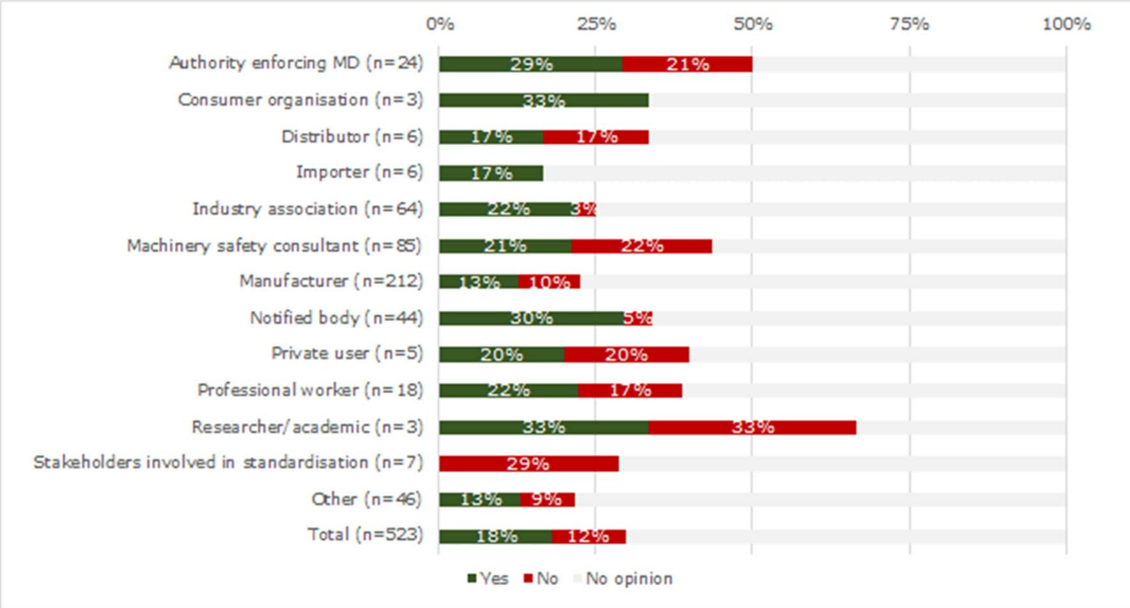
On the issue of what specific provisions to include, respondents' opinions diverged. Some of them listed specific points, including: a requirement for light barrier curtains to have a reaction time at least equal to hold-to-run buttons to be integrated under Annex V; the possibility to use only partially closed supports should be left for industrial elevators only; the merging of the MD with the Lifts Directive 2014/33/EU so as to avoid gaps and overlaps.

While some respondents criticised specific technological innovations (i.e. light barrier curtains not being as safe as physical doors in all situations), several respondents made the general argument that the MD cannot match the pace of innovation and list all state-of-the-art technology. Therefore, a list of innovative technologies and specific safety requirements should be covered under a more flexible framework and harmonised standards, while the MD would only set out clear general safety requirements and legal responsibility of the manufacture.

Machinery for nuclear purposes

When it comes to the MD excluding machinery especially designed for nuclear purposes that may result in an emission of radioactivity in the event of failure and whether the exclusion of the machinery should refer only to machinery that might result in a direct emission of radioactivity of the machinery itself, rather than indirectly, the vast majority of respondents had no opinion (70%). This suggests that also this question was too technical or out of scope for the respondents. About half of the respondents that manufacture nuclear machinery (50%) indicated rather disapproval to the exclusion.

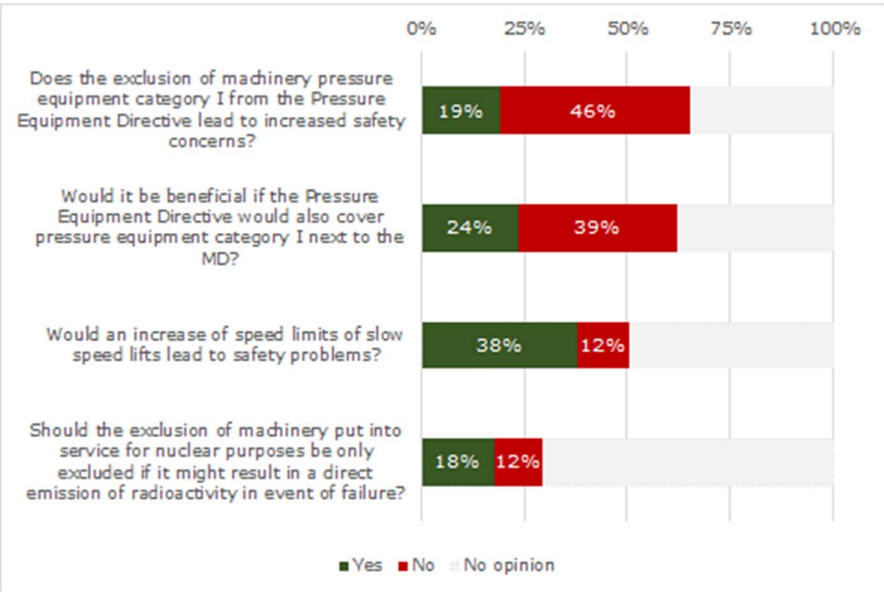
Figure 85: OPC responses on the exclusion of the machinery specially designed or put into service for nuclear purposes, which may result in a direct emission of radioactivity by the machinery itself



Source: OPC results (n=523)

If the exclusion was to be changed, almost all respondents would not expect a change in the costs for their organisation (93%). None would expect the costs to decrease due to the changes, however. Manufacturers of nuclear machinery were split between expecting costs to increase with changes and no costs expected.

Figure 86: Responses regarding the relation between the MD and other Directives



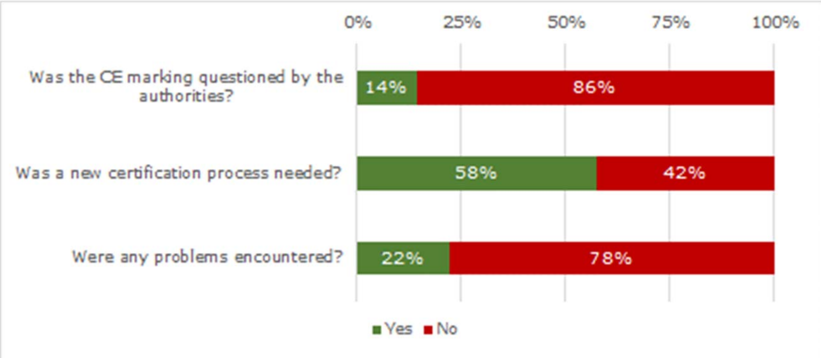
Source: Open Public Consultation (n=523)

Definitions and criteria

The MD applies to products placed on the market for their intended use as described and defined by the manufacturer's instructions. Following the need of establishing criteria for machinery substantially modified during their use that require new declaration of conformity, the PC asked distributors, importers, industry associations and manufacturers whether they had ever modified machinery during its use (Q101). More than half of the respondents indicated that they had modified the machinery during the use (53%). Large companies indicated to have done so more often (58%) than SMEs (48%).

Of those that had done so, the vast majority had their CE marking not questioned by the authorities (86%). The CE marking had been questioned in more instances with SMEs (19%) than large companies (10%). The majority also had to go through a certification process again (58%), SMEs indicated to have done so more often (59%) than large companies (51%) - but the respondents mentioned they did not encounter any problem (78%).

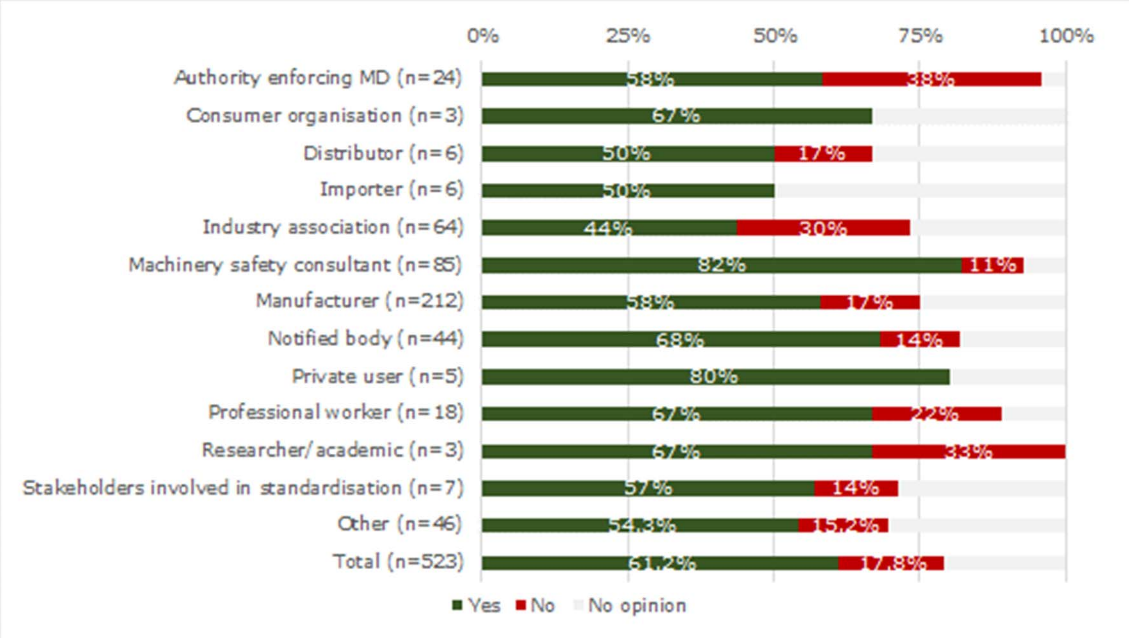
Figure 87: Outcome of substantial modification of machinery during its use



Source: Open Public Consultation (n=153)

Overall, the majority of respondents indicated that the Directive should define criteria for machinery that is substantially modified (61%), compared to 18% who indicated that it should not. The majority of all stakeholder groups with the exception of industry associations preferred the MD to define criteria of substantial modification to be added (see Figure 88). SMEs showed more preference for defining criteria (70%) than large companies (56%).

Figure 88: MD should define criteria for substantial modification



Source: Open Public Consultation (n=523)

Regarding the specification of substantial modification, the most common responses in the consultation mention the Blue Guide on the implementation of the EU regulation on products 2016 (section 2.1, pp. C272/16 to 17) and the flowchart developed by the German Labour Ministry. Several respondents indicated that these criteria are well defined based on the risk assessment factor. The blue guide specifies the need for a new conformity assessment "if the risk assessment leads to the conclusion that the nature of the [safety] hazard has changed, or the level of risk has increased"[349]. This type of specification of criteria is available under the Guide to application of the Lifts Directive page 39. Such a clarification or description included in the Machinery Guide was considered as useful by the majority of respondents.

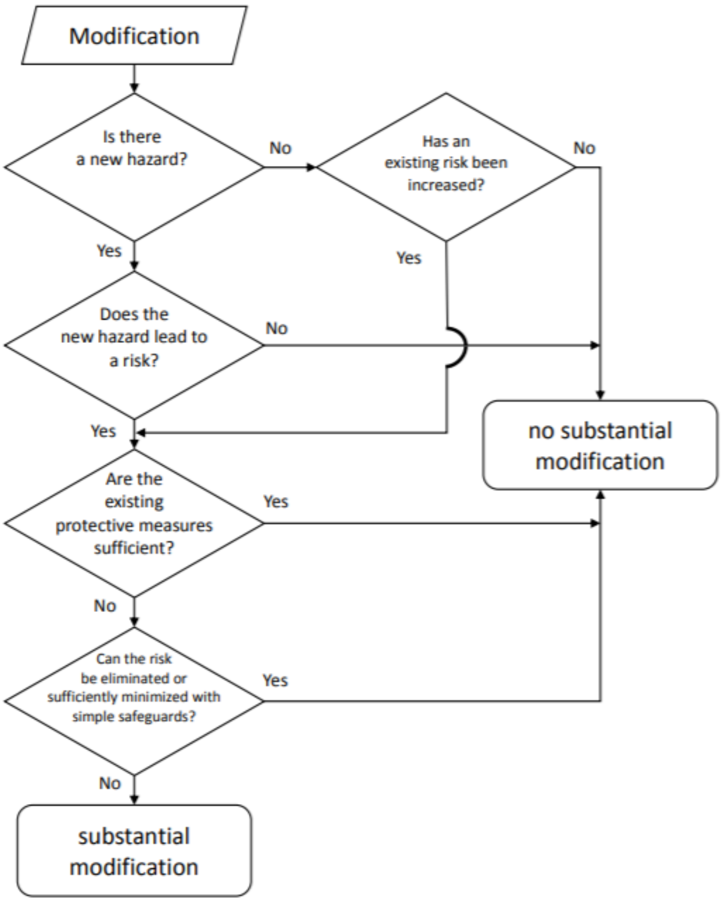
The majority of respondents agree on keeping the risk-based definition, specifying that the criteria relevant to substantial modification shall comprise:

- Different risks after modification;
- New risks after modification;
- Higher risk levels or hazards after modification; and
- Enhanced performance, new functions or fundamental changes in function (e.g. power increases).

In addition, the visualisation of this risk assessment after modification made by the German Federal Ministry of Labour is given as best practice by several respondents of various countries (see Figure 30).

[349] European Commission (2016). Blue Guide on the implementation of EU products (2016/C 272/01), pp. 16. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726(02)&from=BG

Figure 89: Decision steps substantial modification of machinery



Source: German Federal Ministry of Labour and Social Affairs (2015)[350]

Respondents have also indicated that it would be useful to have a valid EU-wide interpretation of substantial modification as the current national interpretive papers such as by Germany or France are not automatically used throughout the whole EU.

One shortcoming related to the unequivocal definition is said to bring too much flexibility to modification without re-assessment of risks. Examples of explicit entries to counter this shortcoming are:

- "A change in the safety function on the machine should require a re-assessment of the risk and proof that the Performance Level safety level is of the same value or higher";
- "Replacement of worn equipment should require proof that the machine's parameters have not changed"; and

[350] Available at: https://www.bmas.de/SharedDocs/Downloads/DE/Thema-Arbeitsschutz/en-interpretation-paper-substantial-modification-to-machinery.pdf;jsessionid=9ABA14919A0962CC5CEB2A556218990E?__blob=publicationFile&v=1

- "The changes carried out require a risk assessment process and demonstration that the machine does not pose additional risks after modification".

Another suggestion provided is to give a list of different European interpretations in all languages under one official webpage. Furthermore, it was specified that the person conducting the modification should be considered the manufacturer after substantial modification as this is often carried out by another party than the original manufacturer.

Several respondents have also indicated that providing specific examples of substantial modifications in the Blue Guide or the Machinery Guide could be useful.

If criteria were to be defined in the Directive, most respondents[351] would not expect a change in their costs for their organisation (71%). About 16% expect the changes to lead to reduced costs.

When it comes to the definitions within Article 2(a), partly completed machinery (PCM) cannot perform a specific application. The term "specific application" is not defined, however. Most respondents indicated that this did not cause any problems. On the other hand, the problems of it leading to a wrong classification of the product and the manufacturer of partly completed machinery not fulfilling all the applicable safety requirements were mentioned almost as often (192 and 180 mentions respectively).

Some differences across stakeholder groups were recorded. The majority of distributors and industry associations did not experience any problems with the current definition of partly completed machinery, while importers and notified bodies indicated that it had led to wrong classification. The majority of machinery safety consultants, professional workers and stakeholders involved in standardisation indicated that it had led to problems with the CE marking (see

[351] Respondents to this question: distributors, importers, industry associations and manufacturers

Table 68). Most SMEs experienced wrong classification of partly completed machinery (47%), while large companies indicated not having experienced any problems (49%). For manufacturers, the majority of nuclear machinery manufacturers indicated problems with wrong classification (7 out of 8). Nevertheless, most of them did not prefer having a change of definition of PCM in the Directive (6 out of 8).

Table 68: Problems encountered with the definition of partly completed machinery

	Q113.1: Partly completed machinery - wrong classification	Q113.2: Partly completed machinery - problems with the CE marking	Q113.3: Partly completed machinery - other problems experienced	Q113.4: Partly completed machinery - no problems experienced
Authority enforcing MD (n=24)	**41.7%**	25.0%	16.7%	29.2%
Consumer organisation (n=3)	0.0%	33.3%	33.3%	33.3%
Distributor (n=6)	0.0%	33.3%	16.7%	**66.7%**
Importer (n=6)	**50.0%**	33.3%	16.7%	33.3%
Industry association (n=64)	29.7%	7.8%	21.9%	**54.7%**
Machinery safety consultant (n=85)	50.6%	**56.5%**	16.5%	24.7%
Manufacturer (n=212)	31.1%	30.7%	12.3%	**49.5%**
Notified body (n=44)	**52.3%**	47.7%	27.3%	40.9%
Private user (n=5)	**40.0%**	20.0%	20.0%	20.0%
Professional worker (n=18)	38.9%	**50.0%**	22.2%	33.3%
Researcher/academic (n=3)	33.3%	0.0%	33.3%	33.3%
Stakeholders involved in standardisation (n=7)	42.9%	**57.1%**	14.3%	42.9%
Other (n=46)	36.7%	34.4%	17%	**43.6%**

Source: Open Public Consultation (n=523)

Within the policy options suggested, certain definitions and criteria are considered to be adapted or changed. The preferences regarding specific changes of concepts varied on the definition in charge.

Overall, most suggested revisions of concepts were not preferred, compared to positive answers, with the exception of partly completed machinery. In this case, the majority of respondents would welcome a revision (52%) (see Figure 28). When looking into the open questions on the definitions of PCM, what often created areas of difficulty is the understanding on who is responsible for CE marking of the final completed machine. One potential solution is to provide a statement in the Machinery Guide and the Directive encouraging commercial agreements between manufacturer and end-provider/end-user (when involved in manufacturing) to make clear who takes this responsibility prior to commercial purchase. Another shortcoming in the current clause is on specific application. More precisely, it was indicated that partially completed machinery could be a self-powered base carrier intended to be combined with a number of different attachment modules. The ability of self-mobility is a specific function, therefore making the clause misleading. One commonly reported problem by German respondents in this case is the translation error from specific application to "specific function". Most respondents would prefer a more clearly described or defined term of "specific application". Another problem that is often mentioned is the use of partly completed machinery for machines intended to be inserted into production lines. This is expected to increase in the future. More precisely, more manufacturers are expected to be involved in completing a machinery, e.g. a robot with AI. Thus, it is considered important that the manufacturer of the sub-assembly should provide information on which EHSR the partly completed machinery complies with, what the hazards are with which the PCM cannot comply and how to build the product together with other sub-assemblies.

According to many respondents, it would be useful to distinguish the following cases:

- A "complete" machine is placed on the market with incomplete safety devices (not compliant);

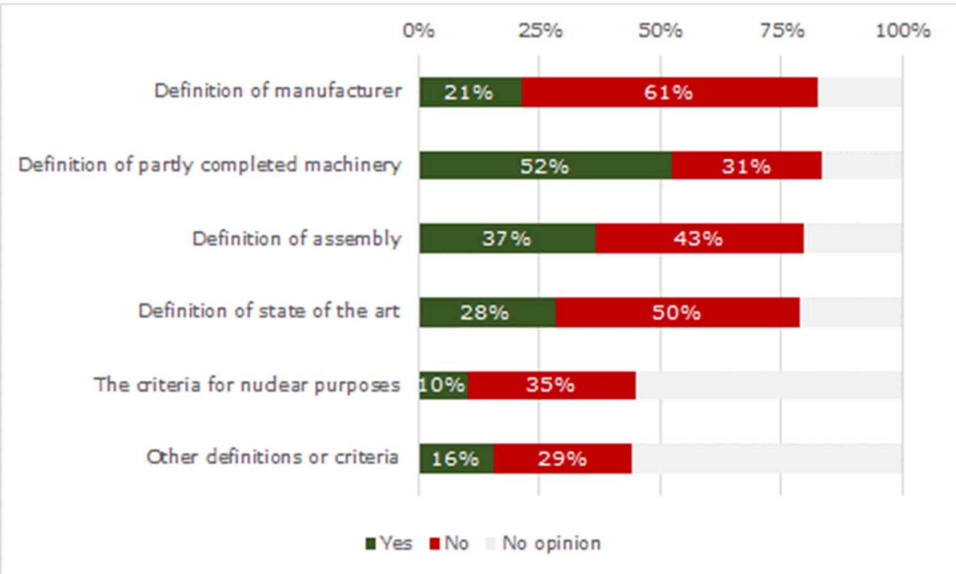
- An incomplete machine is placed on the market as a machine according to 2006/42/EC;
- An incomplete machine with essential components missing which would make the partly completed machine a machine according to 2006/42/EC); and
- An incomplete machine which does not fulfil certain applications (the term 'specific application' is not further defined in the Directive).

It was also considered beneficial that only the "safe machine" should be identified with the manufacturer pointing out residual risks in the operation instructions. This could also apply to the interfaces for a possible integration of machines in industrial plants. If the term "partly completed machinery" still be required, the criteria for this exception should be clearly defined and it could also be clearly stated that machines which lack only the required safety devices or safety components as well as drives or controls are not considered to be incomplete machines.

On the definition of specific application, most respondents mention intended use as main criteria, i.e. specific application refers when the product is suitable for its intended use and can perform its function actively (and safely). Generally, the definition in the Guide was considered appropriate but should be expanded, according to several respondents. Another potential approach could be removing the distinction between incomplete and complete machinery.

Regarding the change of other definitions and criteria, most respondents were against the change of the definition of manufacturers (61%) and state of the art (51%).

Figure 90: Should the following concepts be revised?



Source: Open Public Consultation (n=523)

Comparing the preferences of stakeholder groups, the following deviated from the general trend:

- Changing the definition of manufacturer: general trend against a change but preferred by authorities enforcing the MD (54%);
- Changing the definition of partly completed machinery: general trend for a change of definition, rather against this option are distributors (3 out of 6), industry associations (50%) and researchers (2 out of 3);

- Changing the definition of assembly: no striking preference but rather against an adaptation – preferred by machinery safety consultants (61%), private users (4 out of 5) and professional workers (9 out of 18);
- Changing the definition of state of the art: trend against a change of definitions with the exception of importers (3 out of 6) and professional workers (9 out of 18) being rather in favour; and
- Changing the definition of nuclear purposes: no general preference indicated, the majority of respondents answered, "no opinion". Against this change are most manufacturers of nuclear machinery (63%).

Nevertheless, regarding assembly several respondents indicated that the current definition leads to confusions. A number of respondents linked difficulties experienced with the MD to the fact that machine components are often produced by several companies in different countries before getting assembled, which undermines homogeneity in applying common standards and translating to a single and coherent language. Several companies also underlined how technical implementation requires extensive and specialized expertise that small suppliers may not possess. It was indicated as useful to specify that "assembly ends, where the continuation of hazards ends".

Annex IV and internal checks

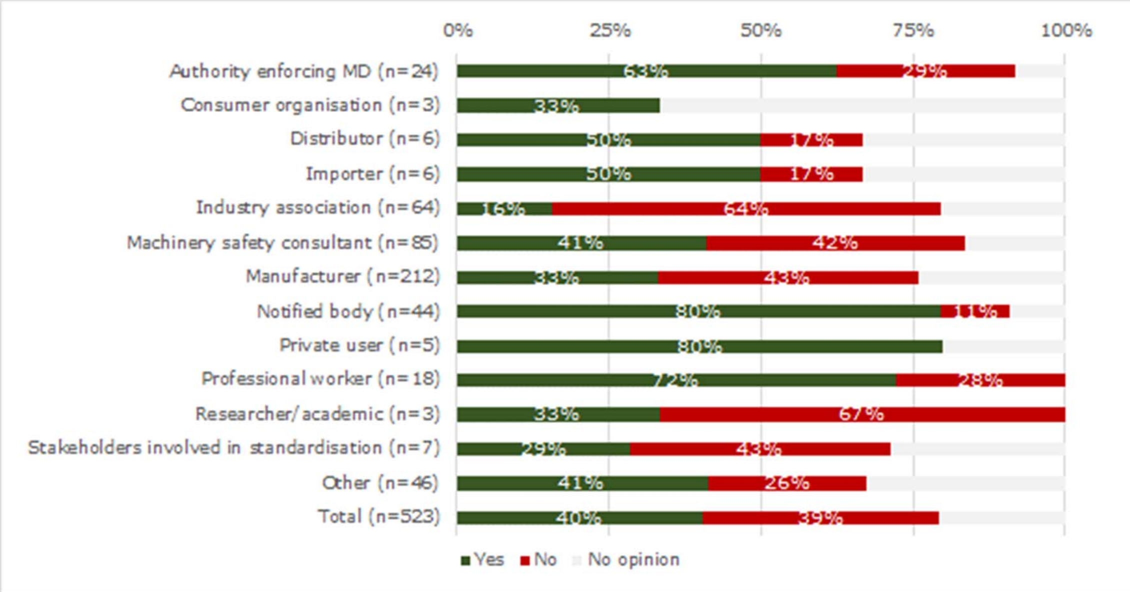
The question to whether the internal checks option in Annex IV of the MD leads to safety concerns received mixed responses with 40% indicating it does and 39% indicating it does not. When comparing the opinion across stakeholder groups, the preferences are as follows:

The respondents indicating that the internal checks option does lead to safety concerns are authorities enforcing the Directive (15 out of 24), distributors (3 out of 6), importers (3 out of 6), notified bodies (80%) and professional workers (13 out of 18); while those indicating that it does not lead to safety concerns are industry associations (64%) and researchers (2 out of 3).

From the manufacturers, only those manufacturing lifts indicated that the internal checks option leads to safety concerns (75%). This tendency was similar for those respondents whose relevant machinery are horticulture (51%) and power tools for personal use (52%).

One of the most common arguments raised by respondents who considered the removal of internal checks a positive amendment, is that manufacturers often do not possess the adequate safety expertise to carry out the evaluation, especially when suppliers are third companies or are based in third countries. In addition, several respondents mentioned that Annex IV machines, and lifts in particular, are too dangerous to risk compromising on safety standards. By contrast, other respondents thought that the removal of internal checks would not be much useful for safety purposes, considering that manufacturers have a very good knowledge of their specific product and are already legally responsible for them. Some of these respondents also argued that harmonising standards and reinforcing market surveillance would be sufficient to avoid possible safety concerns.

Figure 91: Internal checks option for Annex IV machinery leads to safety concerns

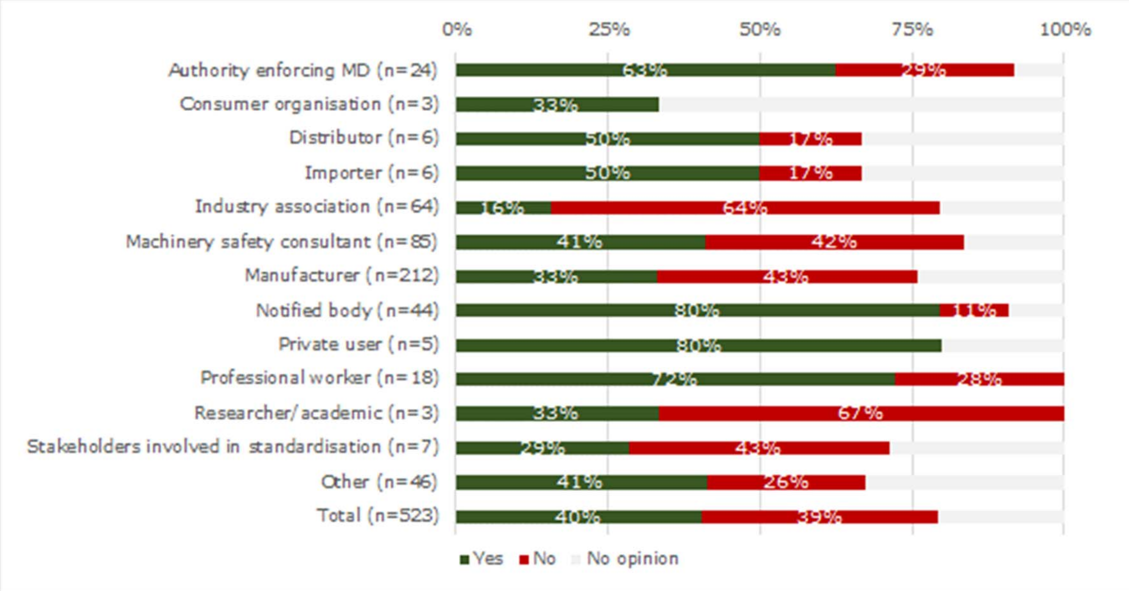


Source: Open public consultation

The removing of the internal checks option is expected to lead to increased costs by more than half of the respondents (55%). No changes are expected by 10% of the respondents and decreased costs by 3%. There were no large differences between SMEs and companies expecting an increase of costs (48% and 52% respectively).

When asking whether other high-risk categories of machinery should be added to Annex IV and thus including them into the conformity assessment involving a third party yielded mixed results with the respondents. Most did not indicate any preference (39%), followed by respondents negating that they should be included (31%). The respondents with a preference for either option are importers (3 out of 6), notified bodies (75%) and professional workers (11 out of 18) that prefer an inclusion of other high-risk categories, compared to industry associations (55%) rather not preferring an inclusion of other categories.

Figure 92: Additional high-risk machinery should be added to Annex IV

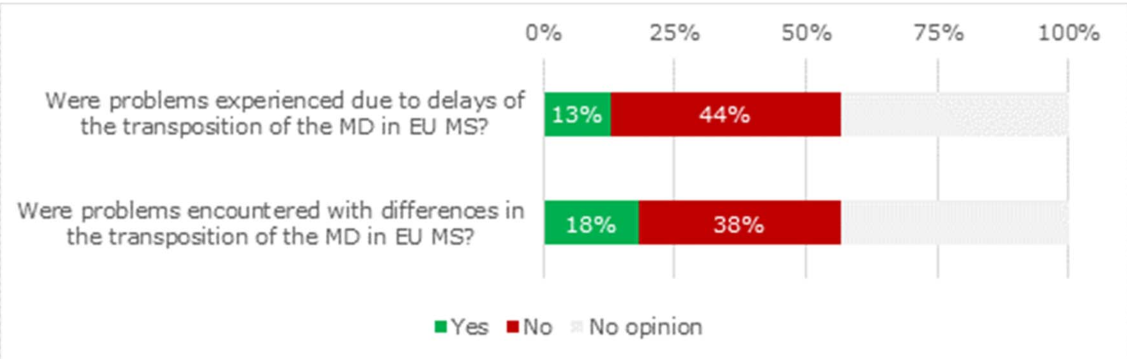


Source: Open Public Consultation (n=523)

Transposition of the Directive

The respondents did not experience any major problems with the delay of some EU Member States in the transposition of the Directive (44% "no", 43% "no opinion"). This is similar regarding whether there were any problems caused due to differences in the transposition of EU MS – 44% indicating no position and 38% indicating not having had experienced any problems.

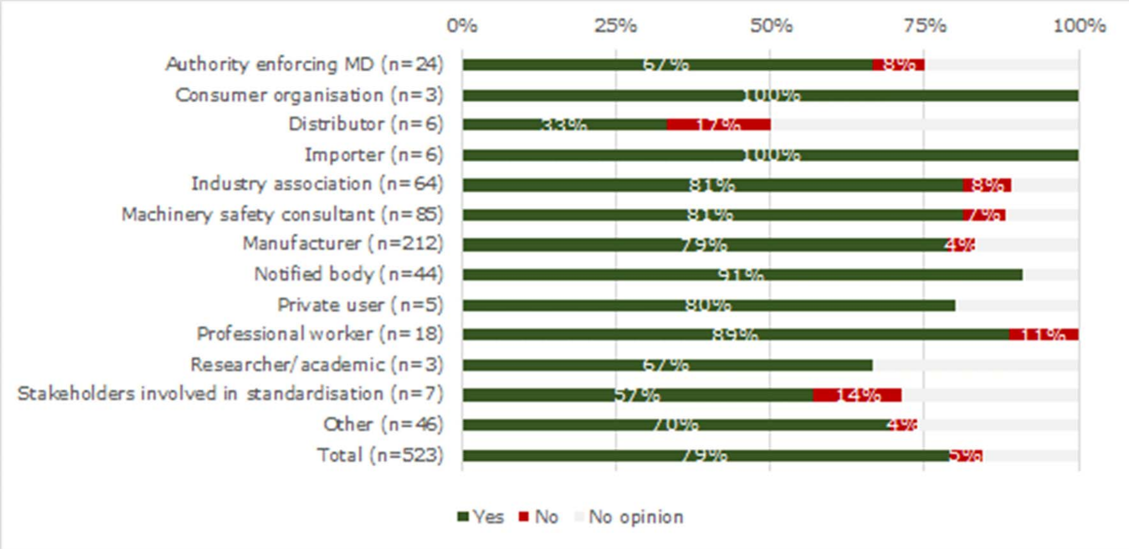
Figure 93: Responses regarding the legal status of the MD



Source: Open public consultation (n=523)

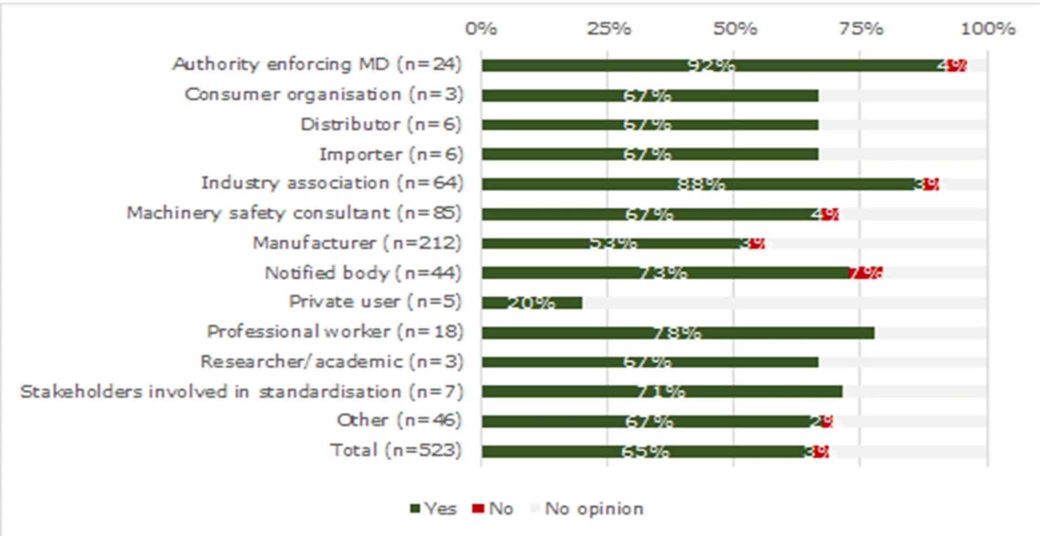
The vast majority of respondents would prefer to convert the Directive into a Regulation (79%) – with 5% of the answers being negative. Similarly, 65% of the respondents would be in favour of aligning the MD to the New Legislative Framework (3% negative answers).

Figure 94: Responses regarding the conversion of the Directive to a Regulation



Source: Open public consultation

Figure 95: Responses to the alignment of the MD to the NLF



Source: Open public consultation (n=523)

1.5. <u>Description of the online survey strategy</u>

1.5.1. Overview

The objective of the online survey was to obtain further data and information from the stakeholders that have previously been less responsive to the other consultation approaches and to complement the results of the semi-structured interviews and public consultation. In addition, it aimed at focusing the questions on those topics that for which data gaps persist.

The implementation of the online survey followed a similar approach to the targeted interviews.

- **Developing the draft survey questionnaire.** Based on the identification of data needs and missing target numbers for stakeholder groups a draft survey questionnaire was developed and shared with the Steering Group;
- **Finalisation of the questionnaire.** The finalised questionnaire was ready once the inputs from the Commission had been received and the changes made;
- **Programming of the survey**. The list of questions was uploaded and encoded into Surveygizmo. The focus in the programming lied on the routing of the survey. The routing is especially important in case only a selection of questions is relevant to a respondent (for example, because of answers to previous questions). This routing was also used to direct respondents with different backgrounds to a different set of questions.
- **Piloting the survey design**. The project team tested the design of the survey in the first week once the programming was finalised. By selecting different answers in the various test runs, mistakes in the survey design were identified. All issues were then addressed by adjusting the design. After the final test of the implemented adjustments, the test results were eliminated from the survey database, after which the survey was ready for launch;
- **Selection of respondents**. A preliminary set of invitees to the survey had been identified within the stakeholder mapping. This list was expanded with the stakeholder mapping conducted for the follow-up interviews, focusing on the relevant stakeholder groups;
- **Launch of the survey**. Online survey invitations were disseminated through email invitations. The email invitations were accompanied by the reference letter received from the Commission in the inception phase of the study;
- **Running the survey and monitoring of response**. Once the survey was published and open for participation, the response rate was continuously monitored in order to identify any imbalances in response rates for the various target groups. In case the progress in response falls short of expectation, the study team will send out e-mail reminders after ten days (at least 2-3 reminders are needed in our experience). If the response at the end of the survey period falls short of expectation, we would consult with the client for follow-up steps;
- **Finalisation of the survey**. The access to the survey was closed and the results of the survey transferred into a statistical programme for further analysis.

1.5.2. Robustness of the results

The online survey received in total 109 responses. The completion rate was of 22% with 24 complete and 85 partial responses. For the purpose of this report, only the completed responses were considered unless there were some important remarks in the individual partial responses.

Regarding the stakeholder type, 92% of respondents were companies/manufacturers. Notified bodies and experts on new technologies were represented by one respondent each. Researchers/academic institutions and stakeholders involved in standardisation did not complete the survey. The table below summarises the response rate per type of targeted stakeholder.

Table 69: Online survey respondents

Stakeholder type	Total
Companies/manufacturers	22
Notified bodies	1
Experts on new technologies	1
Stakeholders involved in standardisation	0
Researchers/academic institutions	0
Total	**24**

Source: Online survey (n=24)

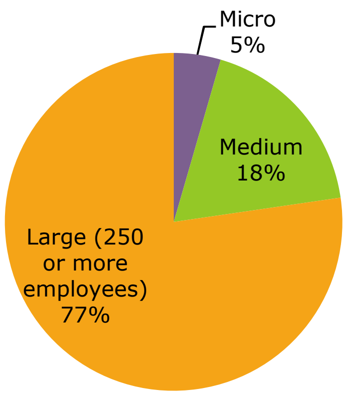
The majority of respondents were from the Netherlands (42%), followed by Italy (21%) and Germany (135). Almost all respondents were from an EU country, the only one non-EU participant originated from Switzerland.

Table 70: Country of origin of responses

Value	Percent	Count
Belgium	4%	1
Finland	4%	1
Germany	13%	3
Italy	21%	5
Netherlands	42%	10
Sweden	8%	2
Switzerland	4%	1
United Kingdom	4%	1
Totals	100%	24

With regards to companies and manufacturers, 77% of respondents represented large companies while the remaining companies were SMEs. In this case the distribution of SMEs and large companies is again not representative of the market structure.

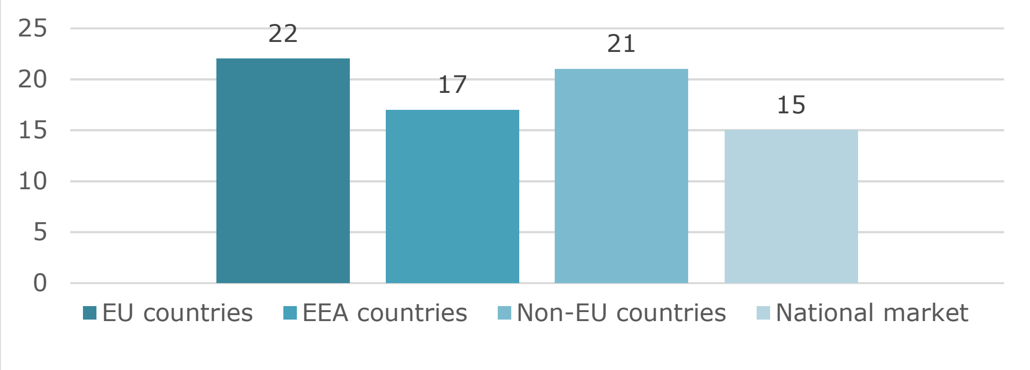
Figure 96: Organisation type



Source: Online survey (n=22)

All of the manufacturers trade products with other EU countries, 96% with non-EU countries, 77% with EEA countries and only 68% of companies within their national markets.

Figure 97: Trade areas of manufacturers



Source: Online survey (n=22)

1.5.3. Results of the online survey

The survey aimed at closing information gaps identified throughout the remaining study methods. It focuses, among others, on new technologies, the scope and definitions, and Annex IV machinery.

Emerging technologies

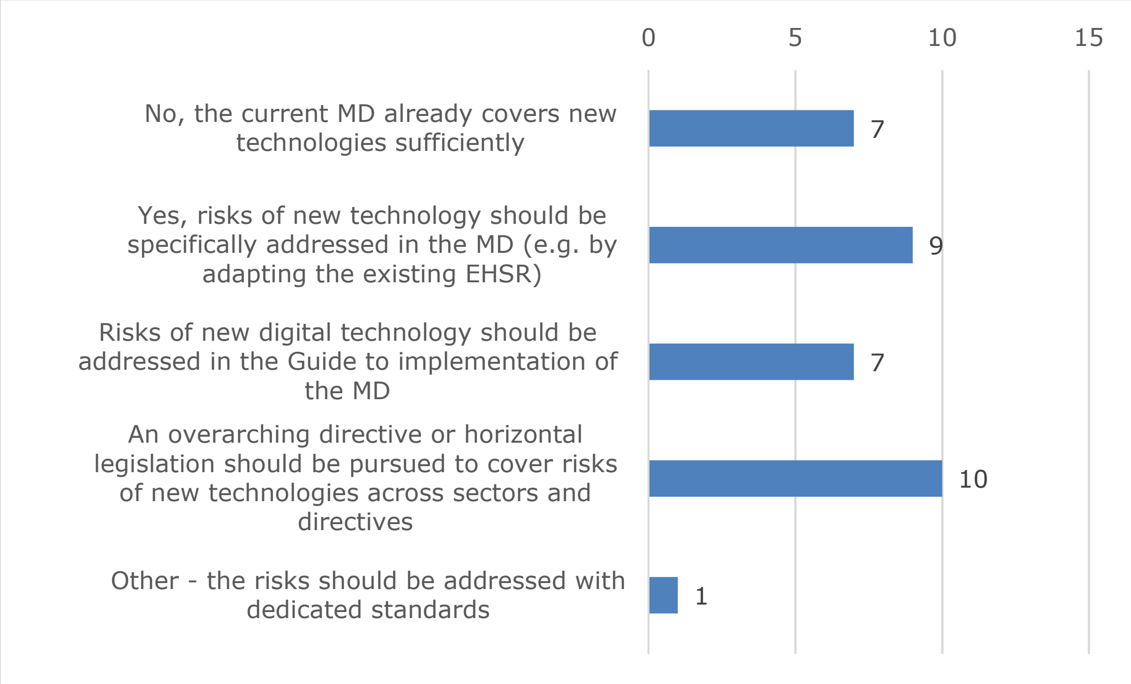
The use of emerging technologies in manufactured products seems to be increasing. Of the manufacturers, 6 indicated that they manufacture machinery with IoT applications or AI and machine learning. These technologies are essential for a small percentage of them (9%, n=2), whereas the rest implements only some solutions (36%, n=8). Over 50% of manufacturers (n=12) report having none or almost none of such technologies used in their products. This is foreseen to change as a large majority of these manufacturers (92%, n=11) plans to increase the use of emerging technologies in their products either strongly (25%, n=3) or to a limited extent (67%, n=8).

An 80% of the manufacturers who have used emerging technologies in their products have conducted a risk or conformity assessment for them. Among these respondents, a large majority believes that the existing risk assessment methodologies are inadequate for addressing the risks of machinery with emerging digital technologies (75%, n=6).

This opinion is also shared by the one notified body who participated in the survey. They have experienced issues in conducting conformity assessment for machinery with AI/IoT applications because the Machinery Directive does not stipulate any information security requirements; therefore IT-security aspects are not part of the conformity assessment procedure even though they can have an impact on the safety and security of machines. Notified bodies would require unrestricted access to product safety-relevant control technology and its software in order to be able to test the safety and security of machinery with AI and IoT applications. It is indicated that notified bodies would welcome updated essential requirements incorporating IT security, including access to algorithms and learning data for AI applications.

The opinions of manufacturers on the other hand are divided with regards to whether the risks related to new technologies should be addressed in the Directive. As the figure below demonstrates, slightly less manufacturers (97 believe that the existing Directive already covers the risks sufficiently than those who would welcome them being addressed in the Directive explicitly (9). However, the highest number of stakeholders chose for the risks to be addressed in a separate legislation covering the risks of new technologies across sectors and directives (10).

Figure 98: Do you consider that the risks stemming from new digital technologies, such as machine learning/AI, should be addressed in the MD?



Source: Online survey (n=22)

In a similar manner the manufacturers were asked whether **cyber-security** should be addressed in the Directive. Here, 27% of respondents agreed that cyber-security aspects and the safety aspect specifically should be explicitly covered in the Directive, compared to only 10% who believed that the current Directive already covers those aspects. Another 45% believes that an overarching or horizontal legislation should be pursued to cover cyber-security across sectors and products, where also 2 respondents indicated that cyber-security requirements should moreover be covered through more specific sectorial legislation.

Figure 99: Do you consider that cyber-security should be addressed in the MD?

Value	Count
No, the current MD sufficiently covers cyber-security aspects	1
No, because the current MD already covers cyber-security affecting safety	1
Yes, cyber-security aspects should be explicitly addressed in the MD (e.g. by adapting the existing EHSR)	4
Yes, cyber-security affecting only safety should be specifically addressed in the MD (e.g. by adapting the existing EHSR)	2
Risks of cyber-attacks should be addressed in the Guide to implementation of the MD	2
I believe that an overarching Directive or horizontal legislation should be pursued to cover cyber-security across the board (sectors and products)	7
I believe that an overarching Directive or horizontal legislation should be pursued to cover cyber-security across the board (sectors and products) + cyber-security requirements through more specific sectorial legislation	2
The current industry initiatives and developments in standardisation are sufficient to cover the risks of new technologies	2
Other – With dedicated standards	1

Source: Online survey (n=22)

The manufacturers were moreover asked whether **harmonised standards** should continue to be applied voluntarily. A vast majority believes that they should remain voluntary (72.7%, n=16), compared to 10% who think that safety standards should be enforced in order to ensure the same level of compliance among manufacturers. Another 18% of respondents indicated that only core safety standards should become obligatory and the rest could remain voluntary.

Given the issues related to the lack of established criteria for **machinery substantially modified** during their use that require new declaration of conformity, manufacturers were asked whether software uploads or updates into an existing machinery not covered by risk assessment would give rise to substantial modification and increase the risks. An overwhelming majority of manufacturers (73%, n=16) believed that such a modification should indeed be considered a substantial modification and therefore require a new CE marking. They were moreover asked whether software components should be covered by the Directive. Only 19% (n=3) of them thought that all software items required to deliver the intended functionalities should be included in the Directive, while 25% (n=4) of manufacturers were against it. The remaining 56% (n=9) indicated that the Directive should cover only the software components which implement safety, control or core functions. Similarly, the notified body indicated that any software update can have an impact on the safety and security of machines and therefore should be treated as a substantial modification. On the other hand, 27% (n=6) of manufacturers believed that software uploads or updates into an existing machinery not covered by risk assessment would not give rise to substantial modification.

Moreover, the manufacturers were asked if they had used or would consider useful to have a flowchart similar to the one used by the German Ministry for Labour for risk assessment after modification. All but one manufacturer (95%, n=21) indicated that this type of visualisation would be useful.

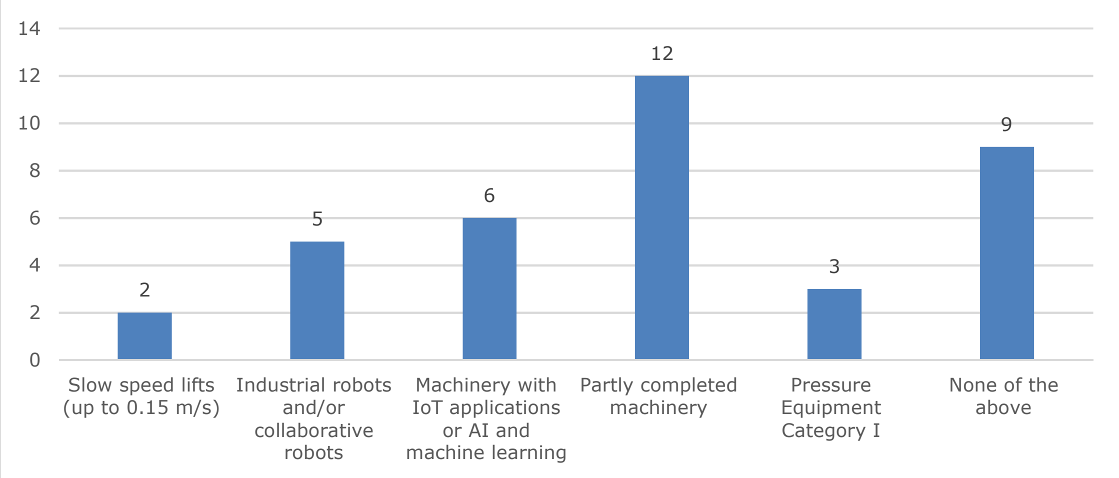
With regards to the safety aspect, the manufacturers were moreover asked whether machinery using digital solutions such as AI and machine learning should be considered as high-risk machinery (Annex IV machinery) and subject to third party conformity assessment if no or not all harmonised standard(s) conferring full presumption of conformity have been used. Half of the respondents (50%) were against adding such machinery to Annex IV, while only 14% would see it beneficial. The remaining 36% had no opinion. Those who would like to see the AI machinery covered by the directive indicated that all machines with control systems driven by AI should be included (n=3).

With relation to connectivity, the manufacturers were asked whether the risks of failure from connectivity are sufficiently covered by other Directives, for example the Radio Equipment Directive. 41% believed that these were fully covered compared to 27% who indicated that the risks are partly covered and 32% who thought that the risks were not covered. Among these, 72% (n=5) believed that changing the legal text of the Directive would protect safety and health of users against the risks of connectivity failure. Moreover, 64% (n=14) of manufacturers indicated that they would welcome the essential requirements of the Radio Equipment Directive being referred to in the Directive in the same way as safety objectives of LVD are already mentioned in the Directive.

Clarity of framework, scope and definitions

In relation to specific machinery, the survey sought to understand what kind of specific machinery the manufacturers produce most often. Manufacturers reported partly completed machinery to be the most common type of manufactured products (n=12) followed by machinery with IoT applications of AI and machine learning (n=6). Almost half of the manufacturers (n=9) however, focus on other types of products.

Figure 100: Types of specific machinery manufactured by survey respondents



Source: Online survey (n=22; multiple answers possible)

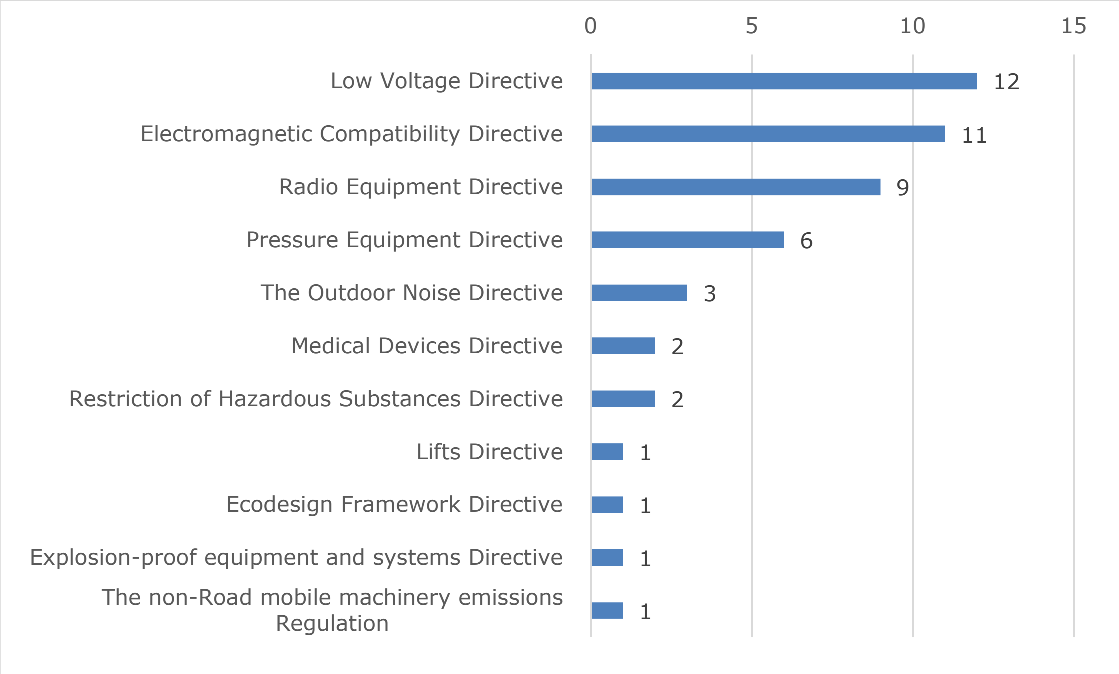
The twelve manufacturers who produce partly completed machinery had divided opinions on whether it would be beneficial to include with the delivery a list of EHSR that their partly completed machinery applies to and complies with. Seven out of 12 agrees with the statement, and five of them did not see it beneficial.

In terms of definitions, for majority of companies (82%) the exclusions under Art.1.2 (b, f, k, l) of the Machinery directive do not lead to any of the safety concerns or unclarity as to which framework to apply. These types of machinery were chosen as problematic in at least one instance each (Art. 1.2. (b), (f), (l)) and in maximum two instances (Art. 1.2 (k)). In case of an amendment of Art 1.2 (k), the wording of "domestic use" and "industrial products/components" should be revised to increase legal clarity (n=1).

The NLF

A large majority of companies (82%) manufacture products under the scope of other New Legislative Directives. The highest number of companies complies with the Low Voltage Directive (67%), followed by Electromagnetic Compatibility Directive (61%), Radio Equipment Directive (50%). Other directives that the companies comply with include: Pressure Equipment Directive (33%), The Outdoor Noise Directive (17%), Medical Devices Directive (11%), Restriction of Hazardous Substances Directive 11%), Lifts Directive (6%), Ecodesign Framework Directive (6%), Explosion-proof equipment and systems Directive (6%), The non-road mobile machinery emissions Regulation (6%).

Figure 101: Compliance with other directives



Source: Online survey (n=18; multiple answers possible)

These companies generally do not find difficulties in the clarity of which of the above directives to apply to their products (83%). All of those who had issues encountered them with regards to the Radio Equipment Directive (n=3), Pressure Equipment Directive (n=1), Electromagnetic Compatibility Directive (n=1) and Low Voltage Directive (n=1). With regards to the latter, removing the exclusion of Low Voltage products would increase clarity as to which legal framework to apply (n=1).

With regards to the impacts of aligning the Machinery Directive to the NLF, all the companies estimated cost reduction due to familiarity with the framework to be the biggest benefit (n=18), followed by increased clarity of the conformity assessment procedure (n=12).

Table 71: Benefits of alignment to the NLF

Benefit	Count
Cost reduction due to familiarity with the framework	6
Increased clarity of the conformity assessment procedure	12
Higher quality of machines on the market through reduction of non-compliant machinery	5
Harmonised market surveillance procedures	18

Source: Online survey (n=18)

2. DESCRIPTION OF THE CASE STUDIES

2.1. Overview

Three case studies have been conducted in order to provide practical, issue-based, and detailed insights on the implications and the developments related to the Machinery Directive. This additional tool contributed to the triangulation of results and, therefore, to their validity and robustness.

A selection of potentially relevant cases was first provided in a draft list after the inception phase and provided in the Annexes of the first progress report. This general list of preliminary topics focused on Artificial Intelligence (AI) and Digital Operations. Throughout the development of the study, the study topics were further streamlined and adjusted. The outcome of this approach led to the selection of the three cases that were ultimately analysed:

- **Digital transformation of machinery**: The world of machinery software development has evolved rapidly, now covering the whole process from single initial installation to continuous updates. Devices and machinery used to be updated only a few times (if any) in their lifetime, mostly through a manual process. Wireless technologies now allow control systems to be updated remotely over the internet in an autonomous manner and on a continuous basis. Post-deployment updates of software can change the functionality and operations of machinery. This creates challenges from a regulatory perspective, notably in terms of ensuring that Essential Health and Safety Requirements are satisfied following software updates and that the relevance and accuracy of required documentation (manuals, EHSR instructions etc.) is safeguarded and accessible to users. This case study examines the impact of digital transformation of machinery and associated control systems on the safety of human supervisors and operators. It describes the challenges that arise from the upload of software in machinery and the resulting safety implications with regards to functional changes and cybersecurity.

- **Production optimisation**: With the sophistication of machine learning (ML), ubiquitous interconnectivity through IoT and the development of increasingly accurate sensors at ever smaller scale, the manufacturing industry has witnessed technology advances at an unprecedented speed. The combination of ML, sensor-based inputs and IoT can unlock a dramatic leap in efficiency and productivity gains, but also pose complex regulatory challenges. IoT is a technology enabler that allows connecting several machinery products - covered by the current MD - in a connected multi-agent interoperable system. By integrating machinery in IoT network, the ex-standalone machinery (subject to risk assessment) becomes far more complex to assess. Machine Learning-enabled control systems embedded in an IoT network can control groups of assets and can adapt the functions of the machinery over time. Currently, software as a safety control component that is placed independently on the market is not considered as a safety component under the MD. This case study focuses on the consequences of the emergence of machine learning techniques and on the implications of ML-enabled applications for the safety of human supervisors. The technical focus of this case study lies on ML models, sensor-based data, IoT and business driven code.

- **Self-driving robots**: Moving robots have been part of the machinery industry for a long time. In the past, they were characterised by the use on fixed paths and human-operated controls. By contrast, recent generations of robots are increasingly able to react to external stimuli based on autonomous data processing. Self-driving robots have two new characteristics that challenge the current regulatory framework: mobility and direct human interaction. The interaction between humans and self-driving robots in dynamic, partially unknown environments introduces complex health and safety risks for regulators to consider. Challenges for regulators arise in terms of defining appropriate guidelines for robot control, stipulating criteria for adequate situation assessment skills, and ensuring required levels of adaptation to the emotional needs of users. Hence this case study covers the specific topics of real time path finding, AI control and human-robot interactions.
- While each of the three case studies focusses on a distinct technology domain and illustrates associated challenges and regulatory options, several cross-cutting aspects apply to all case studies. This notably includes challenges related to cybersecurity

manufacturer's responsibility for the safety of the product being placed on the market, the display of safety-critical information on Human Machine Interfaces, as well as the ownership of software throughout the lifecycle of machinery.

2.2. Results

The content and results of the case studies are presented in three case study reports included in this section of the Annexes. Where relevant, the information within the use cases feeds into the policy impact assessment sections of the impact assessment report.

2.2.1. Digital transformation of machinery

Relevance of the selected case

Digitalisation is an essential aspect of the Machinery Directive (MD). This case study examines the **impact of digital transformation** of machinery and associated control systems. It describes the challenges that arise from the continuous evolution of functionality of machinery through software control, software updates and the potential effects of these updates. Finally, the case study also presents the risks of using machines with functionality that is no longer supported by the manufacturer.

In the past, machines were installed once and updated only in rare occasions. The update of a machine's functionality evolved from installation of a new component to updating the embedded control functionality. Nowadays, the functionality of the machine can be updated using standalone software (see figure below). On modern machinery fleets, machines are designed in such a way that updates can be performed physically or remotely, via networks, depending on whether the manufacturer or its authorised representative have physical access to the machine. Furthermore, the specialization of the software market for machinery means that in some cases, **software updates for machinery can be provided by someone else** than the Original Equipment Manufacturer. In this case, the resulting software is not embedded in the original product, as it was placed on the market, but provided separately by a third party, raising questions in relation to risks (and their management) emerging from software updates that change the functionality and operation of machinery in unintended ways.

Key challenge to regulation

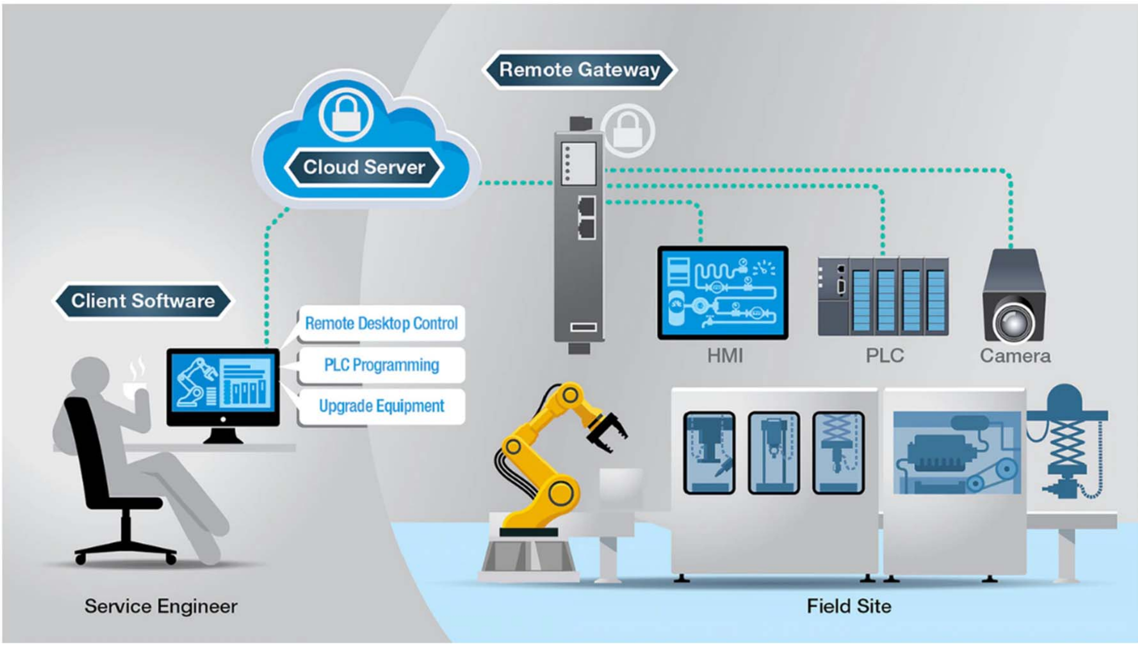
Post-deployment software updates can change the functionality and operations of machinery. This creates challenges from a regulatory perspective, notably in terms of ensuring that Essential Health and Safety Requirements are satisfied following an **integration of independent software** to any (standalone or networked) machinery, in terms of ensuring security of programmable control systems and after software updates.

Modern machinery can be connected to the internet through various wireless networking technology, such as LAN, Wi-Fi, 3G and 4G. Modern assembly lines are steered by a Programmable Logic Controller (PLC), which have built-in or add-on modems to ensure wireless connectivity. Often, routers for industrial PLCs support multiple wireless technologies at the same time, to safeguard for connectivity in case the machinery loses connection to one or more of the networks. For instance, the PLC of a CNC machine can automatically receive remote software updates or security patches via 3G or Wi-Fi. Depending on the complexity and safety requirements of the given machinery operated by a PLC, operators can define whether the received software updates should be installed manually or automatically, e.g. at specific timeframes such as after the end of a production shift.[352]

Remotely operated maintenance operations, for example wireless updates, are more popular since it is easier for the manufacturer to update a fleet on scale. For instance, a car manufacturer may have contracts with a fleet of several millions of connected cars, requiring seamless and continued operation of the vehicles during a remotely initialised internet-based software update.

However, the possibility to upload software remotely to machinery raises concerns with regards to safety because of aspects of cybersecurity and overall cyber-physical security. Remote updates create potential opportunities for malicious third parties to intercept and replace legitimate software with malware that could affect the machinery's operations and hence have an impact on safety. The ever-greater role of software in the once hardware-dominated world of machinery requires considering any new specific risks (in the relevant legislation) and developing new technology-dependent solutions (for example in standards) to mitigate those new risks and ensuring safety throughout the whole lifecycle of machinery, before the placing on the market of the machinery.

Figure 102: Visualisation of remote access to machines



Source: https://www.machinedesign.com/automation-iiot/article/21836802/five-issues-facing-secure-remote-access-to-iiot-machines

Compared with the legacy machinery, digitalisation of machinery also involves continuous collection and analysis of large volumes of data during the whole lifecycle of machinery, e.g. during the development, the manufacturing, the quality control, the deployment, but also during the operation of machinery. During production, sensors attached to automated manufacturing equipment collect data on vibrations, forces and temperatures. The data collected is forwarded to the cloud for aggregation and analysis. A new development in this field is the transformation of such data into a working virtual replica of the physical machinery

352 https://www.machinerytrader.com/blog/construction-equipment-news/2018/12/cat-remote-services-cut-your-machinerys-downtime

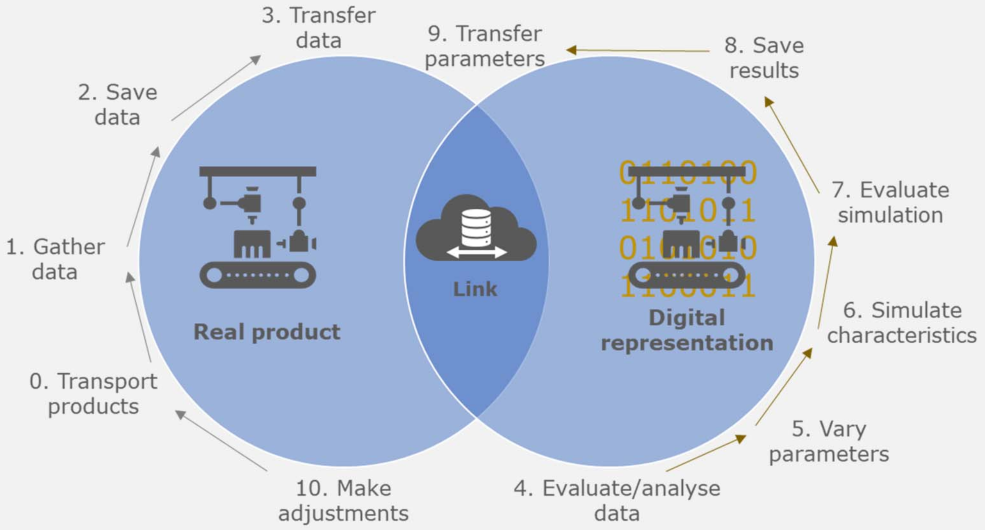
(or a network of machinery), also referred to as digital twin. The more data that is collected, the more accurate the digital twin will be.

Box 9: Digital twin

"A **digital twin** can be defined (…) as an evolving digital profile of the historical and current behaviour of a physical object or process that helps optimise business performance. The digital twin is based on massive, cumulative, real-time, real-world data measurements across an array of dimensions."[353]

Digital twins bring the physical world closer to the digital world through enabling components including sensors and actuators from the physical world, integration, data, and analytics as well as continuously updating the digital twin application in the digital world. Sensors can be distributed throughout the manufacturing process, creating inputs that enable the digital twin to capture operational and environmental data from the physical world. The data captured by the sensors is communicated through integration between the physical and digital world, and vice versa. Once the data arrives in a digital repository, it is combined with enterprise data such as design specifications or materials used. The data is analysed to generate insights and to visualise them. The digital twin combines all the components into a near real time model of the digital world. The objective is to identify deviations on various dimensions, including deviations resulting from issues in the logic or identification of an optimisation. Machine Learning algorithms assess these deviations. This can result in an action in the physical world. If an action is needed, the digital twin can execute via the actuators subject to human intervention.

Figure 103: Visual example of a digital twin



Source: Author's own representation based on Movilitas

Digital twins may play an important role during the utilisation of machinery. During the use of machinery, sensors attached to the machinery may collect the necessary data, e.g. to avoid collisions when humans and the machine interact in the same area. Digital twins and other

[353] Deloitte University Press

recent evolutions of digitalisation in machinery can affect the well-being of human supervisors and other users. In the tele-operated scenario, increased complexity of machinery in terms of components interconnected to a working line means that control room operators need to manage complex data and to take safety-critical decisions in unexpected and rapidly evolving hazardous situations. A new risk that may arise is that an insufficiently clear human-machine interface (HMI) can have negative impacts on safety by causing occupational accidents or excessive stress[354]. Therefore, a specific safety requirement may be needed to ensure this is properly considered at the design stage of the equipment.

Market trends

Accounting for approximately half of global exports, the European manufacturing industry is the largest in the world.[355] The machinery and equipment sector is one of the major sectors of manufacturing within the EU, recording a turnover of EUR 663 billion and employing 2.8 million persons in 2017.[356] However, European machinery operators are facing structural changes brought about by the rapid pace of digitalisation in the manufacturing sector. As the upcoming cyber-physical Internet of Things (IoT) requires new competencies in an increasingly software-driven manufacturing environment, companies using machinery cannot rely on their hardware strengths alone anymore. A survey conducted by Porsche Consulting in 2017 identified that 67% of manufacturing companies in Austria, Germany, Italy and Switzerland reported to have planned, piloted or implemented digitalisation in their production and supply chain, IoT-based digital services, and B2B commerce. The most advanced stages of implementation are in condition monitoring, predictive maintenance, data-driven process control and digital shop floor management.[357]

A digital twin fed with sufficient sensor data can provide highly accurate simulations of real-world processes, allowing design engineers to plan their machining processes, improving safety and reducing resource waste while maximising productivity and accuracy.[358] Digital twins can also be used to train employees and to test new products or procedures before launching them in the real world, where maintenance and post-launch fixes are more expensive and complicated.[359] While there are no reliable figures on the number of digital twins in operation, Gartner predicts that 50% of large industrial companies will use digital twins by 2021, resulting in an average 10% improvement in effectiveness.[360] Other sectors, such as the oil and gas industry, are anticipating cost savings in operation and maintenance of up to 62%.[361] By providing intelligence on how a company's assets are performing both from a maintenance and a profitability perspective, early adoption of digital twins can generate a significant competitive advantage for businesses within and across sectors.[362] Digital twins provide can greatly

[354] The HIVA research group from the KU Leuven conducted a survey interviewing 4,600 blue-collar workers from the Belgian textile and metal manufacturing industries regarding their experience with digitalisation in their respective industries. The research highlighted that employees working with new technologies experience more autonomy but they find their work to be mentally more demanding. See: KU Leuven's Research Institute for Work and Society (Hiva) https://hiva.kuleuven.be/en/news/docs/werk-rapport-2018-01-def.pdf

355 Capitalmind (2016). Industrial Machinery & digital automation Sector and M&A Report

356 https://ec.europa.eu/eurostat/statistics-explained/index.php/Industrial_production_statistics#Overview

357 Porsche Consulting (2018). Digital Machinery Decoded A practical guide for machinery companies to navigate digital transformation and outperform competition

358 Gonzalez, C. (2017, September 28). Digitalization and the Future of Machining. Retrieved February 11, 2020, from https://www.machinedesign.com/mechanical-motion-systems/article/21836014/digitalization-and-the-future-of-machining

359 Andersen, J. (2019, January 2). Where Do Digital Twins Fit In? Retrieved February 11, 2020, from https://www.industryweek.com/technology-and-iiot/article/22026918/where-do-digital-twins-fit-in

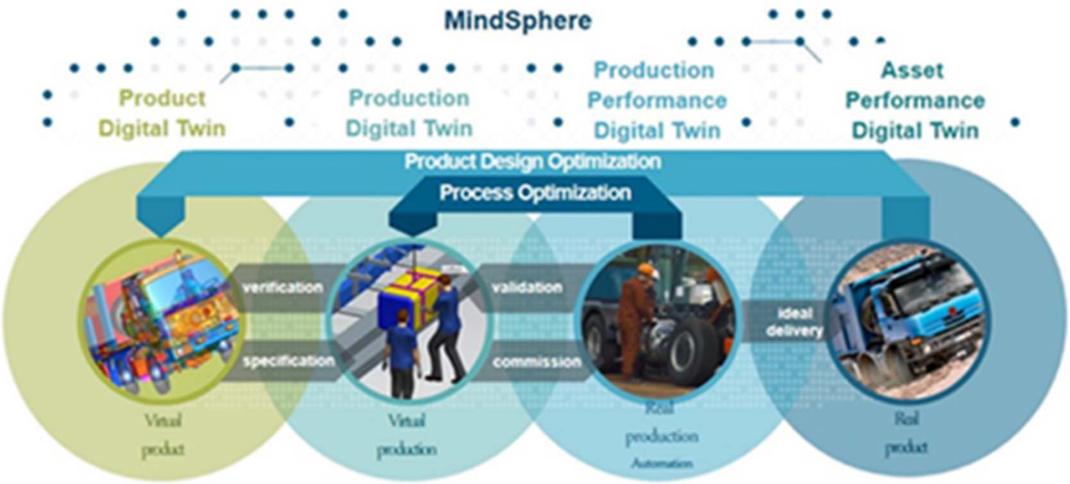
360 Pettey, C. (2017, September 18). Prepare for the Impact of Digital Twins. Retrieved February 11, 2020, from https://www.gartner.com/smarterwithgartner/prepare-for-the-impact-of-digital-twins/

361 https://www.jpglobaldigital.com/digital-twin-can-help-oil-and-gas-operators-achieve-significant-cost-savings/

362 Eshkenazi, A. (2018, September 21). Real Benefits from Digital Twins. Retrieved February 11, 2020, from http://www.apics.org/sites/apics-blog/thinking-supply-chain-topic-search-result/thinking-supply-chain/2018/09/21/real-benefits-from-digital-twins

improve the safety of modern machinery by enabling industrial engineers to run tests, perform fixes, and be alerted to issues in a manner that is cost-effective, time-efficient, and in-house. Digital twins reduce the need for potentially unsafe iterative fixes that change the functionality of machinery because, since the impact of safety-critical software updates and bug fixes can be simulated on the digital twin in advance before being deployed on the machinery itself.[363]

Figure 104: Visualisation of digital twin process in production



Source: Siemens PLM Software

Digitalisation of machinery transcends the stage of production by opening up entirely new use cases for businesses and end users. For instance, Waldmann, a long-standing family-owned German manufacturer specialising in industrial lightning solutions has recently created a new start-up that adds various sensors to their lamps to cater for the smart office market. The sensors detect workplace utilisation, climate and noise levels and - through a real-time analytics suite - enable an improved allocation of workstations in shared offices, automatic indoors climate management, and workplace noise management.[364]

While opening new areas of vulnerability if deployed without corresponding security systems, digitalisation of machinery has the potential to significantly enhance the safety of industrial production processes.[365] For example, smart cameras can gather digital footage which can immediately sense if a human operator has moved into an unsafe area or positioned themselves too close to a particular piece of hazardous equipment. The smart camera systems then either alerts a human supervisor or – as a default response - automatically powers down the machine or, in the case of a collaborative robot, slows it down to a safe speed, enabling the operator to safely move away from the hazardous situation.[366]

[363] https://www.securityinfowatch.com/security-executives/article/21082742/digital-twins-understanding-what-they-are-and-why-they-need-to-be-protected

[364] Preuss, S. (2019, December 7). Wie ein Mittelständler der Digitalisierung begegnet. FAZ. Retrieved from https://www.faz.net/aktuell/wirtschaft/unternehmen/wie-ein-mittelstaendler-der-digitalisierung-begegnet-16515460.html

[365] https://www.ehstoday.com/safety-technology/article/21919570/safety-40-updating-safety-for-industry-40

[366] https://www.controlengeurope.com/article/133867/Safety-first--How-Industry-4-0-can-optimise-safety.aspx

Shortcomings, barriers of the current MD and approach of the sector today

This section presents the case study results on the shortcomings and barriers of the current MD with regards to two interconnected technological issues: i) the upload of software in machines (including by providers other than the OEM) and ii) the resulting safety implications with regards functional change of machinery and cyber security.

The Guide on the application of the MD addresses digitalisation to a limited extent especially when it comes to **continuous update of functionality of machinery**. This is largely due to the status quo of the technology that was present during the MD implementation (and because the Machinery Directive applies only when products are placed for the first time on the EU market). Since then, the lifecycle of machines is changing towards a continuous evolution of functionality, which creates new challenges for regulators. Depending on the scope and impact of software updates on functionality, software updates can constitute either "maintenance of" machinery or a "substantial modification of" machinery. However, relevant market actors have different perspectives on what constitutes a substantial modification as opposed to mere maintenance, an ambiguity that becomes even more complex with Machine Learning-enabled ever-evolving software control systems in which each seemingly minor update can have significant effects on the machinery's functionality also because of the effects of accumulation of series of changes. First, the possibility of externally uploading software to the control unit (Programmable Logic Control, PLC) can have a significant impact on safety, which raises questions with regards to the conformity of the functionality changes with the EHSR. Technology offers two ways of performing updates – remotely via network (for example wirelessly) or locally via physical access to the machinery system. An update of one of the constituents of machinery, for example the embedded system or the micro-controller, can affect the functioning of the rest of the components of machine as a whole because of newly changed interactions between parts. For the sake of clarity, external software updates operated by any legitimate actor (manufacturer of machinery, manufacturer of software, system integrator, or user) have a potential to change the functionality of machinery beyond the scope of the risk assessment initially taken into account by the original manufacturer. In such a case, the machinery design should properly consider **any necessary requirements for software updates**. This is a major development as the MD covers changes performed on embedded control systems, but less so in the context of software.

As noted in the European Commission's Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, on one hand, in most cases, the EU's sector-specific harmonised product safety legislation does not have specific provisions for stand-alone software uploaded after the product has been placed on the market.[367] On the other hand, there are currently no specific requirements for software that ensures a safety function and is placed independently on the market. While the definition of safety component in the MD does not indicate if a safety component must be a physical device, the MD Guide indicates that "safety components are considered to be physical devices (…). Software which perform a safety function, and which is placed independently on the market is not considered by the Guide as a 'safety component'. However, physical components incorporating software (…) are 'safety components' and may also be 'logic units to ensure safety functions' (…)." Thus, while the current MD accounts for software and updates in the case of embedded [control] applications, it does not explicitly cater for the independent software ensuring a safety function that is uploaded to the standalone machine and can control the operations of the machine.[368]

First, errors in the software can have direct adverse effects on safety and wellbeing of human collaborators. With an ever-increasing role of software in the operations and functionality of machinery, it is questionable whether the MD Guide clarification on safety

[367] European Commission (2020). Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics. COM(2020) 64 final. Available at: https://ec.europa.eu/info/sites/info/files/report-safety-liability-artificial-intelligence-feb2020_en_1.pdf
[368] Guide to application of the Machinery Directive, edition 2.2.

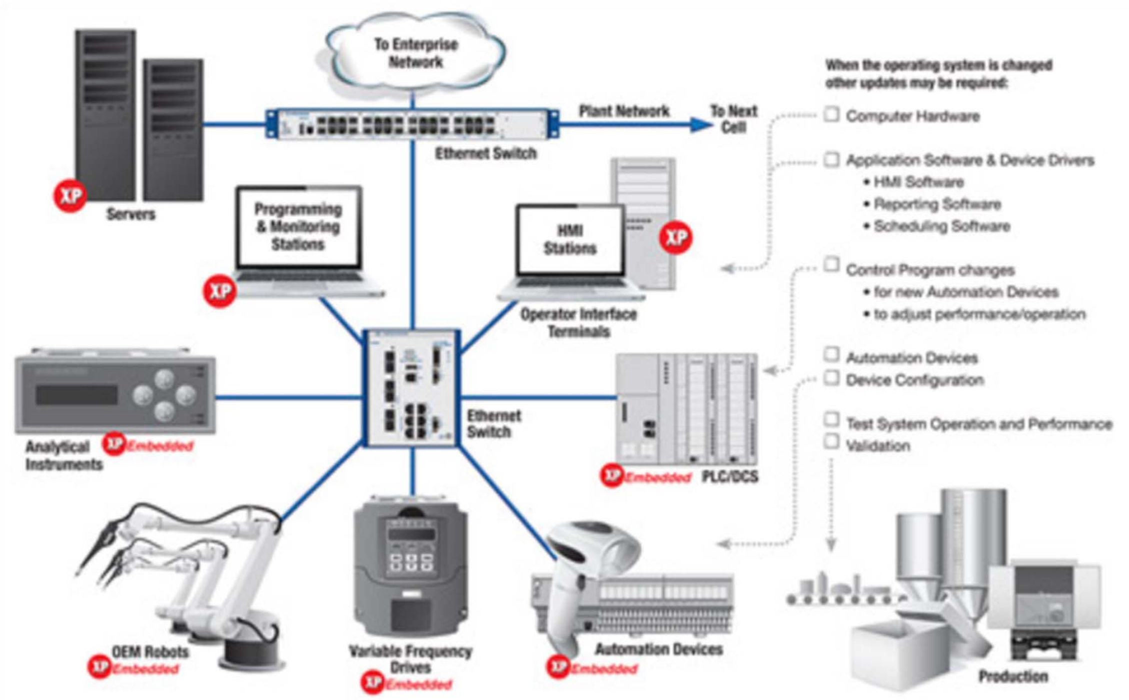
components is still valid. This is particularly the case as independent software that is controlling the operations of machine-learning-enabled assets evolves over time. Associated risks are especially higher when the automated machines have mechanical moving parts which are more challenging to control. In these cases, in order to ensure the safety of human supervisors and machine operators, it requires critical diligence in the programming and deployment of software updates, as workers active on the same floor as a collaborative machine may potentially not be aware of such changes occurring. These updates have various degrees of complexities depending on the type of device, severity of the change and depending on whether the update is on a fixed machine or a remote or mobile application.

Second, issues of manufacturer's responsibility for the safety of the product emerge in case standalone software or software updates are developed by service providers other than the OEM. When the software was clearly not embedded in the original product and since it was not developed by the OEM also does not fall under the ownership and responsibility of the OEM that placed the product on the market respecting the EHSRs of the Machinery Directive. It is hence necessary to assign ownership and responsibility to the software-related functionality changes to the developer. Besides, in case the functionalities of the software control unit are changed and fulfils a safety function, resulting in a change in the intended use function of the machinery, the software should be considered a safety component and require a renewed risk assessment as other substantial modifications.

Third, new challenges emerge during the lifetime of the machine in case the manufacturer stops the support for updates on functionality. This can include the risk of security vulnerabilities, incompatibility of new applications, compliance issues, lack of technical support and poor performance and reliability. One example for this is when Microsoft stopped the support for Windows XP while many manufacturing and calibration systems continued relying on it. According to industry experts, the physical equipment is generally up-to-date, whereas underlying operating software becoming outdated is a critical issue.[369] As it is difficult to upgrade software within complex interconnected systems of machinery, a sudden lack of security support services, such as security patches, can pose severe security risks both to business continuity and user safety. All the components that needed to be reviewed and updated are visualised in the figure below. Indeed, a Verizon security study focussing on both the manufacturing and mass-market sectors, found that over 99% of exploited vulnerabilities of digital equipment are compromised more than a year after the security risk was made public, meaning that lack of appropriate software updates directly leads to higher exploitation rates and compromised equipment.[370]

[369] https://www.theguardian.com/technology/2014/apr/14/windows-xp-support-ends-xpocalypse
[370] https://cybersecurity.idaho.gov/wp-content/uploads/sites/87/2019/04/data-breach-investigation-report_2015.pdf

Figure 105: Visual example of the components in need of revision after the discontinuation of Windows XP



Source: https://www.globalsecuritymag.fr/Upgrading-Windows-XP-Mitigate-the,20140514,45041.html

There are also risks associated with using the machinery when updates are not supported by the manufacturer. There could be conformity or safety risks that could occur in this case, for example when there is a safety-related defect identified in a machine, it may not be able to be updated anymore because the manufacturer has stopped the support.

Finally, if an unauthorised third party manages to upload code or software to a safety-critical piece of machinery, this could have severe consequence for machinery users, for example if warning systems are turned off or the functionality of machinery is changed to sabotage operations. A number of relevant stakeholders believe that a horizontal legislation accompanied by an amendment of Annex I, §1.2.1 to clarify the inclusion of cybersecurity within 'external influence' could be a viable option to address this issue. However, many stakeholders underlined that cybersecurity should be considered a broader issue that should not be specifically addressed in the MD.

Expectations for changes to the MD

One of the potential revisions of the Directive under consideration is to which extent the MD can address challenges brought about by the digital transformation of machinery, especially while keeping the technology-neutral approach of the legal text.

The first aspect discussed before relates to standalone software that is delivered and uploaded to the machinery independently from the OEM's product. One of the questions related to the revision of the Directive is how the revised text might deal with these products.

Box 10: Software that ensures a safety function and is placed independently on the market

The stakeholder consultation showed that the vast majority across groups is in favour of the revised Directive covering software that ensures a safety function and is placed independently on the market. These would then fall under the category of safety components.

The second aspect relates to the functionality controlling the operations of machinery, which can be continuously updated. The operation of the machines can change considerably such that the initial scope of risk assessments performed by the manufacturers is no longer valid. The issue of continuous updates of functionality, contrasting the updates intended by the OEM and major updates that could render the initial risk assessment invalid, was also discussed with stakeholders. Here, risks associated with a lack of continued support of updates were highlighted. There was a lack of consensus on how the revisions of the Directive could tackle these issues beyond providing some clarifications on the Guide, i.e. what constitutes a substantial modification. The challenges and risks that arise from the digital technologies should thus be explored further, including questions such as the impacts of the updates from third party, costs, safety and compliance effects on machinery for which updates are no longer supported by the manufacturer.

Digital twins provide a powerful new layer of dynamic risk assessment for software updates. The advancement in complex simulation techniques and improved connectivity technologies such as 5G enable digital twins to simulate and test a major update on a machine's control software with a view to perform a safety and risk assessment before actually implementing the change to the real world. The machinery, automobile, aeronautics and pharmaceutical sectors are already using the capabilities of digital twins in order to simulate the effect of software updates.[371][372] Digital twins can hence predict unwanted changes to a machinery's control system brought about by an inadequately developed software update/patch or even by a malicious cyber-attack on networks and systems. They can provide technical assurance of new or modified software before it is installed on the physical version of the software control unit. A new safety requirement in that sense could be added to Annex I of the MD.

Overall, there are various options that can be considered when it comes to adapting the MD: i) defining EHSRs and related harmonised standards for software updates; ii) specifying responsibility for safety-relevant software updates in case they are developed and/or delivered by a party other than the OEM and involving a substantial modification requiring a renewed risk assessment; and iii) making it mandatory for OEMs to provide software updates that ensure the safety of machinery throughout its lifetime .

Defining EHSRs and related harmonised standards for software updates. Additional obligations may be needed to ensure that manufacturers provide features that prevent that the upload of software has an impact on safety during the lifetime of machinery.[373] A revision of the MD could stipulate the requirements for software updates, i.e. specifying the EHRS and

[371] https://www.plm.automation.siemens.com/global/en/topic/industrial-machinery-digitalization/56602

[372] https://www2.deloitte.com/us/en/insights/focus/tech-trends/2020/digital-twin-applications-bridging-the-physical-and-digital.html

[373] European Commission (2020). Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics. COM(2020) 64 final. Available at: https://ec.europa.eu/info/sites/info/files/report-safety-liability-artificial-intelligence-feb2020_en_1.pdf

economic operators' obligations that need to be in place in order for software updates to be safe. The robustness of the update is critical and there should be a bootloader that supports the update of the OS/kernel level. In case the update fails, the system should be robust enough to restore to a safe condition, if possible, to the last working firmware. If an update is performed on mobile machines, it should be ensured that these machines come to a safe state before the update starts.

Furthermore, precautions should be taken such as encryption especially for wireless updates as a person can intercept the data between the wireless medium and the machine. The mechanism of roll-back should be effective and immediate as a failed update should not cause the machine to go out of control. If the update is performed on a mission-critical machine that cannot be stopped while the update is performed there should be suitable design considerations foreseen such that the old functionality stays in control while the update is being installed in parallel. The switch to the new functionality must be instant and should not interrupt the state of machine. Depending on the degree of complexity of the software, **a revised MD could stipulate restrictions for the authorised personnel that may enact the update (some updates may be performed automatically, while others may require supervision of an expert).**

A revision of the MD could furthermore stipulate special reporting procedures in case an update has safety implications or has the possibility to significantly change the functionality of machines. The details of the update should be shared with the MSA, including if the conformity regarding risks and safety should be reassessed or not, depending on the type of update. For instance, updating the interface of an infotainment system of a self-driving car has little impacts on safety and there is no need for reassessment. However, an update to the lane-changing feature can affect other safety features related to the self-driving functionalities of the car and might require a renewed conformity assessment.

Finally, version management is a challenge especially when a company deploys a large fleet of machines that run different versions of firmware. It is critical to prevent any tampering of safety-critical software and ensure that any changes and updates performed on the software are tested and logged along with the previously working code and its configurations. Keeping track of the version management is important especially when documentation and user manuals are provided to ensure the documentation and firmware are in sync. This can ideally be done with a version control repository that tracks all the changes and keeps the historic version of the working software. An example of such a control system is Arduino H7 which is a low-cost device but contains hardware-based encryption for validity of the code. Also, in case a particular firmware version has been decommissioned, none of the machines should be running this version.

The Machinery Directive is technology-neutral, and hence cannot stipulate specific technologies to ensure safety in relation to the deployment, transmission and installation of remote software updates. Specific technical solutions can however be provided via voluntary harmonised standards published in the Official Journal of the European Union (OJEU) without imposing particular technologies or via alternative technical solutions presented by manufacturers under certain conditions. Due to the proven effectiveness of digital twin technology in mitigating safety risks of software updates, future standardisation could focus on digital twin technology for the pre-deployment simulation and testing of the effects of software updates on the functionality of machinery prior to the installation on the real-world control unit. However, this would require a mutually agreed minimum definition of adequate digital twin technology (difficult due to the versatility of use cases).

Specifying responsibility for safety-relevant software updates in case they are developed and/or delivered by a party other than the OEM and involving a substantial modification requiring a renewed risk assessment. As noted before, economic operators' responsibility on the product safety is a question that arises when standalone software or software updates are developed by service providers other than the

OEM. For such cases, a revised MD could clearly assign responsibility to the developer for those software-related functionality changes which have an impact on the safety of machinery. As noted by the European Commission's Report on the safety and liability implications of Artificial Intelligence, explicit provisions could be added that require cooperation between all relevant economic actors in the value chain who have an impact on the product safety.[374] These actors, including OEMs, software producers, service providers and end users could be made responsible for provide the next actor in the value chain with the necessary information and measures to ensure safety of the final product. Furthermore, software updates could be required to be documented in a software release management system that is transparent for users and MSAs.

Making it mandatory for OEMs to provide software updates that ensure the safety of machinery throughout its lifetime. As the embedded and independent software controlling the operations of machine is running on an Operating System [further mentioned in the document as OS], the OS as well as the software require maintenance and support including bug fixes, security and safety updates as mentioned in the example in section 1. For this purpose, a revision of the MD could require the manufacturer to support OS security risks and bug fixes for entire lifetime of the machinery.

Conclusions and recommendations

The agile nature of the digital market along with decreasing costs of application deployment and constant innovation have shortened the time to market for machinery with emerging technologies. The MD should be adapted to remain relevant and to facilitate this pace of digitalisation in a safe manner. As this case study scenarios have shown, adapting to digital technologies can result in enhanced safety (e.g. re-assessment of risk in case of a major update and updating the EHSR instructions along with the update).

The extent to which challenges arising from these technologies should be addressed, however, were seen controversially by stakeholders, some of them invoking the technology-neutral aspects of the MD. While some reform scenarios to the MD were widely supported by stakeholders, others were more controversially discussed, e.g. whether the challenges coming from the digital technologies should be addressed by domain experts via standardisation or through a change in the MD.

Possible reforms of the MD to ensure machinery safety include: i) specifying EHSRs and related harmonised standards for software updates; ii) specifying responsibility for safety-relevant software updates in case they are developed and/or delivered by a party other than the OEM and involving a substantial modification requiring a renewed risk assessment; and iii) making it mandatory for OEMs to provide software updates that ensure the safety of machinery throughout its lifetime. However, no overwhelming support in favour or against these options could be identified. On the other hand, providing technical clarifications of what constitutes a machine substantially modified, also in relation to major software updates that might render the initial risk assessment invalid, and to cover standalone software that ensures a safety function as safety component yielded positive responses by the majority of respondents.

[374] ibid.

Table 72: Summary of challenges and potential changes to the Directive

Focus	Challenges	Expectation of change of the MD
Upload of software in machines	• Potential changes to functionality of the machinery can have a significant impact on safety risks, which raises questions with regards to the conformity of the functionality changes with EHSR. • Issues of responsibility on the machinery safety emerge in case standalone software or software updates are developed by service providers other than the OEM. • New risks emerge during the lifetime of the machine in case the manufacturer stops the support for updates on functionality. • The possibility of externally uploading software to the control unit of machinery raises issues of cybersecurity.	• Defining EHSRs and related harmonised standards for software updates. A revision of the MD could specify the EHRS and economic operators' obligations that need to be in place in order for software updates to be safe. • Specifying the economic operator's responsibility for safety-relevant software updates in case they are developed and/or delivered by a party other than the OEM. • Making it mandatory for OEMs to provide software updates that ensure the safety of machinery throughout its lifetime.

2.2.2. Production optimisation

Relevance of the selected case

With the sophistication of machine learning (ML), ubiquitous interconnectivity through Internet of Things (IoT) and the development of increasingly accurate sensors at ever smaller scale, the manufacturing industry has witnessed technology advances at an unprecedented speed. While any of these three technology clusters could greatly optimize production on their own, it is the very combination of ML, sensor-based data and IoT that can unlock a dramatic leap in efficiency and safety of production.

Another objective is to consider definitions, as it was mentioned by the stakeholders that terms such as "Artificial intelligence" are understood differently in different contexts. Non-consistent use of definitions increases the risk of confusion and causes difficulties for standardisation. While definitions for Artificial Intelligence (AI) or ML may not to be required within a revised MD itself, they could be included in a future Guide.

Box 11: Definitions of the key technologies in scope

Sensor-based data:

"Sensor data is the output of a device that detects and responds to some type of input from the physical environment. The output may be used to provide information or input to another system or to guide a process."[375]

Internet of Things (IoT):

The new generation of IoT (also called IoT 2.0) can be described as the "infrastructure of interconnected objects, people, systems, and information resources together with intelligent services to allow them to process information of the physical and the virtual world and react".[376]

Machine Learning (ML):

Machine learning "denotes the ability of a software/computer to learn from its environment or from a very large set of representative data, enabling systems to adapt their behaviour to changing circumstances or to perform tasks for which they have not been explicitly programmed".[377]

Artificial Intelligence (AI):

Artificial Intelligence (AI) systems are "software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can

[375] https://internetofthingsagenda.techtarget.com/definition/sensor-data
[376] ISO (2014). Internet of Things (IoT) Preliminary Report 2014, Available at: https://www.iso.org/files/live/sites/isoorg/files/developing_standards/docs/en/internet_of_things_report-jtc1.pdf
[377] https://ec.europa.eu/digital-single-market/en/artificial-intelligence

either use symbolic rules or learn a numeric model, and they can also adapt their behaviour by analysing how the environment is affected by their previous actions.[378] Samolli et al. (2020) have developed an operational definition of AI based on a differentiated AI taxonomy, comprising the domains of reasoning, learning, communication, perception, integration and interaction, services as well as ethics and philosophy. [379]

The principle of IoT is to create, communicate, aggregate, analyse and act.[380] As the emerging IoT (also referred to as IoT 2.0) is considered essential for the implementation of the Digital Transformation, it is also sometimes referred to as the "Internet of Transformation".[381] The IoT is a digital solution that may be implemented within smart manufacturing. Creating represents data captured by sensors, communication requires **transfer of this captured data in the digital world** in an operable format and aggregation refers to the part where the captured data is ingested in a digital repository possibly combined with data from other repositories such as Enterprise Resource Planning (ERP) to perform further analysis. IoT enables parties to combine Information Technology with Operations Technology and enhance interactions with the physical world.

This case study explores the challenges arising from the usage of machine learning models and sensor data to improve machine performance and safety, **in real-time and without human interaction**. The use case will focus on the consequences of sensor-supported machine learning techniques and the usage of ML-enabled networks of applications within a larger IoT. The emerging IoT generates new challenges deriving from the use of multi-agent networked collaborative systems and peculiarities of evolutionary programming that can make the behaviour of machinery unpredictable.[382]

Key challenge

IoT is a technology enabler that allows connecting several machinery products - covered by the current MD - in a connected multi-agent interoperable system. By integrating machinery in IoT networks, the ex-standalone machinery (subject to risk assessment) becomes far more complex to assess. Machine Learning-enabled control systems embedded in an IoT network can control groups of assets and can adapt the functions of the machinery over time. Currently, software as a safety or control component is not considered independently in the MD.

[378] High Level Expert Group on Artificial Intelligence (HLEG) definition of Artificial Intelligence, 2019, as reported in Sofia Samoili & Montserrat Lopez Cobo & Emilia Gomez & Giuditta De Prato & Fernando Martinez-Plumed & Blagoj Delipetrev, 2020. "AI Watch. Defining Artificial Intelligence. Towards an operational definition and taxonomy of artificial intelligence," JRC Working Papers JRC118163, Joint Research Centre

[379] Sofia Samoili & Montserrat Lopez Cobo & Emilia Gomez & Giuditta De Prato & Fernando Martinez-Plumed & Blagoj Delipetrev, 2020. "AI Watch. Defining Artificial Intelligence. Towards an operational definition and taxonomy of artificial intelligence," JRC Working Papers JRC118163, Joint Research Centre

[380] https://www2.deloitte.com/content/dam/insights/us/articles/iot-primer-iot-technologies-applications/DUP_1102_InsideTheInternetOfThings.pdf

[381] https://www.i-scoop.eu/digital-transformation/digital-transformation-technologies-iot/

[382] The scope of this use case is limited to existing technologies. Possible advancement in the technology will not be covered as it is hard to predict the future of technologies. Furthermore, the challenges related to Augmented and Virtual reality technology will not be examined as these devices are considered to be another method to interact with the machines.

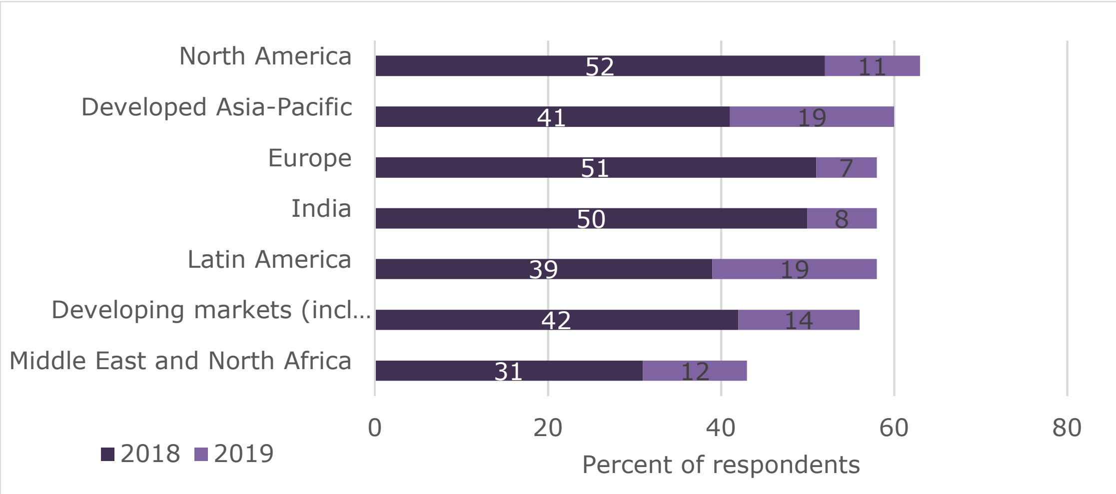
Market trends

Machine learning

The global machine learning (ML) market is expected to grow at a compound annual growth rate of approximately 40.1% between 2019 and 2026, reaching a market value of EUR 68.8 billion by 2026. ML projects received over EUR 38 billion funding globally in 2019, more than all other artificial intelligence (AI) solutions combined. Other projects using AI, including advancing smart robots, virtual assistants, and natural language processing, received EUR 34.5 billion in total.[383] While deployment of ML in a company is associated with significant initial investments, ML shows a high median return on investment (ROI) of 17%. Companies in the industrial services and products sector are witnessing the highest investment-to-return ratio, with a ROI of almost 20%.[384]

According to the Artificial Intelligence Index, AI adoption is becoming more homogenously distributed across regions (see Figure 106). The developed Asia-Pacific region reported the highest growth in adoption since 2018 (19%), compared to a 7% year-on-year growth in Europe.[385] These trends suggest that **AI, including ML, are becoming a mature technology** that companies across regions and sectors are eager to invest in.

Figure 106: AI capabilities embedded in at least one function or business unit (2018-2019)[386]



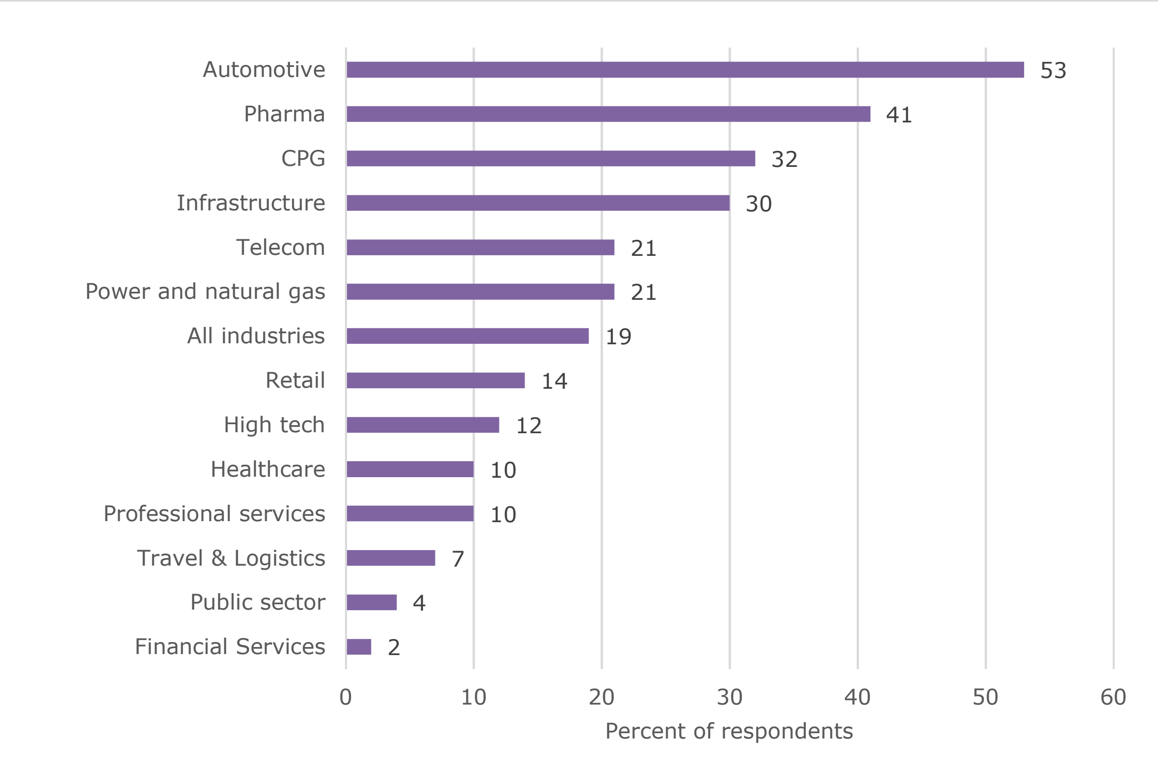
In Western Europe the financial sector is leading with €2.6 billion of AI spending expected for 2018.[387] Analysts estimate that 37% of large-scale European financial institutions had adopted Machine Learning at the core of operations by the end of 2018.[388] By contrast, 47% of businesses from various sectors reported to have scaled up and industrialized ML or are moving

[383] Richter, F. (2019, May 10). Infographic: Machine Learning Tops AI Dollars. Retrieved February 6, 2020, from https://www.statista.com/chart/17966/worldwide-artificial-intelligence-funding
[384] Deloitte (2018). State of AI in the Enterprise, 2nd Edition
[385] AI Index (2019). 2019 Annual Report
[386] AI Index (2019). 2019 Annual Report
[387] IDC. (2018, September 12). Banking Will Drive Cognitive/Artificial Intelligence Systems Spending in 2018 in Western Europe, but Healthcare Investments Will Grow Faster, Says IDC. Retrieved February 11, 2020, from https://www.idc.com/getdoc.jsp?containerId=prEMEA44275018
[388] ML is a software-driven solution lacking a clearly shared definition in different market segments, with only limited research so far conducted on the level of advancement and adoption in different industries and sectors.

projects into production.[389] In an international survey of financial institutions on the future of ML, 71% of respondents in Europe stated that automation is the main ML application in their operations (compared to 53% in North America and 56% in Asia).[390]

Zooming in on manufacturing functions, research indicates that the Automotive, Pharma and Consumer Packaged Goods (CPG) industries are most advanced in AI adoption (see Figure 107). Companies tend to adopt AI in operations that provide core value in their industry, with the automotive industry **most likely to adopt AI in manufacturing**, while financial service operators are more likely to it for risk management functions.

Figure 107: AI adoption for manufacturing purposes, by industry 2019[391]



In terms of research and development, the EU has more ML researchers and a larger research output than either the USA or China, with the latter rapidly increasing its research output in the recent three years.[392] According to a 2020 Techno-Economic Segment analysis of AI globally, the EU holds the third position worldwide – behind China and the USA – in terms of the number of activities in Machine learning and Connected and Automated vehicles, the latter mainly driven by Germany, UK and Sweden. [393] While the large majority of EU AI firms have a core business that is AI-related, they are less involved in patenting technological developments

[389] KPMG (2019). Easing the pressure points: The state of intelligent automation
[390] Refinitiv (2019). Smarter Humans. Smarter Machines. Insights from the Refinitiv 2019 Artificial Intelligence / Machine Learning Global Study
[391] AI Index (2019). 2019 Annual Report
[392] 28 percent of AI research papers originate in Europe, the largest percentage of any region, according to AI Index (2018). 2018 Annual Report
[393] Samoili, S., Righi, R., Cardona, M., Lopez Cobo, M., Vazquez-Prada Baillet, M. and De Prato, G., TES analysis of AI Worldwide Ecosystem in 2009-2018 , EUR 30109 EN, Publications Office of the European Union, Luxembourg, 2020, ISBILLION 978-92-76-16661-0 (online), Available at https://ec.europa.eu/jrc/en/publication/tes-analysis-ai-worldwide-ecosystem-2009-2018

of AI and ML that the USA and China. The EU lags behind in terms of patent volume, pace of ML adoption and funding, as exemplified by the fact that ML start-ups both in the US and China received more venture capital and private equity funding in 2017 alone than EU start-ups received in the three years between 2016 and 2018.[394,395] This disconnect between research and development output on the one hand and commercial adoption on the other hand underlines the importance of creating a future regulatory environment in the EU that balances the need for constant innovation with adequate safeguards for safety, health and privacy.

Top players driving the evolution and patent race in the machine learning market are cloud platform providers such as Amazon Web Services, Google Cloud Platform, IBM Cloud and Microsoft Azure.[396,397] However, the burgeoning ML market sparks the emergence of many new players, including many European start-ups such as Sparkbit, German Autolabs, as well as incubators such as Merantix.[398] To expand their geographical reach and customer base, market players collaborate with established service providers in end-user industries.[399]

Sensor-based data

ML technology **requires data** for learning. Micro-sensors provide crucial real-time information for many ML applications. The accuracy of available market research on the volume and growth of the IoT- and ML-specific sensors market is inherently limited, as micro sensor manufacturers often lack the knowledge of the exact class of final products in which their sensors are eventually installed along the value chain (see Figure 108). Modern micro sensors, such as nanoelectromechanical and microelectromechanical systems (NEMS/MEMS), are integrated in a plethora of applications, including smartphones, wearables, autonomous vehicles and other evolving IoT segments, such as remote sensing, connected driving and smart cities.

With these analytical limitations in mind, the European IoT Sensor market has been estimated to account for EUR 2.6 bln in 2019 and is expected to grow to EUR 15.5 bln in 2027, based on a CAGR of 24.9%.[400] While driven by evolving applications in various market segments, the IoT sensors market is estimated to continue to generate most revenues in the consumer electronics industry, which is forecasted to account for approximately 60% of the industry's revenues.[401]

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[394] Castro, D. (2019, August 30). Who Is Winning the AI Race: China, the EU or the United States? Retrieved February 11, 2020, from https://www.datainnovation.org/2019/08/who-is-winning-the-ai-race-china-the-eu-or-the-united-states/

[395] Samoili, S., Righi, R., Cardona, M., Lopez Cobo, M., Vazquez-Prada Baillet, M. and De Prato, G., TES analysis of AI Worldwide Ecosystem in 2009-2018 , EUR 30109 EN, Publications Office of the European Union, Luxembourg, 2020, ISBILLION 978-92-76-16661-0 (online), Available at https://ec.europa.eu/jrc/en/publication/tes-analysis-ai-worldwide-ecosystem-2009-2018

[396] Acumen Research and Consulting (2019). Machine Learning Market – Global Industry Analysis, Market Size, Opportunities And Forecast, 2019 - 2026

[397] Columbus, L. (2019, April 3). Roundup Of Machine Learning Forecasts And Market Estimates For 2019. Retrieved February 11, 2020, from https://www.forbes.com/sites/louiscolumbus/2019/03/27/roundup-of-machine-learning-forecasts-and-market-estimates-2019/#79529e517695

[398] The Manifest. (2020, February 1). Top 25 Machine Learning Companies: February 2020: The Manifest. Retrieved February 11, 2020, from https://themanifest.com/artificial-intelligence/machine-learning/companies

[399] Acumen Research and Consulting (2019). Machine Learning Market – Global Industry Analysis, Market Size, Opportunities And Forecast, 2019 - 2026

[400] The Insight Partners (2019). Europe IoT Sensor Market to 2027 - Analysis and Forecasts by Type; Connectivity Type; and Application

[401] Allied Market Research, 2015. Global sensor market forecast 2022.

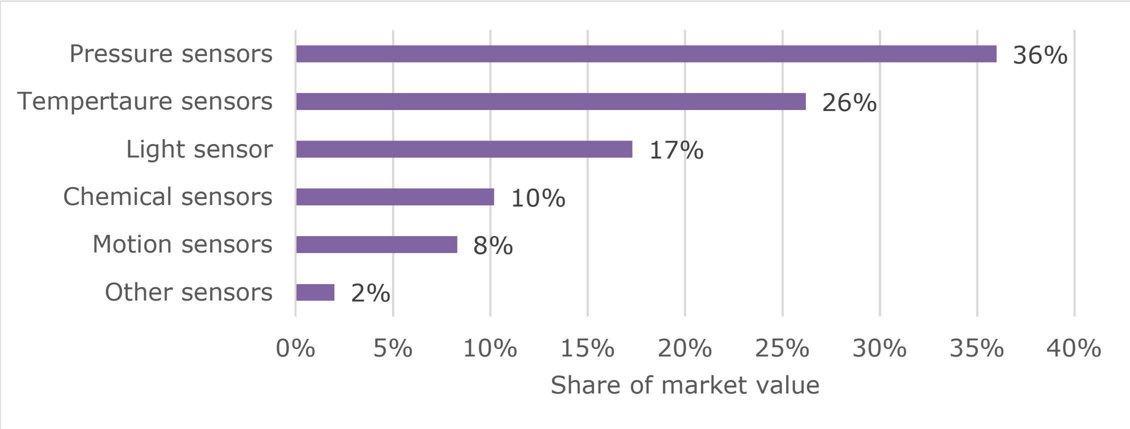
Figure 108: IoT Sensor Value Chain

Sensors supply big data collections that differ in terms of **variability (V[1])**, be it optical, temperature, flow, shock, vibration, pressure and many other categories of data necessary for a ML system to operate and leverage on an accruing **volume (V[2])** of data over time **(velocity V[3])** to improve its operation. For instance, the new wireless gateway controllers use vibration sensors installed in industrial machines to enable ML-based computers to improve monitoring of machine operation and health over time.

When remotely (wirelessly) connected to a central terminal, a single human supervisor can monitor a fleet of machinery based on ML-based diagnostics. If disconnected, human supervisor might be unable to control remotely said machinery. To deal with this hazard, a new **requirement on networked connectivity** may be needed.

By 2022, pressure and temperature sensors are estimated to account for 62% of all globally enabled IoT sensors, followed by light, chemical and motion sensors (Figure 109).

Figure 109: Global IoT-enabled sensors market in 2022, share of revenue by sensor type[402]



IoT networking

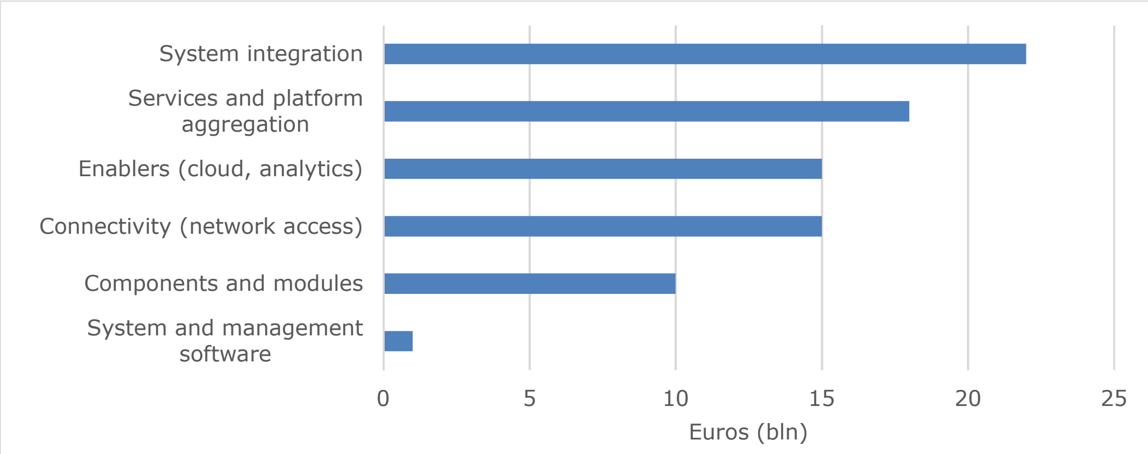
IoT is a technology enabler that exploits networking technology to allow incorporating several - ex-standalone - machines into an "always-on" connected multi-agent interoperable cooperative system. By integrating networked IoT applications in the manufacturing process, companies can reduce supervision costs, drive production optimisation, improve inter-machine collaboration and reduce waste. From a regulatory perspective, however, the IoT-enabled superordinate multi-agent network is far more challenging to assess than the previously standalone pieces of machinery. Compared with legacy machinery designed to operate

402 Wagner, I. (2019, October 9). IoT sensors global market breakdown: enabled sensors 2022. Retrieved February 6, 2020, from https://www.statista.com/statistics/480114/global-internet-of-things-enabled-sensors-market-size-by-segment/

standalone, the IoT trend emerges new requirement of considering a category of networked machinery, new "super-assembly" of interacting machines, that delivers very different network-wide self-organized functionality of cooperating machines.

By the end of 2020, an estimated 25 to 30 billion internet-connected devices will be operating worldwide, averaging more than three units for every human being. [403,404] However, the IoT market is not so much driven by the number of hardware units than by **cloud-based** analytics, **system integration and platform aggregation** technologies. The IoT market in the EU is estimated to grow to EUR 8 bln in 2025 (see Figure 110). This trend suggests considering the **role of system integrators** in the machinery sector. System integrators and services (including platform aggregation) will be the key drivers of the European IoT market, whereas components and modules, i.e. the core hardware, is estimated to only account for 12.3% of overall market revenues.

Figure 110: Forecasted Internet of Things (IoT) solutions market in the European Union in 2025[405]



To quantify the market worldwide, the global installed base of IoT devices approximates 30 billion in 2020, with the majority of units (13.5 bln) estimated to be installed in the consumer sector, compared to 7.6 bln in the business sector.[406] Between 2017 and 2025, the number of IoT applications in the EU industry (IIoT) is expected to rise from 263 mln units to 305 mln units.[407] By contrast, analysts predict the global quantity of installed IIoT devices to jump from 237 million in 2015 to 923 million in 2020[408], indicating that IIOT adoption is advancing at a higher pace globally than in the EU. Bolstered by evolving automation in transport and

[403] Gartner. (2018, November 7). Gartner Identifies Top 10 Strategic IoT Technologies and Trends. Retrieved February 13, 2020, from https://www.gartner.com/en/newsroom/press-releases/2018-11-07-gartner-identifies-top-10-strategic-iot-technologies-and-trends

[404] DG Connect (2019). Study on mapping Internet of Things innovation clusters in Europe. Available on https://ec.europa.eu/digital-single-market/en/news/study-mapping-internet-things-innovation-clusters-europe

[405] Statista Research Department. (2018, January 17). IoT solutions market in the EU 2025. Retrieved February 6, 2020, from https://www.statista.com/statistics/686198/iot-solutions-market-in-the-european-union-eu/

[406] DG Connect (2019). Study on mapping Internet of Things innovation clusters in Europe. Available on https://ec.europa.eu/digital-single-market/en/news/study-mapping-internet-things-innovation-clusters-europe and https://www.businesswire.com/news/home/20190516005700/en/Strategy-Analytics-Internet-Things-Numbers-22-Billion

[407] O'Dea, S. (2019, May 27). IoT electronics EU 2017-2025. Retrieved February 6, 2020, from https://www.statista.com/statistics/691885/iot-electronics-in-the-eu/

[408] Atwell, C. (2019, June 15). How Do Advances in Industrial IoT Impact the Labor Market? Retrieved February 13, 2020, from https://www.electronicdesign.com/technologies/iot/article/21808191/how-do-advances-in-industrial-iot-impact-the-labor-market

multimodal logistics, the EU transport sector is estimated to witness an increase from 2.6 mln to 3.7 million units between 2017 and 2025.[409] Other segments, notably agriculture, healthcare and security, currently have a far lower volume of IoT units in usage, but are estimated to witness much higher growth rates until 2025.[410]

To depict better the composition of that market, the industries that are most eagerly investing in IoT technologies are manufacturing companies, financial service providers and technology enterprises. While a precise attribution of efficiency gains to IoT deployment is difficult due to the plethora of use cases and network architectures, Capgemini's Digital Transformation Institute estimates that the global manufacturing industry may have generated between EUR 477 and EUR 629 billion in value-added revenue by 2020 through the development and sale of IoT-enabled devices.[411]

Shortcomings, barriers of the current MD and approach of the sector today

The introduction of ML-enabled machinery integrated in an IoT network that **controls a group of machinery assets** has raised new challenges for regulators across the globe. The scale of the challenges is growing, as the control is no longer limited to a single asset. Stakeholders voiced concerns on the current scope of the Directive with regards to be fit for purpose to cover risks of emerging technologies sufficiently, such as IoT and Machine Learning that are enabling systems to be increasingly autonomous to an extent that the machines can function independently without the need of human intervention. This is especially the case with ML-enabled, IoT-connected collaborative robots, mobile robots and wireless applications/controls. To remain technology-independent, new requirements may be needed to consider risks deriving from the transformation of local-only control systems into **networked-control systems that are no longer limited to a single asset.** The main issue in that case is the variability of manufacturers of individual assets going to be networked together by a system integrator (new role).

The MD defines 'machinery' as "an assembly (…) of linked parts or components, at least one of which moves (…)". As such, this definition could be understood to encompass machinery ranging from lawnmowers, to construction machinery up to complete automated industrial production lines. However, physically assembling parts or components is not necessarily what specifically defines an IoT systems (see Box 1), and hence the coverage and effectiveness of the MD for a broad section of IoT devices need to be inspected.

There are also challenges related to sensor-acquired data and overall data quality aspects, as issues can rise because of defective sensors, inability to detect changes, or networking fault situation causing the impossibility for one machine to deliver correct data to the corresponding remote-control application. This may generate new risks such as a permanent loss of communication, intermittent connection, Denial of Service, or other situations when sensor or camera capturing the physical world is creating erroneous or still/frozen data. As a consequence, a new **safety requirement for networking** may be needed: if data from the physical world or the created and aggregated data is incorrect or delayed, the analysis

[409] Statista Research Department. (2020, January 31). IoT transport EU 2017-2025. Retrieved February 6, 2020, from https://www.statista.com/statistics/691855/transport-iot-units-in-the-eu

[410] O'Dea, S. (2019, May 27). Security IoT EU 2017-2025. Retrieved February 6, 2020, from https://www.statista.com/statistics/691875/security-iot-units-in-the-eu/
O'Dea, S. (2019, May 27). Agriculture IoT active connections EU 2016-2025. Retrieved February 6, 2020, from https://www.statista.com/statistics/691880/agriculture-iot-active-connections-in-the-eu/
O'Dea, S. (2019, May 27). IoT active connections in healthcare EU 2016-2025. Retrieved February 6, 2020, from https://www.statista.com/statistics/691848/iot-active-connections-in-healthcare-in-the-eu

[411] Capgemini Digital Transformation Institute. (2018, June 21). Smart, connected products to add up to $685 billion to manufacturing revenue by 2020. Retrieved February 13, 2020, from https://www.capgemini.com/news/digital-engineering

performed may not be correct or the decision taken (such as stopping a machine to prevent overheating) could not be valid anymore depending on the extent of the delay.

Sensor and other input-related safety issues

Currently, the MD does not explicitly cover input sources and any sensor data, input data, training data that feed into ML-enabled machinery applications. It concerns robots and all other automated machines, those supervised directly and manually operated, remotely controlled, and autonomous machinery. Direct impacts on safety may pose the need of a new **requirement on how to regulate data collection process, its outcome, and the minimally acceptable data quality**. In terms of safety, the robustness, reliability, accuracy and timeliness of data captured and transmitted by sensors and other input sources is crucial to the safe operation and effective optimisation of ML-enabled applications, irrespective of whether they are embedded in an IoT. If the inputs are inaccurate, because of any network-resource dependent circumstance, the ML-enabled functionality of an application will not effectively be optimised or may even deteriorate in such a way to cause severe accident (damage of machinery, collision with human operator, injury). If a data stream is compromised in any way (network fault, resource unavailability, hacking or other), or wrong decisions about an object are made by an ML-enabled application, the machinery can produce an unforeseen or undesired collision which could endanger, injure or kill a human. Specific protective measures might therefore be required. There is also a major risk of safety due to incorrect data coming from faulty input sources such as sensors.

The severity of safety issues related to incorrect control decision taken based on the sensorial data is highlighted by an accidents' analysis from the industrial automation study conducted by the French Ministry of Ecology, Sustainable development and Energy. According to the Ministry, "between 1981 and 2009, 42% of automated control and safety malfunctions at the facilities of 10 international petroleum groups were due to sensor failure (compared to 8% for processing functions and 50% for actuator functions, based on a panel of 987 sensor models, 907 valve models and 10 control logic unit models)."[412] According to the study, sensor-related accidents were observed mostly in operations such as restart, stop and shutdown. Compared with standalone machinery, safety of networked operations requires consideration of all interactions between networked machinery assets. Malfunction accounted for more than 50% accidents related to sensors, of which 66% of causes included either human error or a lack of maintenance, insufficient connectivity or lack of cleaning. The study highlighted the positive effects on the prevention of accidents by the use of sensors in targeted sectors while recommendations were made to conduct strategic assessments, strict specifications on installing sensors, taking environmental and process constraints, inspections and maintenance by qualitative technical organisations and periodic testing and calibrations of sensors to avoid accidents related to sensors

Machine learning

The emergence of Machine Learning technologies and Deep learning have changed the spectrum of how machines operate. These technologies operate on various levels, such as software only providing assistance to users, for example through products like personal assistants, or chat bots for marketing and social media. The EHSRs do not generally specifically refer to Machine Learning as it is, and the extent to which challenges in case of autonomous and/or remote control is addressed is unsure. Among specific concerns mentioned by stakeholders are the increasingly autonomous function of complex embedded software systems, data collection, security in installations, and remote control. Machinery that uses ML technology operates differently because it can change its behaviour based on newly learnt

[412] Can be found at: https://www.aria.developpement-durable.gouv.fr/wp-content/files_mf/Sensorsindustrialautomation_GB.pdf

data. ML capacity is delivered by **new software- and data- assets** going to be incorporated in new generation machinery (hardware plus software plus data).

First, independent software is not included in the definition of control systems. ML software can control a group of assets and can adapt the functions of the machines as compared to pre-defined set of controls. However, software as a safety or control component is not considered independently in the MD, as presented in the first case study. Dysfunctional ML outputs can be caused either by errors in the ML software itself (as highlighted in the previous case study) or by erroneous data inputs (training data, operational data or sensor inputs). Both can have direct adverse effects on safety and wellbeing of human collaborators.

Box 12: Example of "Lights Out" factories

To highlight the extent of control that machines have, "Lights Out" factories can be presented as an example. The concept is that manufacturing can be automated to such an extent that there is no need to turn on the lights of the factories or warehouses, as there is limited presence of high skill workers to perform certain specialised tasks. Fanuc in Japan has been operating with the lights out since 2001. Their 22 windowless automated factories produce robots. Fanuc has also launched FIELD System (FANUC Intelligent Edge Link & Drive System) in 2016 that connects and collect data from their manufacturing robots worldwide. Deep Learning is applied on this data to teach the robots. This resulted in significant improvement on the tasks such as bin picking. Instead of skilled programmers writing code to teach the machine how to perform the tasks, Fanuc's robots are teaching themselves. After 1,000 attempts success rate of 60% is achieved while after 5,000 attempts the robot can pick up 90% of all parts. No line of code is needed for this purpose.[413]

Second, the MD does not provide minimum standards for the display of safety-critical information of ML-enabled processes. The MD does not cover the types of information that need to be displayed on the Human Machine Interfaces (HMIs) of ML-enabled applications. All ML systems generate insights that can be displayed on dashboards, but due to the large **volumes** of data generated, or due to high **velocity**, or because of other "big data" factors, these insights need to be classified in order to ensure that only the information that is relevant to human supervisors is displayed. This poses challenges that may need to be tackled via new requirements related to classification (data taxonomy), data security and data integrity.

Third, the MD does not provide minimum standards for data logging and storage of ML-driven data and decision-making processes. One of the most important aspects for establishing trust, safety and transparency vis-a-vis machine learning algorithms is the concept of lineage. In order to establish lineage, the development, learning, training data and decision-making process underpinning ML-enabled applications need to be documented for traceability. This enables users and manufacturers to understand the decision-making process in greater detail compared to a black box. For instance, programmable logic controllers (PLCs) act based on streams of data. If this stream and the actions of the PLCs are not logged there are only limited opportunities to identify failure root causes and prevent possible issues from occurring in the future. However, service providers today are not logging all data for machine learning and neural networks. There may a need for new requirements on the establishment of lineage of machine learning algorithms.

[413] Bloomberg Businessweek This Company's robots are making everything and reshaping the world, can be found at: https://www.bloomberg.com/news/features/2017-10-18/this-company-s-robots-are-making-everything-and-reshaping-the-world

Fourth, the clause in MD Annex I - 1.2.1. Safety and reliability of control systems for cable-less control in case of loss of communication could be dangerous. The clause for cable-less control could be dangerous as a machine that is functioning properly can come to a halt due to a temporary lapse in communication that might not have affected the functions of the machinery. What if the networked machine has an edge device that can still control the operations in case of loss of communication? New networking requirement suggests that additional care should be taken if the machine is mobile, and consideration should be taken for the machine stopping in a safe state even in a cooperative networked scenario.

Finally, machine learning process requires that the machinery is delivered to the installation place first, integrated with the necessary sensors and other elements of the networked control system, and operated to start with in learning modality. Once learning data collection is acquired, the system integrator needs to finalize the tuning process. As soon as this is completed, the machinery can start performing its function. This is the moment when the machinery is placed on the market and needs to be CE-labelled. Therefore, a new requirement may emerge in terms of the CE-marking procedures since more and more manufacturers of hardware and software and system integrators will be acting in tight cooperation.

Internet of Things

The above-mentioned regulatory challenges raised by evolutions in ML-enabled applications are further compounded by **integration of numerous applications** in a complex IoT system. Challenges are escalated as the interconnectivity of assets can lead to issue propagation, since assets are no longer isolated. There are various challenges concerning IoT in terms of EHSR as mentioned in the MD.

First, control systems are not defined in the MD as physically or logically connected entities. IoT systems enable the monitoring and control of assets simultaneously. The adoption of IoT technology transforms local control systems into networked control systems. This poses new hazards because the control of machinery assets via automated systems has direct implications on safety, hence new essential health and safety requirements may be necessary. IoT has enabled the possibility of remote monitoring. ML enables continuous adaption of operational fleet management as well as tracking and tracing of assets. As a single ML control system is able to control a large group of assets (e.g. all the assets on a factory floor), a possible dysfunctional ML output that affects several applications at the same time can cause significant health and safety risks, including unpredicted behaviour of moving parts of the machines that can possibly cause an accident.

Other requirements might derive from networking. While asset monitoring has confidentiality issues, (e.g. if a manufacturer is monitoring locally or remotely the machines of the customer, he can easily understand IP protected manufacturing secrets such as what is the optimal temperature to produce high quality plastic), the risks of safety are almost non-existent unless a human intervention is performed based on faulty data/results. Here the question is raised about proportionality of an obligation to share, not to share, or how to share data.

Second, the MD does not specify requirements for communication processes and channels for IoT-embedded machinery. The availability and the effective utilization of network connectivity as a shared resource may not depend on the manufacturer. IoT-embedded fleet operations pose challenges in terms of establishing and maintaining a channel of communication, maintaining integrity of data to and from the entities, delays and loss of data. The telemetric data captured in a diverse fleet follows various routes before being integrated in a digital repository. This data needs to be aggregated with metadata from other repositories from the enterprise to make sense of it. It is crucial to maintain the integrity of this data until it reaches the digital repository and back to the actuator as instructed by the control system. This is important especially since this data can be translated into different formats in each layer. These challenges did not exist when the MD was first drafted, hence they are not covered in major details by MD. Networked connectivity can be wired (not covered by RED) or wireless (covered by RED). With regards to wireless connectivity, clause 1.2.1 in Annex I on wireless control of systems is considered to cover most issues with connected machinery, including withstanding external influences. In particular, control systems that are using wireless technology are required to turn off or go to safe position when connection is missing. Yet with regards to wired connectivity new requirements may need to be considered.

However, the supervisor of a large IIoT network needs be able to rapidly identify the cause of a network dysfunction, e.g. whether it is a short-term network error or instead a (malicious) denial of service (DoS) attack and adapt the risk management strategy accordingly. If a DoS condition (not only an attack by hackers but also any other contingency) affects an assembly of machinery in a large manufacturing plant with components critically relying on connectivity, it can shutdown entire production lines. At the same time, it is the very proliferation of IoT devices that increases the pool of possible botnet nodes that can potentially be exploited by hackers for distributed DoS attacks. As such the rapidly growing number of global IoT devices paradoxically increases the potential impact of botnet attacks against other IoT networks, including the machinery sector. Hence new security layers are required to quickly identify the root causes of a connectivity issue, with recent advances made in detecting IoT attacks in packet core networks.[414] This suggests that new safety requirements on networked control systems may be necessary.

Box 13: Example of evolution of wireless communication in the context of IoT optimisation

An example[415] in the evolution of wireless communication in the context of IoT optimising production is the Nokia's 5G "factory of the future" in Oulu, Finland. This factory produces approximately a thousand base stations for 4G and 5G on a daily basis. Nokia implemented 5G and (4.9G/LTE) private networks to connect all assets in the factory through the wireless connectivity. Nokia also used its edge cloud to run IoT analytics for creating a real time digital twin of the factory's operations. The AGVs present at the factory floor also improved performance and stoppages due to hand over between the wireless access points. This resulted in significant annual improvements such as 30 percent gains in productivity while the time to market was reduced to half and the annual costs saving of 30 million euros.

While ensuring sustained and **safe connectivity** is itself challenging, ubiquitous connectivity also poses the risk of malfunction due to interference or from a malicious attack. Security risks include hackers being able to tamper with the machine learning system. For instance, some industrial processes can be conveniently managed through mobile apps. While such remote controls may increase production efficiency, they also create additional targets for cyber-attacks. That means that cybersecurity has a direct impact on workplace safety and that it is now a prerequisite element of ensuring safety in industrial control systems and networks.

Expectations for changes to the MD

Reflecting the structure of the challenges and barriers identified in section 2.2, this section presents the expectations for changes to the MD for i) sensor input-related safety issues, ii) Machine Learning and iii) IoT in distinct sub-sections. Where overlaps between the technology domains occur, this will be highlighted in the analysis.

Sensor and other input-related safety issues

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[414] Khaing, M. S., Thant, Y. M., Tun, T., Htwe, C. S., & Thwin, M. M. S. (2020, February). IoT Botnet Detection Mechanism Based on UDP Protocol. In 2020 IEEE Conference on Computer Applications (ICCA) (pp. 1-7). IEEE.
[415] Details can be found at: https://www.automationworld.com/products/networks/article/13320089/nokia-employs-5g-in-its-own-factory

Regulating safety requirements for data streams (training, sensor or input data) that feed into ML-enabled applications. In machine learning, learning from data is one of the most important components as it affects the decision-making process and the ML model of the Machine learning. ML-enabled machinery requires a steady flow of data from sensors to materialise the context resolution. In order for sensorial-based perception functions to work, sensors need to be permanently connected to the software to offer an uninterruptible stream of data. This needs to be elaborated in real time before taking control decisions. Obstacle recognition and collision avoidance are tasks that require sensorial data for ML. Software has to recognise if the data stream is blocked, becomes unavailable etc. in order to be always sure that the control decision is based on true data.

Furthermore, the model and the learning data should not contain bias to avoid any un-fair treatment to certain groups (as mentioned in the white paper from EU), this relates to the pillars of fairness to ensure trust in AI. The model can learn bias from the training set intentionally or un-internally as the example of Amazon's recruitment tool that was biased against women as the training data contained predominantly male profiles over a period of 10 years[416]. To counter such issues, it is important that the data used for learning for the models should be examined by the experts so it can be trusted. The ideal solution in this case would be to have the training data certified by experts and only use certified data in order to train models for machine learning. The model should also be tested with various data sets with extensive human oversight in order to avoid any surprises in the future.

Machine learning

As noted in section 2.2, the MD does not currently cover relevant aspects of software. Among specific concerns mentioned by stakeholders are the increasingly autonomous function of complex embedded software systems, data collection, security in installations, and remote control.

Independent software could be included in the definition of control systems. The incorporation of software as a safety or control component could be considered independently in the MD. Machinery with empty software needs to be risk assessed before the installation to get CE mark. Once a ML period is ended, the machinery should be re-assessed again if substantial modifications have occurred, again requiring to be CE-marked again. If ML is not blocked, the machinery will continue evolving its behaviour, hence it requires continuous risk assessment and tracing the operations over time, similar to a black box.

Involving machine learning scientists and engineers is key to enhance the quality of learning of these systems and to ensure that resulting outputs are human-centric. The principle of human-centric ML is for the machine to learn not only from data but also from people. Involving qualified experts , particularly in the initial learning phase, can counter challenges like un-intended bias such as a ML algorithm teaching itself based on historic recruitment data to prefer men over women, as happened with the recruitment tool developed for Amazon[417]. Using the human-centric ML principle, experts can counter the un-intended bias to teach the machine not to consider a particular historic fact. ML applications show promising results in the healthcare domains, where experts such as doctors and nurses can teach care robots to engage in human-centric behaviour. In critical fields such as healthcare, it is particularly important that domain experts (e.g. healthcare professionals) are supported by machine learning scientists and engineers in order to ensure the desired outcomes of the human-centric machine learning on subsequent engagement with patients.

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416 https://www.reuters.com/article/us-amazon-com-jobs-automation-insight/amazon-scraps-secret-ai-recruiting-tool-that-showed-bias-against-women-idUSKCN1MK08G

417 Can be found at: https://www.reuters.com/article/us-amazon-com-jobs-automation-insight/amazon-scraps-secret-ai-recruiting-tool-that-showed-bias-against-women-idUSKCN1MK08G

A revised MD could provide minimum standards regarding the display of safety-critical information of ML-enabled processes. Such minimum standards could also specify required data logging and storage of ML-driven data and decision-making processes. A single autonomous vehicle is anticipated to generate between 300GB and 1TB of data per day. Processing and storage of these large volumes of data will be very costly for the responsible owner but play an essential role in ex-post incident analysis, insurance claims, security safeguards and product optimisation. The crucial question from a regulatory perspective is how to cope with the data, as well as how much and which data is needed to safeguard for adequate process tracing and logging.

The recently published White Paper "On Artificial Intelligence - A European approach to excellence and trust" has the potential to address this uncertainty as it specifies the records, documentation and data sets that need to be retained for a certain time period to ensure the enforcement of relevant legislation. It also specifies the type of data that should be made available upon request to the competent authorities for inspection[418]. The enforcement of this guideline is necessary to ensure that the service providers actually log the required data.

Internet of Things

IoT is a technology enabler that allows connecting several machinery products - covered by the current MD - in a connected multi-agent interoperable system. By integrating machinery in IoT network, the ex-standalone machinery (subject to risk assessment) becomes far more complex to assess. As noted in section 6.1, the MD does not currently cover relevant aspects of connectivity and data ownership that become relevant due to the advent of IoT-embedded control systems.

A revised MD could include physically or logically connected entities in the definition of control systems. For instance, the MD could require an assessment of a new "whole" of the interconnected system, i.e. comprising each machine as well as all interactions between the machines, which would require a significant change in the risk assessment procedures. However, due to the continuously evolving nature of IoT systems (e.g. if a piece of machinery, or a set of sensors is integrated), it is not feasible to conduct a comprehensive re-assessment following each evolution of the network. As each industrial IoT network is unique, it would hence be difficult to specify a generally applicable threshold for an IoT network evolution following which a new risk assessment would be required.

A revised MD could specify requirements for communication processes and channels for IoT-embedded machinery. Stable and security communication is critical as in IoT-embedded machinery networks, data is communicated between the physical and digital world. There could be several layers in between, e.g. data from sensors can be transferred to edge devices where the data captured from sensors is translated and rearranged in a format that is encrypted and compressed to have a minimum load on the communication medium.

The architecture and security norms should be technology neutral in accordance with the MD principles. Manufacturers are already adapting standards such as ISA 95 and NOMA (Non-orthogonal Multiple Access) which include various security standards to ensure cyber security, NOMA tackles especially how the data from IoT is used. NOMA is a technique that can integrate in next generation wireless communication systems. It can fundamentally fulfil the emerging requirements as it uses the power and control domain for multiple access, whereas the previous generations of mobile networks have been relying on the time/frequency/code domain. It can realise multiple access by utilising power domain in a spectrally efficient way and can serve multiple IoT devices in the same sub-carrier. This can be achieved by allocating different power levels to different IoT devices. Most of the industry stakeholders did

[418] https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf

recommend to address only immediate safety related risks regarding cyber security and to not go to a further extent in the MD. Cybersecurity threats to products are transversal and not only applicable to the MD but also others. Therefore, it is suggested to ensure wider aspects of cyber security through other directives which also cover other devices.

Conclusions and recommendations

According to the reflection published by CONNECT Advisory Forum (CAF) about the European approach to the Internet of Things, Europe is in an excellent position to become a global IoT leader.[419] The emergence of technologies such as Machine Learning has resulted control shifting from humans to autonomous functionalities of the machines. This brings forward challenges such as safety risks.

The scope of this case study was to assess the challenges limited to existing technologies related to sensor-based control, machine learning and IoT. In combination with ML-enabled applications, IoT brings forth several challenges including ensuring accuracy of data inputs (sensors and others), facilitating for safe communication and high-integrity aggregation of data, and ultimately ensuring safe outputs of ML-enabled control units.

The MD should facilitate the innovation of emerging technologies and help in strengthening the position of EU as the leader in Machine Learning and IoT. There are several challenges that need to be addressed on a broader level. These include the wider incorporation of independent software when it comes to control and enhancing the EHSRs to incorporate safety risks that arise from connectivity and machine centric control.

Other challenges include the continuous updating of the control software changing the operations of machines. The risks that arise from Machine Learning such as machine taking control over human beings, ethical dilemmas, designing the autonomous systems such that humans stay in control and the risks are minimised. These challenges are respectively covered in the Digital transformation of machinery and the Self-driving robots case studies.

[419] Available at: http://ec.europa.eu/information_society/newsroom/cf/dae/document.cfm?action=display&doc_id=8606 (pdf).

Table 73: Summary of challenges and potential changes to the Directive

Focus	Challenges	Expectation of change of the MD
Sensor input-related safety issues	• The MD does not explicitly cover input sources (sensor data, input data, training data) that feed into ML-enabled applications (robots or other). The reliability, accuracy and timeliness of data captured and transmitted by sensors and other input sources is crucial to the safe operation and effective optimisation of ML-enabled applications, irrespective of whether they are embedded in an IoT.	• Regulating safety requirements for data streams (training, sensor or input data) that feed into ML-enabled applications
Machine Learning	• Independent software is not included in the MD definition of control systems. • The MD does not provide minimum standards for the display of safety-critical information of ML-enabled processes. • The MD does not provide minimum standards for data logging and storage of ML-driven data and decision-making processes. • The MD's clause on cable-less control in case of loss of communication can be dangerous.	• Independent software could be included in the MD definition of control systems. • A revised MD could provide minimum standards regarding the display of safety-critical information of ML-enabled processes. • A revised MD could provide minimum standards for data logging and storage of ML-driven data and decision-making processes.
Internet of Things	• Control systems are not defined in the MD as physically or logically connected entities. • The MD does not specify requirements for communication processes and channels for IoT-embedded machinery.	• A revised MD could include physically or logically connected entities in the definition of control systems. • A revised MD could specify requirements for communication processes and channels for IoT-embedded machinery.

2.2.3. Self-driving robots

<u>Relevance of the selected case</u>

Emerging technologies such as machine learning and Artificial Intelligence (AI) have enabled machine operations to be increasingly autonomous. These machines are mobile thanks to robotics and the use of portable power sources. The extent of autonomous actions is evolving from narrow AI (an algorithm designed to solve a specific task) to general AI (learning about problems and identifying how to solve them). While still in its infancy, recent years have seen a rapid evolution of AI capabilities.

Robotics is a rapidly advancing industry which has adapted general AI as one of its essential components for enabling robots to become autonomous. This has resulted in machinery moving beyond the 'cage' and seen the emergence of collaborative robots working alongside people. Examples include agricultural robots.[420] The technology is also gaining a foothold in the consumer market with an increasing popularity of service and self-care robots. The technology is also gaining a foothold in the consumer market with an increasing popularity of service and self-care robots. This case study sheds light on some key regulatory issues that are to be addressed for a self-driving robot to share space and tasks with humans and presents possible solutions to these challenges.

Key challenge

The interaction between humans and self-driving robots in dynamic, partially unknown environments introduces complex health and safety risks for regulators to consider. Challenges for regulators arise in terms of defining appropriate guidelines and safety standards for robot control, stipulating criteria for adequate situation assessment skills, and ensuring required levels of adaptation to the emotional needs of users.

Interaction and collaboration between self-driving robots and humans in dynamic, partially unknown environments, carries risks. Therefore, it requires appropriate tests to be conducted as well as the monitoring, documentation and assessment of the outcomes of AI models to check for possible un-intended biases. It may become increasingly important to be able to test autonomous machines not only in laboratory conditions but in 'real-life' environments in which they will operate. This may include allowing self-driving robots to be tested in warehouses or care robots that are used to facilitate nursing to be tested with subjects with whom they will work in real life such as with elderly in the nursing homes. A requirement for transparency would enable to disclose the functionality of AI systems to the general population or to trace AI systems' decision-making process.

[420] For example, Naïo Technologies Oz Robotic market garden weeder and AGROINTELLI ROBOTTI autonomous tool carrier

Human Robot Collaboration

The safety issues occur from the evoloution of robots and their unintended use

Release 1

Robots utilised in the industrial context inside cages

The robots were initially placed in cages and the HRC and safety implications were limited as the operators were not allowed to go in the cage while the robots were operational.

Non existent HRC | Intended use

Release 2

Robots come out of the cage

The HRC & safety risks increased as robots were installed out of the cages and worked in collaboraiton with the trained operators with in a fixed radius.

Minimum HRC | Intended use

Release 3

Robots are mounted on autonomous mobile platforms

The robots are mounted on mobile autonomous platforms and able to access the entire shop floor as the fixed radius of operations and collaboration expanded.

Increased HRC | Intended use

Release 4

Robots are utilised for consumer applications

The robots intended for industrial use are utilised for consumer applications such as beer brewing in an environment not foreseen by the manufacturer during the risk assesment .

Extensive HRC | Intended use

Legend: Conform | Deviation possible | Outside intended use

How to ensure the safety via the intended use?

This question of the intended use and utilising the robots with in the boundaries defined by the manufacturer becomes very important and critical to safety given the evolution of robots and their utilisation in industrial as well as consumer applications.

Take Kuka's LBR iiwa as an example as they are used in light-weight industrial applications in manufacturing. They can be used as fixed robots or mounted on a mobile platform. The same robots are also used for brewing beer for consumers.

In line with safe exploration principles, self-driving robots require safety mechanisms such as emergency stops if sensors identify a collision risk with persons or objects. Also, self-driving robots bring forward new challenges in terms of the degree to which ethical dilemmas can be anticipated and hard-wired. Should the programmer be allowed to code such dilemmas in the software of autonomous systems? Should users have control over the decision-making process of these systems in situations when a machine may be risking to harm a human? AI algorithms need to ensure responsible outputs that protect the safety of humans, as it is important that these algorithms are trusted by employees, companies and customers alike. This also requires AI-enabled robots to have Human Machine Interfaces (HMIs) which provide information on the behaviour of machinery in a manner that is transparent and intelligible to the human supervisor or co-operator.

Self-driving robots must have ethical considerations in-built, which are aligned to the core principles of the company, employees and the society. This essentially entails the design of human-centric systems, as the deployment of collaborative robots and other AI systems can generate mental health risks for users deriving, for example related to user's perceived threat of physical harm that may come from the emerging digital technology.[421] In this context, the case study will also explore consumers' and workers' level of trust towards self-driving robots and the resulting impact on users' mental well-being. There are also concerns regarding the social aspect, as there is a fear of losing jobs with the introduction of robotics that are making industries increasingly automated, e.g. the "Lights Out factory". The skills of the population will also shift, as robots will help people in labour intensive work environments, allowing people to focus on more specialised tasks.

Some service robots interact with humans in a social capacity[422]. Social robots exhibit personality and interact with humans using high level communication and/or gestures in the social context[423]. Service robots are in use for health care in personal as well as professional capacity[424]. Beyond the factory floor, these human robot interactions can facilitate tasks in health care and caring. For instance, social robots can assist elderly to be physically active, reminding them of taking medicine or triggering social interactions like calling a family member to motivate them to take a medicine. Social robots operate in private households, hospital and nursing homes where they can monitor the environment, interact with humans and obtain medically sensitive information such as blood pressure.

Box 14: Definition of service robots

The ISO standard 8373 published in 2012 distinguishes between industrial and service robots. Service robots are further categorised to be for personal or professional use:

- A robot is an actuated mechanism programmable in two or more axes with a degree of autonomy, moving within its environment to perform intended tasks
- An industrial robot is an automatically controlled, reprogrammable multipurpose manipulator programmable in three or more axes, which can be either fixed in place or mobile for use in industrial automation applications

[421] European Commission (2020). Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics. COM(2020) 64 final. Available at: https://ec.europa.eu/info/sites/info/files/report-safety-liability-artificial-intelligence-feb2020_en_1.pdf

[422] Dautenhahn, K, Billard, A (1999) Bringing up robots or—the psychology of socially intelligent robots: From theory to implementation. In: Proceedings of the Third Annual Conference on Autonomous Agents, Seattle, WA, pp. 366-367.

[423] Fong T, Nourbakhsh I, Dautenhahn, K (2003) A survey of socially interactive robots. Robotics and autonomous systems 42:143-166.

[424] Garmann-Johnsen, N, Mettler, T, Sprenger, M (2014) Service robotics in healthcare: A perspective for nformation systems researchers? In: Proceedings of the 2014 International Conference on Information Systems – ICIS, Auckland, pp. 1-12.

- A service robot is a robot that performs useful tasks for humans or equipment excluding industrial automation applications. (Note: the distinction of a robot into industrial robot or service robot is done according to its intended application).
- A personal service robot or a service robot for personal use is a service robot used for a non-commercial task, usually by lay persons. Examples include domestic servant robot, automated wheelchair, personal mobility assist robot, and pet exercising robot.
- A professional service robot or a service robot for professional use is a service robot used for a commercial task, usually operated by a properly trained operator. Examples include cleaning robot for public places, delivery robot in offices or hospitals, fire-fighting robot, rehabilitation robot and surgery robot in hospitals.

The Communication on Artificial Intelligence[425] states that "the EU safety framework already addresses the intended use and foreseeable (mis)use of products when placed on the market. This has led to the development of a solid body of standards in the area of AI-enabled devices that is continuously being adapted in line with technological progress. The further development and promotion of such safety standards and support in EU and international standardisation organisations will help enable European businesses to benefit from a competitive advantage and increase consumer trust."[426]

Market trends

A modern manufacturing plant features operation with varying degrees of automation, ranging from manual, to human assisted, up to fully automated processes. Fully automated self-driving robots, also known as Autonomous Mobile Robots (AMRs), are a new evolution in mobile robotics that is rapidly being deployed in manufacturing plants across the globe. AMRs can autonomously navigate in an uncontrolled environment by integrating sensors, 3D vision and AI, and are often designed to interact and cooperate with humans.

Due to novelty of AMRs and a rapidly evolving market environment, there are no dependable figures on the market volume and adoption rate of self-driving robots. While some researchers suggest that the value of the global self-driving robotics market could reach EUR 36.2 billion by 2026[427], others project the market to attain solely EUR 549 million by 2025.[428] Despite the substantial divergences in market assessments, analysts concur that the annual growth rate of the self-driving robot market will remain high over the next five years, ranging between 12.9% and 21.5% per annum.[429,430,431]

The EU's rapidly growing installed base of conventional industrial robots (see Figure 111) underlines the potential for increasing autonomy in production facilities and on the shop floor. Germany, Spain, France and Italy alone witnessed an increase of 47.600 units of industrial robots in 2018.

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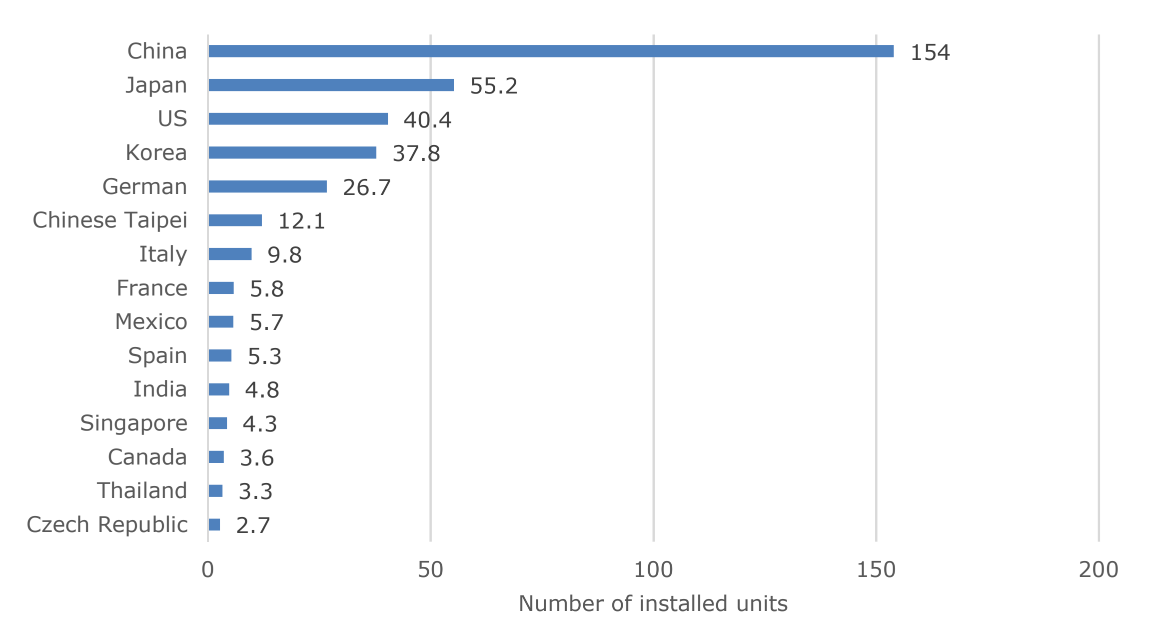
[425] COM(2018) 237 final, Communication from the Commission to the European Parliament, the European Council, the Council, The European Economic and Social Committee and the Committee of the Regions: Artificial Intelligence for Europe. Available at: https://ec.europa.eu/digital-single-market/en/news/communication-artificial-intelligence-europe.
[426] COM(2018) 237 final, Communication from the Commission to the European Parliament, the European Council, the Council, The European Economic and Social Committee and the Committee of the Regions: Artificial Intelligence for Europe, p.16. Available at: https://ec.europa.eu/digital-single-market/en/news/communication-artificial-intelligence-europe.
[427] Allied Market Research (2019). Mobile Robotics Market - Global Opportunity Analysis and Industry Forecast, 2019 - 2026
[428] 360 Market Updates (2019). Global Autonomous Mobile Robots Market Insights, Forecast To 2025
[429] ibid.
[430] Allied Market Research (2019). Mobile Robotics Market - Global Opportunity Analysis and Industry Forecast, 2019 - 2026
[431] Wilkins, J. (2019, October 23). The Challenges of Using Mobile Robots. Retrieved February 12, 2020, from https://www.ehstoday.com/safety-technology/article/21920421/the-challenges-of-using-mobile-robots

Figure 111: Annual installations of industrial robots ('000s of units), 2018[432]



A number of new robotics companies have emerged in the EU in recent years, including Universal Robots, FerRobotics, Franka Emika, BioRob-Arm, F&P Robotics and MRK Systeme. Many of these new European players specialise in collaborative industrial robotics (co-bots), which represent a quickly growing segment of the dynamic European industrial robotics market. The EU co-bots market accounted for EUR 343 million in 2019 and is expected to grow at a rate of 40.73% annually between 2020 and 2026.[433] Indeed, most established European robotics OEMs have introduced collaborative industrial robots in their product portfolios, with key players including Comau, Festo, ABB, Bosch, Stäubli, and Mabi Robotic. Of the key players in the global collaborative robotics market, the majority are European companies.[434]

By combining new cloud computing with vertical-specific AMRs, new business models are emerging on the global market. To reduce capital barriers for robotics, AMR manufacturers are increasingly embracing the Robots-as-a-Service (RaaS) model of ownership that allows end users to lease either the cloud computing capabilities or the robots themselves as variable cost services. RaaS is likely to contribute to a rapidly expanding installed base of self-driving robots both in the EU and beyond.[435]

Using a plethora of technology including sensors, LIDAR, infrared and machine vision, AMRs are now able to respond to environmental changes in novel environments. In order to solve employment and flexibility challenges, the warehousing and logistics industries have been at the forefront of adopting self-driving robots. However, recent improvements in AMRs' payload – new models such as KUKA's KMR 1500 and AMR's MAV3K have payloads of 1.5 tons and 1.3 tons respectively – enable their expansion to new sectors, most notably the manufacturing, aerospace and automotive industries.[436,437] Another emerging market is

432 AI Index (2019). 2019 Annual Report
433 Research And Markets (2020). Europe Collaborative Robots Market to Grow with a CAGR of 40.73% During the Forecast Period, 2020-2026
434 DG Research and Innovation (2020). Unlocking the potential of industrial human–robot collaboration
435 Radfar, H. (2019, July 1). The rise of robots-as-a-service. Retrieved February 13, 2020, from https://venturebeat.com/2019/06/30/the-rise-of-robots-as-a-service/
436 Hitch, J. (2018, October 15). Manufacturing Safety in the Age of Auto Bots. Retrieved February 13, 2020, from https://www.ehstoday.com/safety-technology/article/21919829/manufacturing-safety-in-the-age-of-auto-bots
437 Wilkins, J. (2019, October 23). The Challenges of Using Mobile Robots. Retrieved February 13, 2020, from https://www.ehstoday.com/safety-technology/article/21920421/the-challenges-of-using-mobile-robots

driven by service robots for professional use are experiencing a technological revolution. The International Federation of Robotics estimates the combined value of the professional service robots' market for the 2019-2021 period to be worth EUR 34 billion.[438]

While the evolution of AMRs is advancing at a high pace, many technological challenges are still not overcome, particularly in the domains of environment perception and simultaneous localization and mapping (SLAM) in unknown environments. The past years have witnessed the bankruptcy of several robot start-ups, such as with Jibo inc., Anki and Mayfield Robotics due to technological glitches, and insufficient demand due to consumers' privacy concerns.[439,440,441]

Shortcomings, barriers of the current MD and approach of the sector today

Using AI, algorithms can autonomously control the operations of Automated Guided Vehicles (AGVs), collaborative robots (co-bots) and service robots operating on factory floors, warehouses and private homes. The notion of robotic control is hence evolving from human-centric to machine-centric. The MD follows a technology neutral approach, but some stakeholders voiced that the notion of software needs to be broadly covered by the MD because of the increasing control algorithms exert over machinery.

A key requirement for the deployment of self-driving robots is that the humans interacting with them are able and willing to trust them. This requires addressing challenges regarding security, safety, privacy, fairness, sustainability, accountability, and transparency. This in turns evokes the principle of responsible robotics. With the introduction of co-bots and service robots for domestic, commercial and care purposes, manufacturers have to ensure safety compliance of their robots in all situations and environments, even if extreme or unpredictable. In addition to the direct implication of an incident involving a self-driving robot, any accident can further harm the trust of users, given that the accidents arising from these technologies are subject to extensive public discussions and can compromise the positive impact that these technologies have achieved until today.

In addition to self-driving robots, this chapter presents a second case that is challenging from a regulatory perspective, i.e. the concept of partly completed machinery (PCM). PCM is a term under the MD for an assembly of parts which is almost machinery, but which cannot in itself perform a specific application. It is often unclear what constitutes a complete machinery, as even incomplete machines have a specific function, i.e. a sub-function of the overall machine in which they are integrated. The challenge, from a regulatory point of view, is that PCMs are capable to implement sub-functions, but are not pre-programmed by the manufacturer to realize an intended function.

Self-driving, collaborative robots

Box 15: Example of a *collaborative* industrial robot

Comau's AURA is an advanced use robotic arm aimed to support human collaborators in industrial processes without the need for barriers or fences. AURA is designed for direct interaction with a human within a defined collaborative workspace, i.e. a safeguarded space where the robot and a human can perform tasks simultaneously during production operation.[442] The co-bot falls under the Machinery Directive. According to Comau, AURA has the highest payload and reach in the market, at 170 kg and 2.8 m respectively.[443] The co-bot is fitted with proximity sensors, contact sensors and laser scanners to detect

438 International Federation of Robotics (2019). World Robotics 2018 Service Robots report.

439 https://spectrum.ieee.org/automaton/robotics/home-robots/consumer-robotics-company-anki-abruptly-shuts-down

440 https://spectrum.ieee.org/automaton/robotics/home-robots/jibo-is-probably-totally-dead-now

441 https://spectrum.ieee.org/automaton/robotics/home-robots/mayfield-robotics-cancels-kuri-social-home-robot

442 DG Research and Innovation (2020). Unlocking the potential of industrial human–robot collaboration

443 https://www.comau.com/Download/our-competences/robotics/Automation_Products/Folder_Aura%20Doppie.pdf

and respond to the movements of operators and avoid collisions. AURA can be programmed through a HMI or manually guided by a human operator.

Figure 112: Aura as advertised on Comau's website[444]

Several features make AURA a particularly relevant example from a regulatory perspective:

First, AURA can be used in a collaborative mode or a non-collaborative high-speed mode as needed. In the speed and separation monitoring mode, the AURA's automatic motion discontinues when a human comes closer to the co-bot than the pre-programmed minimum separation distance allows. During the non-collaborative high-speed mode, the AURA exerts kinetic forces that could cause serious injury to human collaborators. While a sophisticated laser sensor enables emergency interruptions in case a moving object is detected close to the AURA, and the frame of the co-bot is fitted with soft foam[445], a potential failure of the sensor input could still lead to a severe workplace injury. As noted by a stakeholder, the MD's clause according to which "the moving parts of machinery must be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or must, where risks persist, be fitted with guards or protective devices" may be considered limiting with regards to human-robot collaboration.

In addition to automatic switches between collaborative and non-collaborative modes, operators can stop the AURA at any time. While the Machinery Directive requires that machinery needs to be able to be overruled by humans, overruling a co-bot can also pose a risk. In practice, some co-bots should not be able to be overruled by all users. A situation could occur, for example, in which an AURA shuts down during an emergency in a complex collaborative workflow and overruling the co-bot could pose a risk to humans or equipment at subsequent stages of the workflow.[446]

Second, AURA is intended to work in proximity of human co-workers, and can be manually or autonomously switched between collaborative and non-collaborative mode, during which the co-bot performs high-velocity movements.[447] Human operators on the factory floor need to be aware of the operational mode the AURA is currently functioning in order not to involuntarily shut down operations by getting too

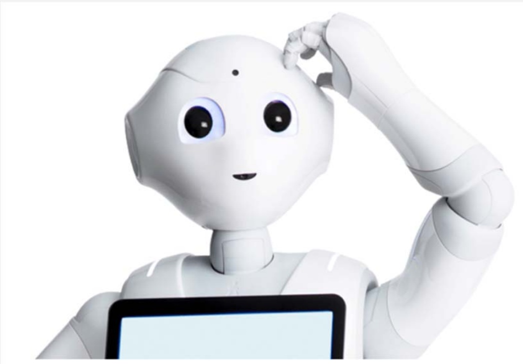
[444] https://www.comau.com/en/our-competences/robotics/automation-products/collaborativerobotsaura
[445] https://www.comau.com/Download/our-competences/robotics/Automation_Products/Folder_Aura%20Doppie.pdf
[446] TNO (2018). Emergent risks to workplace safety: working in the same space as a co-bot. Available at: https://repository.tudelft.nl/view/tno/uuid%3A6dc7b018-e77f-4bc2-8988-63a96a510f11.
[447] https://www.comau.com/Download/our-competences/robotics/Automation_Products/Folder_Aura%20Doppie.pdf

close to the co-bot.[448] This heightened degree of required vigilance – from a workflow efficiency perspective – can create an additional cognitive burden on human collaborators that might cause mental distress in the long run. In addition, human collaborators are exposed to the additional stress factor of being in the vicinity of a co-bot that is at times collaborative, and at other times not. This may induce fear of dangerous contact itself, although the AURA has passed all required safety assessments before being deployed on the factory floor.[449]

Box 16: Example of a self-driving social robot

SoftBank's Pepper robot provides a concrete case of an AGV challenging the current regulatory framework. The biomorphic Pepper robot, developed by SoftBank and manufactured by Foxconn, is able to socially interact with humans based on emotion reading and learning capabilities via cloud computing. Pepper can assess human emotions, respond to inquiries and interact with human beings.

Figure 113: Pepper as advertised on SoftBank's website[450]



Several features make Pepper an insightful example from a regulatory perspective:

First, Pepper is sold as a product in compliance with the Radio-Equipment Directive (RED) and the Restriction of Hazardous Substances Directive (RoHS 2), but not labelled in accordance with the Machinery Directive.[451] Pepper can be self-driven, but the ad-hoc software in not pre-loaded but dynamically overlaid.[452] New updates and firmware can be remotely downloaded without the user's permission. In addition, users themselves can install a growing number of applications from the Aldebaran Store.[453] As Pepper is a collaborative robot, i.e. specifically developed to interact with humans, there is a risk of post-deployment firmware upgrades or software updates to generate behaviour unforeseen by its producers at the time of deployment (either due to the machine learning process or by unintentional failures[454]). Recent evidence shows that Pepper's ML abilities are substantial. During an experiment, an operator demonstrated to a Pepper how to play ball-in-the-cup. After the operator physically executed a movement, the robot was asked to replicate the task until it got the movement right. This seemingly simple replication required Pepper to master complex functions, including determination of goal point and adjusting joint positions, velocity and acceleration to perform a perfect throw.[455] As Pepper is used in sensitive human-system

[448] Although the specific mode in which the AURA currently operates is signalled through a bright LED lamp
[449] DG Research and Innovation (2020). Unlocking the potential of industrial human–robot collaboration
[450] SoftBank (2020). pepper. Retrieved February 12, 2020, from https://www.softbankrobotics.com/emea/en/pepper
[451] SoftBank (2020). EU Declaration of Conformity. Retrieved February 12, 2020, from https://www.softbankrobotics.com/emea/sites/default/files/inline-files/declaration-of-conformity-pepper-1.8.pdf
[452] https://www.theconstructsim.com/rdp-010-pepper-and-ros-with-florian-lier-2/
[453] https://store.aldebaran.com/
[454] No unintentional failures could be identified in the public domain
[455] https://developer.softbankrobotics.com/blog/pepper-plays-ball-cup

interactions such as educational facilities and private homes, this possibility of unintentional changes of behaviour following deployment raise concerns of EHSR conformity. This scenario is particularly relevant in cases where an emotionally vulnerable person (e.g. a child or elderly person) has developed a trust relationship with a Pepper, and undesirable changes in the robot's behaviour may cause harm to the human.

Second, Pepper captures and processes voice data, including potentially personal or other sensitive information, which may affect the mental well-being of users. The sharing of personal data with third parties may result in personal information being transmitted to third-party providers located outside the EU. Users' data may hence no longer fall under the scope of the GDPR.[456] This might have negative effects on the mental health of users, who may experience discomfort or stress when being in the vicinity of a robot such as Pepper with both speech and image recognition functions, as they fear that their privacy could be violated when potentially sensitive data may be shared with third parties beyond their control.[457] Indeed, such fears would not be entirely unfounded with a Pepper who relies on cloud-based analytics for the processing of speech and emotions.[458] To counter potential risks to the mental wellbeing of users, an option for regulation would be to specify precisely the information that must to be processed locally by a robot vs. the information that can be sent back to an external party (service provider, external cloud operator, or other) for troubleshooting, analysis or other purposes.

These two case studies exemplify a number of shortcomings and barriers of the current MD in terms of providing a comprehensive regulatory environment for self-driving robots:

First, the MD makes no explicit mention of the required testing environment of self-driving robots. In the case of autonomous robots, it is also important to test in the real operating environment. There is, however, a notion of "the state of the art" as a general principle of EHSRs that manufacturer or its authorised representative should take into account, which states that "the essential health and safety requirements should be satisfied in order to ensure that machinery is safe; these requirements should be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements."[459]

The concept of "the state of the art" thus serves as a reference point for applying EHSRs. It can be considered for emerging technologies as well. This is crucial as it implies that EHSRs are not absolute, hence a manufacturer must strive to achieve the EHSRs' objectives to the furthest extent possible according to the current technical and economic status. The technical solutions adopted to fulfil the EHSRs must employ the most effective technical means that are available at the time for a cost that is reasonable taking in account the total cost of the category of machinery concerned, the seriousness of harm machinery can entail and the risk reduction required to address it. This also means "the state of the art" considered for the machinery when it was built might no longer be valid in the future.

Second, there is currently no regulation on the governance and usage of social robots. As social robots are used in sensitive human-system interactions such as educational facilities and private homes, the possibility of unintentional behavioural dysfunctions as a reaction to specific external inputs raises concerns of EHSR conformity. As noted, this scenario is particularly relevant in cases where an emotionally vulnerable person has developed a trust relationship with a social robot. Indeed, mental health risks – as an integral element of health and safety - should be explicitly

[456] Chatzimichali, A., & Chrysostomou, D. (2019, November). Human-data interaction and user rights at the personal robot era. In 4th International Conference on Robot Ethics and Standards.
[457] European Commission (2020). Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics. COM(2020) 64 final. Available at: https://ec.europa.eu/info/sites/info/files/report-safety-liability-artificial-intelligence-feb2020_en_1.pdf
[458] Bertolini, A., & Aiello, G. (2018). Robot companions: A legal and ethical analysis. The Information Society, 34(3), 130-140.
[459] Extract from Machine Directive 2006/42/EC, 14

covered within the concept of product safety in the legislative framework. [460] A ESHR could be inserted in this sense in the MD, and experts indeed believe that the focus should be on ethical guidelines that should be addressed in an enforceable format[461]. For instance, current autonomous social care robots are not able to interact effectively in a group. How does such a robot interact with children, middle aged and elderly in an effective way? Should there be a minimum age defined for interaction? For example, there was an incident in Japan where children beat a robot in the mall.[462]

Third, the MD does not sufficiently cover potential physical and mental health risks arising from human-robot collaborations. This is particularly the case for co-bots such as the AURA, which can operate in collaborative mode or non-collaborative mode depending on the required functionality in the given manufacturing process. During the non-collaborative high-speed mode, the co-bots such as AURA can exert kinetic forces that could cause serious physical injury to human collaborators in case of a potential failure of the sensor input or proximity detection system. Indeed, Annex I, 1.3.7 and 1.3.8.2 on moving parts and mechanical hazards may be too limited for the emerging domain of human-robot collaboration. In addition to physical harm, human collaborators working closely with such hybrid mode co-bots may experience stress related to fear of dangerous contact itself, or simply because they want to avoid the emergency shutdown function of the co-bot, which might interrupt important production processes. The additional vigilance required by the human operators may produce mental distress and fatigue, both of which can pose a risk to mental health in the long run. [463]

Fourth, the MD does not cover relevant aspects of data privacy of social robotics which can have an impact on the mental health of human operators. Social robots operate in private households, hospital and nursing homes where they can monitor the environment, interact with humans and obtain medically sensitive information such as blood pressure. This might have negative effects on the mental health of users, who may experience discomfort or stress when being in the vicinity of a robot with voice, speech and image recognition functions and other sensors, as they fear that their privacy could be violated when potentially sensitive data may be shared with third parties beyond their control. The risks to users' mental health due to long-term exposure to a social robot is a serious issue that requires regulatory attention.[464] It is feasible that a growing number of users experience worries and concerns over the loss of control over the data, including sensitive data, due to recent widely reported media accounts of apparent privacy violations of speech recognition applications. For instance, in 2018, an Amazon customer in Germany was mistakenly sent about 1,700 audio files from another customer's Amazon Echo voice assistant, which provided him enough information to name and locate the user and his girlfriend.[465] In another widely reported case, a user in the US found out that her Amazon Echo had sent recordings of private conversations to one of her husband's employees.[466] This raises concerns regarding the mental well-being of users in relation to i) transparency on the type of data measured and ii) how this data is shared, analysed and stored. Furthermore, the security related implications of a social robot being hacked would be drastic.

[460] European Commission (2020). Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics. COM(2020) 64 final. Available at: https://ec.europa.eu/info/sites/info/files/report-safety-liability-artificial-intelligence-feb2020_en_1.pdf

[461] Fosch Villaronga, Eduard and Tamò-Larrieux, Aurelia and Lutz, Christoph, Did I Tell You My New Therapist is a Robot? Ethical, Legal, and Societal Issues of Healthcare and Therapeutic Robots(October 17, 2018). Available at SSRN: https://ssrn.com/abstract=3267832 or http://dx.doi.org/10.2139/ssrn.3267832

[462] Nomura, T, Kanda, T, Kidokoro, H, Suehiro, Y, Yamada, S (2017) Why do children abuse robots? Interaction Studies 17:347-369.

[463] Eurogip (2018). Prevention in the field of collaborative robotics. Available at: https://eurogip.fr/wp-content/uploads/2019/11/Collaborative_robotics_Prevention_EUROGIP.pdf

[464] European Commission (2020). Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics. COM(2020) 64 final. Available at: https://ec.europa.eu/info/sites/info/files/report-safety-liability-artificial-intelligence-feb2020_en_1.pdf

[465] https://www.theguardian.com/technology/2019/oct/09/alexa-are-you-invading-my-privacy-the-dark-side-of-our-voice-assistants

[466] https://www.theguardian.com/technology/2018/may/24/amazon-alexa-recorded-conversation

Fifth, the MD does not specify situations in which robots' autonomy needs to be curtailed in favour of human control. It could be postulated that a robot can more rationally assess a critical short-term decision and should hence be able to override a human decision when it comes to safety and security. This beckons the question whether there should be a hierarchal process in which an expert is supervising the decision making of a robot. On the other hand, while machinery needs to be able to be overruled by humans, overruling a co-bot can also pose a risk. In practice, some co-bots should not be able to be overruled by all users. The risks of interaction between co-bots and users in safety-critical situations needs to be identified. [467]

Sixth, the MD does not currently specify the conditions and manner in which specific safety- or trust-relevant information should be made visible to the human user on an HMI system. AI and machine learning imply the possibility of self-modification, in which an individual AI robot/terminal changes its operating code without external inputs or supervision by the manufacturer. Manufacturers cannot be expected to issue individually tailored manuals for independently evolving software of an initially homogenous class of self-driving robots. This requires AI-enabled robots to have HMI systems which provide specific information on the individual behaviour of the robot in a manner that is transparent and intelligible to the human supervisor or co-operator. On the other hand, it is essential not to overburden the human supervisor with unnecessary or irrelevant information on the robotic behaviour. Recent advancements in Web Ontology Languages (OWLs) and description logics can enable real-time oversight of relevant AI behaviour by human supervisors, including alerting supervisors in cases that might require human intervention (see point above).[468]

Partly completed machinery

The Mitsubishi robot 2F-TBSTS-01 is retailed as Partly Completed Machinery (PCM) capable to implement various operations[469], but it is not pre-programmed to realise an intended function.[470] According to the Machinery Directive, it is hence not until the necessary programming for the robot is in place that it achieves a specific purpose and is therefore defined as final machinery. Under the current approach, the integrator - which is often the end user, such as the operator of a large manufacturing plant - becomes responsible for the safety assessment after assembling the 2F-TBSTS-01 into a complete machinery, including CE marking. This requires a costly risk assessment, which is inherently challenging due to the hybridisation of work areas with PCMs such as the 2F-TBSTS-01, which enable applications that collaborate with humans in shared workspaces. Risk analysis requires diligent consideration of the movements of supervisors and the hazards posed by the robot's operation. As the financial burden of CE marking is placed on the integrator (i.e. end customer), it is important to revisit the implications of the current definition of incomplete machines on the specific value chain segments burdened by potentially costly procedures required for ensuring compliance with the MD.

While one may think that incomplete machinery has no particular application, it indeed has a specific range of applications that it can however not fulfil on its own. For instance, gripper systems or tool changing systems for robots are manufactured to enable collaborative robots to perform complex operations on a factory floor. However, they cannot fulfil this function if they are not incorporated with a PLC and mobile platform to constitute the (complete) collaborate robot.

Hence even incomplete machines fulfil specific functions within the overall machine in which they are integrated. The manufacturer of a PCM generally determines which safety and health protection requirements of Annex I of the MD it complies with. According to the MD,

[467] TNO (2018). Emergent risks to workplace safety: working in the same space as a co-bot. Available at: https://repository.tudelft.nl/view/tno/uuid%3A6dc7b018-e77f-4bc2-8988-63a96a510f11.
[468] https://www.cio.com/article/3442727/an-achievable-view-of-artificial-intelligence.html
[469] https://eu3a.mitsubishielectric.com/fa/en/dl/11619/EC_Declaration_MELFA_2F-TBSTS-01_en.pdf
[470] Partly completed machinery according to Machinery Directive 2006/42/EC means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies.

the manufacturer only needs to specify those requirements in the declaration of incorporation which are actually applied (in terms of the foreseen enabled applications) and complied with (in terms of compliance with Annex I). Hence manufacturers do not need to specify which requirements the PCM has not met, which is however an essential information for the buyer of the PCM, as final users may need to know for which future operations (currently envisioned or not yet envisioned) the PCM provides sufficient safety of operations. Buyers of such PCM hence often need to enter specific private law agreements to safeguard for EHSR compliance of specific interfaces before the purchase, e.g. by requesting an extended declaration of incorporation.[471] While freedom for individual manufacturer-buyer arrangements is essential due to the inherent versatility of use cases for PCMs, there is scope for improving certainty for final users. For instance, a revised MD could require manufacturers of PCMto disclose relevant aspects of the PCM's technical file that do not fall under IP for review.

This case study exemplifies a number of shortcomings and barriers of the current MD in terms of providing a comprehensive regulatory environment for PCMs. First, the MD does not explicitly specify the concept of partly completed machinery in all relevant aspects. The main shortcoming of the current definition indicated by manufacturers is that often products that are by definition incomplete machines are often defined as components. Manufacturers indicated that it is sometimes not clear what a complete machine is, as even incomplete machines have a specific function, i.e. a sub-function of the overall machine in which they are integrated. Furthermore, the MD does not require to disclose relevant aspects of the PCM's technical file that do not fall under IP for review.

Expectations to the changes of the Directive

A major question that arises is the extent to which the MD should address the shortcoming and barriers outlined in the previous section, i.e. whether the MD should sustain the current technology neutral approach or define a more comprehensive regulatory framework that addresses specific emerging challenges of new technologies. Stakeholders have different opinions on this matter. Some of the stakeholders reason that the current degree of incorporation of software in the MD is not sufficient, especially since algorithms exert ever greater control over the increasingly autonomous operations of the machinery. As noted, this creates risks related to health and safety aspects of such machinery and the MD should address these issues. Other stakeholders do not agree with this point of view as they favour the current technology neutral approach and recommend the challenges to be addressed by domain experts via the establishment of standards and certifications.

A concrete example of this is AGVs which transport materials around the factory floor. In the past, they were moving on pre-planned routes based on fixed logic (if-this-then-that) and stopped as long as they detect an obstacle on the fixed route. These mobile platforms are now autonomous as they are equipped with sensors, cameras, localisation technologies and ML software that adapts to its environment, hence helping them navigate by adjusting its course on the go. For instance, AGVs can stop or can manoeuvre around in a free space if they sense a worker entering in the designated area. This scenario highlights the concern from the stakeholders who recommend that the MD should be adapted to consider the incorporation of software and treat the updates in software as a significant change in machinery.

Self-driving robots

Specifying testing parameters and testing environment for self-driving robots. Ensuring safe collaboration of humans and self-driving robots in dynamic and unpredictable environments may require the option to test AI-enabled robots in real-life or life-like environments. Some stakeholders used the example of self-driving cars in order to advocate for the greater leeway to test autonomous systems in real environments. While this may

[471] Ostermann, H.J. (2019). Unvollständige Maschinen Ein Teil vom Ganzen - "A Never Ending Story" Im Europäischen Maschinen-Binnenmarkt. Retrieved February 13, 2020, from www.maschinenrichtlinie.de/fileadmin/veroeffentlichungen/Unvollstaendige_Maschinen_Maschinenrichtlinie_2006-42-EG.pdf

accelerate the pace of innovation, un-foreseen situations in real operating environments can risk users' safety, for example the crash of a Tesla Model X in California on 23 March 2018. The Tesla operated on autopilot and followed a car in front of it which changed lanes to take the highway. The autopilot then increased its speed to 70MPH trying to achieve the set limit of 75MPH and moved towards the left side before crashing on a roadside barrier, catching fire and killing the driver. The press release from Tesla blamed the driver but the autopilot did not attempt to stop the car prior to the crash once the obstacle was detected.[472]

There are contrasting positive examples for testing self-driving robots in real-life environments. In Japan, the Tokku approach allows the social robots to be tested in living labs where the elderly patients are taken care of. Policies are then made based on the lessons learned from the labs. One such example is the Shin-tomi nursing home located in Tokyo. It utilises up to 20 different social care robots for assisting the elderly. The government of Japan sees it as a model to utilise the country's expertise in robotics to cope up with the nursing requirements of the increasing population of elders and the dwindling workforce.[473]

It can also imply to design and test safety features in the ML that are human centric as recommended in the draft report with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)) published by the committee of legal affairs in May 2016: "(…) whereas, until such time, if ever, that robots become or are made self-aware, Asimov's Laws[474] must be regarded as being directed at the designers, producers and operators of robots, since those laws cannot be converted into machine code (…)".[475]

Regulating relevant aspects of data privacy of social robotics if having an impact on safety and mental health. As noted before, social robots can capture and process voice, visual and other data that can include potentially personal or other sensitive information. The sharing of personal data with third parties may result in personal information being transmitted to third-party providers located outside the EU. Users' data may hence no longer fall under the scope of the GDPR.[476] This might have negative effects on the mental health of users, who may experience discomfort or stress when being in the vicinity of a social robot, as they fear that their privacy could be violated when potentially sensitive data may be shared with third parties beyond their control. The risks to users' mental health due to exposure to a social robot is hence a serious issue that requires regulatory attention.[477] An option for regulation would be to specify precisely the information that must to be processed locally by a robot vs. the information that can be sent back to an external party (service provider, external cloud operator, or other) for troubleshooting, analysis or other purposes. Transparency and intelligibility regarding the data privacy management of social robotics can reduce suspicion, stress and fear of users. Informing users in simple terms about the way that private data is handled, processes and stress hence may prevent mental health risks. Another option is to collect data only if the users explicitly grant consent. The surveillance data from the social robot should also be anonymised as much as possible, e.g. in case of a camera not recording the users above the knees. Finally, questions on autonomy, clarity, transparency and division of responsibilities were identified as key aspects by experts.[478]

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[472] Can be found at: https://www.ntsb.gov/investigations/AccidentReports/Pages/HWY18FH011-preliminary.aspx
[473] Can be found at: https://widerimage.reuters.com/story/ageing-japan-robots-role-in-future-of-elder-care
[474] The three laws, as are follows: 1) A robot may not injure a human being or, through inaction, allow a human being to come to harm; 2) A robot must obey the orders given it by human beings except where such orders would conflict with the First Law; 3) A robot must protect its own existence as long as such protection does not conflict with the First or Second Laws.
[475] Extract from draft report with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)):
[476] Chatzimichali, A., & Chrysostomou, D. (2019, November). Human-data interaction and user rights at the personal robot era. In 4th International Conference on Robot Ethics and Standards.
[477] European Commission (2020). Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics. COM(2020) 64 final. Available at: https://ec.europa.eu/info/sites/info/files/report-safety-liability-artificial-intelligence-feb2020_en_1.pdf
[478] Fosch Villaronga, Eduard and Tamò-Larrieux, Aurelia and Lutz, Christoph, Did I Tell You My New Therapist is a Robot? Ethical, Legal, and Societal Issues of Healthcare and Therapeutic Robots (October 17, 2018). Available at SSRN: https://ssrn.com/abstract=3267832 or http://dx.doi.org/10.2139/ssrn.3267832

Defining obligations for OEMs of collaborative robots to avoid physical and mental health risks for human collaborators. As noted above, when operating in non-collaborative mode, co-bots such as AURA can exert kinetic forces that could cause serious physical injury to human collaborators in case of a potential failure of the sensor input or proximity detection system. As noted by a stakeholder, Annex I, 1.3.7 and 1.3.8.2 on moving parts and mechanical hazards may be too limited for the emerging domain of human-robot collaboration. To reduce associated risks, new EHSRs could be imposed to limit impact and pressure forces on a worker, e.g. through systems that are able to identify workers as opposed to objects. In addition to mitigating the risk of physical harm posed by the proliferation of co-bots on the European market, the revision of the MD should take into account psychological risks associated with human-robot collaboration. For instance, a change to the MD could stipulate obligations for producers of collaborative robots to explicitly consider the immaterial harm their products could cause to users. While this is particularly important for more vulnerable user groups, such as older people or children[479], the regulation should also take into account industrial applications, in which a professional may need to work in close vicinity to a co-bot for 8 hours or longer.

Specifying situations in which robots' autonomy need to be curtailed in favour of human control to ensure safety. In some situations, an emergency stop of the robot might be less desirable than a handover to a human operator. This is for instance the case with social care robots, e.g. if faced with a patient displaying unusual signs of agitation. In such a case, the robot should be able to alert a human supervisor to assess the situation and take appropriate steps to ensure patient well-being and safety. The question about decision making and when a human should be in control can be catered through a hierarchal decision-making process in certain scenarios. An example of such decision-making hierarchies is present in hospitals across the globe, where doctors' opinions have more weight than that of a healthcare professional or a patient. Such a model can be applied when it comes to social robots. The robot should follow an instruction from the healthcare professional or the doctor compared to the patient. Although the patient should not be exposed to harm when it comes to following the instructions from the doctor or nurse. As noted by a study carried out in the Netherlands, self-driving robots could be required to be programmed in such a way as to not be "permitted to make decisions or assessments in relation to injury to people or damage on the surroundings".[480] On the other hand, overruling a co-bot in certain complex workflows can also pose a risk to humans or equipment at subsequent stages of the the workflow. A revision of the MD could prescribe that only certain categories of users (e.g. operational managers, emergency responders) may overrule a co-bot in certain situations.

Specifying the conditions under which specific safety- or trust-relevant information on robotic behaviour should be made visible to human operators on an HMI system. Before important decisions, human supervisors need to understand how the AI arrived at a certain conclusion or output. Many narrow forms of AI can be pre-programmed to identify relevant scenarios that require the communication of specific behavioural processes or decision-making dilemmas via a HMI. OWL and other types of formal logical representation can enable real-time oversight of relevant AI behaviour by human supervisors. However, next-generation general AI-enabled robots based on convolutional neural networks perform operations that are very difficult to trace in terms of the underlying decision-making process. For instance, in 2017 Facebook researchers utilized AI-enabled chatbots to simulate sales negotiations between themselves. After a short time of conversing in English, the bots started to communicate in a strange new language and nonetheless sometimes successfully negotiated a trade in this manner. Researchers found out that the bots effectively developed their own language – unreadable to humans - to make negotiation easier for the bots because they were not instructed to only communicate

[479] European Commission (2020). Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics. COM(2020) 64 final. Available at: https://ec.europa.eu/info/sites/info/files/report-safety-liability-artificial-intelligence-feb2020_en_1.pdf

[480] TNO (2018). Essential H&S requirements for industrial machines equipped with machine learning. (14 September 2018). Available at: https://www.arboportaal.nl/onderwerpen/arbeidsmiddelen/nieuws/2018/10/03/reeks-onderzoeken-tno-over-opkomende-risico%E2%80%99s-voor-arbeidsveiligheid

in human readable English.[481] This raises the question whether next-generation AI-enabled robots will be able to convey behaviour and decision-making process in a manner that can be guaranteed to be intelligible to humans. From a regulatory perspective, this challenges the viability of specifying universally valid conditions under which specific safety- or trust-relevant information on robotic behaviour should be made visible to human operators. While this appears feasible for AI-systems based on formal logical representation, this cannot be guaranteed for emerging classes of AIs based on complex deep neural networks.

Partly completed machinery

Requiring manufacturers of PCM to provide additional information to buyers. Manufacturers could be required to specify which requirements the PCM has not met, which is an essential information for buyers of PCM. However, such an approach needs to carefully balance the manufacturers' legitimate interest to safeguard IP with the buyers' interests to know not only the functions but also the limitations of PCM. For instance, are revised MD could request manufactures to disclose relevant aspects of the PCM's technical file that do not fall under IP for review.

Conclusions and recommendations

AI-enabled robotics create a plethora of new opportunities and use cases but are also highly challenging for regulators. These challenges did not exist when the MD was first implemented. The objective of this case study was to identify and assess these challenges and to explore the extent to which current and emerging challenges should be covered by the MD. A key take-away of the case study is that establishing and maintaining human safety and trust in self-driving robotics in the sine qua non for the proliferation of this technology.

The case studies showcased the importance of transparency and ensured responsibility for autonomous functionality, as well as the importance of designing autonomous systems in a way that is human centric. The systems should be taught not only by using data but also by certified experts to be able to counter biases. The data sets used for learning and the decision-making process should be transparent and traceable. Autonomous robots should be tested in real-life environments to better attune their behaviour to the real world and asses if there are un-intended consequences or flaws in the underlying algorithmic model.

It is clear from the market research that the EU is one of the global leaders in the development of these emerging technologies. The MD should stay relevant and facilitate these technologies to promote safety in the usage of these technologies. Consulted stakeholders had differences of opinions regarding the need to revise the MD, and if yes, to which degree. There are various options when it comes to adapting for these technologies. These include adapting the MD and/or the Guide. There are other options such as standardisation via harmonised standards.

[481] https://interestingengineering.com/ais-continue-to-act-in-unpredictable-ways-should-we-panic

Table 74: Summary of challenges and potential changes to the Directive

Focus	Challenges	Expectation of change of the MD
Self-driving robots	• The MD makes no explicit mention of the required testing environment of self-driving robots. • There is currently no regulation on the safety impact of the governance and usage of social robots. • The MD does not sufficiently cover potential physical and mental health risks arising from human-robot collaboration. • The MD does not cover relevant aspects of data privacy of social robotics having an impact on security and safety. • The MD does not specify situations in which robots' autonomy needs to be curtailed in favour of human control. • The MD does not specify EHSRs requiring that specific safety- or trust-relevant information should be made visible to the human user on a HMI system.	• Requiring testing parameters and testing environment for self-driving robots. • Regulating relevant aspects of data privacy of social robotics if having an impact on safety and mental health. • Defining obligations for OEMs of collaborative robots to avoid physical and mental health risks for human collaborators. • Requiring that robots' autonomy need to be curtailed in favour of human control depending on the risk. • Requiring that specific safety- or trust-relevant information on robots' decision-making and behaviour should be made visible to human operators on a HMI system.
Partly Completed Machinery	• The MD does not explicitly specify the concept of partly completed machinery in all relevant aspects. • The MD does not require manufacturers of PCM to disclose relevant aspects of the PCM's technical file that do not fall under IP for review.	• Requiring manufacturers of PCM to provide additional information to buyers. Manufacturers could be required to specify which requirements the PCM has not met, which is an essential information for buyers of PCM. However, such an approach needs to carefully balance the manufacturers' legitimate interest to safeguard IP with the buyers' interests to know not only the functions but also the limitations of PCM.

ANNEX III: MARKET ANALYSIS RESULTS

1. Introduction

This chapter provides an extensive economic and market research of the market covered by the Machinery Directive. A wide variety of data sources is used to provide a full picture of the market, its development and segments. The main aim of this chapter is to provide a detailed background and context to the Machinery directive. Related to the Directive this chapter covers the machinery industry defined as 'Machinery and equipment n.e.c.' in the NACE rev. 2 classification system, division C28.

The main tasks of this chapter are:

- To give a detailed sectoral overview of the machinery and equipment sector within the European Union and its Member States in terms of turnover and employment, the structure of enterprises and its innovation performance
- To compare the sector with main competitors in the world, including the US, Japan, South Korea and China
- To analyse the importance and emergence of digital technologies; and
- To provide more detail on the robotics sector, with a view to identify key producers in the EU and globally and to look at the importance and extent of FDI in the robotics sector.

In order to provide a detailed economic and market assessment various data are used including Eurostat Structural Business Statistics, Eurostat National Accounts, EU KLEMS, OECD Stan Industrial Database, UNIDO Industrial Database, UN Comtrade, and the World Input-Output Database (WIOD; or OECD TiVA).

Within the statistical classification of economic activities in the European Community (NACE rev. 2), manufacturing of equipment in the scope of the Machinery Directive falls under manufacture of 'machinery and equipment n.e.c.' (not elsewhere classified) division (C28). The sector includes the manufacture of special-purpose machinery, that is the machinery for exclusive use in an industry or small cluster of industries, and general-purpose machinery, which is machinery that is being used in a wide range of industries. A detailed list of all sub-industries, which can be divided into groups and classes is provided in Annex A. Previous studies on the Evaluation of the Machinery Directive[482] used this NACE sector to describe the market. Robots are not covered separately in one NACE class. Only certain products are listed, these are 'mechanical manipulators and industrial robots specifically designed for lifting, handling, loading or unloading' within NACE class 28.22 'Manufacture of lifting and handling equipment', and 'manufacture of industrial robots performing multiple tasks for special purposes' within NACE class 28.99 'Manufacture of other special-purpose machinery n.e.c.'.

2. The machinery industry in the European Union

The machinery and equipment sector (also short 'machinery sector' or 'machinery industry'), is one of the major sectors of manufacturing within the European Union483. In 2017, it recorded a turnover of EUR 663 billion, production of EUR 609 billion and a value added of EUR 191 billion. The machinery sector employed 2.8 million persons in 2017 and registered 82,350 enterprises. As such, the machinery sector accounted for 9.4% of manufacturing turnover, 9.5% of manufacturing production and 11.2% of value added. The machinery sector employed 9.9% of all persons employed in manufacturing and registered 4.1% of all manufacturing enterprises.

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[482] European Commission (2018), Evaluation of the Machinery Directive, Commission Staff Working Document, SWD (2018), 160 final, 7.5.2018, Brussels, available at: https://ec.europa.eu/docsroom/documents/29232.
Technopolis Group (2017), Evaluation of Directive 2006/42/EC on Machinery, Final Report, available at: http://ec.europa.eu/docsroom/documents/25661

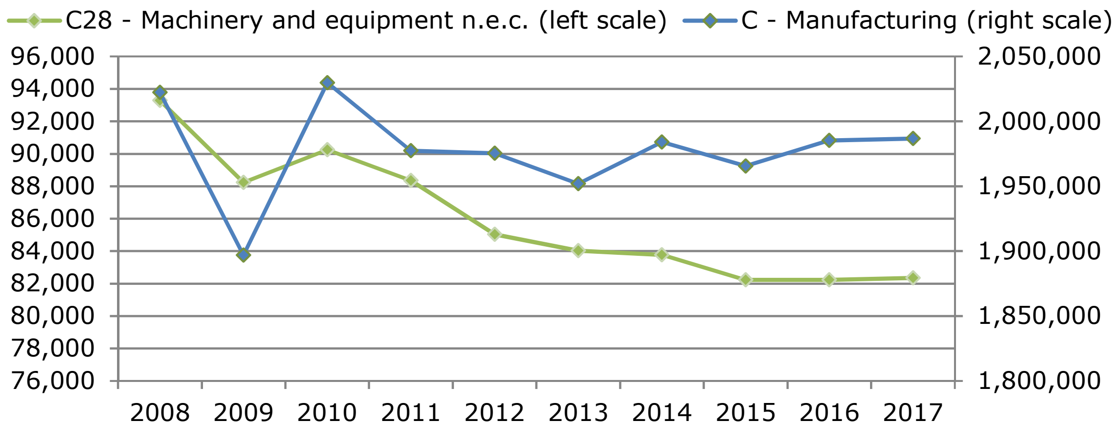
[483] The European Union includes the countries of the European Union as of 2019 (EU-27_2019). It encompasses 27 countries and excludes the United Kingdom. Where data on the Member State level is given, also the data of the United Kingdom is provided at the end.

2.1. Enterprises and persons employed

In 2017, there were about 82,350 enterprises operating in the machinery and equipment sector in the EU, representing 4.1% of all manufacturing enterprises. Starting with 93,280 enterprises in 2008 (see Figure 114), the number fell sharply in 2009 due to the financial and economic crisis, recovered slightly in 2010 but was on a continuous downward trend since then. Only since 2015, the number of enterprises remained stable. Compared to total manufacturing the downward trend becomes particularly visible.

Table A1 in the Annex 1 presents an overview on the number of enterprises in each Member State and their relevance within the EU and the individual countries. What can be seen is that, Italy registered 27% of all machinery enterprises in the EU, followed by Germany with 19%. Specialisation, i.e. the share of machinery enterprises within total manufacturing, was largest in Denmark with 11.2%. On average the number of enterprises declined between 2008 and 2017, with the largest negative average annual change occurring in Hungary and France. In a number of countries, however, the number of enterprises grew, with Slovakia registering the most pronounced increase.

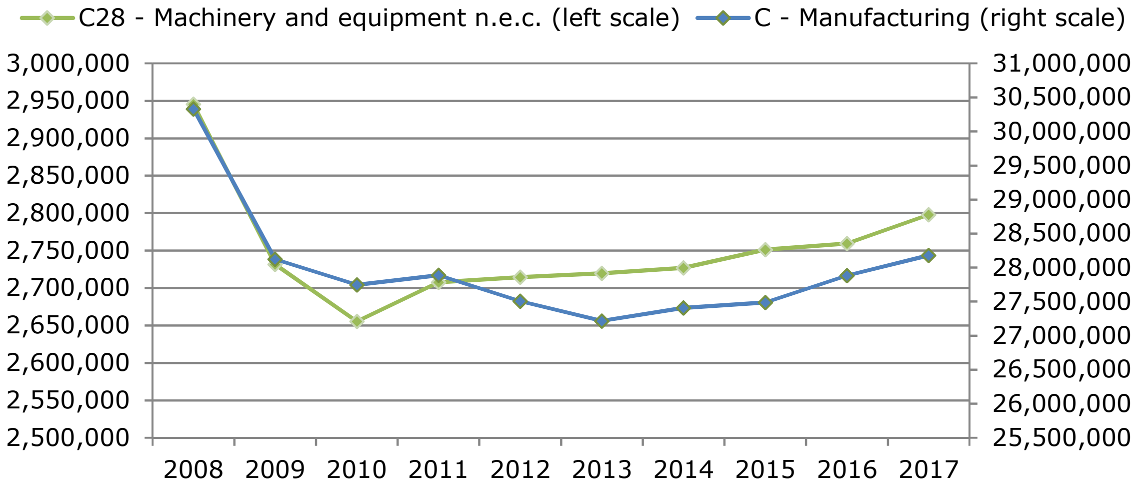
Figure 114: Number of enterprises in the machinery & equipment sector, EU-27 (without UK)



Source: Eurostat Structural Business Statistics [sbs_na_ind_r2]

In 2017, the number of persons employed in the machinery and equipment sector reached 2,798 thousand in the EU, representing 9.9% of all persons employed in manufacturing. Figure 115 depicts the large decrease of persons employed in 2009 due to the financial and economic crisis and the upward trend which occurred thereafter. Still, the number of persons employed in the sector is still far lower than before the crisis. Compared to manufacturing, the machinery sector recovered earlier.

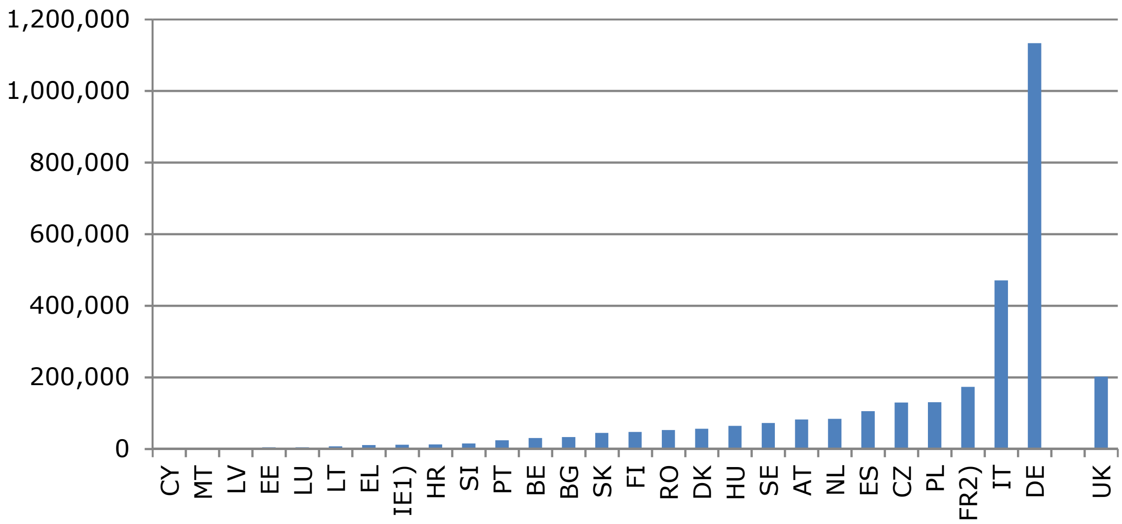
Figure 115: Number of persons employed in the machinery & equipment sector, EU-27 (without UK)



Source: Eurostat Structural Business Statistics [sbs_na_ind_r2]

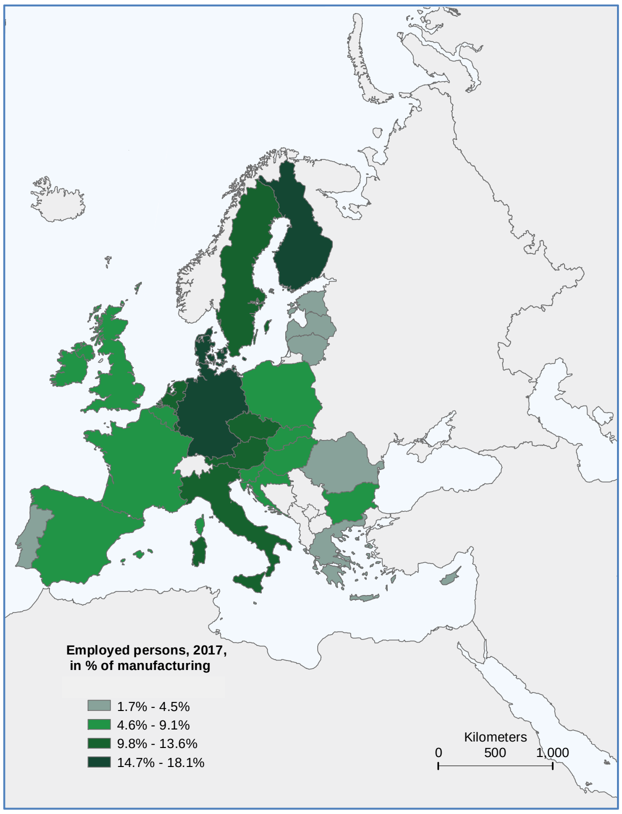
In order to provide a visual overview, Figure 116 depicts the number of persons employed per Member State. As can be seen, Germany employed by far the largest number persons, with 1,130 thousand in 2017, followed by Italy with 470 thousand.

Figure 116: Number of persons employed in the machinery & equipment sector, 2017



Notes: 1) Data for Ireland for 2014. 2) Data for France for 2016.
Source: Eurostat Structural Business Statistics [sbs_na_ind_r2]

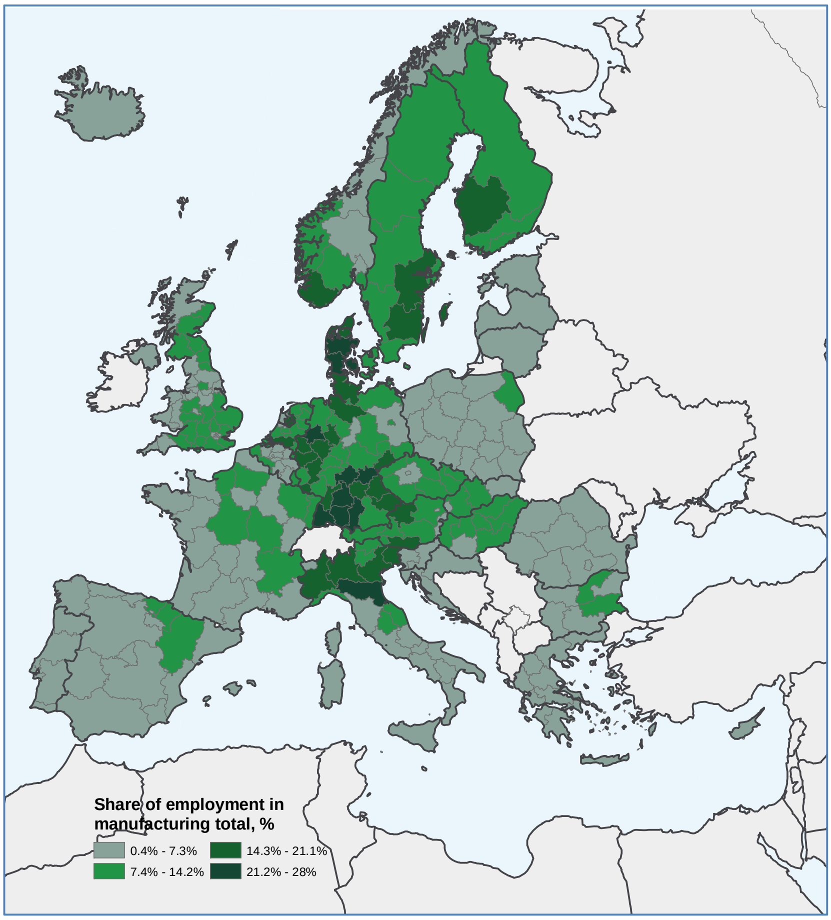
Map 1: Persons employed in the machinery & equipment sector, 2017, in % of manufacturing, Country level



Notes: Ireland data from 2014. France data from 2016 for employed persons. Source: Eurostat Structural Business Statistics [sbs_na_ind_r2]

Map 1 illustrates the pattern of specialisation with the European Union at the country level measured as a share of the machinery sector within manufacturing. The share of persons employed in machinery within total manufacturing, was on EU average 9.9% in 2017. Specialisation was much higher in Denmark (18%), Germany and Finland (about 15%), Austria and Italy (13%), Sweden, Luxembourg and the Netherlands (about 12%). The least specialised countries were Greece, Lithuania and Latvia (about 3%), Malta and Cyprus (2.5% and only 1.7%). Map 2 depicts the pattern of specialisation at the NUTS 2 level. On average, the number of persons was notably smaller in 2017 compared to 2008. The largest average annual decline in the machinery sector occurred in Greece, a smaller one occurred in Belgium, France, Romania and Denmark. However, in some countries the number of persons employed increased, such as Hungary, Luxembourg and Lithuania with the largest increase, followed by Austria.

Map 2: Persons employed in the machinery & equipment sector, 2016, in % of manufacturing, NUTS 2 level



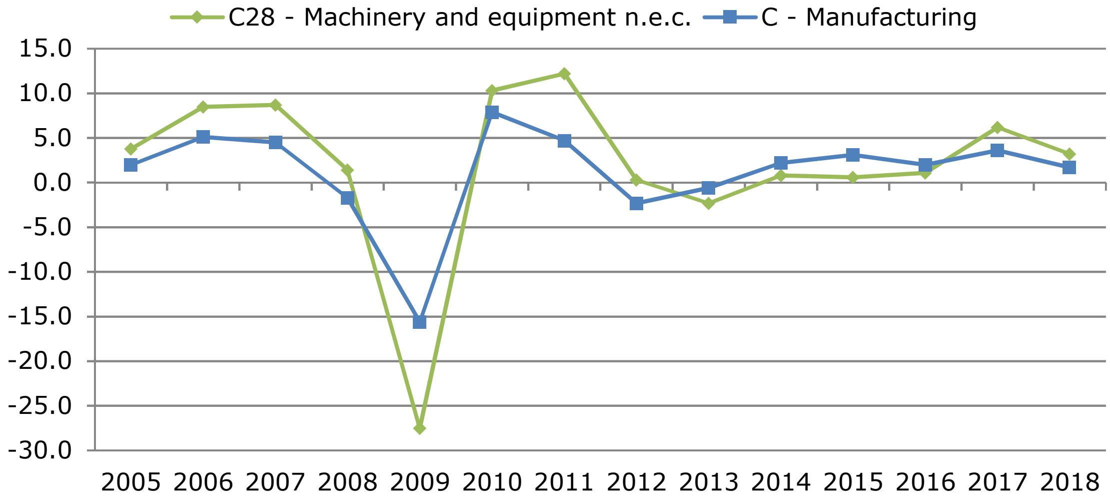
Source: Eurostat Structural Business Statistics [sbs_r_nuts06_r2].

2.2. Turnover, production and value added

In 2017, the machinery and equipment sector recorded a turnover of EUR 663 billion, production volume of EUR 609 billion and a value added of EUR 191 billion. As share in manufacturing, the machinery sector accounted for 9.4% of manufacturing turnover, 9.5% of manufacturing production and 11.2% of value added. Figure 117 depicts the growth rates of the machinery sector: Basically, the machinery and equipment sector produces investment goods and components and is a cyclical sector.[484] Thus, the sector was heavily affected by the financial and economic crisis, with production declining by 27.5% in 2009, much more than manufacturing. Production recovered in 2010 and 2011 but growth rates were rather moderate between 2012 and 2106. The sector suffered from the weak investment dynamics in the European Union in the post-crisis period. Only in 2017 and 2018 growth rates were above that of manufacturing and reached 6.2% and 3.2% for these two latest years.

[484] See for example CECIMO (2011), CECIMO study on the competitiveness of the European machine tool industry, December.

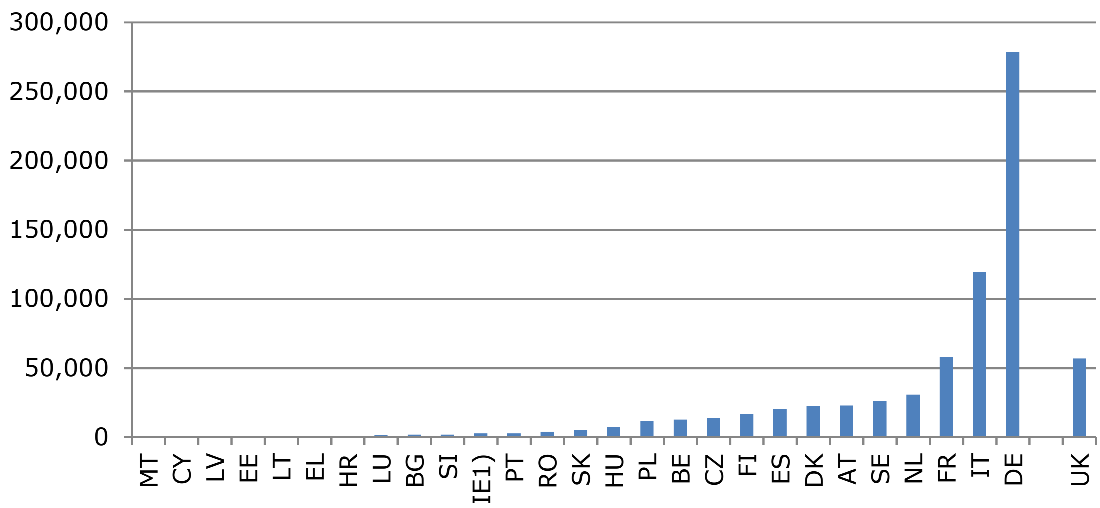
Figure 117: Production growth rates in the machinery & equipment sector, EU-27 (without UK), percentage change compared to the same period in the previous year



Source: Eurostat Short-term Business Statistics [sts_impr_a]

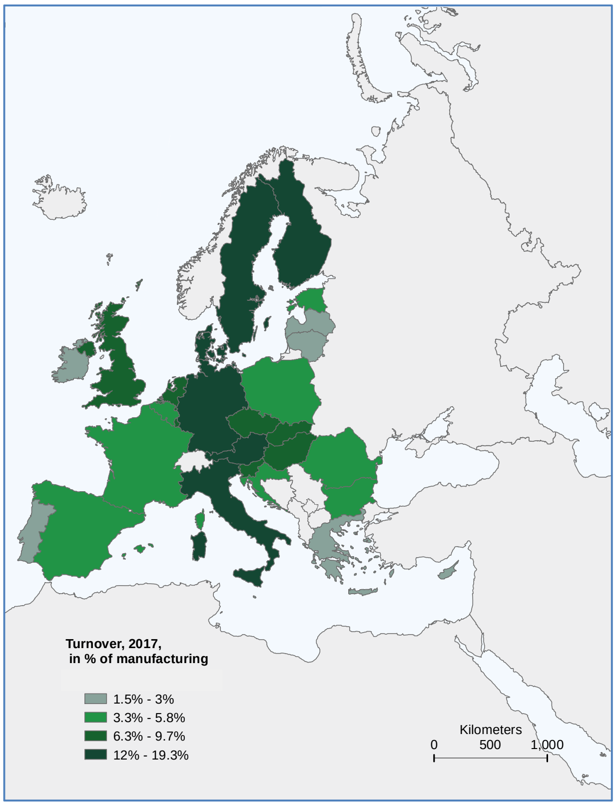
Table A3 and A4 in the Annex 1 presents an overview on turnover, production and value added in each Member State and their relevance within the EU and the individual countries. A visual overview is presented in Figure 118 and Map 2, looking at turnover figures and specialisation patterns in the European Union. Looking at turnover in billions of Euro, Germanys registered about 280 billion of turnover in 2017, representing 42% of total EU turnover, followed by Italy and France. Together these three countries accounted for 69% of EU turnover. Turning to specialisation, the share of in machinery within total manufacturing was 9.4% in 2017 for the EU-average. Countries most specialist on the machinery sector were Denmark (19%), Germany and Italy (about 13%), Finland, Sweden and Austria (about 12%). The least specialist countries were Ireland, Cyrus and Greece (all about 2%) and Malta (only 1.5%).

Figure 118: Turnover in the machinery & equipment sector, 2017, EUR million



Notes: 1) Data for Ireland for 2014.
Source: Eurostat Structural Business Statistics [sbs_na_ind_r2]

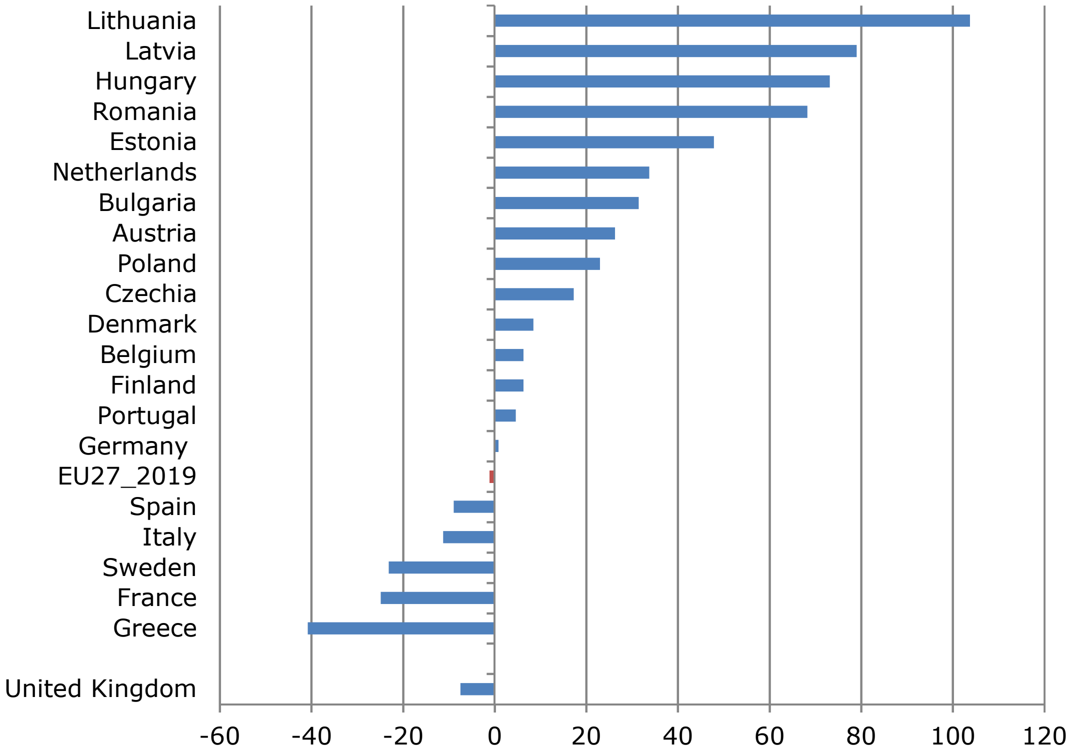
Map 3: Turnover in the machinery & equipment sector, 2017, in % of manufacturing



Notes: Data for Ireland for 2014.
Source: Eurostat Structural Business Statistics [sbs_na_ind_r2]

Looking into more detail at the growth performance of individual countries, Figure 6 depicts the cumulative growth for the period 2009 to 2018. Overall, for the EU-27, growth was more or less zero, meaning that the machinery sector reached the volume of 2008-production only in 2018. Most of the large machinery producers as well as Southern countries showed a poor growth performance. In Germany, the machinery sector grew by a mere 1%, in Spain and Italy it fell 9% and 11%, in Sweden and France by about 23% and 25% and in Greece by 40%. Growth was mostly seen in the Baltic countries, and a large range of Central and Eastern European countries, on top with Hungary, Romania and Bulgaria.

Figure 119: Cumulative growth 2009-2018 of the machinery sector, in %



Source: Eurostat Structural Business Statistics [sbs_na_ind_r2]

However, one cannot infer from growth rates whether production has shifted from the West European countries to the Central and Eastern European Member countries. In fact, machinery growth rates largely follow GDP trends. Central and Eastern European countries – due to their lower income level and convergence process taking place – normally grow about 2% faster than Western European counties.[485] Therefore, in order to depict specialisation and relocation over time we use an indicator of specialisation for 2008 and 2017. The indictor compares the share of machinery in one country with the share of machinery in the whole EU.[486] Figure 13 presents specialisation for the year 2017 to the change between 2008 and 2017. Overall, those countries specialised on the machinery sector – i.e. showing a specialisation indicator above 1 – are seen in the upper part the graph. In fact, most of them held their specialisation (Finland, Austria, and Sweden) or even expanded it (Germany and Italy). Only, Denmark was the largest looser and saw a strong decline in its specialisation, although it still remained the most specialist country on the machinery sector in the EU. In lower part of the graph countries with a lack of specialisation can be found (specialisation indicator below 1). Over time, specialisation increased in a range of New EU Member States (seen on the right-hand side of the graph), headed by Hungary. In a number of countries, specialisation fell (seen on the left-hand side of the graph). In fact, also here some New Member States are located (the Czech Republic, Hungary and

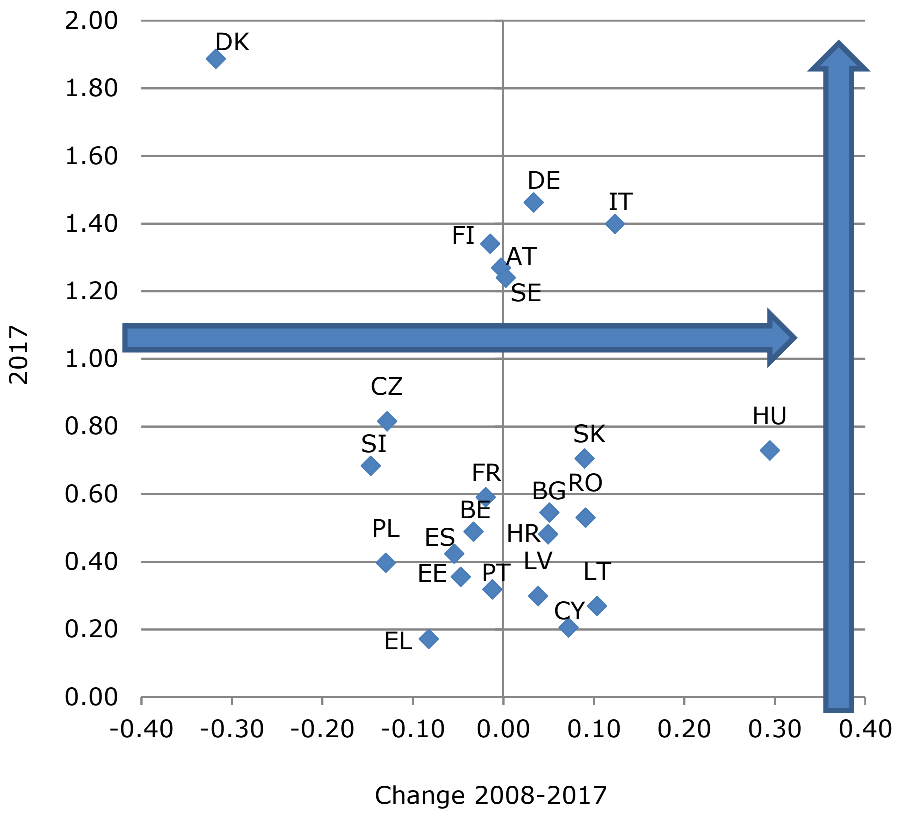
[485] See for example Astov, V. et al. (2019), Moving Into the Slow Lane, wiiw Forecast Report No. Spring 2019, March.

[486] The sectoral specialisation indicator for the machinery industry compares the share of the machinery sector in one country to the share of the machinery sector in the EU. The index is calculated for country i and industry j, which is here the machinery and equipment sector. A value above 1 means a specialisation of the country in that sector, a value below one a lack of specialisation. See European Commission (2009), 'EU industrial structure 2009: Performance and competitiveness', Luxembourg.

$$S_{i,j} = \frac{\frac{PROD_{i,j}}{\Sigma j PROD_{i,j}}}{\frac{PROD_{EU,j}}{\Sigma j PROD_{EU,j}}}$$

Slovenia). Thus, in fact one cannot say per se that there was a relocation of the machinery sector from the West to the Central and Eastern European countries.

Figure 120: Specialisation and relocation in the machinery sector, specialisation indictor 2017 and change of specialisation indicator 2008-2017 (based on production data)



Source: Eurostat Structural Business Statistics [sbs_na_ind_r2]

2.3. Enterprise structure

Looking at various indicators across different company sizes shows the role of small and large firms in the machinery sector (see Figure 121). While 64% of all enterprises are micro enterprises (defined as having 0-9 persons employed), these micro enterprises account for only 6% of all persons employed, 3.3% of turnover and 3.6% of value added. On the other hand, large enterprises (defined as having 250 persons employed or more) account for only 2% of all enterprises but for 48% of persons employed, 59% of turnover and 56% of value added. Medium-sized enterprises (50-249 persons employed) have a share of 9% in terms of enterprises and less than one third in the other indictors. Small enterprises (both categories 10-19 and 20-29) hold about 25% of enterprises and 17% of persons employed, 12% of turnover and 14% of value added.

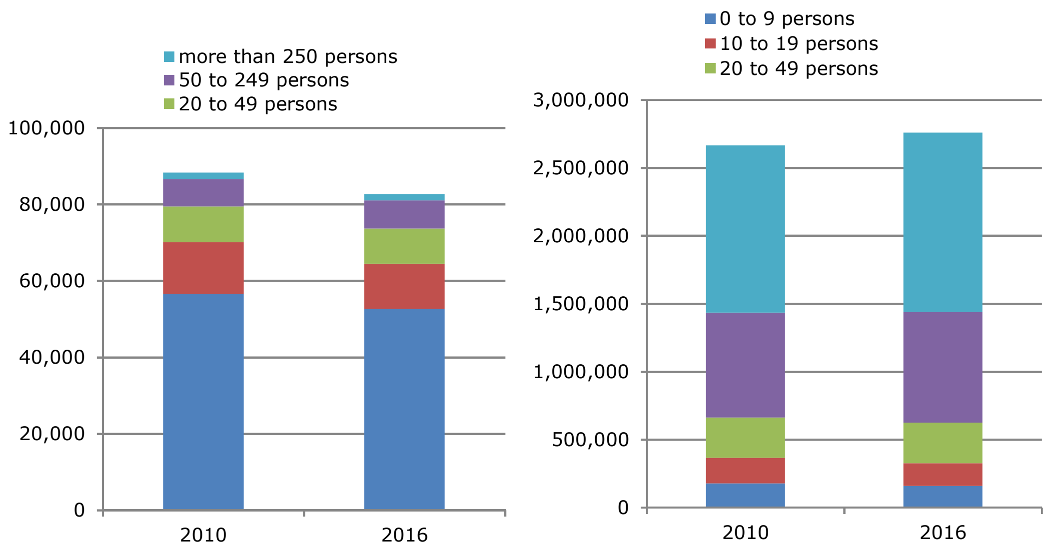
Figure 121: Machinery & equipment sector per company size class, 2016, EU-27 (without UK), in % of total

Source: Eurostat Structural Business Statistics [sbs_sc_ind_r2]

More detailed information on the Member State level is available in the Annex, Table A5. Summarising the main findings of this table, in terms of turnover, large firms dominate particularly in Germany and Hungary where they accounted for 73% of the turnover in 2016. The turnover of large firms is smallest in Slovenia, Portugal and Spain (22-27%), which show a quite different firm size distribution compared to the EU-average.

Figure 122: Machinery & equipment sector per company size class, 2010 and 2016, EU-27 number of enterprises and number of persons employed

Number of enterprises | Number of persons employed



Source: Eurostat Structural Business Statistics [sbs_sc_ind_r2]

Overserving trends over time, between 2010 and 2016 micro enterprises and small enterprises (10-19) lost both in terms of number of enterprises as well as persons employed while medium-sized enterprises (50-249) and large enterprises gained in both respects (see Figure 122).

2.4. The structure of the sector in detail (by NACE 4-digit industries)

Looking in detail at the structure of the machinery sector by 3-digit (groups) and 4-digit industries (classes) reveals the largest industries contributing to the sector turnover and enterprises. Table 75 provides a first overview for 3-digit industries: General-purpose machinery (C281) accounted for 32% of turnover but only 13% of enterprises of the whole machinery sector in 2016. Other general-purpose machinery (C282) held large shares both in terms of turnover (30%) and also enterprises (40%). Agricultural & forestry machinery (C283) as well as metal-forming machinery and machine tools (C284) were smaller industries (about 7% of turnover and 8% of enterprises). Other special-purpose machinery (C285) was again a main industry with 25% and 32% of enterprises.

On an even more detailed level, Figure 123 depicts sub-sectors of the machinery sectors by 4-digit industries by turnover (now leaving out 3-digit industries). In fact, engines & turbines except aircraft, vehicle and cycle engines is by far the largest industry with almost EUR 80 billion turnover in 2016. It is followed by other general-purpose machinery n.e.c. (EUR 65 billion), lifting and handling equipment (EUR 56 billion) and other special-purpose machinery n.e.c. (EUR 54 billion). In terms of number enterprises (Figure 124) the sequence is slightly different: Here, most companies are registered in other general-purpose machinery n.e.c. (13,850 companies), followed by other special-purpose machinery n.e.c. (10,770 companies) and lifting and handling equipment (7,700 companies). Non-domestic cooling and ventilation equipment comes fourth with 7,500 companies.

More detailed information on the Member State level is available in the Annex, Table A6. It looks at turnover at the 4-digit level per Member State so that specialisation patterns per country become visible. With shares of turnover above 10%, eleven countries are specialised on lifting & handling equipment (C2822) and non-domestic cooling & ventilation equipment (C2825), ten countries on engines & turbines (C2811). Otherwise, only one country is specialised on fluid power equipment (C2812) - that is Bulgaria - and one country on machinery for paper & paperboard production (C2895) - namely Finland.

Looking at trends over time, between 2008 and 2018 the machinery sector declined by 1.2%. The large sub-sectors of the machinery sector did not do well: engines & turbines fell by 0.5%, other general-purpose machinery n.e.c. by 1%, lifting and handling equipment by 7% and other special-purpose machinery n.e.c by 9%. Only some small sub-sectors grew: machinery for textile, apparel & leather production increased by 24%, plastic & rubber machinery by 10% and fluid power equipment by 8% (see Table 75).

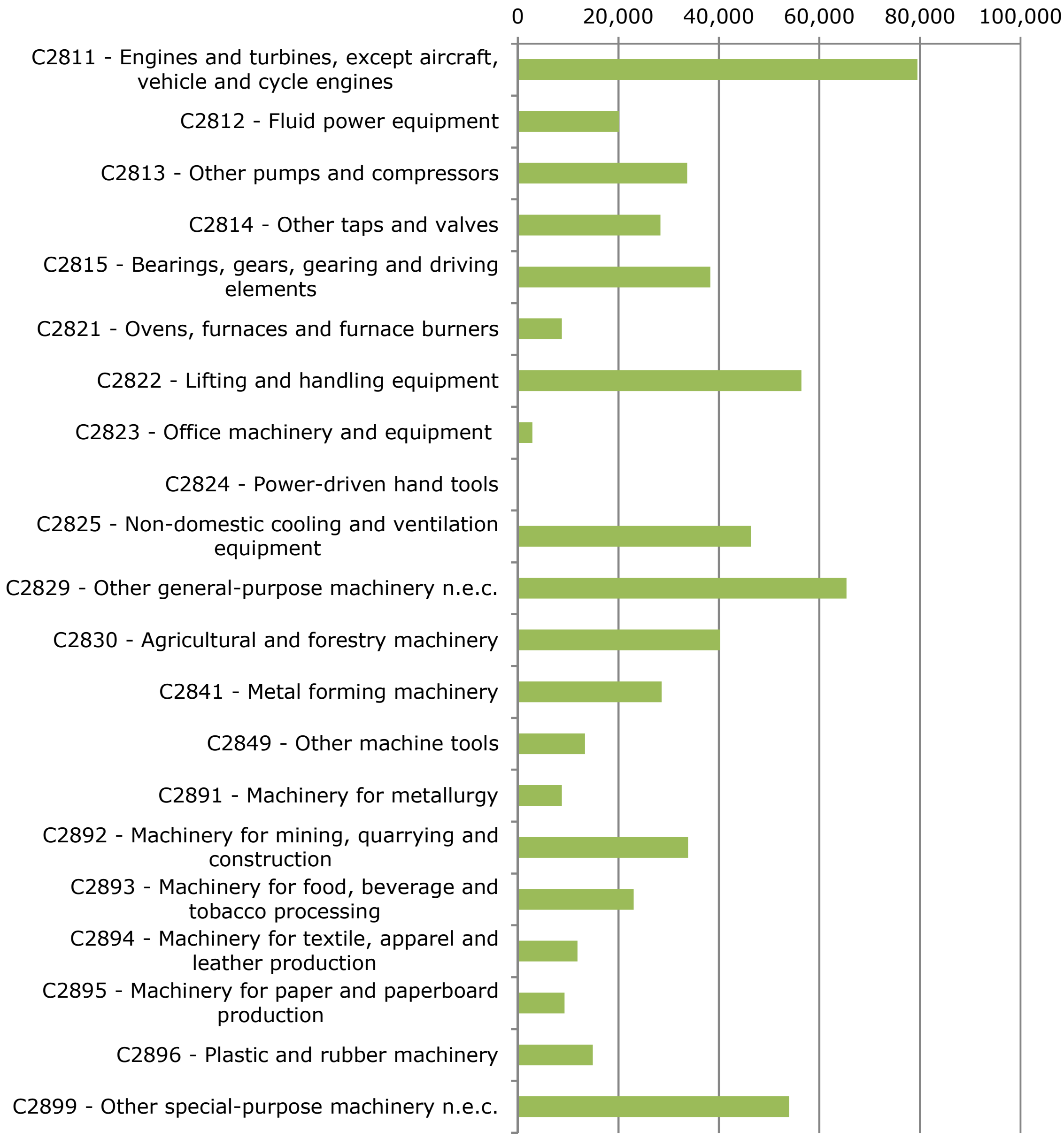
Table 75: Overview: Structure of machinery and equipment by 3-digit and 4-digit industries, EU-27 (without UK), 2016

	Turnover		Enterprises		Production Cumulative growth
	EUR million	in %	Number	in %	2008-18
C28 - Manufacture of machinery and equipment n.e.c.	**624,294**	**100.0**	**82,239**	**100.0**	**-1.2**
C281 - General-purpose machinery	**200,110**	**32.1**	**10,439**	**12.7**	**-3.0**
C2811 - Engines & turbines, except aircraft, vehicle & cycle engines	79,502	12.7	1,429	1.7	-0.5
C2812 - Fluid power equipment	20,157	3.2	1,994	2.4	7.9
C2813 - Other pumps and compressors	33,737	5.4	2,015	2.5	-10.2
C2814 - Other taps and valves	28,391	4.5	2,444	3.0	-8.7
C2815 - Bearings, gears, gearing and driving elements	38,323	6.1	2,488 [2)]	3.0 [2)]	-15.5
C282 - Other general-purpose machinery	**186,418**	**29.9**	**32,468**	**39.5**	**-8.4**
C2821 - Ovens, furnaces and furnace burners	8,788	1.4	2,021	2.5	-25.4
C2822 - Lifting and handling equipment	56,463	9.0	7,699	9.4	-6.6
C2823 - Office machinery and equipment	2,928 [1)]	0.5 [1)]	845	1.0	n.a.
C2824 - Power-driven hand tools	n.a.	n.a.	506 [2)]	0.6 [2)]	n.a.

	Turnover		Enterprises		Production Cumulative growth
	EUR million	in %	Number	in %	2008-18
C2825 - Non-domestic cooling and ventilation equipment	46,427	7.4	7,481	9.1	-13.9
C2829 - Other general-purpose machinery n.e.c.	65,399	10.5	13,850	16.8	-1.0
C283 - Agricultural and forestry machinery	**40,276**	**6.5**	**6,517**	**7.9**	**-15.5**
C2830 - Agricultural and forestry machinery	40,276	6.5	6,517	7.9	-15.5
C284 - Metal forming machinery and machine tools	**41,324**	**6.6**	**7,197**	**8.8**	**-1.1**
C2841 - Metal forming machinery	28,615	4.6	3,777	4.6	0.1
C2849 - Other machine tools	13,390	2.1	3,550	4.3	-5.1
C289 - Other special-purpose machinery	**155,931**	**25.0**	**25,903**	**31.5**	**2.4**
C2891 - Machinery for metallurgy	8,785	1.4	2,409	2.9	-0.9
C2892 - Machinery for mining, quarrying and construction	33,880	5.4	2,743	3.3	-33.1
C2893 - Machinery for food, beverage and tobacco processing	23,084	3.7	5,552	6.8	-3.3
C2894 - Machinery for textile, apparel and leather production	11,913	1.9	1,846	2.2	24.0
C2895 - Machinery for paper and paperboard production	9,346	1.5	822	1.0	n.a.
C2896 - Plastic and rubber machinery	14,930	2.4	1,772	2.2	10.3
C2899 - Other special-purpose machinery n.e.c.	53,992	8.6	10,770	13.1	-8.9

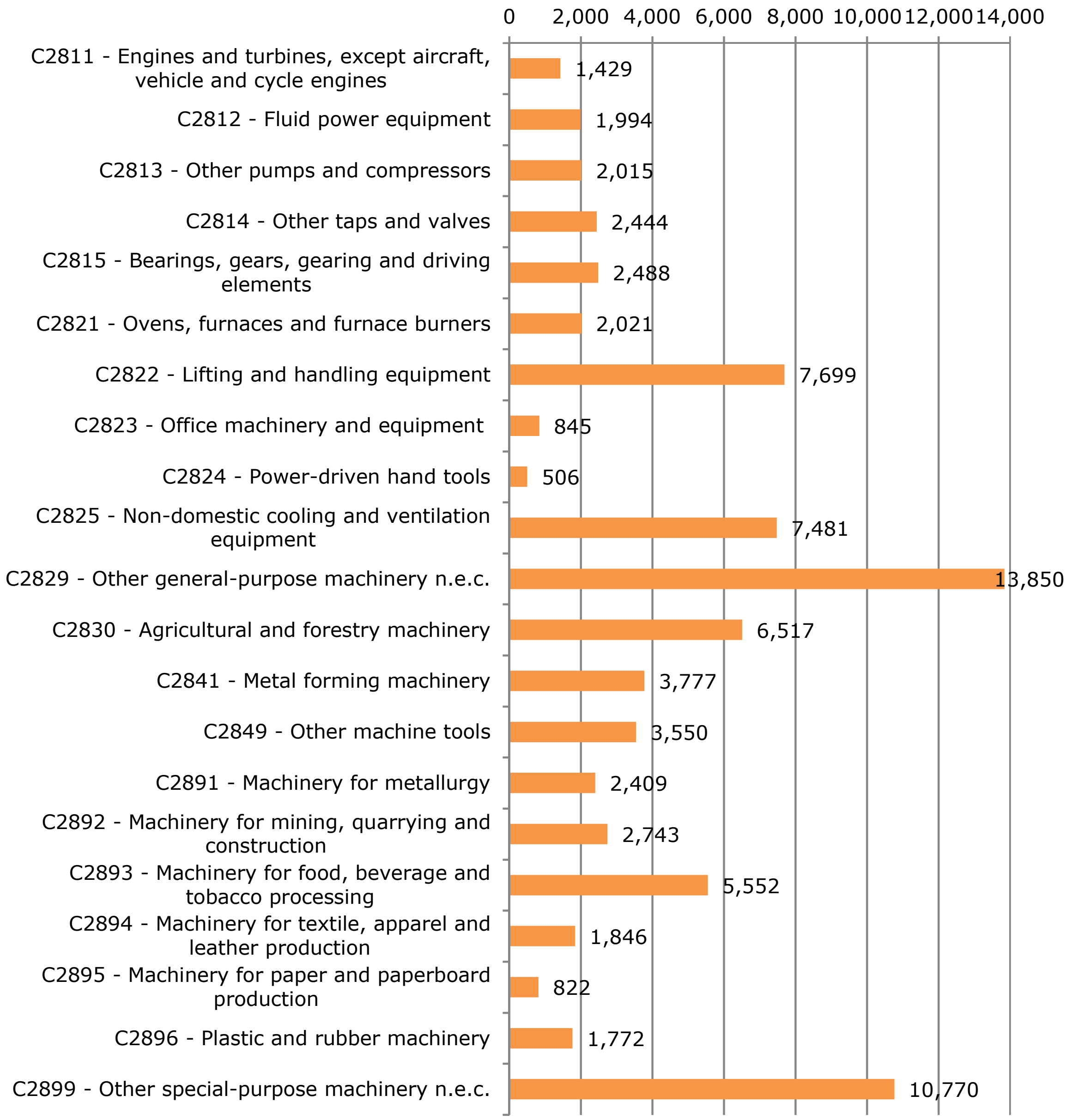
Notes: 1) Office machinery and equipment data from 2014. 2) Data from 2015.
Source: Eurostat Structural Business Statistics [sbs_na_ind_r2]

Figure 123: Turnover in machinery & equipment n.e.c., 4-digit industries, 2016, EU-27 (without UK), EUR million



Notes: Office machinery and equipment data from 2014. Power-driven hand tools data not available.
Source: Eurostat Structural Business Statistics [sbs_na_ind_r2]

Figure 124: Number of enterprises in machinery & equipment n.e.c., 4-digit industries, 2016, EU-27 (without UK)



Notes: Bearings, gears, gearing & driving elements and power-driven hand tools data from 2015. Source: Eurostat Structural Business Statistics [sbs_na_ind_r2]

2.5. Innovation performance in the machinery sector

The machinery sector is generally classified as a medium-high technology sector[487] that is R&D expenditures as a percentage of output is quite high and plays a major role. Innovation performance indicators encompass both input and output indicators. Looking first at the most well-known input indicator - R&D expenditures -, we find that in the EU-27, enterprises in the machinery sector spent EUR 12. 3 billion on R&D in 2013. Due to missing country

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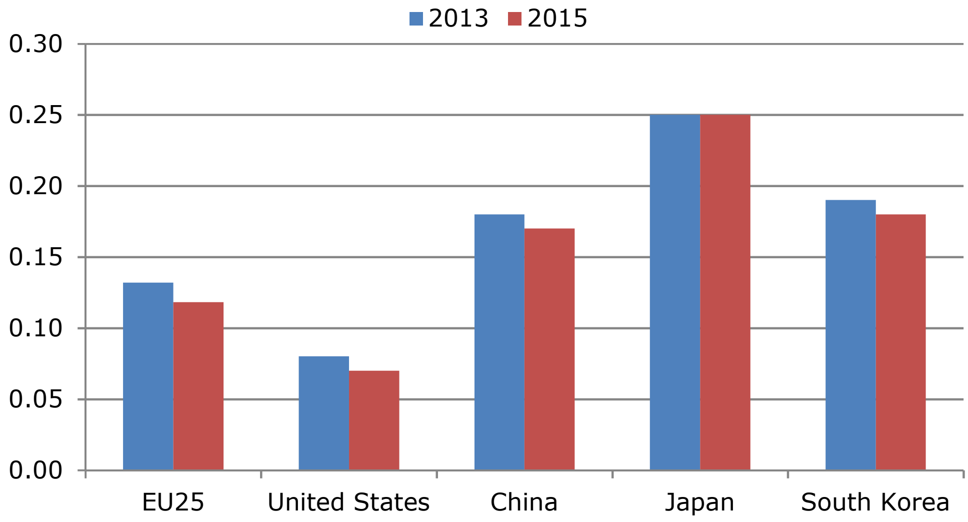
[487] Hatzichronoglou, T. (1997), "Revision of the High-Technology Sector and Product Classification", OECD Science, Technology and Industry Working Papers, No. 2997/02. Doi: 10.1787/134337307632. European Commission (2012), An introduction to Mechanical Engineering. Study on the Competitiveness of the EU Mechanical Engineering Industry, Within the Framework Contract of Sectoral Competitiveness Studies -ENTR/06/054, available at: http://ec.europa.eu/DocsRoom/documents/12329/.

data, only aggregates for EU-25 (without France and Luxembourg) can be compared over time. Between 2013 and 2015 R&D expenditures increased from EUR 11.3 billion to EUR 11.8 billion, representing only a small cumulative increase of 4.3% over two years.[488] While in fifteen Member States R&D expenditures grew, in another ten countries it declined.

Figure 125 compares the EU to its main competitors in terms of R&D intensity of the machinery sector. While in the EU-25, the R&D intensity of the machinery sector reached 0.12% of GDP in 2015, it was by far surpassed by Japan with 0.25%, South Korea with 0.18% and China with 0.17%. Interestingly, the R&D intensity of the machinery sector was lower in the United States where it reached 0.07%. Between 2014 and 2015, the R&D intensity slightly declined in all regions except Japan, which might be due also to fluctuations over years.

Figure 125: R&D intensity in major competitor regions, Business enterprise R&D (BERD) in the machinery sector in % of GDP



Notes: EU-25 without France and Luxembourg.
Source: Eurostat [rd_e_berdindr_2]

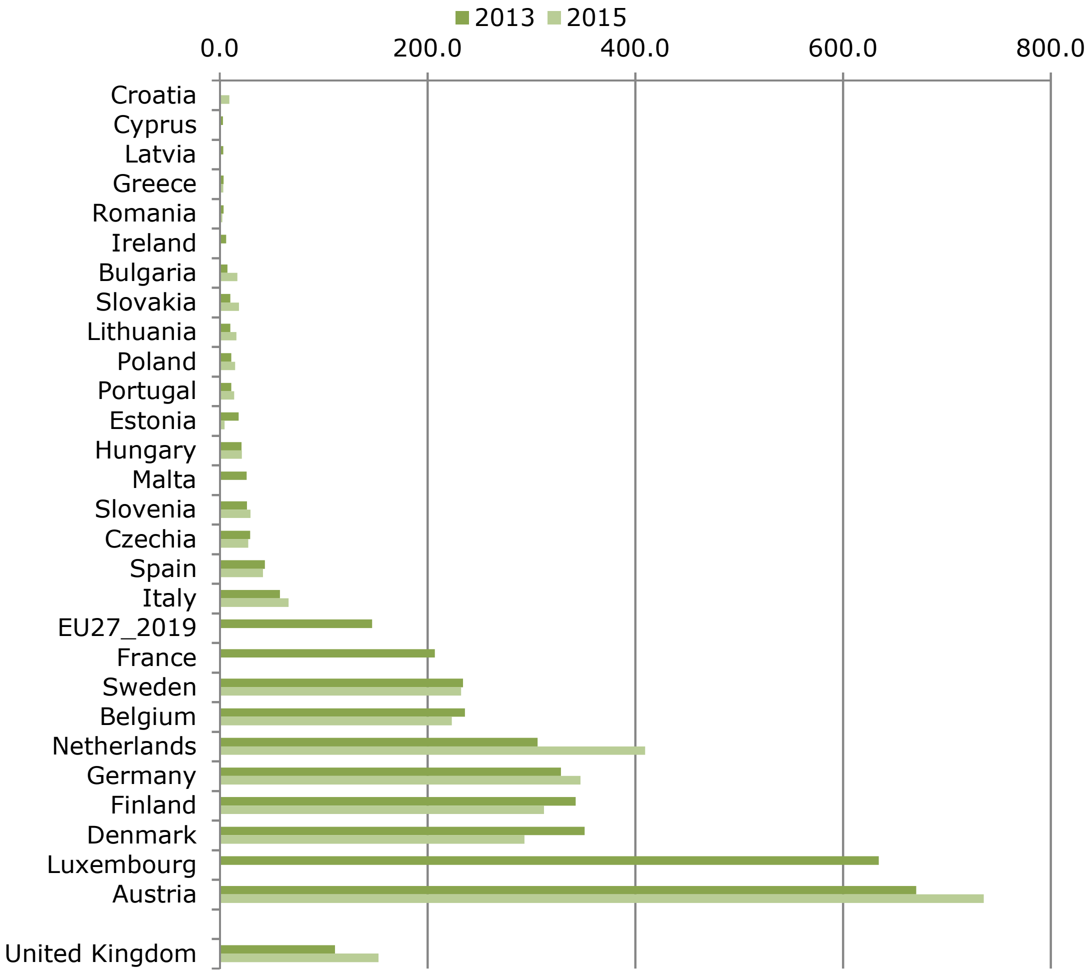
Annex III, Table A7, shows data for EU Member States for the years 2013 and 2015. Overall, the largest R&D expenditures were accounted for by Germany with EUR 5.5 billion in 2015, followed with a large gap by Italy (EUR 1.5 billion), then probably France (2013 data: EUR 1 billion), the Netherlands and Austria. Figure 126 depicts the average business enterprise R&D expenditure per business. It was above EU average for (France), Sweden, Belgium, the Netherlands, Germany, Finland, Denmark, (Luxembourg) and Austria. Between 2013 and 2015 it increased strongly in the Netherlands and Austria on the one hand but decreased markedly in Denmark and Finland on the other.

In order to look at the innovation performance of the machinery sector from the output side selected information from the latest Community Innovation Survey (CIS) from 2016 is presented. Overall, 67% of enterprises in the machinery sector in the EU were innovative enterprises in 2016, compared to 53% in manufacturing. 49% of all enterprises were classified as product innovative enterprises. Here again, the machinery sector did better than total manufacturing, where 29% of enterprises were classified as product innovative enterprises. Detailed analysis per Member State is available in Annex 1, Table A8. The highest proportion of enterprises with innovation activity in the machinery sector can be found in Finland (86%), Austria (80%), Portugal (78%) and Germany (77%). On the bottom end, only 9% of enterprises were innovative in Romania, followed with a gap by Hungary

[488] 2013 is the only year for which all country data is available. Due to missing data, an update to a more recent year than 2015 is not possible.

(31%) and Poland (34%). Product innovative companies account for the highest share in Finland again (75%) and have the lowest share in Romania (4%).

Figure 126: Average business enterprise R&D expenditure (BERD) per business in the machinery and equipment sector, 2013 and 2015, EUR thousands

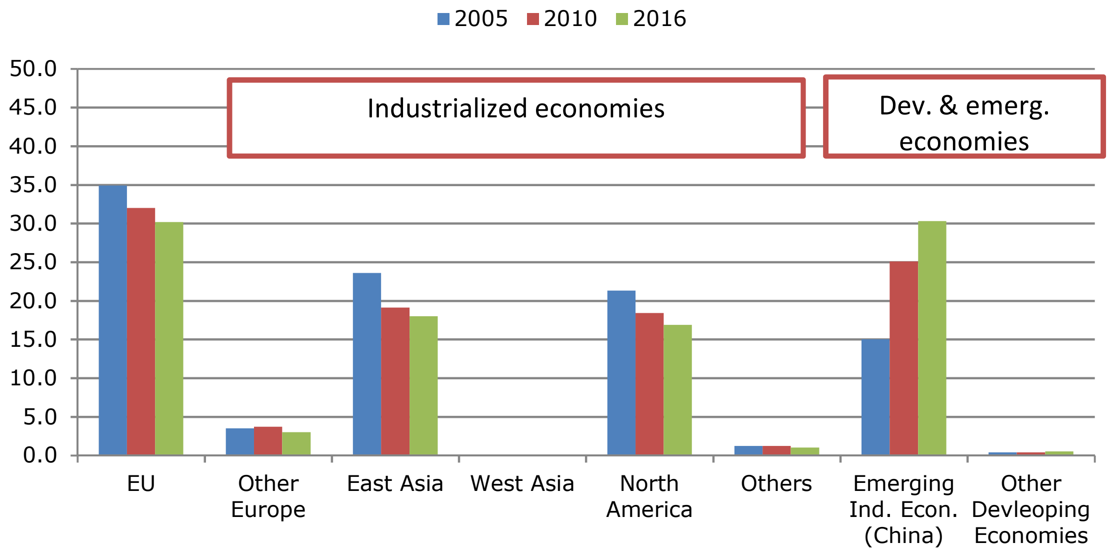


Source: Eurostat [rd_e_berdindr_2] and Eurostat Structural Business Statistics [sbs_na_ind_r2].

2.6. Main competitors and trade performance

The UNIDO Industrial Statistical Yearbook[489] shows that two thirds of world value added for the machinery and equipment sector (ISIC 28) was created in the industrialized economies and one third in the developing & emerging industrial economies in 2016. However, between 2005 and 2016, the share of value added in industrialized economies has constantly diminished, accounting for 85% of world value added still in 2005, 75% in 2010 but falling to 70% in 2016. Within industrialized economies (see Figure 127) all major regions lost shares: The EU share fell from 35% to 30%, the East Asian share from 24% to 18% and the North American share from 21% to 17%. The share of emerging industrial economies, which include China, doubled on the other hand, from 15% in 2005 to 30% in 2016.

Figure 127: Machinery & equipment in the world, distribution of world value added in %



Source: UNIDO (2018), International Yearbook of Industrial Statistics 2018.

In in 2010 major top producers of machinery and equipment according to UNIDO[490] were the US, Japan, China and Germany, followed by Italy, the United Kingdom, Brazil, India, France and Canada. On place 11-15 were the Russian Federation, the Republic of Korea, Switzerland, the Netherlands and Spain. For 2016, the top ranks had shifted, and China gained the top position, followed by Japan, the US and Germany. Then came Italy, Canada, the United Kingdom, France, India and Brazil. On place 11-15, there were the Republic of Korea, the Russian Federation, the Netherlands, Spain and Austria.

Table 76 presents the main economic indicators for the machinery sector for the EU-27 compared to its major competitors, the US, Japan, South Korea and China. The upper table refers to the year 2010 the lower table to the year 2015/16. In 2016, the EU-27 machinery output was double that of the US or Japan, while China's output was double that of the EU-27. South Korea's machinery output reached about one sixth of the EU. In terms of labour productivity, the highest labour productivity was observed in the US and Japan, while they were lowest one in China. EU's labour productivity was about two thirds of the US. The highest labour costs were also registered in the US and Japan, the lowest ones in China. EU's labour costs amounted to 60% of the US. Regarding the trade performance, all countries, except the US, showed a trade surplus in machinery trade. The EU-27 exhibited a trade surplus in trade with its competitors, except with Japan.

[489] UNIDO (2018), International Yearbook of Industrial Statistics 2018, United Nations Industrial Development Organization, Vienna.
[490] Ibid.

Table 76: Key indicators for the machinery & equipment sector across major competitor countries, 2010 and 2016

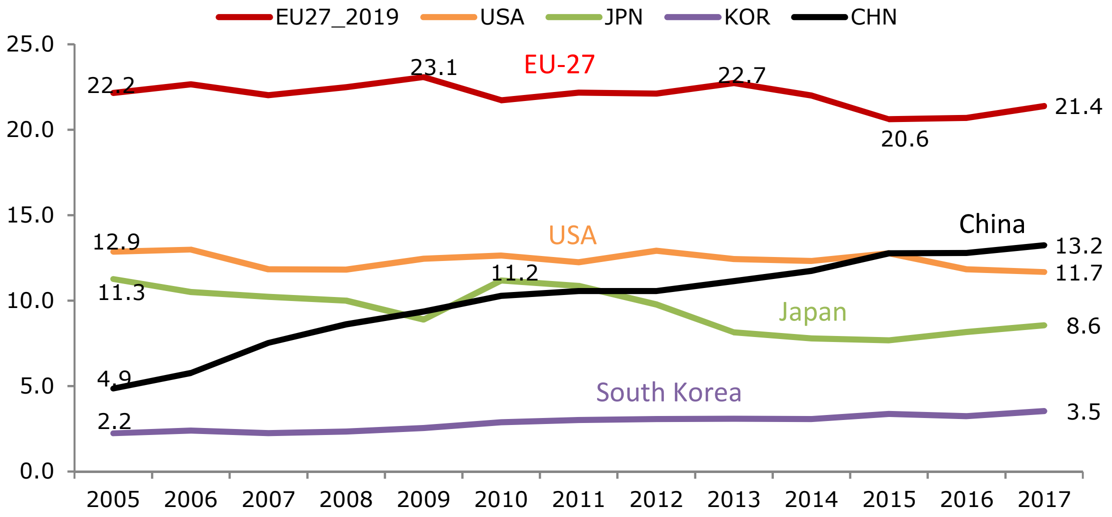
		EU-27_2019	USA	Japan	South Korea	China
		2010	2010	2010	2010	2010
Output	Euro billion	576,2	238,4	258,8	68,6	716,5
Value added	Euro billion	174,5	92,1	113,6	18,9	153,3
Employees	million	2,6	1,0	1,3	0,4	6,1
Labour productivity (value added per employee)	Euro	66.290	92.648	85.290	49.654	25.135
Labour costs (per employee)	Euro	40.175	57.041	48.386	24.510	3.700
Domestic demand (production + imports - exports)	Euro billion	576,2	249,2	250,0	73,7	728,7
Machinery & equipment imports (total)**	Euro billion	95,1	105,1	23,3	29,3	95,4
Machinery & equipment exports (total)**	Euro billion	203,6	118,5	104,9	27,0	96,3
Machinery imports from EU-27_2019	Euro billion		25,0	3,7	7,5	29,0
Machinery exports to EU-27_2019	Euro billion		14,2	12,6	2,3	16,8

		EU-27_2019	USA	Japan	South Korea	China
		2016	2016	2016	2015	2015
Output	Euro billion	663,1	329,6	300,5	98,3	1.077,7
Value added	Euro billion	233,1	128,4	140,4	30,2	242,8
Employees	million	2,8	1,1	1,3	0,5	7,3
Labour productivity (value added per employee)	Euro	82.285	119.699	110.893	67.139	33.173
Labour costs (per employee)	Euro	46.152	76.559	50.056	37.858	7.797
Domestic demand (production + imports - exports)	Euro billion	663,1	351,8	293,9	101,0	1.083,6
Machinery & equipment imports (total)**	Euro billion	114,4	159,9	28,7	26,4	83,8
Machinery & equipment exports (total)**	Euro billion	238,3	136,3	94,1	37,3	147,3
Machinery imports from EU-27_2019	Euro billion		41,1	4,9	6,9	27,5
Machinery exports to EU-27_2019	Euro billion		18,9	11,4	4,2	21,5

Notes: Based on National Accounts. *For the EU, Extra-EU trade only. Source: Eurostat National Accounts (EU data). OECD STAN (USA, Japan, South Korea), OECD TiVA and UNIDO (China), UN COMTRADE (trade data).

Looking in more detail at the machinery & equipment sector's trade, the trade performance of the EU and its competitors is assessed by showing the development of market shares, reflecting the external competitiveness of the sector (see Figure 15). In 2017, the EU machinery export share reached 21%, far ahead of its competitor countries: China's machinery exports accounted for 13% of world exports, the USA for 12% and Japan for about 9%. South Korea had a smaller share with 3.5%. What is particularly striking is the strong increase of China's market share between 2005 and 2017: It increased from 5% in 2005 to 13% in 2017 making up 8 percentage points. Also, South Korea's market share increased (by 1.3pp). On the other side, market shares for EU and US machinery exports slightly decreased (by about 1 pp), the Japanese market share dropped by 3pp.

Figure 128: World market shares of main competitor countries of machinery & equipment, 2005-2017, in % of total world trade



Notes: For the EU, Extra-EU trade only. NACE rev.2, C28.
Source: UN COMTRADE.

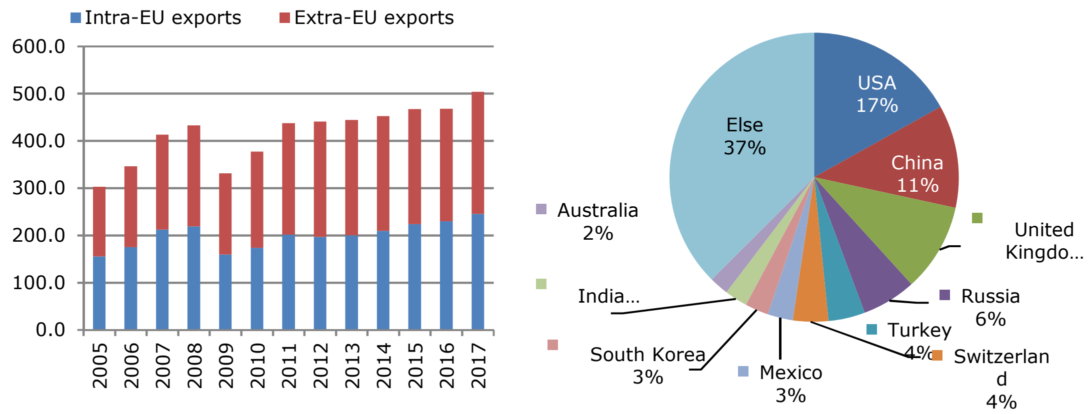
Total EU machinery & equipment exports amounted to EUR 503 billion in 2017, of which 49% were exported to EU member countries (i.e. intra-EU exports), while 51% were exported to countries outside the EU (extra-EU exports). Looking at trends, there was a slight shift towards extra-EU countries between 2005 and 2017, due to lower demand on the EU markets following the economic and financial crisis. Before in 2005, 51% of exports went to EU member countries, while 49% was exported abroad.

Main export destinations outside the EU in 2017 were the US (17%), China (10%), the United Kingdom (10%), Russia (6%) and Turkey (4%). On placed 6-10 were exports to Switzerland, Mexico, South Korea, India and Australia. The ten most important export destinations together accounted for slightly more than 60% of all extra-EU exports.

Within the European Union, main exporters in 2017 were Germany, Italy, France, the Netherlands and Belgium. In the Annex III, Table A8 lists exports per Member States. While Germany and Italy exported almost 60% to extra-EU countries, Belgium was focused on EU-markets instead and exported only 42% abroad.

Figure 129: EU-27 machinery & equipment exports overview

Exports of machinery & equipment, EUR billion | Main extra-EU export destinations, in %



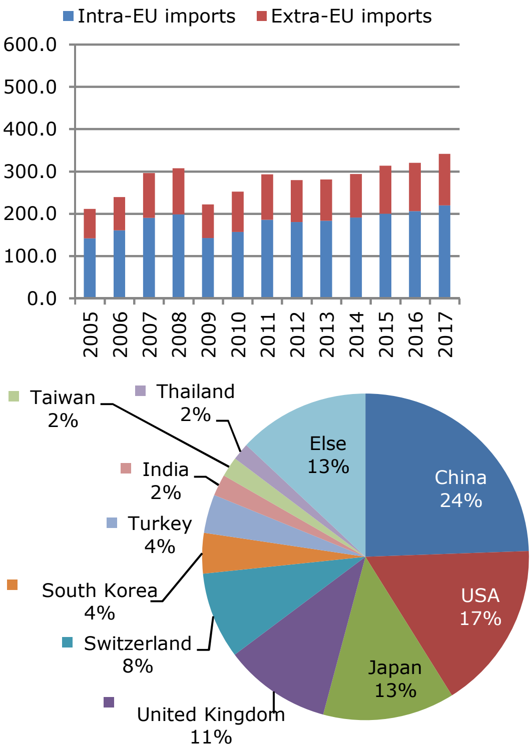
Source: UN COMTRADE.

Total EU machinery & equipment imports amounted to EUR 342 billion in 2017, of which 64% were imported from EU member countries (ie intra-EU imports), while 36% were imported from countries outside the EU (extra-EU imports). Looking at trends, there was again a slisght shift towards imports from countries outside the EU, with intra-EU imports accounting for 67% of imports in 2005.

Most important import sources from outside the EU are China (24%), the US (17%), Japan (13%), the United Kingdom (11%) and Switzerland (9%). On place 6-10 are South Korea, Turkey, India, Taiwan and Thailand. The ten most important import countries together accounted for 87% of all extra-EU imports.

Figure 130: EU-27 machinery & equipment import overview

Imports of machinery & equipment, EUR billion | Main extra-EU import sources, in %



Source: UN COMTRADE.

Within the European Union, main importers in 2017 were again Germany, France, Italy, the Netherlands and Belgium. In the Annex 1, Table A8 lists imports per Member States. Germany imported almost half of machinery products from outside the EU, while in the other four countries this share was much smaller (30-40%).

Overall, the machinery and equipment sector plays an important role as it contributes to the EU current account surplus. The machinery sector showed a pronounced (extra-EU) trade surplus of EUR 136 billion, expanding since the financial crisis. Within the EU, a positive trade balance indicator (defined as exports-imports/exports+imports) is exhibited by eleven countries: Italy, Germany, Denmark, Finland, Czechia, the Netherlands, Sweden, Austria, Slovenia, Belgium and Slovakia.

Table 77 goes into more detail at the sectoral level and shows the ten most competitive exports and the ten least competitive ones as measured by revealed comparative advantage (RCA) indicator.[491] Quite interestingly, the top four products are machines specialised for particular industries. Whereas at the lower end are office machines and automatic data-processing machines and parts thereof. Between 2008 and 2018, RCAs declined for all industries, except for 714 "Engines & motors, non-electric and parts" and stayed constant for 722 "Tractors".

Table 77: Ranking of machinery sectors with highest and lowest RCAs, 2017

Weakest machinery exports		
749	Non-electric parts and accessories of machinery n.e.s.	0.96
728	Other machinery and equipment specialized for particular industries, n.e.s.	0.91
724	Textile and leather machinery and parts	0.90
714	Engines and motors, non-electric and parts	0.90
723	Civil engineering and contractors' plant and equipment and parts	0.89
712	Steam turbines and other vapour turbines and parts	0.86
751	Office machines	0.75
711	Steam or other vapour-generating boilers and parts	0.69
752	Automatic data-processing machines	0.48
759	Parts and accessories, for office machines and automatic d-p machines	0.38
Top machinery exports		
727	Food-processing machines (excluding domestic) and parts	1.66
725	Paper mill and pulp mill machinery and parts	1.55
721	Agricultural machinery (excluding tractors) and parts	1.53
726	Printing and bookbinding machinery and parts	1.39
745	Non-electrical machinery, tools and mechanical apparatus and parts	1.37
744	Mechanical handling equipment and parts	1.35
735	Parts, n.e.s., for machine tools	1.32
722	Tractors (excl. 744.14 and 744.15)	1.31
733	Machine tools for working metal	1.23
718	Power-generating machinery and parts	1.23

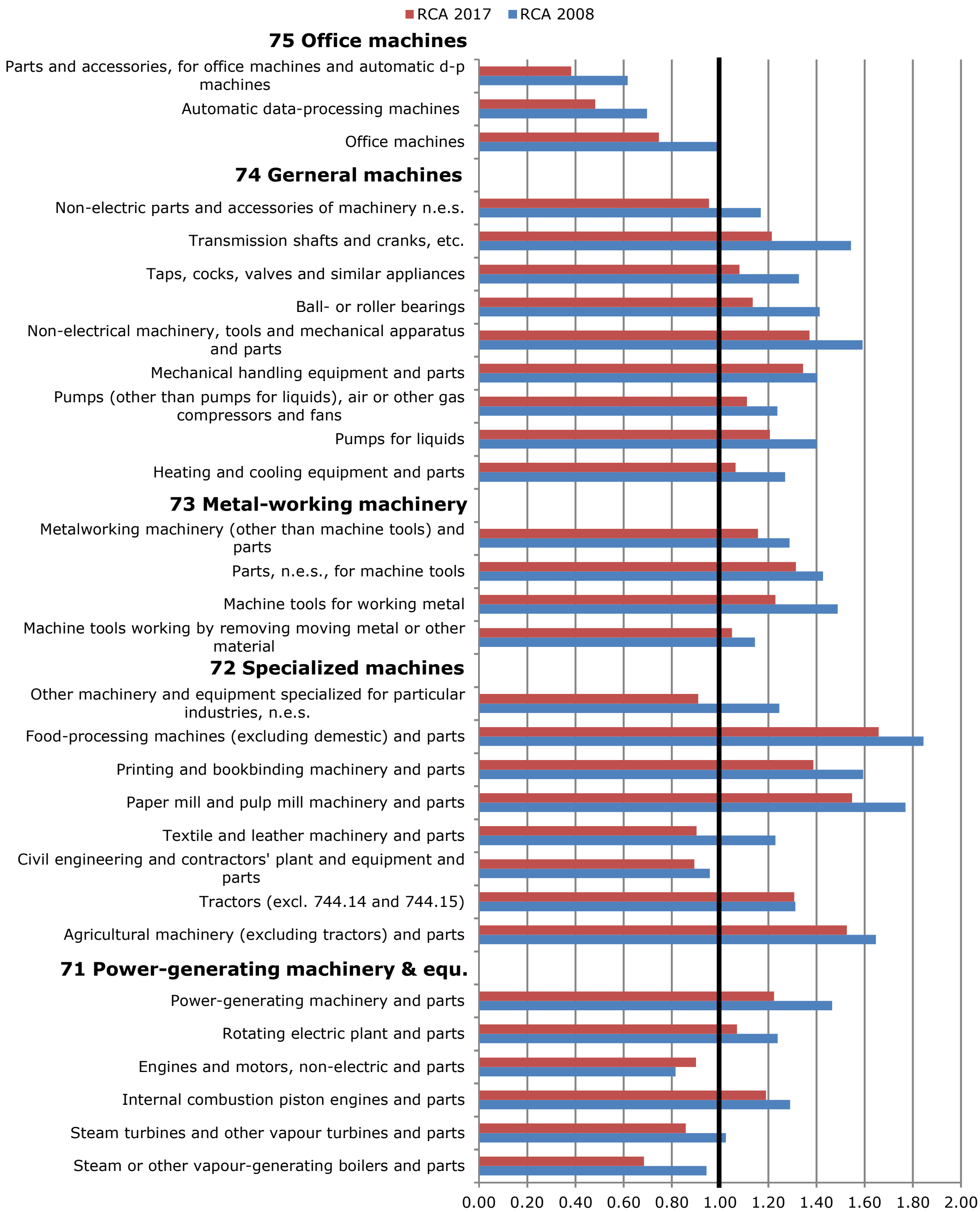
Notes: SITC rev. 4, 71,72,73,74,75
Source: UN COMTRADE.

491 As a measure of revealed comparative advantage (RCA), the Balassa Index is used. This index, which is based on exports only, is defined as

$$\mathrm{RCA_{ijt}} = \frac{\frac{\mathrm{EXP_{ijt}}}{\mathrm{EXP_{jt}}}}{\frac{\mathrm{EXP_{it}}}{\mathrm{EXP_{t}}}}$$

where $\mathrm{RCA_{ijt}}$ refers to the revealed compared advantage of industry i of country (or country group) j at time t; $\mathrm{EXP_{ijt}}$ refers to the exports of industry i of country j at time t; and $\mathrm{EXP_{it}}$ refers to global exports of that industry. Similarly, $\mathrm{EXP_{jt}}$ and $\mathrm{EXP_{t}}$ refer, respectively, to total exports of country j, and to total global exports at time t.

Figure 131: RCAs of machinery exports, 2008 and 2017



Notes: SITC rev. 4, 71,72,73,74,75
Source: UN COMTRADE.

2.7. Input-output structure of the machinery sector

Based on the World Input-Output Database (WIOD) the main input and output structure of the machinery and equipment sector for the EU-27 (NACE rev. 2, C28) will be explored in detail. While the input side represents the cost structure of the sector, the output side the sales structure. Both will be explored for the most recent year (2014) and one comparison year (2000). This will capture important inter-industry linkages as well as inter-country linkages, by explicitly looking at foreign inputs and sales.

Considering the **input side of the EU-27 machinery sector** (cost structure), the total input of the EU-27 machinery and equipment sector in 2014 totalled USD 748 billion. Of these the main inputs were:

- Intermediate inputs, accounting for 63% (of which 13% were foreign inputs)
- Value added, representing 36%

Looking at intermediate inputs in more detail (see Table 78) main inputs were generally coming from the manufacturing sector itself, accounting for 66% of all inputs in 2014. Here medium-low tech and medium high-tech inputs held about 30% of all inputs each. Business services inputs played a large role with 15%, followed by wholesale inputs with 8% and transport with 4%. About 13% of all inputs were sourced internationally. This share was even higher in medium-high tech and high-tech manufacturing, with 21% and 20% respectively. Between 2000 and 2014, the input structure was rather stable, the foreign share slightly increased.

Table 78: Structure of intermediate costs of the EU-27 machinery and equipment sector

	in USD million 2000	Structure in % 2000	Share of foreign costs 2000	in USD million 2014	Structure in % 2014	Share of foreign costs 2014	Change of structure 2000-2014	Change of foreign costs 2000-2014
Agriculture	147	0.1	5.5	276	0.1	8.7	0.0	3.2
Mining and utilities	3603	1.7	8.1	11186	2.4	11.4	0.7	3.3
Low tech manufacturing	3268	1.5	8.5	5798	1.2	14.6	-0.3	6.0
Medium-low tech manufacturing	62502	29.1	7.9	134407	28.8	9.7	-0.3	1.8
Medium-high tech manufacturing	66464	30.9	18.1	147246	31.5	21.4	0.6	3.3
High tech manufacturing	10467	4.9	13.6	20707	4.4	19.5	-0.4	5.9
Construction	2330	1.1	0.8	4907	1.0	1.1	0.0	0.3
Wholesale	16511	7.7	3.4	38668	8.3	6.2	0.6	2.7
Retail	5985	2.8	1.7	6718	1.4	4.1	-1.3	2.4
Transport	7609	3.5	6.4	17299	3.7	7.2	0.2	0.9
Other transport and communication	1912	0.9	4.3	4367	0.9	5.2	0.0	0.8
Accommodation etc.	1083	0.5	15.3	2187	0.5	17.1	0.0	1.7
Business services	30583	14.2	5.6	68139	14.6	6.6	0.3	1.1
Public and other services	2302	1.1	4.8	5551	1.2	4.7	0.1	-0.2
Total intermediate costs	**214764**	**100.0**	**10.3**	**467456**	**100.0**	**12.8**	**.**	**2.5**

Notes: Machinery and equipment belongs to the medium high-tech sector.
Source: WIOD (Release 2016)

Looking at the **output side of the EU-27 machinery sector** (sales structure), the total output the EU-27 machinery and equipment sector in 2014 totalled USD 748 billion (inputs and outputs are equal). Of these the sales were going to:

- Intermediate sales, accounting for 49% (of which 33% were foreign sales)
- Final consumption of government, households and NGOs, representing 4.4%
- Gross fixed capital formation, with 45%

Regarding intermediate sales in more detail (see Table 79) 67% of sales went to the manufacturing sector itself. More precisely 50% went to medium-high tech manufacturing, 10% to medium-low tech manufacturing. Main customers were also construction with 9%, mining& utilities with 7% and business services with 5%. The share of intermediate sales going abroad was pronounced and reached 33% in 2014. Foreign sales to mining & utilities even account for 65% of sales going to this sector. Between 2000 and 2014, the output structure was quite stable. There was a remarkable shift towards foreign sales during this time period, the share increased by 11 percentage points.

Table 79: Structure of intermediate sales of the EU-27 machinery and equipment sector

	in USD million 2000	Structure in % 2000	Share of foreign sales 2000	in USD million 2014	Structure in % 2014	Share of foreign sales 2014	Change of structure 2000-2014	Change of foreign sales 2000-2014
Agriculture	2628	1.7	24.7	5999	1.6	41.5	-0.1	16.9
Mining and utilities	8138	5.3	42.9	24758	6.7	65.3	1.5	22.4
Low tech manufacturing	5703	3.7	19.4	11911	3.2	30.7	-0.4	11.3
Medium-low tech manufacturing	17410	11.3	14.4	38975	10.6	28.4	-0.6	14.0
Medium-high tech manufacturing	76547	49.5	19.1	182065	49.6	27.5	0.1	8.4
High tech manufacturing	4632	3.0	23.1	12128	3.3	38.4	0.3	15.2
Construction	16175	10.5	23.5	32916	9.0	32.3	-1.5	8.9
Wholesale	5696	3.7	26.8	10847	3.0	29.5	-0.7	2.8
Retail	1236	0.8	18.4	2653	0.7	23.2	-0.1	4.8
Transport	3317	2.1	31.3	9829	2.7	41.6	0.5	10.4
Other transport and communication	1188	0.8	15.0	2522	0.7	21.6	-0.1	6.6
Accommodation etc.	977	0.6	14.1	1975	0.5	19.3	-0.1	5.3
Business services	6663	4.3	21.1	17040	4.6	28.7	0.3	7.6
Public and other services	4403	2.8	35.8	13295	3.6	51.8	0.8	16.0
Total intermediate sales	**154711**	**100.0**	**21.6**	**366914**	**100.0**	**32.5**	.	**11.0**

Notes: Machinery and equipment belongs to the medium high-tech sector.
Source: WIOD (Release 2016).

2.8. Digitalisation of the machinery sector

In order to analyse the importance and emergence of digital technologies in the machinery and equipment sector, the relevance of Information and Communication Technologies' (ICT) capital is assessed by using EU KLEMS database, which was updated at the end of 2019.[492] This database provides relevant indicators (e.g. the ICT growth rates in the machinery sector, the contribution of ICT capital to growth and the ICT capital stock in % of total capital stock) for some EU countries, the US and now also Japan.

The pace of digitalisation is measured by ICT capital services growth. While there was a drop in the pace of digitalisation during the economic and financial crisis in the machinery sector it has recovered in numerous countries since then: in the EU11 as well as in the US ICT capital services grew faster after the financial crisis than before, while in Japan it slowed down significantly in the latter period. In the post crisis period, cumulative growth ranged between 3% in Germany to 75-70% in Czechia, Austria, Denmark and the Netherlands. Romania and Slovakia were the only two countries with a negative performance.

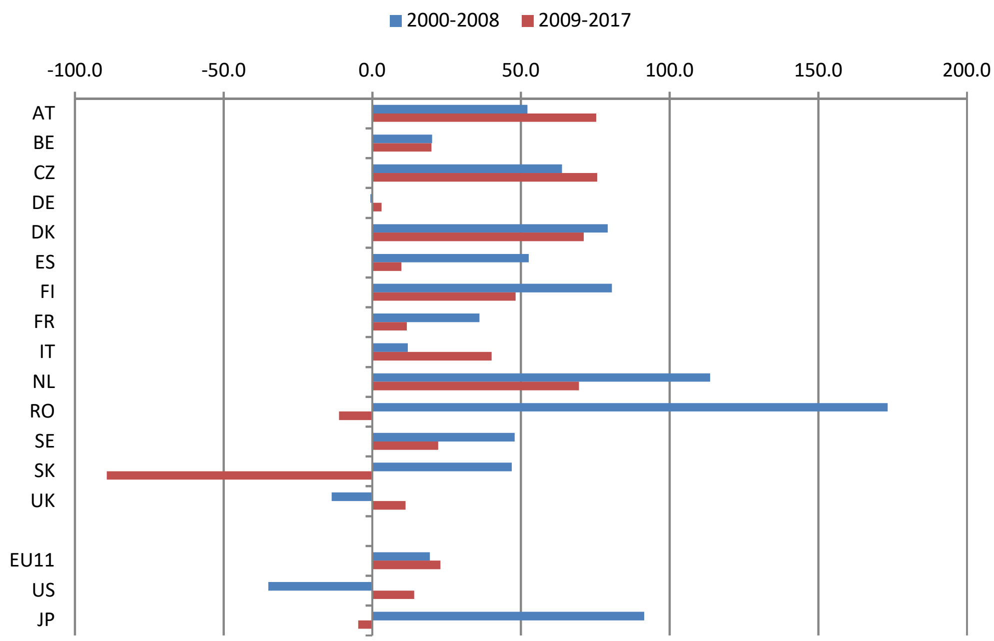
Looking at the ICT capital stock in the machinery sector as a percentage of total capital stock (see Figure 19), this share is remarkably larger compared to manufacturing, signalising a higher level of digitalisation in the machinery sector in 2017. In a number of countries, the share of ICT capital stock was higher in manufacturing (Czechia, Greece, Sweden, Slovakia, US and also Japan). The share was largest in France with 14%, followed by Finland with

[492] Release 2019. Available at www.euklems.eu

8.5% and the Netherlands with 8%. The lowest share with 1% only was registered in Slovakia. For comparison: in the US, the share reached 3%, in Japan 6.3%.

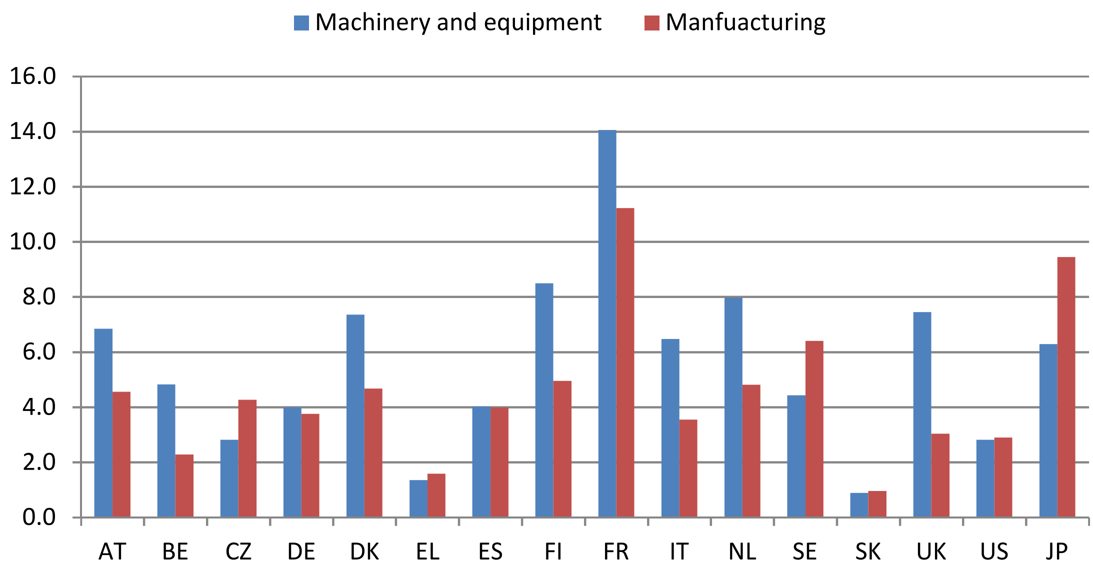
Also, the structure of ICT capital in the machinery sector is interesting but differs quite a lot across countries (see Figure 132). Distinguishing between communications equipment, computing equipment and computer software & databases, the latter one took the largest share in most countries. Computing equipment held a very high share in Czechia and Slovakia. Communications equipment was most pronounced in Spain and Sweden. In Germany, Denmark and Greece the three asset types were distributed more equally.

Figure 132: ICT capital services in the machinery sector (NACE rev. 2, C28), cumulative growth rates 2000-2008 and 2009-2017



Notes: EU11 including AT, BE, CZ, DE, DK, ES, FI, FR, IT, NL and SE.
Data for Spain, Romania, Sweden and UK for 2009-2016, data for Japan for 2009-2015.
Source: EU KLEMS, Release 2019.

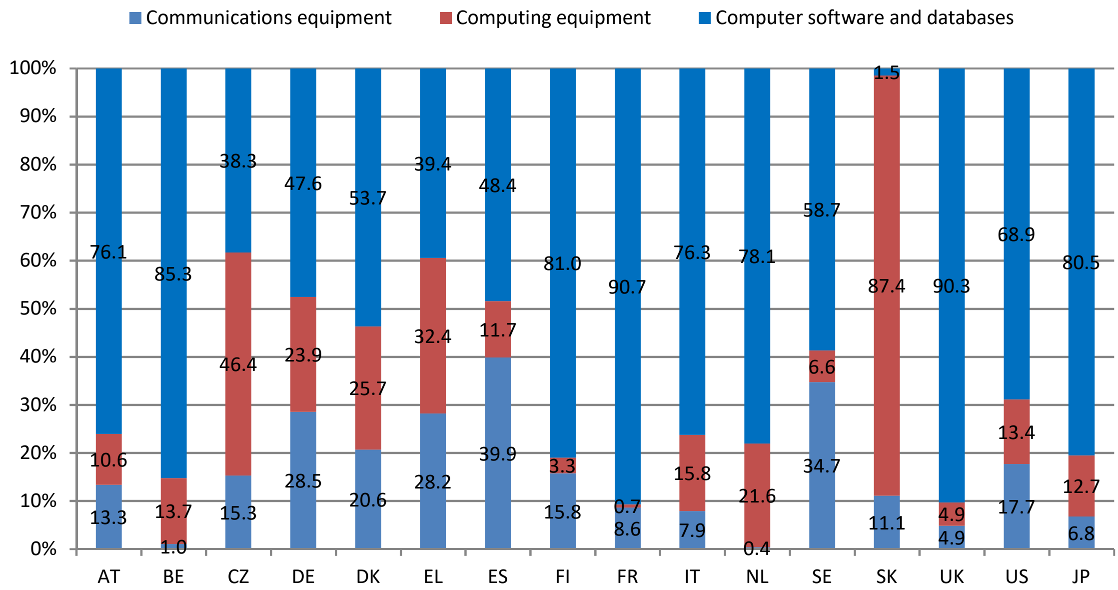
Figure 133: ICT capital stock in % total capital stock, in current prices, 2017



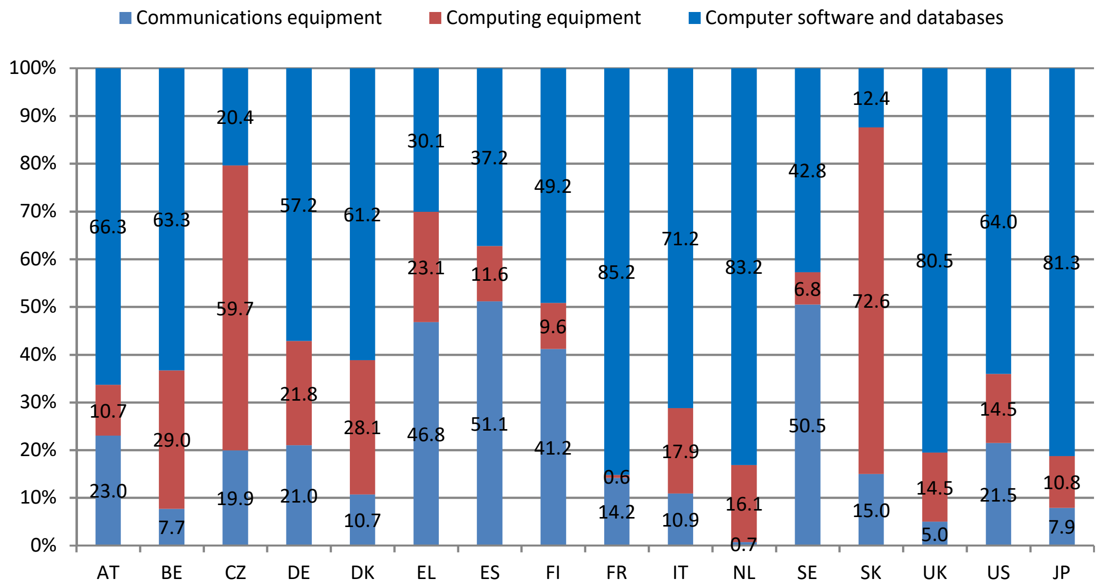
Notes: Data for Greece, Spain and Sweden for 2016. Data for Japan for 2015.
Source: EU KLEMS, Release 2019.

Figure 134: Structure of ICT capital services stock, in % total, 2017

Machinery and equipment



Manufacturing



Notes: Data for Greece, Spain and Sweden for 2016. Data for Japan for 2015.
Source: EU KLEMS, Release 2019.

3. SPECIAL FOCUS ON ROBOTICS

Robotics is a growing industry and a highly topical issue.[493] Robots are moving beyond operating in enclosed areas and are increasingly collaborating with people, moving into other

[493] IFR (2018), World Robotics 2018 – Industrial Robots

application area, or are being developed to so called humanoids. A humanoid robot resembles the human body.[494] Technical progress implies that safety standards may have to adapt.

Data on robots most often focus on the use of robots in the economy. The main provider of data is the International of Robotics (IFR).[495] Thus, in the economic literature the effects of the use of robots is mainly investigated. First of all, the effect of the use of robots on employment is of main interest, due to concerns of robots substituting people leading to massive spread of "technological unemployment". While results have been controversial, the overall effects are unclear. Research has also explored effects on specific tasks (routine task being replaced more), qualifications (medium-skilled jobs being more effected, so called "polarisation hypothesis"), or wages.[496] Effects of the use of robots on productivity and vale added or on global value chains have also been investigated recently.[497]

The supply side, i.e. the production of robots and its main producers is less well-documented.[498] On the one hand, IFR does not publish information on the main industrial robot producers stating data protection reasons; on the other hand IFR provides more information on the production of service robots and also publishes company names.

Statistics published by the IFR distinguish between industrial robots and service robots. In the ISO-Standard 8372, effective since 2012, 'robots and robotic devices' have been specified in the following way:[499]

- A **robot** is an actuated mechanism programmable in two or more axes with a degree of autonomy, moving within its environment to perform intended tasks
- An **industrial robot** is an automatically controlled, reprogrammable multipurpose manipulator programmable in three or more axes, which can be either fixed in place or mobile for use in industrial automation applications
- A **service robot** is a robot that performs useful tasks for humans or equipment excluding industrial automation applications. (Note: the distinction of a robot into industrial robot or service robot is done according to its intended application).
- A **personal service robot** or a service robot for personal use is a service robot used for a non-commercial task, usually by lay persons. Examples include domestic servant robot, automated wheelchair, personal mobility assist robot, and pet exercising robot.
- A **professional service robot** or a service robot for professional use is a service robot used for a commercial task, usually operated by a properly trained operator. Examples include cleaning robot for public places, delivery robot in offices or hospitals, fire-fighting robot, rehabilitation robot and surgery robot in hospitals.

[494] https://www.sciencedaily.com/terms/humanoid_robot.htm

[495] IFR (2018), World Robotics 2018 – Industrial Robots IFR (2018), World Robotics 2018 – Service Robots.

[496] For an overview of literature on the effects of robotics and automatization see for example Beckert, Bernd et al. (2016), 'Automatisierung und Robotik-Systeme", Studien zum deutschen Innovationssystem, No.11-2016, Expertenkommission Forschung und Innovation (EFI), Berlin. OECD (2019),'Determinants and Impact of Automation', DSTI/CDEP/MADE(2016/FINAL.

[497] See for example Graetz G. & Michaels G. (2015), 'Robots at Work', CEP Discussion Papers dp1335, Centre for Economic Performance, LSE. DeBacker, K., DeStefano, T., Menon, C. and J. Ran Suh (2018), 'Industrial robotics and the global organisation of production', OECD Working Papers 2018/03, https://dx.doi.org/10.1787/dd98ff58-en

[498] This has also been recognized in the EU project on robots "ROCK eu^2 - Robotics Coordination Action for Europe Two". See https://www.eu-robotics.net/eurobotics/about/projects/rockeu2.html

[499] https://www.iso.org/obp/ui/#iso:std:iso:8373:ed-2:v1:en

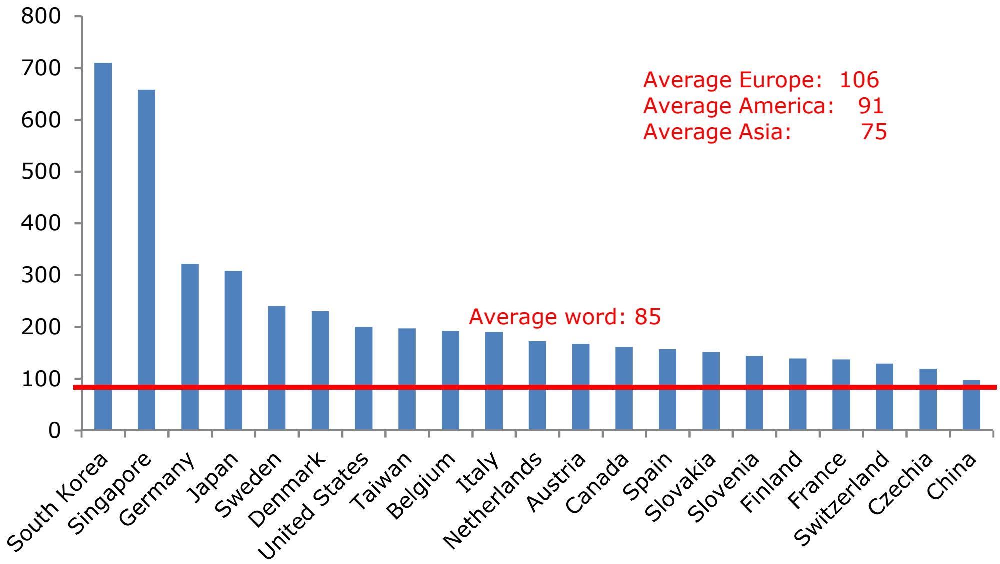
3.1. Industrial robots

High growth rates of robotics sales have occurred in 2017 according to the International Federation of Robotics.[500] Industrial robotics grew by 30% and about 381,000 units were sold in 2017 with an overall sales volume of USD 16.2 billion. When adding software, peripherals and systems engineering, the market value of these robotic systems increases to USD 48 billion. For 2018, statistics show a 6% increase to 422,271 units with a value of USD 16.5 billion.[501] The new forecast foresees a stagnating trend for the year 2019, but a yearly average increase of 12% for the period 2020 to 2022.[502]

The five major markets for industrial robots are China, Japan, South Korea, the United States and Germany. These countries accounted for 74% of global installations in the year 2018.[503]

For comparison among countries the robot density indictor is used, which shows the number of robots per 10,000 employees. For manufacturing as a whole, South Korea and Singapore showed the highest robot density in 2017, with 710 and 658 robots per 10,000 employees. In South Korea the robot density was fostered by growing robots in the electrical/electronics and automotive industries since 2010. In Singapore the density rate doubled between 2014 and 2017 due to the increase of robots in the electronics industry and low employee numbers. With a large gap, Germany and Japan follow with 322 and 308 robots. The US is ranked 7th, with 200 robots, China is placed 21st with 97 robots, still above the world average of 85. Besides EU-countries the non-EU countries Taiwan, Canada and Switzerland are among the list of countries with the highest robot density.[504]

Figure 135: Number of installed industrial robots per 10,000 employees in the manufacturing industry, 2017



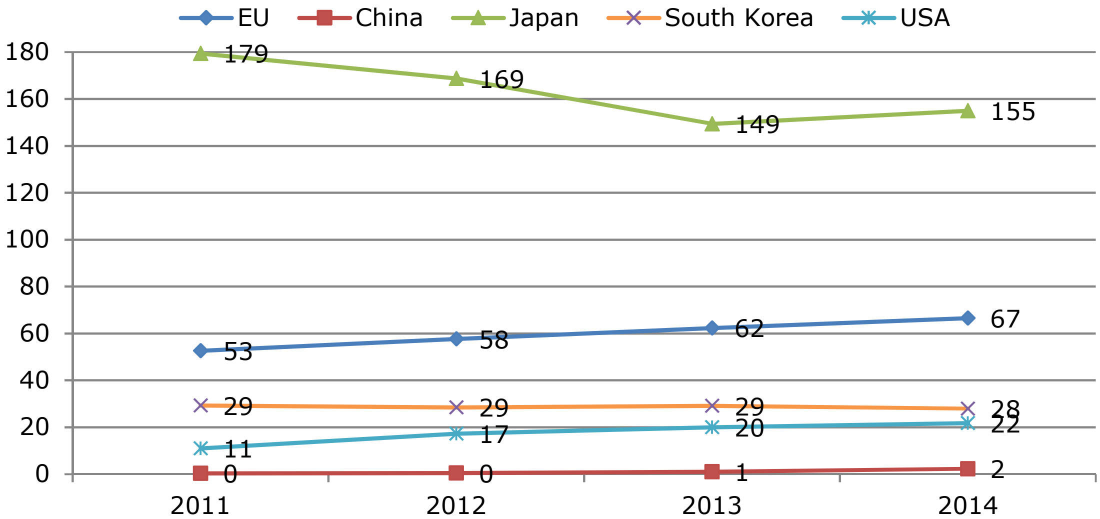
Source: IFR World Robotics 2018 – Industrial Robots, Table 2.6

The automotive industry was the largest customer of robots.[505] In 2017, about 36% of the operational stock was installed in the automotive industry, followed by the electrical/electronics industry with 24%. About 10% was installed in metal and machinery (3.3% in machinery), 8% in the chemicals & plastics industry and 3% in the food & beverage industry. Thus, as less robots go into the machinery sector also robot density is smaller in this sector. The Figure below reveals that among EU competitor countries, the largest robot

500 www.ifr.org
501 https://ifr.org/ifr-press-releases/news/robot-investment-reaches-record-16.5-billion-usd download 29th November 2019.
502 Ibid.
503 Ibid.
504 IFR (2018), World Robotics 2018 – Industrial Robots
505 Ibid.

density in the machinery sector is found in Japan with 155 robots per person engaged, compared to 67 robots in Europe, 28 in South Korea, 22 in the US, and 2 in China.

Figure 136: Robot intensity of the machinery sector, robots per 10,000 persons engaged



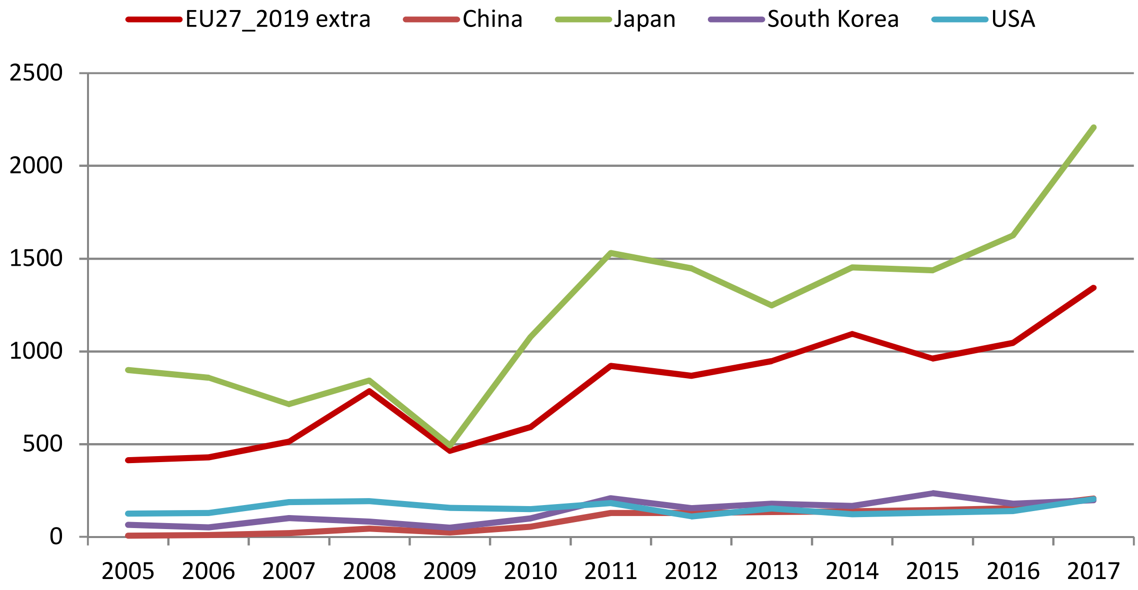
Notes: EU includes EU-25 (without UK, Cyprus and Luxembourg).
Source: International Federation of Robotics (IFR; for stock of robots) and WIOD (for persons engaged).

Regarding industrial robotics producers, the focus turns again to Asia and here to Japan, where many large robotics manufacturers are based. Overall, IFR states that about 55% of all industrial robots sold in 2017 were produced in Japan, 7% in South Korea and 6% in Germany (data available only for these three countries). The Japanese share came down from 71% in 2006, as production increased in Europe, America, Korea and China thereafter.[506]

In order to gain an overview on the importance of industrial robots, trade data for industrial robots for multiple uses (HS code 847950) serve as a proxy. World export market shares for this category were largest for Japan in 2017, accounting for 37% of world exports. Extra-EU exports held the second largest market share with 22.4%. China, the United States and South Korea only held a small share of 3.4% each. Figure 22 depicts the export trend over time for the EU and its main competitor countries.

[506] IFR (2018), World Robotics 2018 – Industrial Robots. Based on number of units.

Figure 137: Exports of industrial robots for multiple uses (HS 847950), USD million



Source: UN COMTRADE.

Because of data protection, information on main companies is more difficult to find. Newspaper or magazines tend to publish lists of main companies, which then however might not be complete. In the US Robotics Business Review RBR 2019 Top 50 Robotics company list[507], main companies in the field of industrial automation and robotics are (in alphabetic order) ABB (Switzerland), EPSON Robots (US), FANUC (Japan), KUKA (Germany), OMRON Automation (US), Stäubli (Switzerland) and Yaskawa (Japan). The German Automation magazine offers a world ranking of industrial robotics companies,[508] in which Fanuc (Japan) tops the list, followed by Yaskawa (Japan). Also large producers in Europe are Swiss ABB and German KUKA, which was acquired by Chinese Midea Group in 2016. On the fifth place is again a Japanese company, Kawasaki Robotics.[509] The full ranking can be seen in table below. While eleven Japanese companies are included, only one from the US is there.

Global industrial robotics companies, 2018 (ranked by robot install base worldwide)[510]:

- FANUC, Japan
- YASKAWA, Japan
- ABB, Switzerland
- KUKA, Germany/China
- Kawasaki Robotics, Japan
- NACHI, Japan
- DENSO, Japan
- OTC, Japan
- EPSON, Japan
- Panasonic, Japan
- IAI, Japan
- Hirata, Japan
- Wittmann, Austria
- OMRON, USA
- Stäubli, Switzerland
- Sepro Group, France
- Mitsubishi Electric, Japan

[507] https://www.roboticsbusinessreview.com/download/rbr50-2019-top-robotics-companies-and-the-winners-are/ download 6th June 2019.
[508] See https://www.automationnet.de/weltrangliste-roboterhersteller/; download 6th June 2019.
[509] See https://www.automationnet.de/weltrangliste-roboterhersteller/; download 6th June 2019.
[510] See https://www.automationnet.de/weltrangliste-roboterhersteller/; download 6th June 2019.

- Universal Robots, Denmark
- SIASUN, China
- CLOOS, Germany
- IGM Robotersysteme, Austria
- b+m surface systems, Germany
- RO-BER Industrieroboter, Germany
- roTeg Robotertechnologie, Germany

Main European industrial robot companies (in alphabetical order)[511]:

- ABB, Switzerland
- b+m surface systems, Germany
- CLOOS, Germany
- Codian Robotics, Netherlands
- COMAU, Italy
- Engel Austria, Austria
- F&P Robotics, Switzerland
- Güdel, Switzerland
- Hahn Robotics, Germany
- IGM Robotersysteme, Austria
- Kassow Robotics, Denmark
- KUKA, Germany/China
- MABI Robotics, Switzerland
- Pilz, Germany
- RO-BER Industrieroboter, Germany
- roTeg Robotertechnologie, Germany
- Sepro Group, France
- Stäubli, Switzerland
- Universal Robots, Denmark
- Voith Robotics / Franka Emika, Germany
- Wittmann, Austria

In China,[512] there are two types of producers present: on the one hand international robot companies, which have set up production plants in the country and on the other hand Chinese robot suppliers. In 2017, these Chinese firms had a market share of 25% of sales, foreign firms (production in China and imports) 75%. Main Chinese companies are: Foxconn Technology Group (Foxbot robots), Siasun Robot & Automation Co Ltd., Efort Intelligent Equipment Co Ltd., Shanghai STEP Robotics Corporation, Estun Automation Co Ltd.

In South Korea, main industrial robot producers are:[513] Hyundai Robotics, Robostar, DSTRobot and TES-Robot.

In the United States,[514] Japanese and European robot companies have set up production plants including Fanuc, Kawasaki, Yaskawa-Motoman from Japan, Kuka from Germany, ABB and Stäubli from Switzerland. The number of US robot companies is small and include Adept Technology, Inc. (Pleasanton, CA, taken over in 2015 by the Japanese Omron), Genmark Automation, Inc. (Milpitas, CA), Rethink Robotics, Incl. (Boson, MA) and SAGE Automation, Inc. (Beaumont, TX). However, there are many important robot system integrators.[515]

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511 See https://www.automationnet.de/weltrangliste-roboterhersteller/; download 6th June 2019; verified and extended by IFR through e-mail inquiry.

512 See IFR (2018), World Robotics 2018 – Industrial Robots.
See Xinyu, Tan, 'Top 5 industrial robot producers in China', in: China Daily (2017), 23 August, http://www.chinadaily.com.cn/business/2017top10/2017-08/23/content_30985971_3.htm.

513 Youngho, Lee 'South Korea's Robot Industries Continue to Show Steady Growth', in: ETNews-Korea IT News (2017), 18 December, http://english.etnews.com/20171218200003

514 See IFR (2018), World Robotics 2018 – Industrial Robots.
See Stanton-Geddes, M. and Fravel, D. (2014), U.S. Manufacturing Companies are Global Leaders in Industrial Robot Consumption, USITC Executive Briefings on Trade, May. See https://www.usitc.gov/publications/332/ebotindustrialrobots5-14-14.pdf

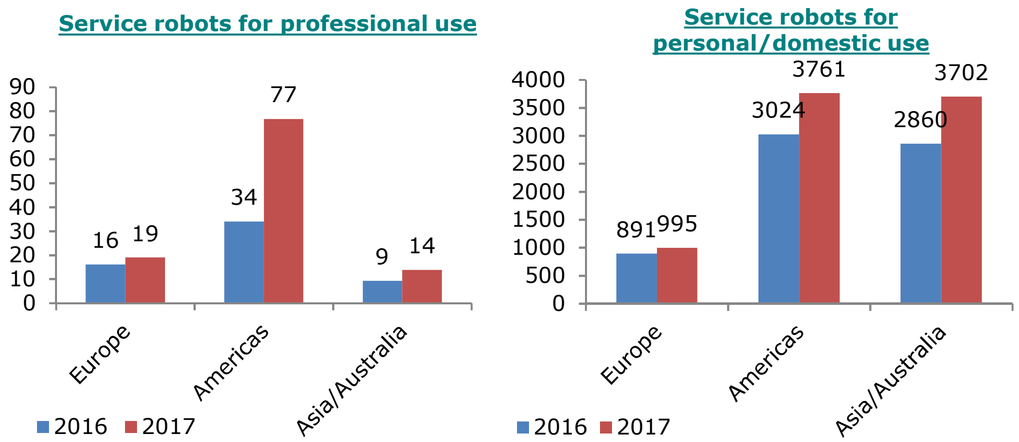
515 See for example https://www.robotics.org/Meet-The-Certified-Integrators

3.2. Service robots

Even higher growth rates of robot sales took place when looking at a second category of robots – *service robots*. According to the International Federation of Robotics[516] in 2017, about 109,500 professional service robots were sold in 2017, 85% more than in 2016, with a sales volume of USD 6.6 billion. New data for 2018 show an increase to 271,000 units with a value of USD 9.2 billion and a growth forecast of yearly 41% between 2020 and 2022.[517] Looking at private/personal service robots, also service robots for domestic/household task increased by 31% and reached 6.1 million units in 2017. Service robots for entertainment grew somewhat less with 12% and numbered 2.4 million units. Private Service robots had a sales volume of USD 2.1 billion. Together, professional and private/personal service robots sales account for about half of industrial robot sales. The forecast for service robots for domestics/household tasks foresees an increase of 40% per annum between 2020 and 2022, that of robots for entertainment at yearly 10%.[518]

Looking at the sales by region of origin (i.e. place of production, see Figure 23), about 17% of all service robots for professional use came from Europe, 13% from Asia, while 70% came from America. For service robots for personal/domestic use, Europe accounted for only for 12%, while the majority came from America and Asia with about 44% each. Service robots show a large variety of applications. In the professional field, robots have already a large impact in agriculture, surgery, logistics and underwater applications. In the domestic field, there are a few mass-market products with strong global growth, i.e. floor cleaning robots, robo-lawn movers and robots for entertainment.[519] In terms of applications, Europe has a large share in field robots (88%), medical robots (63%) and entertainment robots (38%). In the main application area, logistics, Europe has only a share of 5%.

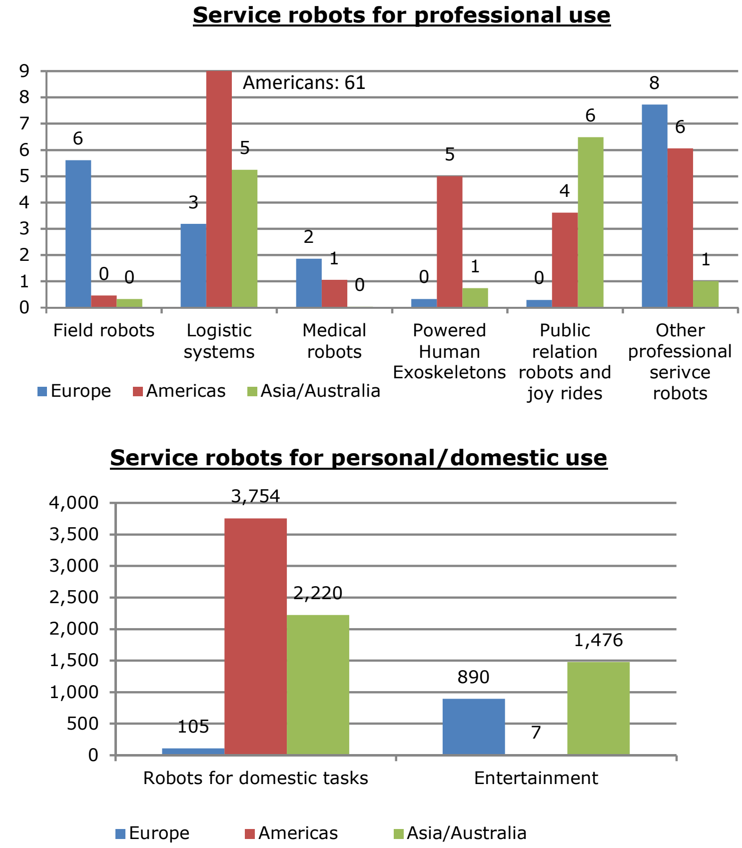
Figure 138: Service robot sales by region of origin, in 1000 of units, 2016 and 2017



Source: IFR World Robotics 2018 – Service Robots, Table 2.5 and Table 2.6.

[516] IFR (2018), World Robotics 2018 – Service Robots
[517] https://ifr.org/ifr-press-releases/news/service-robots-global-sales-value-reaches-12.9-billion-usd; download 29 November 2019.
[518] https://ifr.org/ifr-press-releases/news/service-robots-global-sales-value-reaches-12.9-billion-usd; download 29 November 2019.
[519] IFR World Robotics 2018 – Service Robots, p. 3.

Figure 139: Service robot sales by region of origin, by main application areas, in 1000 of units, 2017



Source: IFR World Robotics 2018 – Service Robots, Table 2.5 and Table 2.6.

The IFR counts 700 registered companies manufacturing service robots. Of these, 43% (300 manufacturers) are based in Europe, 35% (250 manufacturers) in North America and 18% (or 130 manufactures) in Asia. It characterises this segment of robotics as very dynamic and progressive, showing a high share of young start-up companies being less than five years old. They even account for 30% of service robot manufacturers.[520] The IFR has altogether 719 worldwide companies in this database and publishes all company names in this domain in its Service Robots Report. Dynamic trends in the market make changes probable. The IFR states that "the overview and numbers of suppliers from North America and Europe should be reliable, while some uncertainties are expected with companies located in Russia, China and India".[521] The IFR states all company names by employment size class, start-up (yes), country, region and application area/robot type.

Looking at one particular field of interest, that is exoskeletons, human powered exoskeletons are to be found in the group of service robots for professional use (see Figure 24), of which 82% of units sold came from America. Overall, sales grew from 5,581 units in 2016, to 6,700 units in 2107 and further to 7,300 in 2018. For the next years, these products do have a large potential for growth.[522] Human powered exoskeletons are defined as an "active mechanical device that is essentially anthropomorphic in nature, is worn by an operator and fits closely to his or her bods, and works in concert with the operator's movements"[523], hence in short can be also termed 'wearable robotics/robots'. Their main aim is to assist and protect the wearer. In the medical field, exoskeletons can give mobility assistance for aged people

520 Source: IFR World Robotics 2018 – Service Robots, page 273.
521 Source: IFR World Robotics 2018 – Service Robots, page 272.
522 Source: IFR World Robotics 2018 – Service Robots, page 13.
523 Source: IFR World Robotics 2018 – Service Robots, page 186.

or people who need rehabilitation, or they can help augment forces e.g. for soldiers, construction or industry workers.

Different types of exoskeletons do exist, e.g., related to body parts, differentiating between full body exoskeletons, lower limb exoskeletons or upper limb exoskeletons.[524] Main application areas are in the medical field, in defence, industry and commercial/consumer exoskeletons.[525]

- The primary market for exoskeletons at the moment is in the medical field for rehabilitation. E.g. Lokomat ® from Hocoma (Switzerland) is a robotic exoskeleton worn by the patient during treadmill walking.[526]
- Industrial exoskeletons are at a nascent stage; however, market potentials are huge. Exoskeletons support manual labour tasks and aim to decrease injuries. They are at the moment particularly adopted in the automotive industry, logistics, retail and construction area.[527] E.g. the Robo-Mate exoskeleton, previously a research project, co-funded by EU, is a modular exoskeleton for industry designed for lifting activities and static postures.[528]
- In the military field, exoskeletons help to carry weight and to protect vulnerable areas. Examples of full body powered exoskeletons for the military are HULC by Lockheed Martin and Ekso Bionics; XSO and XSO2 by Sarcos/Raytheo.[529]
- Other fields of commercial/consumer use, e.g for skiing (e.g. Ski~Mojo by SkiMojo; Againer by Againer-Ski) or hiking.[530]

The box below provides a list of main producers in the field of exoskeletons (as there is a large overlap also companies in the area of rehabilitation systems are listed).

Box 17: Main producers of exoskeletons

Human powered exoskeletons

Asia: CYBERDYNE (Japan), HONDA (Japan) , INNOPHYS (Japan), Panasonic Electric Works (Japan), Skeletonics (Japan), Daewoo Shipbuilding & Marine Equipment DSME (South Korea), Hexar Systems (South Korea), Bama Teknoloji (Turkey)

Europe: Gobio Robot (France), RB3D (France), German Bionic Systems (Germany), IUVO (Italy), KineteK Division (Italy), Laevo (Netherlands), AXO Suits (Romania), TWIICE (Switzerland), MyoSwiss (Switzerland), Rex Bionic (UK)

North America: Bionic Power (Canada), Bionik Laboratories (Canada), b-teamia (Canada), Dexta Robotics (US), Ekso Bionics (US), Pathway (US), ReWalk Robotics (US), Roam Robotics (US), Sarcos (US), StrongArm Technologies (US), SuitX (US), Mobius Bionics (US)

Russia: Android Technics

Rehabilitations Systems

Asia: Rehab-Robotics (Hongkong), Panasonic Electric Works (Japan), TOKI Corporation (Japan), Hexar Systems (South Korea), Walkbot (South Korea), Bama Teknoloji (Turkey)

Europe: TyroMotion (Austria), Techno Concept (France), KUKA (Germany), Reactive Robotics (Germany), Reha-Stim (Germany), IUVO (Italy), KineteK Division (Italy), Movendo Technology (Italy), Gogoa (Spain), marsi-bionics (Spain), Dynamic Devices (Switzerland), Reha Technology (Switzerland), RSLSteeper (UK), Touch Bionics (UK)

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524 See also https://exoskeletonreport.com/2015/08/types-and-classifications-of-exoskeletons/
525 A good overview can be found at the Wearable Robotics Association: http://www.wearablerobotics.com/wearable-robots/
526 Source: IFR World Robotics 2018 – Service Robots, page 143.
527 Kara, D. (2018), Industrial exoskeletons: new systems, improved technologies, increasing adoption, at: https://www.therobotreport.com/industrial-exoskeletons/
528 http://www.robo-mate.eu/
529 https://exoskeletonreport.com/2016/07/military-exoskeletons/
530 https://exoskeletonreport.com/2016/08/commercial-exoskeletons/

North America: Bionik Laboratories (Canada), GaitTronics (Canada), Kinova (Canada), AlterG (prev Tibion Bionic, US), Bionik (US), Freedom Innovations (US), Encompass Health (US), Indego (Parker Hannifin, US), Motorika (US), Myomo (US), Pathway (US)

Russia: Android Technics, ExoAtlet

Source: IFR World Robotics 2018 – Service Robots.

4. ACCIDENTS AT WORK

While accidents with robots take place occasionally and are then covered extensively in the media, they are considered as rare. When a worker was killed in a Volkswagen plant in Germany in 2015, experts stated that 'the incident should be understood as an extremely rare industrial accident.'[531]

Accidents at work with robots are not directly tracked at the EU level. In the US, the US Department of Labour, Occupational Safety & Health Administration, registered 20 accidents with robots, of which 14 were fatal in a time period between Dec 2001 and Oct 2019.[532] For Germany, the German Social Accident Insurance (DGUV, 2015) noted a downward trend for accidents with robots between 2005 and 2012. It registered 377 cases for occupational accidents in 2005 (defined as loss of working hours for more than three days) and 291 cases in 2012. Serious occupational accidents (defined as payment of accident benefits e.g. in case of loss of limbs or fatal occupational accidents) numbered 11 in 2005 and 6 in 2012.[533] It states that industrial robots involve hazards that are atypical to those of other machines due to the complexity of the production process (high number of robots and machines linked to each other, complex sequences of motion, unforeseeable changes of position and speed, waiting positions and unexpected start-up, secondary hazards related to the process, e.g. laser).

Eurostat data on European Statistics on Accidents at Work provide a source to construct a proxy of accident with robots in the EU. An accident at work is defined as 'a discrete occurrence in the course of work which leads to physical or mental harm'.[534] The data include only fatal and non-fatal accidents involving more than 3 calendar days of absence from work. If the accident does not lead to the death of the victim, it is called a 'non-fatal' (or 'serious') accident. A fatal accident at work is defined as an accident which leads to the death of a victim within one year of the accident.

The main characteristics of the accident and of the employer, so called 'Phase I' and 'Phase II' variables of ESAW, are based on compulsory data provided by individual companies and reported by countries with a more or less coherent method. However, partial data limitations are present. Some country data is missing before 2011, while the EU aggregates availability differs by composition and years. In some cases, standardised incidence rates are computed, while in others only absolute numbers are provided (as in the case of ISCO classification).

In order to provide an overview of accidents at work related to robots specifically, Figure 35 depicts accidents of machine operators and assemblers of employees (ISCO main group 8). In 2017, the overall number of non-fatal accidents stood at 357,000 cases for Europe as a whole, and at 750 for fatal accidents. Between 2011 and 2016, the number of accidents declined first, reached the lowest number in 2013 and then slightly moved up again. Non-fatal accidents declined by 21% during that time period, that of fatal accidents by 23%. For both indicators, 2013 was the year with the lowest number of accidents.

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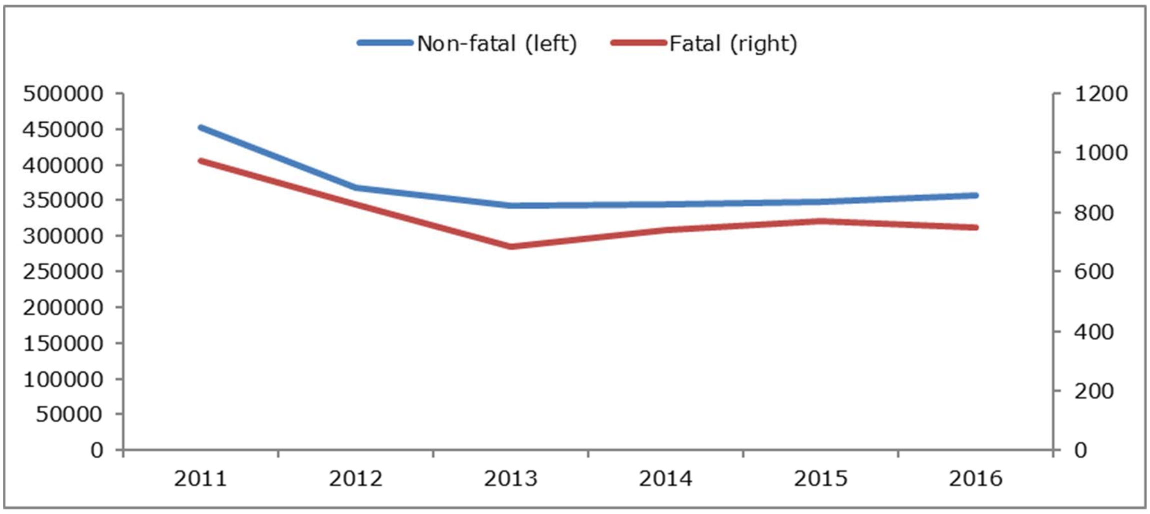
[531] Financial Times. 2015. "Robot-related deaths are rare and becoming rarer", 2 July. Available at: http://www.ft.com/intl/cms/s/0/c9851cde-20b3-11e5-aa5a-398b2169cf79.html?siteedition=intl#axzz43WtQCyPl.

[532] See https://www.osha.gov/pls/imis/AccidentSearch.search?acc_keyword=%22Robot%22&keyword_list=on

[533] Data for years in between fluctuate: 2006 (138/4), 2007 (278/3), 2008 (218/10), 2009 (312/15), 2010 (352/5), 2011 (244/5), 2012 (291/6). See DGUV (2015), p.13.

[534] https://ec.europa.eu/eurostat/cache/metadata/en/hsw_acc_work_esms.htm

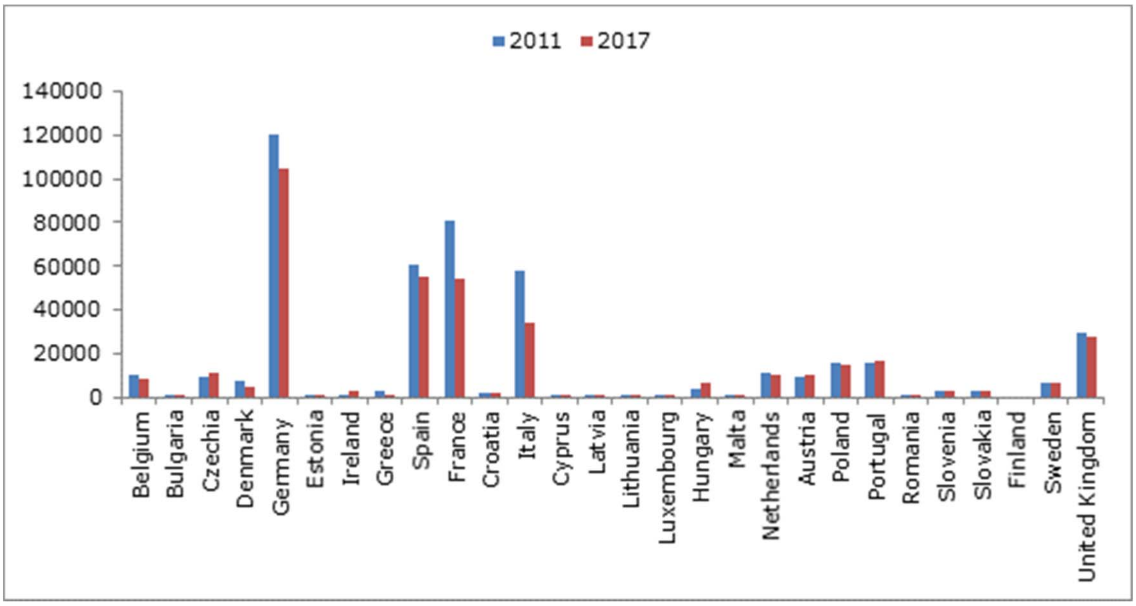
Figure 140: Fatal (right) and non-fatal (left) accidents at work of plant and machine operators and assemblers (ISCO main group 8), EU-28, employees, 2011-2016 (number)



Source: Eurostat ESAW [hsw_mi05]

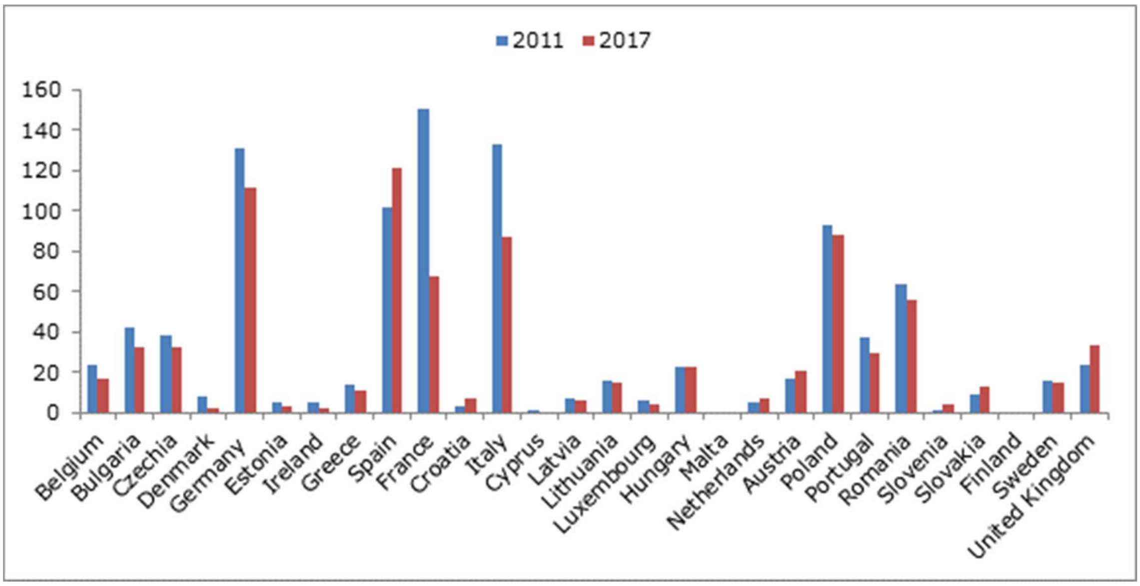
The figures below present an overview of accidents by Member State. In line with population, the largest number of non-fatal accidents (Figure 141) occurred in the largest countries, Germany, Spain, France, Italy and the United Kingdom; fatal accidents (Figure 142) also in Poland and Romania. Comparing the numbers between 2011and 2017, in 13 countries the number of non-fatal accidents was higher in 2017 than in 2011, but only in seven countries for fatal accidents. In Croatia, Austria and Slovakia the number was higher in 2017 for both non-fatal and fatal accidents.

Figure 141: Non-fatal accidents at work of plant and machine operators and assemblers (ISCO main group 8), EU-28, employees, 2011-2016 (number)



Source: Eurostat ESAW [hsw_mi05]

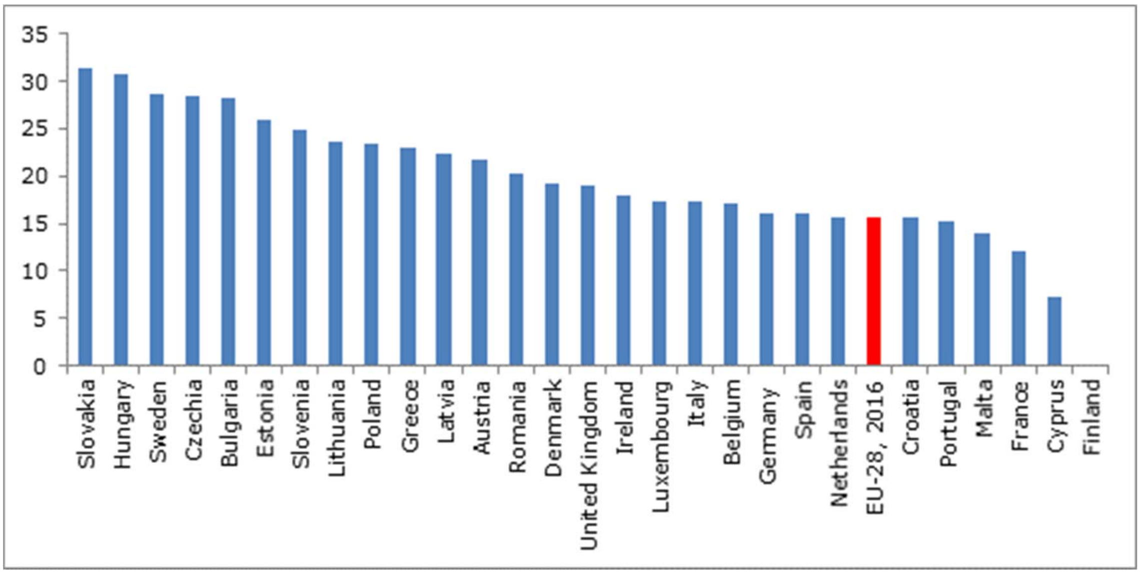
Figure 142: Fatal accidents at work of plant and machine operators and assemblers (ISCO main group 8), EU-28, employees, 2011-2017 (number)



Source: Eurostat ESAW [hsw_mi05]

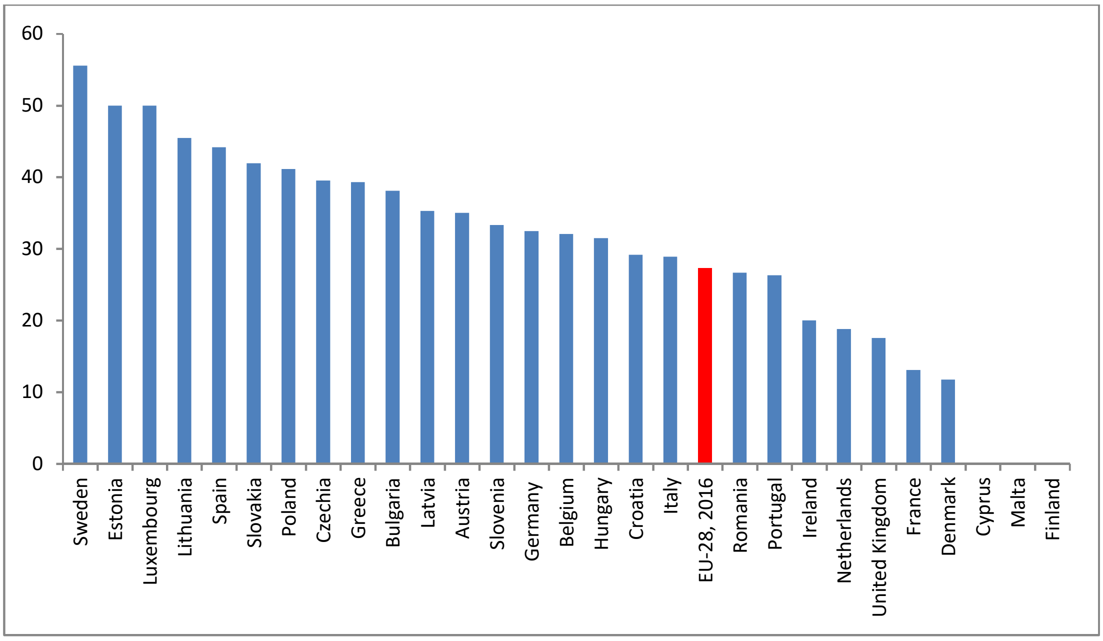
The figures below show the share of accidents of plant and machine operators and assemblers in all occupations. For non-fatal accidents, in 2017, this share ranged between above 30% in Slovakia and Hungary at the top to 7% in Cyprus at the bottom. For fatal accidents, in Sweden 56% of fatal accidents concern plant and machine operators and assemblers, 50% in Estonia and Luxembourg to 13% in France and Denmark.

Figure 143: Non-fatal accidents at work of plant and machine operators and assemblers (ISCO main group 8), EU-28, share in total occupations, employees, 2017 (number)



Source: Eurostat ESAW [hsw_mi05]

Figure 144: Fatal accidents at work of plant and machine operators and assemblers (ISCO main group 8), EU-28, share in total occupations, employees, 2017 (number)



Source: Eurostat ESAW [hsw_mi05]

The variables on the causes and circumstances of accidents (so-called 'Phase III' variables) are then combined to better approximate the domain of accidents at work related to robots. The main advantage of these variables is their specificity, since they provide information on the exact location and mode of impact. Nonetheless, severe data limitations should be kept in mind. Data are only available for the 2014-2017 period and suffer from partial and non-homogenous reporting. The reason is that reporting is not compulsory for companies; as such, availability and reliability varies strongly between countries. For instance, looking at Germany - the country with the highest robot density in the EU - data for fatal accidents are only available for 4 variables out of 8. In 2017, 41 fatal accidents happened in industrial sites ('working environment'); 33 fatal accidents were caused by a loss of control ('deviation'); 10 accidents can be associated with machines and equipment-fixed ('material agent of deviation'); in 23 accidents people were trapped or crashed ('contact mode of injury').

Nevertheless, some variables provide particularly interesting information. In particular, the 'material agent of the deviation' is defined as 'the tool, object, or instrument being used by the victim when the accident happened, just before the accident' and 'may or may not be implicated in the accident'[535]. Out of the 20 categories of material agents listed in the dataset, four have been selected as proxies for robots falling under scope of the MD:

- Hand-held or hand-guided tools, mechanical;
- Hand tools - without specification of power source;
- Machines and equipment - portable or mobile;
- Machines and equipment – fixed.

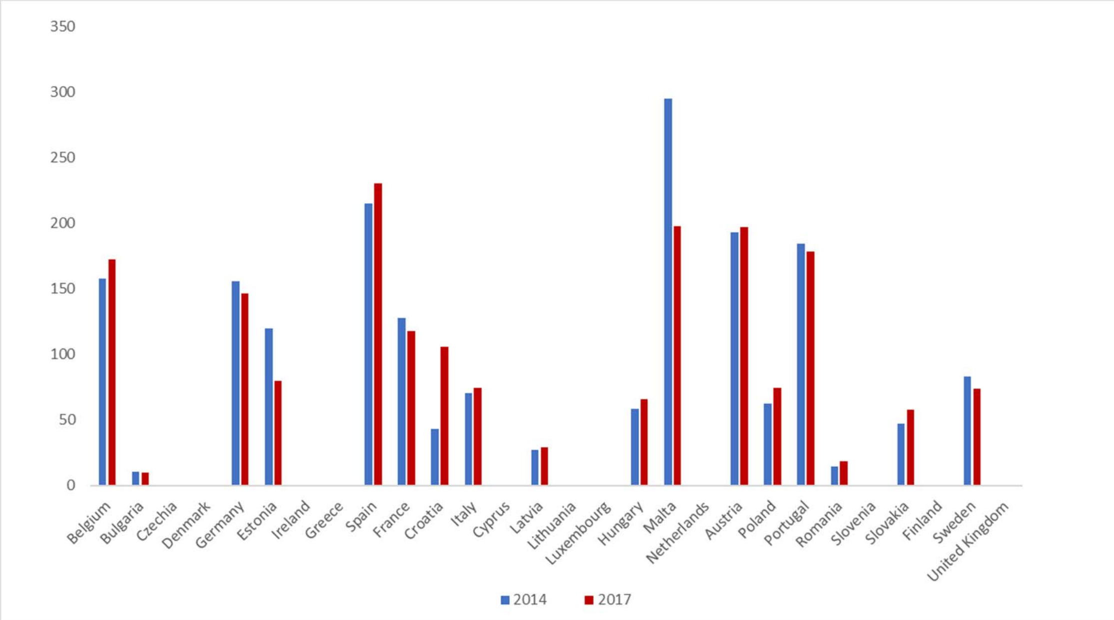
The figures below report the incidence rates of accidents at work[536] by country combining the selected categories of material agents. The figures are highly likely to underestimate the actual number and incidence rate of cases. In fact, in addition to the general lack of reporting, potentially important details such as the material agent of the deviation are often not reported. Therefore, the figures should only be seen as indicative proxies.

For non-fatal accidents (Figure 145), there is no clear time trend between 2014 and 2017. Malta depicts the highest rate, although declining from 2014 to 2017. For fatal accidents

535 https://ec.europa.eu/eurostat/cache/metadata/en/hsw_acc_work_esms.htm
536 Number of accidents per 100,000 employees.

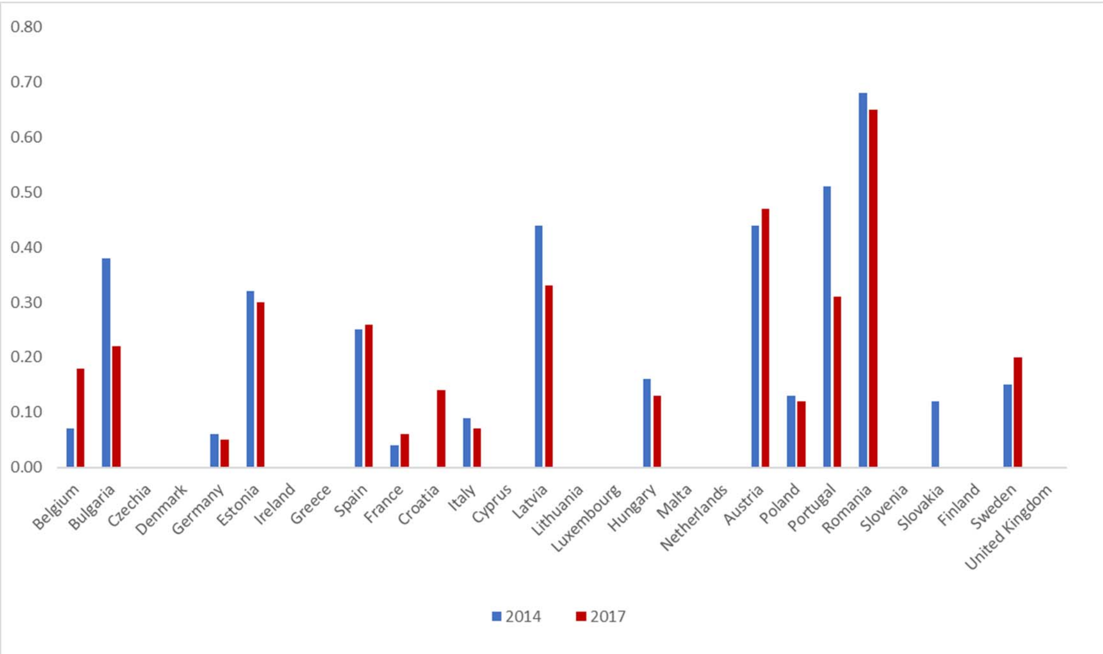
(Figure 146), Romania shows the highest value. A majority of countries reports a lower incidence rate in 2017 as compared to 2014.

Figure 145: Non-fatal accidents by country, EU-28, 2014 and 2017 (accidents per 100,000 employees)



Source: Eurostat ESAW [hsw_ph3_07]

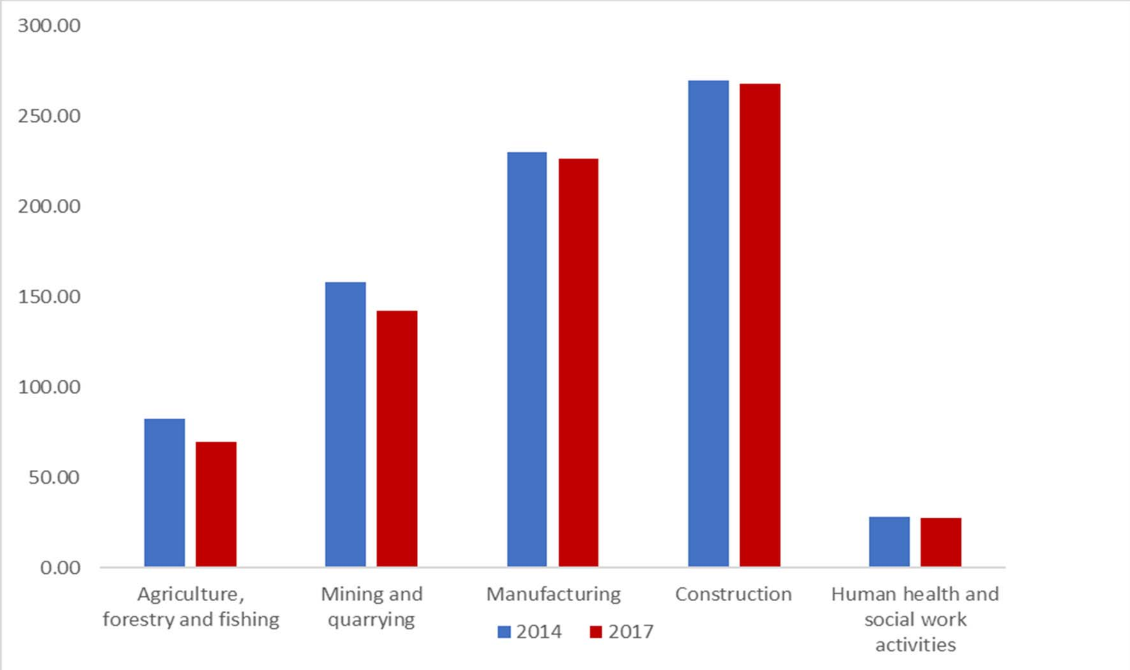
Figure 146: Fatal accidents by country, EU-28, 2014 and 2017 (accidents per 100,000 employees)



Source: Eurostat ESAW [hsw_ph3_07]

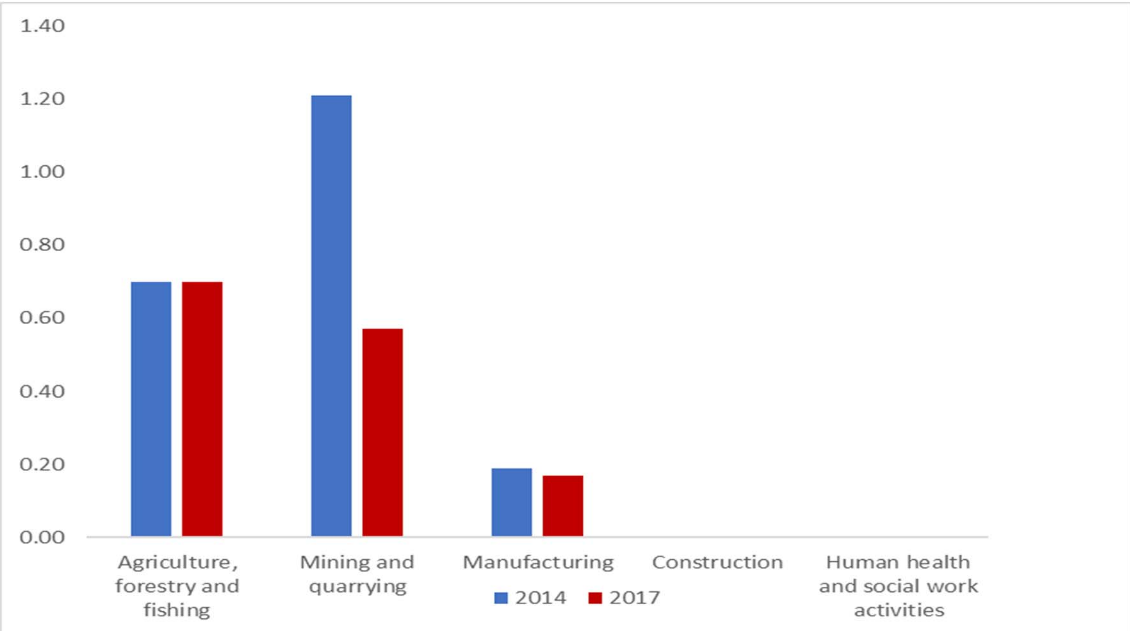
Figure 147 and Figure 148 break down results by relevant sector. For non-fatal accidents (Figure 147), construction reports the highest rates, followed by manufacturing, while human health and social work activities reports the lowest. For fatal accidents (Figure 148), mining and quarrying reports the highest values, followed by agriculture, forestry and fishing,. For both fatal and non-fatal accidents, there seems to be a clear downwards trend, with most sectors going down and no sectors reporting a higher value in 2017 as compared to 2014.

Figure 147: Non-fatal accidents by sector in the EU-28, 2014 and 2017 (accidents per 100,000 employees)



Source: Eurostat ESAW [hsw_ph3_07]

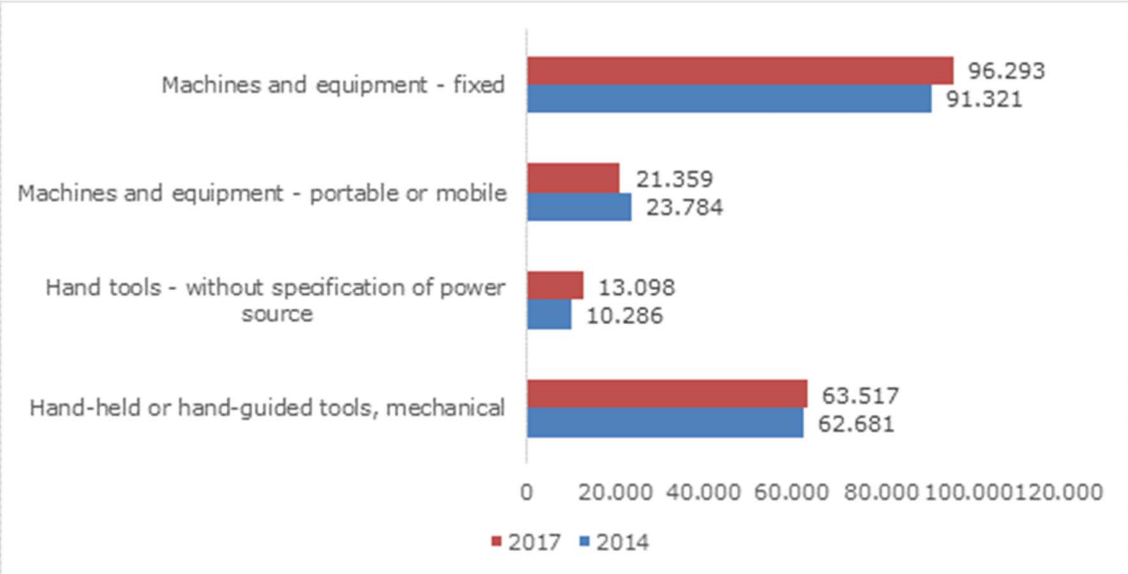
Figure 148: Fatal accidents by sector in the EU-28, 2014 and 2017 (accidents per 100,000 employees)



Source: Eurostat ESAW [hsw_ph3_07]

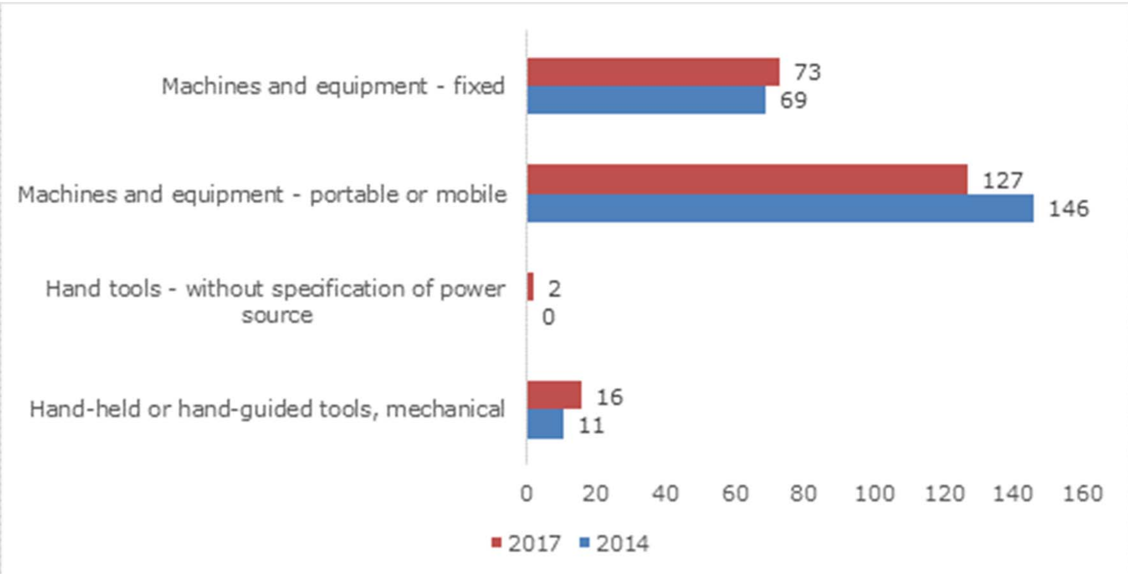
Figure 149 and Figure 150 break down accidents by type of material agent. Fixed machines and equipment and mechanical hand-held tools are associated with the highest number of non-fatal accidents, around 90,000 and 60,000 respectively in both years, with mobile machines and equipment and hand tools reporting much lower values, around 20,000 and 10,000 respectively in both years. For fatal accidents, mobile machines and equipment are associated with the largest value, decreasing from about 150 in 2014 to just above 120 in 2017, while mechanical hand-held tools and hand tools report few cases or none at all. There is no clear overall time trend from 2014 to 2017 for both non-fatal and fatal accidents.

Figure 149: Non-fatal accidents by material agent of deviation in the EU-28, 2014 and 2017 (number)



Source: Eurostat ESAW [hsw_ph3_07]

Figure 150: Fatal accidents by material agent of deviation in the EU-28, 2014 and 2017 (number)

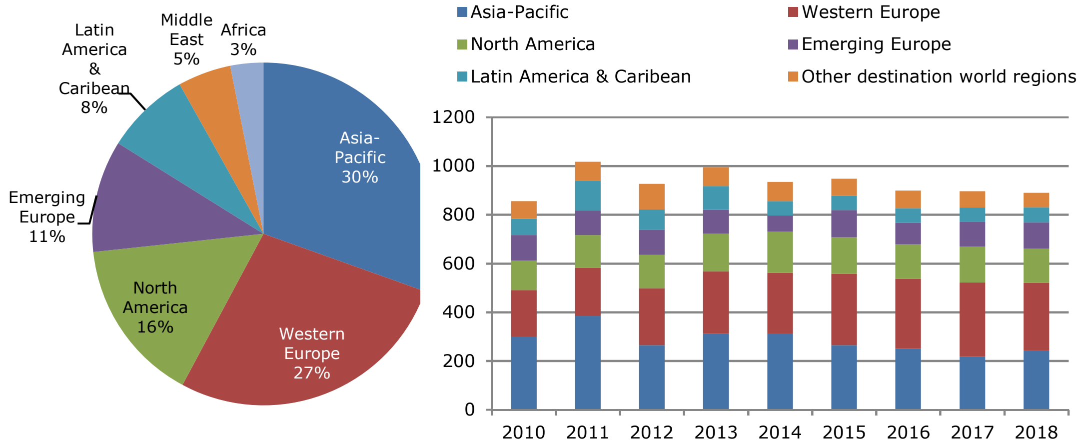


Source: Eurostat ESAW [hsw_ph3_07]

5. FDI TREND ANALYSIS

In order to look at recent trends in foreign direct investment in robotics and its extent, information from the fDi Markets database, a database provided by fDi Intelligence, a division of Financial Times Ltd, are structured and analysed. The fid Markets database is based on media reports referring to individual investment projects. The database also includes (often estimated) data on the value of investment commitment and the number of jobs to be created.

Figure 151: FDI projects by destination region for industrial equipment, 2010-2018, total period and yearly, shares in total number of projects



Period 2010-2018 For individual years

Notes: Western Europe includes: Andorra, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Greenland, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Counties included by fDi Intelligence in the category 'Emerging Europe' include: Albania, Belarus, Bosnia-Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Moldova, Montenegro, North Macedonia, Poland, Romania, Russia, Serbia, Slovakia, Slovenia, Turkey and Ukraine.; Source: fDiMarkets.com

As robot companies are not listed in an own sector, as a first step, a preliminary analysis is presented for the sector "industrial equipment" (not covering engines), in which robot companies are located. Between January 2010 and December 2018, about 8,400 FDI projects were registered in this sector, presenting 4.7% of global FDI projects. The number of jobs created amounted to 180,000, total investment was pledged at EUR 40 million for the total period. FDI projects peaked in the year 2011. As of designation regions, over the whole period, 30% of all FDI projects by number of projects went to the Asian-Pacific region, 27% to Western Europe and 16% to North America (see Figure 25, left panel). Figure 25 on the right side shows the destination regions over time. Looking at individual countries, out of the 129 destination countries, the top five countries accounted for almost half of all projects. The United States is the top destination country, with more than one eight of all projects registered there. On places 2-5 were Germany, China, India, and the United Kingdom. Places 6 to 10 were France, Brazil, Mexico, Russia and United Arab Emirates.

In a next step, the analysis encompassed companies which include "Robot" in their name, plus main industrial robot producers identified before when covered by fDiMarkets database. However, large groups producing a range of products from automotive to electric components were excluded. As such, the final selection included 72 companies, which during the period January 2010 to December 2018 accounted 197 FDI projects. During this time period only a small number of projects were announced between 2010 and 2015, while more than half of all projects were announced between 2016 and 2018. Looking at destination regions over the whole period Western Europe accounted for 35% of all projects (by number), Asia-Pacific and North America for 26% each, Emerging Europe for 7%, Latina America & Caribbean for 6%, and the Middle East for about 1%. The top five destination countries were the US, Germany, China, the United Kingdom and France, with 57%. The top 10 companies were responsible for 81 projects and included: Yaskawa Electric (Japan), Engel (Austria), Fanuc America (Japan), Fanuc (Japan), Universal Robots (Denmark), Mobile Industrial Robots (Denmark), Grey Orange Robotics (India), Sepro Robotique (France), Pilz (Germany) and Kuka (Germany).

6. SUMMARY

The machinery and equipment sector (NACE rev. 2, division C28) is one of the major sectors of manufacturing within the European Union together with motor vehicles, the food industry and basic metals & fabricated metal products In 2017, it recorded a turnover of EUR 663 billion and employed 2.8 million persons. As such, it accounted for 9.4% of manufacturing turnover and 9.9% of all manufacturing employment. Specialisation on the sector is particularly high in Denmark, Germany, Italy, Finland, Sweden and Austria (by turnover). In terms of sub-industries engines & turbines, other general-purpose machinery n.e.c., lifting & handling equipment as well as other special-purpose machinery n.e.c. play a major role. The machinery sector was heavily affected by the financial and economic crisis in 2009. Although it recovered afterwards, the sector could not reach pre-crisis employment levels or production growth rates again. Better growth performance only occurred recently, with 6.2% in 2017 and 3.2% in 2018. With 82,350 enterprises, the machinery sector accounts for 4.1% of all manufacturing enterprises. Although micro-enterprises dominate (64% of all enterprises), large enterprise are responsible for half of employment and 60% of turnover. Classified as a medium-high technology sector, business enterprise R&D expenditure in the machinery sector grew only slightly over the last years. Over the last decade, China has emerged as a main competitor. China’s world export market shares nearly tripled between 2005 and 2017, overtaking the US in 2015. The EU slightly lost in market shares (-0.8pp) but still accounts for 22% of world exports. The EU exhibits a revealed comparative advantage in trade of machines specialised for particular industries. Digitalisation of the EU machinery sector has proceeded faster than that of manufacturing. Robotics is a dynamic and innovative part of the machinery sector, showing a wide variety of new application areas. Main companies producing industrial robots are situated in Japan and Europe. In the field of service robots, the Americans dominate sales of robots for professional use, the Americans and Asians sales of robots for personal/domestic use.

As regards special sub-industries of interest, the following can be summarised:

- Lifting & handling equipment (C28.22) is an important sub-industry, accounting for 9% of the machinery sector’s turnover and 9.4% of enterprises. Eleven countries are specialised on this industry.
- Other pumps and compressors (28.13) is a medium-sized industry, with 5.4% of the machinery sector’s turnover and 2.5% of enterprises. Three countries are specialised on this industry that are Belgium, France and Slovakia.

Office machinery & equipment (C28.23) is a tiny industry, holding only 0.5% of the machinery sector’s turnover and 1% of enterprises. No country is specialised on this industry.

ANNEX IV: REFERENCES AND DATABASES

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https://interestingengineering.com/ais-continue-to-act-in-unpredictable-ways-should-we-panic

ANNEX V: WHO IS AFFECTED AND HOW?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

Given that the policy options are not mutually exclusive, the changes are summarised in general.

First, substantive changes to the Essential Health and Safety Requirements (EHSR) will lead to additional direct compliance costs borne by manufacturers in terms of adaptation to the changes, training and familiarity with the new approach. Standardisation bodies will also be affected by the necessity to review the transferability of the revised EHSR to the list of harmonised standards in the OJEU. This is likely to slow down the recurrent procedure of revising the existing standards on the status and will require a high amount of resources. Other stakeholder groups, including notified bodies and market surveillance authorities are also likely to be affected by a need to familiarise with the new legal requirements. National authorities are expected to require resources to prepare for legal adoption.

Second, the impacts generated by a change of EHSR can be mitigated by keeping the numbering of the new or adapted EHSR close to the existing list or by providing a reference table between the current EHSR and the new ones. If new EHSR are provided, the costs can be mitigated by adding a new chapter.

Third, an alignment to the NLF and a conversion of the Directive to a regulation has the opportunity of harmonising the market surveillance process and decrease costs of compliance borne by manufacturers through a reduction of differences in interpretation across Member States.

Fourth, providing clarifications on definitions and criteria provides the opportunity of improving compliance and increasing the safety of machinery for users.

2. SUMMARY OF COSTS AND BENEFITS

This table summarises the potential costs and benefits of all the potential changes applicable and preferred, details are provided in Chapter 6 and 7 of this report. The majority of the costs are expected to be one-off as the compliance costs currently at place will continue to apply.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Administrative cost reductions	EUR 100 to 2 billion	These benefits for all economic operators in the machinery sector might be captured through a conversion of a Directive to a Regulation, decreasing additional administrative costs to resolve unclarities, the larger benefits are expected to stem from a decrease in printing costs through allowing digital documentation.
Compliance cost reductions	EUR 5,000 to 10,000 per instance	These cost reductions for economic operators could be achieved through clarifications in

		scope and definitions resulting from lowering the costs related to resolving unclarities.
Increased legal certainty	Not quantifiable	A change of the EHSR in terms of new technologies can lead to improved legal certainty and maintain a level playing field, particularly for manufacturers.
Indirect benefits		
Safety of products on the market	26% reduction of non-compliant products The removal of the internal checks option for conformity assessments of Annex IV machinery is expected to increase the effectiveness of the Directive to ensure the protection of health and safety of users.	Machinery users would indirectly benefit from a clarification of the scope and definitions through a reduction of non-compliant products on the market. This benefit might especially be captured if the online market is controlled and the Directive is aligned to the NLF.

(1) Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section;(3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in compliance costs, administrative costs, regulatory charges, enforcement costs, etc.; see section 6 of the attached guidance).

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Policy option 1	Direct costs			EUR 202 to 607 thousand	Up to EUR 76 thousand for manufacturers of independent software that ensures a safety function	Adaptation costs to changes likely	
	Indirect costs						
	Direct costs			0 to 1 million depending	0 to 68 thousand depending	Adaptation costs to	

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Policy option 2				on changes	on changes	changes likely	
	Indirect costs						
Policy option 3	Direct costs			Up to EUR 425 thousand (depending on changes)	Up to EUR 2 thousand (depending on changes)	Adaptation costs to changes likely	
	Indirect costs						
Policy option 4	Direct costs			Some adaptation costs likely but expected to be marginal		Some adaptation costs likely but expected to be marginal	
	Indirect costs						

(1) Estimates to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the preferred option otherwise for all retained options when no preferred option is specified; (3) If relevant and available, please present information on costs according to the standard typology of costs (compliance costs, regulatory charges, hassle costs, administrative costs, enforcement costs, indirect costs; see section 6 of the attached guidance).

ANNEX VI: SYNOPSIS REPORT

1. INTRODUCTION

In the context of the impact assessment study on the revision of the Machinery Directive (2006/42/EC), various consultation activities were conducted between March and December 2019. The aim was to assess the potential areas of revision and the impacts of the suggested policy options on different stakeholder groups

The consultation activities included semi-structured interviews, an open public consultation and a targeted online survey. This report summarises the main results of these activities, more detailed information is provided in the Final Report.

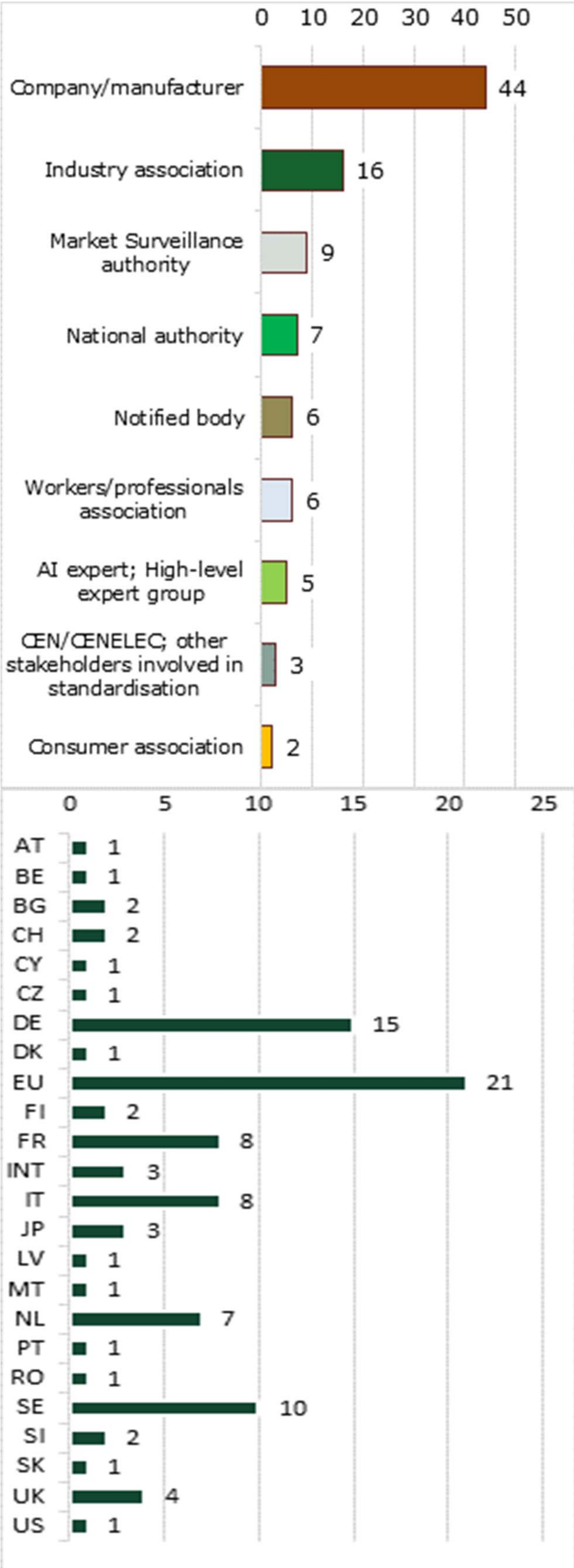
2. OVERVIEW OF THE PARTICIPANTS

For all consultation activities, the main stakeholder groups addressed were:

- CEN/CENELEC and other stakeholders involved in standardisation;
- Companies/manufacturers, importers and distributors;
- Consumer associations;
- Experts on AI, AI High Level Expert Group;
- Industry associations;
- Market Surveillance Authorities;
- National authorities;
- Notified bodies;
- Others, such as citizens and other NGOs;
- Workers/professionals' associations.

Over the course of the study, 98 stakeholders were interviewed. The majority of the interviewees were representatives from the industry, such as manufacturers and industry associations. The graphs below summarise the participation of the different stakeholder groups in the semi-structured interviews and the country of origin. The majority of the interviewed stakeholders were EU-level based associations, followed by Germany.

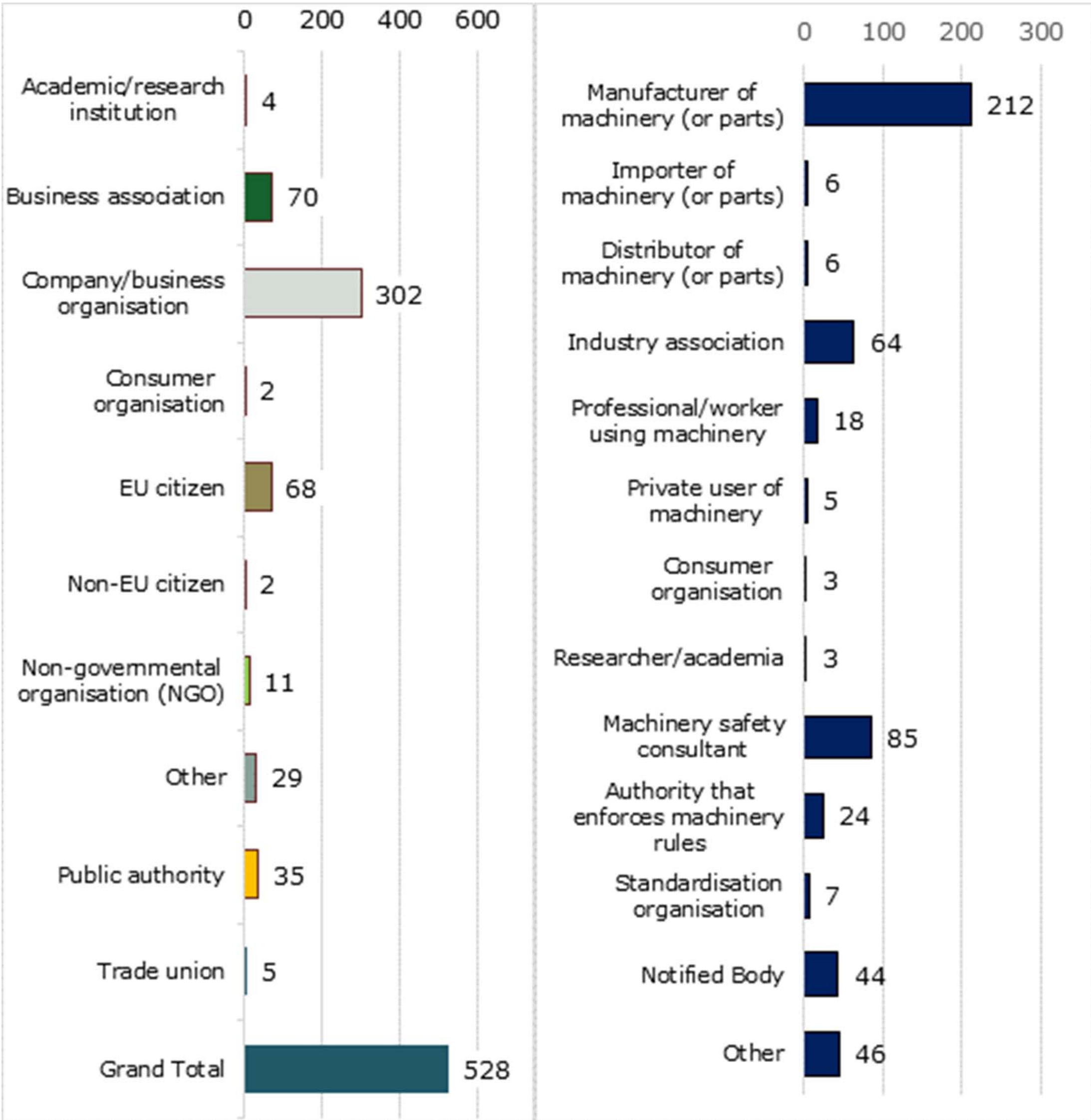
Figure 152: Participants in the semi-structured interviews

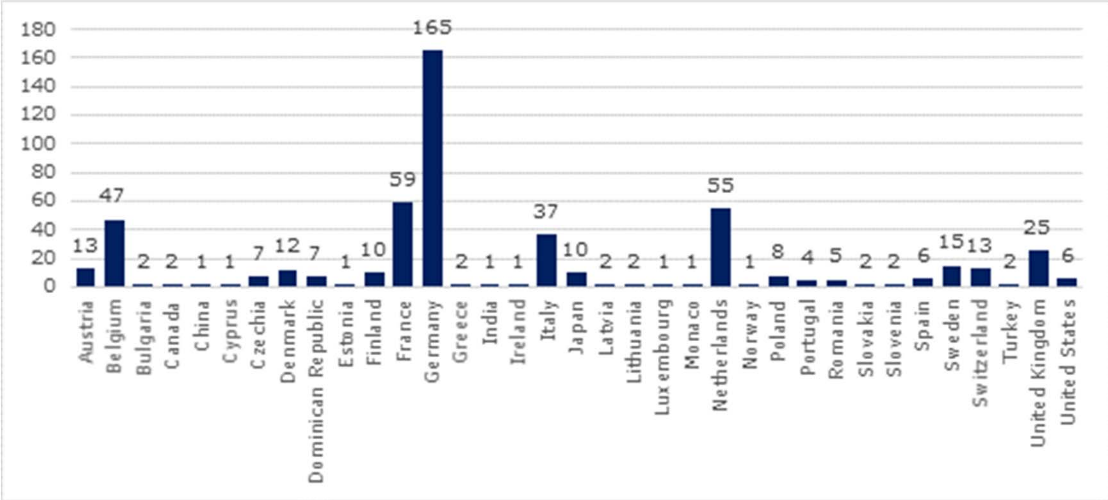


The Open Public Consultation ran from June to end of August 2019 for 12 weeks. A total of 523 responses were recorded, 5 additional responses were submitted digitally afterwards.

The majority of respondents were companies, followed by industry associations. Indeed, most respondents were manufacturers, followed by machinery safety consultants and industry associations. The majority of respondents were from Germany, followed by France, the Netherlands, Belgium and Italy. Most companies that participated in the OPC were large companies (61%). To account for the differences between large companies and SMEs, the results have also been compared along this category to identify potential differences in positions. The graphs below indicate the distribution of stakeholder groups that participated in the Open Public Consultation and their country of origin.

Figure 153: Participants in the Open Public Consultation





The targeted online survey was conducted during November 2019. The aim was to close certain information gaps identified throughout the study. A total of 24 stakeholders participated in the survey: i) companies/manufacturers (22); ii) notified bodies (1); and Experts on new technologies (1).

3. SUMMARY OF RESULTS

This report provides a short overview of the main consultation results with regards to the main four policy options assessed. A more detailed overview and additional information is provided within the Final Report.

3.1. Policy option 1: Addressing new challenges posed by technological developments in digitisation

The consultation activities asked stakeholders whether they have experienced or are aware of any safety incidents with machinery using new technologies, which types of new technologies they own and for manufacturers, what the expected trend for employing new technologies is.

In general, most stakeholders of all groups participating in the 98 semi-structured interviews did not report any instances of **health and/or safety incidents resulting from the use of machinery with AI or IoT implementations**. Of the respondents to the OPC, the majority had not encountered (or heard about) situations in which the safety of users (or domestic animals or property) was at risk as a result of the internet connection of the machinery (71%), 14% said they had. Of those 14%, a few mentioned having heard of the cyberattacks on nuclear power plants and weak security or insufficient application of a firewall of the software especially for older machinery. Some stakeholders were also concerned by remote maintenance or updates conducted, potentially while a machine operator being at work. Most of them indicated. The majority did not own an autonomous domestic robot (n=417). Of those that did own a device, most indicated to possess a robot vacuum cleaner (n=66), a robot lawn mower (n=19), a drone (n=19) or a robotic toy (physical robot intended for entertainment purposes only) (n=19). Most of these devices are not connected to the internet (59%), compared to about 30% that are connected to the internet. Again, the majority of domestic robot owners had not encountered situations in which the safety of the user was at risk (81%). Of those 14 that had encountered problems mentioned " near fly-into incidents or animals trying to catch the drone", "tripping hazard of robot vacuum cleaners" or "robotic vacuum cleaner pushing a loudspeaker towards the edge of a staircase, causing the fall of the loudspeaker" and dangers of electric shocks or static electricity. When it comes to the use of new technologies, six of the manufacturers that responded to the online survey indicated a use of these in their products, whereas more than half of the respondents indicated none or almost no application of these technologies in their products. However, most foresee an increase in uptake of these technologies in the future (n=11), either strongly (n=3) or to a limited extent (n=8).

Whether the risks of new technologies should be addressed in the Machinery Directive led to different results across stakeholder groups and type of application. Most respondents to the online survey showed preference to an overarching directive or horizontal legislation to cover risks of new technologies across sectors and directives (n=10), followed by those indicating that the risks should be specifically addressed in the MD (n=9). The results of the OPC showed that most importers are in favour of voluntary certification. In comparison, consumer organisations, machinery safety consultants and manufacturers rather preferred sectorial legislation with regards to implementing cybersecurity requirements in the EU. Cross-cutting legislation to all products was selected by most stakeholders involved in standardisation. Authorities, private users and professional workers indicated preference towards cross-cutting legislation with specific requirements. Finally, other ways of implementation were selected by most distributors, industry associations and notified bodies. The interview results showed similar discrepancies with an overall preference towards a horizontal legislation on cybersecurity across the sectorial legislations.

On the question as to whether the current Essential Health and Safety Requirements (EHSR) sufficiently covers the safety of human-robot collaboration, the majority of OPC respondents answered negatively (36%), compared to 29% positive responses. The only stakeholder group that considered the current requirements to suffice were industry associations. Again, more respondents indicated a preference towards adapting the current EHSR to take into account humans and robots sharing a space (32%) than those answering negatively (27%). Slightly more respondents indicated a preference on adding new EHSR (29%) than not (27%). With regards to the interview responses, many stakeholders, in particular manufacturers, referred to the limitations of the current EHSR 1.3.7. risks related to moving parts. These are said to represent the most commonly used approaches of physically separating robots from persons through fences and guards, and therefore no longer successfully cover the inherent nature of human-robot collaboration.

With regards to cybersecurity, the vast majority of stakeholders recognised the risks stemming from (malicious) interference across all groups and consultation activities. Most respondents to the OPC indicated that the current Directive does not sufficiently cover cyber threats (47%), with the exception of importers and industry associations. Most of the online survey respondents indicated a preference towards pursuing an overarching Directive or horizontal legislation to cover cyber-security across the board (n=7). The OPC showed that if requirements on cybersecurity were to be added, these should focus on safety and security requirements (46%) or no obligatory requirements (31%). Many interviewed stakeholders, in particular industry representatives but also notified bodies, referred to the already existing requirements set out in EHSR 1.2.1 on control systems under "external influences". In this regard, cyberattacks were considered to fall under such "external influences". However, a clearer demarcation of this relation in the current legal text was mentioned as option to provide additional legal clarity.

Finally, on risks of AI and machine learning, the responses are varied across stakeholder groups and specific aspects on AI and machine learning. First, on transparency of algorithms and datasets, more respondents to the OPC negated that this should be addressed in the MD (30%), compared to those that agreed it should (27%). Second, on software updates, more stakeholders indicated a preference towards addressing software updates in the Directive (41%) than those against it (26%). Many interviewed industry representatives (manufacturers and industry associations) and some notified bodies pointed out that differences of degrees in updates exists, referring to either maintenance with regards to minor updates or machinery substantially modified with major updates. Third, the vast majority of OPC respondents indicated a preference towards covering software which ensures a safety function and is placed independently on the market within the MD as a safety component (57%).

In contrast to the sub-option on changing the EHSR to address new challenges posed by emerging technologies, the majority of interviewed stakeholders were against the sub-option of self-regulation of the market. They indicated a risk of creating an unfair level-playing field and different degrees in safety levels across manufacturers, if a self-regulation of the market was to be followed.

3.2. Policy option 2: Addressing the problems identified during the evaluation of the Machinery Directive

The first sub-option of policy option 2 is a full alignment of the Machinery Directive to the New Legislative Framework. The results of the stakeholder consultation procedures indicate a large majority of all stakeholder groups being in favour of an alignment (65%), in particular authorities enforcing the Directive (92%) and industry associations (88%).

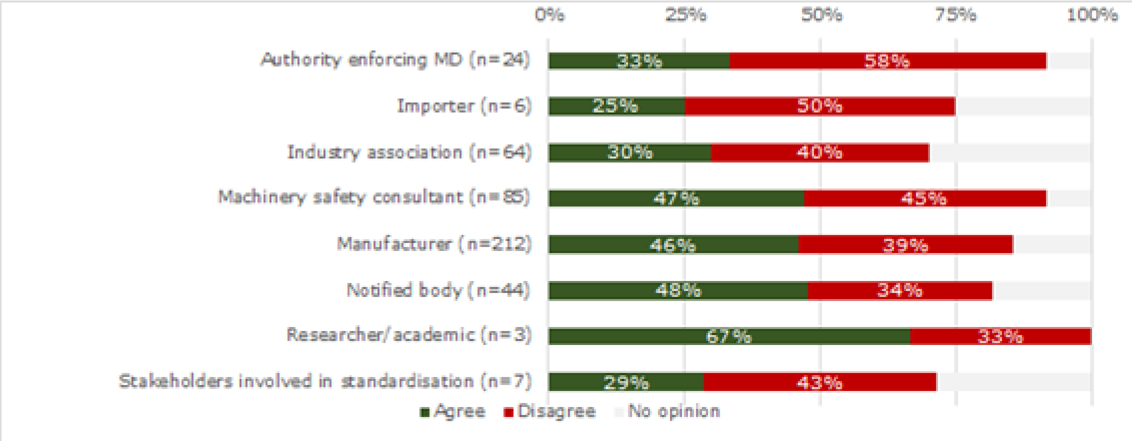
3.2.1. Adapting the scope and definitions

The second sub-option dives into changes in the scope and definitions, with a particular focus on the list of low voltage products, reviewing the threshold speed for slow-speed lifts and improving the definition of partly completed machinery.

On the question whether the current exclusion of low voltage products covered by the Low-Voltage Directive (LVD) in Art. 1.2(k) of the MD caused any problems, the majority of the respondents to the OPC answered that it did not (58%). Most of the offered alternatives were not preferred by most industry respondents to the OPC, though with differences in opinion across stakeholder groups.

Manufacturers, machinery safety consultants, notified bodies and researchers, for example, did agree that explicitly differentiating between consumer and commercial/professional products, so that low voltage machinery for consumer use is excluded, whereas the products for commercial/professional use are not, could facilitate the application of the Directive. Interviewees and open questions, however, often mention the risk that certain products or product categories could be used in both consumer and professional contexts.

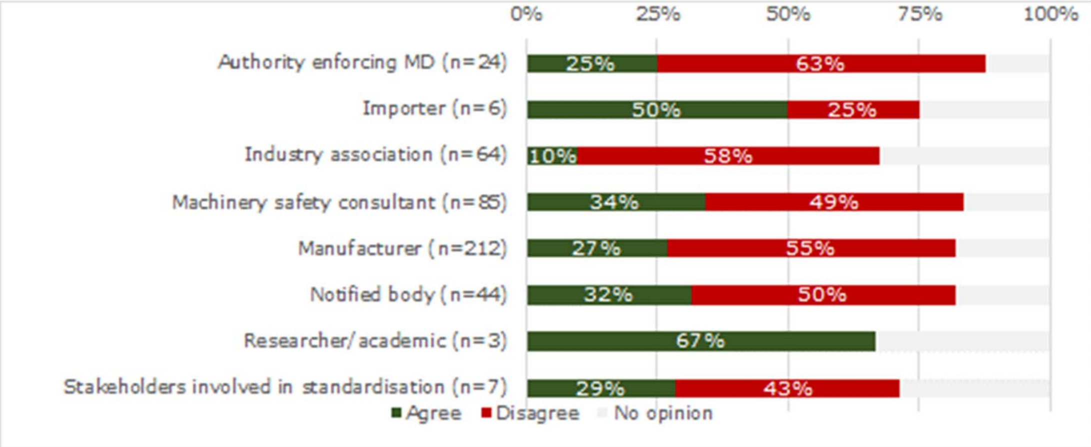
Figure 154: Respondents' opinion on differentiating between consumer and professional products for Art. 1.2(k), by stakeholder group



Source: Open public consultation (n=296)

Importers of machinery (50%) and manufacturers (27%) could also imagine a removal of the exclusion of low voltage machinery in Art. 1.2(k), so that the machinery whose risks are mainly of electrical origin are covered exclusively by the LVD. Most stakeholder groups, however, were not in favour of a removal of the exclusion.

Figure 155: Respondents' opinion on removing the exclusion of low voltage products in Art. 1.2(k), by stakeholder group



Source: Open public consultation (n=296)

In **terms of low speed lifts being covered by the Machinery Directive, the question whether an increase of the maximum speed from 0.15 m/s to 0.50 m/s** would create safety problems appeared to be too technical for the respondents, with 50% providing no opinion. 38% indicated that it would create safety problems, compared to 12% who answered it would not. Most notified bodies (77%) expect safety problems to arise with an increase of speed limits, followed by authorities enforcing the Directive (67%). Especially manufacturers of lifts see a potential increase of the speed limits of slow-speed lifts leading to safety concerns (78%).

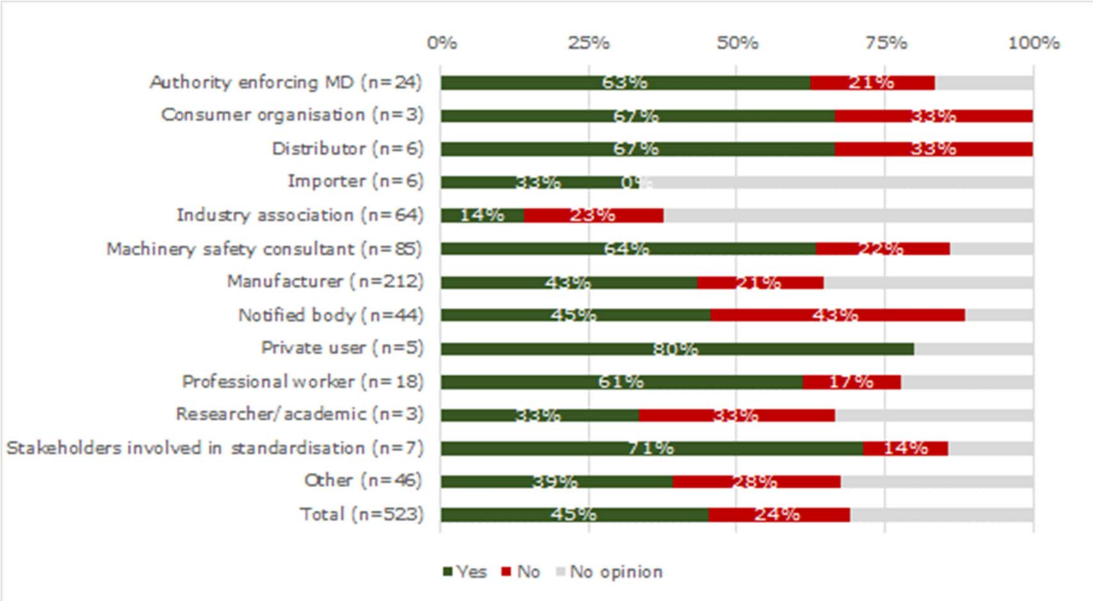
Finally, on **the definition of partly completed machinery**, the majority of stakeholders did not experience any problems with the definition, according to the OPC results (43.6%). In particular distributors (67%), industry associations (55%) and manufacturers (50%) did not indicate any problems. In comparison, authorities (42%), importers (50%), notified bodies (52%) and private users (40%) mentioned that it had led to the wrong classification of the product. Machinery safety consultants (57%), professional workers (50%) and stakeholders involved in standardisation (57%) indicated that it had led to problems with the CE marking. Most of the interviewed stakeholders that gave a response to this question did not prefer a removal of the concept of partly completed machinery.

3.2.2. Adapting the Essential Health and Safety Requirements (EHSR)

Within this sub-option of policy option 2, the main focus lies on the adaptation of the requirements on carrier and run-control for slow-speed lifts and allowing digital formats for documentation.

On the changing of **requirements on carrier and run-control for slow-speed lifts**, the majority of the stakeholders indicated in the public consultation that the requirements should be revised (45%). Against a revision were only industry associations (23%), if the responses of 'no opinion' are excluded. Lifts manufacturers were also largely against a revision of the requirements (64%). Within the open questions and the interviews, stakeholders were in favour of allowing alternative solutions but stressed the importance of keeping the same level or reaching higher levels of safety in comparison to the current requirements. They also stressed the differences between product categories, as alternative solutions could not be as effective in limiting the risk of falling of persons or objects as well as a physical barrier.

Figure 156: The requirements for carriers or run-controls for slow-speed lifts should be revised



Source: Open public consultation

On **allowing digital formats for documentation**, the OPC asked a few questions on the experiences with user manuals. The majority of the stakeholders across groups (with the exception of consumer organisations and industry associations) indicated that the user manuals were difficult to understand (59%). The most common mentioned difficulties were related to 'manuals being badly written' (47%), followed by other reasons (29%) and the manual being too complex (10%). The stakeholder groups representing the industry in majority indicated that they have had the need to update their manuals (87%) and almost all of them answered that electronic manuals would have facilitated the process (98%). With regards to the preferences on the way user manuals should be provided, the majority of stakeholders indicated 'always digital' (63%), followed by 'short printed Quick Start Guide (QSG) and in-depth online manual' (51%). Stakeholder groups showed different opinions. While the option of always having a digital manual was preferred by importers (67%), industry associations (63%), machinery safety consultants (57%), notified bodies (55%), private users (all), professional workers (72%), most authorities (58%) preferred always having a printed version. A combination of a QSG and a more in-depth online version of the manual was preferred by most distributors (67%), consumer organisations (67%) and a potential alternative for authorities (46%).

Table 80: Preferences on the delivery of user manuals by stakeholder group

	Q32.1: Delivery user manual - always printed	**Q32.2: Delivery user manual - printed on demand**	**Q32.3: Delivery user manual - digital**	**Q32.4: Delivery user manual - external device (DVD/USB)**	**Q32.5: Delivery user manual - QSG**	**Q32.6: Delivery user manual - other**
Authority enforcing MD	58.3%	12.5%	33.3%	20.8%	45.8%	25.0%
Consumer organisation	0.0%	0.0%	33.3%	0.0%	66.7%	33.3%
Distributor	16.7%	66.7%	33.3%	16.7%	66.7%	0.0%
Importer	16.7%	16.7%	66.7%	16.7%	16.7%	16.7%
Industry association	12.5%	25.0%	62.5%	14.1%	57.8%	51.6%
Machinery safety consultant	45.9%	16.5%	56.5%	22.4%	50.6%	12.9%
Manufacturer	19.3%	27.4%	69.3%	21.7%	49.5%	13.2%
Notified body	38.6%	11.4%	54.5%	15.9%	52.3%	31.8%
Private user	40.0%	20.0%	100.0%	20.0%	60.0%	0.0%
Professional worker	50.0%	22.2%	72.2%	11.1%	44.4%	11.1%
Researcher/academic	0.0%	0.0%	33.3%	33.3%	33.3%	33.3%

	Q32.1: Delivery user manual - always printed	Q32.2: Delivery user manual - printed on demand	Q32.3: Delivery user manual - digital	Q32.4: Delivery user manual - external device (DVD/USB)	Q32.5: Delivery user manual - QSG	Q32.6: Delivery user manual - other
Stakeholders involved in standardisation	14.3%	14.3%	57.1%	0.0%	71.4%	28.6%
Other	52.2%	2.2%	67.4%	15.2%	47.8%	30.4%

Source: Open Public Consultation (n=523)

If a combination of an in-depth online manual with a printed QSG was selected, most mentioned information that should be included in the Guide was 'basic handling information' (40 mentions), followed by 'details of safety control systems' (34 mentions). The expected effects of moving to online manuals only was 'access to manual would be difficult without internet' (55%) and 'users would only print the relevant parts' (44%). Within the open questions and the interview responses, the majority of industry stakeholders expected high cost savings of switching to digital documentation.

3.3. Policy option 3: Modifying Annex IV

Annex IV covers a list of high-risk machinery and includes other requirements for the conformity assessment procedure of these products.

The question to whether the internal checks option in Annex IV of the MD leads to safety concerns received mixed responses in the OPC, with 40% indicating it does and 39% indicating it does not. In particular the majority of authorities (63%), consumer organisations (33%), distributors and importers (both 50%), notified bodies (80%), private users (80%), professional workers (72%) indicated that it does lead to safety concerns. In contrast, most industry associations (64%), machinery safety consultants (42%), manufacturers (43%), researchers (67%) and stakeholders involved in standardisation (43%) negated higher safety concerns due to internal checks.

Removing the option for internal checks of Annex IV machinery was expected to lead to increased costs by more than half of the respondents (55%). On the question whether other high-risk categories of machinery should be added to the Annex yielded mixed results. Most did not indicate any preference (39%), followed by respondents negating that they should be included (31%). The respondents with a preference for either option are importers (3 out of 6), notified bodies (75%) and professional workers (11 out of 18) that prefer an inclusion of other high-risk categories, compared to industry associations (55%) rather not preferring an inclusion of other categories. The interview responses, on the other hand often referred to an adaptation and regular updates of the Annex IV as potential to bring benefits. Most interview responses were also rather not in favour of removing the Annex IV completely.

3.4. Policy option 4: Conversion to a regulation

The last policy option focuses on the potential of converting the Directive into a Regulation. Most of the stakeholders that participated in the OPC did not indicate any problems experienced through delays of transposition (44%) or due to differences in transposition across the Member States (MS) (38%), with the exception of stakeholders involved in standardisation. Nevertheless, even though no problems arose from potential differences in transposition, most stakeholders mentioned potential benefits of converting the Directive into a Regulation. For manufacturers, a conversion could lead to a decrease of additional costs related to differences in interpretation across MS. Indeed, the vast majority of stakeholders across groups showed a clear preference of converting the Directive into a regulation (79%).

ANNEX VII: SME TEST

(1) Preliminary assessment of businesses likely to be affected	
According to the study consultations, no specific business sector were mentioned as being particularly or disproportionally affected by the policy options. The industry association Orgalim did however mention that SMEs are predominantly manufacturers of Annex IV products in during the interviews. Certain changes in the Annex, such as potential removal of the Annex, could create savings for those SMEs.	See section 6.3.2
(2) Consultation with SMEs representatives	
SMEs taking part in the open public consultation (OPC) did not report any difficulties in buying/selling machinery from/to EU/EFTA/CH/TK (42%, n=119). Similarly, a majority of SMEs did not report any difficulties in identifying the relevant risks (59%, n=67). SMEs in majority also reported no difficulties in identifying eHSRs (55.2%) or finding right standards (41.8%, n=67). A majority of SMEs experienced no difficulties in doing conformity assessment (46.3%), no difficulties in preparing the documentation (41.8%), no difficulties in receiving correct declaration of conformity (44.8%), no difficulties in receiving correct instructions (44.85) and no difficulties understanding responsibility for CE marking (41.8%) (n=67). SMEs did report some difficulties in translating documentation in other EU languages (37.3%, n=67). A majority of SMEs (57.1%) reported experiencing situations in which safety of users was at risk for using machinery (n=119). For majority of SMEs (75.6%), internet connection was not the main cause of safety risks for the users (n=119). SMEs reported in large majority (75%) experienced problems were caused by machines from EU/EFTA/CH/TK (n=68). On the other hand, a majority of SMEs (80%) experience problems when ensuring compliance for product (n=5), however the results for this observation can be distorted due to the small number of participant SMEs. Open public consultation with SME representatives produced the following results about the 4 policy options: 1) Addressing new challenges posed by technological developments in digitalisation SMEs remained rather non-informative when asked about future technical developments and its impacts, as most of the times SMEs responded with “no opinion”. A majority of SMEs participating in the OPC do not have an opinion (40.9%) on whether the MD sufficiently covers human-robot collaboration (n=115). 36.5% of participant SMEs responded that the MD does not sufficiently covers the human-robot collaboration, compared to 22.6% of SMEs who believe that MD covers sufficiently the human-robot collaboration (n=115). Almost half of the participant SMEs (49.6%) in the study’s OPC also do not have an opinion on whether EHSR should be adapted t cover the human-robot collaboration (n=115). 30.4% of SMEs on the hand believes that EHSR should be adapted in order to account human and robots in shared space. 26.1% of SMEs believe that new EHSR should be added to cover human-robot collaboration (n=115). According to the 45% of the	See Annex II

consulted SMEs in the OPC report that changes made to the EHSR in order to take int account human-robots collaboration will results in the production costs (n=20). SMEs responded in majority with "no opinion" on the possible MD addressing transparency of algorithms (53.9%) and software updates (45.2%) (n=115). On the other hand, SMEs believe in majority (60.9%) that the MD should cover independent software as safety component and that placing on the market should be considered as relevant when software updates are added (48.7%) (n=115). More than half of the SMEs (55.7%) believe that concept of foreseeable misuse is still relevant (n=115). Regarding cybersecurity, a majority of SMEs (45.2%) believe that MD does not cover cybersecurity well (n=115) and 47.8% of SMEs believe that safety and security requirements should be added to specifically address the issue of cybersecurity. However, on the question on how the cybersecurity requirements should be implemented in the EU, majority of SMEs (29.6%) believes that the best approach to do so is via sectoral legislation (n=115). 2) Addressing the problems identified during the evaluation of the Machinery Directive 53.9% of SMEs agrees with the alignment of MD to the New Legislative Framework (n=115). When discussing clarifications about the scope and definitions, 47% of SMEs reported facing problems with partly completed machinery due to its wrong classification. More than half of the SMEs (52.2%) agree with the change of the definition - partly completed machinery. Majority of SMEs on the other hand does not see any need for making changes in the definition of the assembly (41.7%) and the definition of the "state of the art" as 46.1% of SMEs responded negatively (n=115). Majority of SMEs (48.7%) does not have an opinion whether the changes to the safety concerns covering speed lifts should be made. 34.8% of SMEs however believes that safety concerns should be changed (n-115). Large majority of SMEs (88.1%) believes that if changes to the safety concerns covering speed lifts were to be made, there would be no changes in costs (neither increase nor decrease of costs) (n=67). 61.3% of SMEs reported having difficulty in understanding user manual. For majority of SMEs (45.3%), the main reason are badly written manuals (n=115). Large majority of SMEs (85.7%) reported to have the need to update manuals and 93.8% of SMEs believes that electronic manuals would make updating easier (n=115). More than half of the SMEs believe that digital manuals would create cost savings due to the paper savings (n=115). 3) Modifying Annex IV 44.3% of SMEs believe that internal checks conducted by manufacturers themselves can lead to safety concerns (n=115). On the other hand. 33.9% of SMEs believe there are no safety concerns associated with the internal checks. Removing internal checks option would in the opinion of a majority of SMEs (47.8%) lead to an increase of costs (n=67). Removing internal checks option would for 39.8% of SMEs mostly affect the production cost (39.8% of SMEs) and turnover (39.8% of SMEs). A majority of SMEs participating in the OPC however does not have an opinion on the possibility of updating the Annex IV by adding higher risk category machinery (45.2%). From those SMEs	

that answered the question, 29.6% of SMEs would support adding the higher risk categories of machinery to the Annex IV compared to 25.2% of SMEs that are against this update (n=115). Updating the Annex IV by adding high risk categories of machinery would according to most SMEs (47.1%) affect the production costs. 4) Conversion into Regulation Majority of SMEs participating in the OPC (78.3%) would support the conversion of the Directive into regulation (n=115).	
(3) Measurement of the impact on SMEs	
Quantifiable impacts on SMEs have been reported in the section 6.3 on the Impacts of the policy option 3, in particular in relation to the process of conformity assessment. Calculations of the costs were made on the assumption that the overall compliance costs with the Directive do not exceed 1% of the company's annual turnover. Based on this it was calculated that the total annual compliance costs for SMEs (up to 1% of annual turnover) amount on average EUR 31,422 per year. Average estimated costs of compliance through internal checks amount EUR 7,070 per firm/SME. Average estimated costs of compliance through third-party assessment on the other hand is calculated to amount EUR 17,828. This makes the costs savings related to self-conformity process compared to the third-party assessments of EUR 10,212. If the option of conformity assessments with internal checks of machinery under Annex IV was to be removed, manufacturers expected a cost impact of about 5.9% of annual turnover on average. Removing the option for internal checks would generate an average of EUR 10,758 additional costs per SME. Total yearly cost of producing documentation for conformity assessment per SME is estimated at EUR 9,427.	See section 6.3.1 Costs related to internal checks and third-party involvement and 6.3.2 Impacts of modifying Annex IV
4) Assess alternative options and mitigating measures	
SMEs supported all four presented policy options. The highest agreement was expressed with the policy option 4: conversion of the Directive into regulation, where 78.3% of SMEs participating in the OPC responded positively. The expressed share of agreement was lower for other presented policy options. In particular, SMEs were not sure about the policy option 3: modifying Annex IV, where majority of SMEs participating in the OPC did not have an opinion on the matter. 45.2% of SMEs have no opinion on whether higher-risk categories of machinery should be added to Annex IV or not. The detailed statistical responses of the SMEs on all policy options is described below. **Impacts of policy Option 1: Addressing new challenges posed by technological developments in digitalisation** - 47.8% of SMEs would agree adding Safety and security requirements covering innovative technologies to the MD (n=115). 70.1% of SMEs believe that changing safety requirements would not have any impact on their costs (n=67). 40% of SMEs believe that changing safety requirements would mostly impact the turnover, whereas 35% of the SMEs report the change would impact costs of production, and 25% of SMEs report to expect changes in the man-hour costs resulting from the change of safety requirements.	See section 6.3

Impact of policy option 2: Addressing the problems identified during the evaluation of the Machinery Directive • Alignment to NLF: 53.9% of SMEs agrees with the alignment of MD to the New Legislative Framework. The benefits mentioned include harmonisation of the EU legislation and ensuring common approach to conformity assessment procedure. It was also mentioned that alignment to the NLF could prevent nonconformities and invalid CE marking of machinery. Bringing MD in line with the NLF also negates the need for MD and LVD being separate directives/regulations. • Adapting the scope and definitions in the Directive: SMEs agreed in majority (52.2%) to change the definition of partly completed machinery (n=115). On the other hand, SMEs did not see the need to change the definitions of manufacturer, assembly, state of the art and nuclear purposes. • Adapt the list of low voltage products excluded: a majority of SMEs (47.6%) does not agree with the removal of the article 1.2(k). This result is in line with the other stakeholder groups consulted (industry associations, national authorises etc), who in majority did not see the removal of the exclusion of the article 1.2.(k) as beneficial. Overall, in majority the SMEs did not have a prevailing opinion about the possibility of changing the list of low voltage products. SMEs in majority (38.1%) responded with "no opinion" on the possibility of making more standards available as to clarify which products to fall under MD and which under LVD. Similarly, majority of SMEs (7.4%) did not have an opinion on possible other solutions. **Impacts of policy Option 3: Modifying Annex IV** – A majority of SMEs (45.2%) have no opinion on whether higher-risk categories should be added to the Annex IV and thus being subject to conformity assessment procedures involving a notified body. 29.6% of SMEs agreed with adding higher-risk categories to the Annex IV and 25.2% of SMEs is against it. For majority of SMEs (47.1%) adding other risk categories to the Annex would reflect in the cost of production share. On the other hand, majority of SMEs (46.3%) report having no difficulties in doing the conformity assessment. SMEs report to follow an ad-hoc approach in familiarisation and preparatory work for internal checks. Similarly, majority of SMEs (41.8%) do not report difficulties in understanding the responsibility for CE marking. **Impact of policy option 4: Conversion of the Directive into a Regulation** - 78.3% of SMEs agrees with the conversion of the MD into regulation. The main argumentation in favour of converting MD into a regulation is possibility to avoid different legislative requirements for design, manufacturing and placing on the market, as Regulation would impose the same rules and obligations applicable to all Member States.	

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