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IMPACT ASSESSMENT

Accompanying the

Proposal for a Regulation of the European Parliament and of the Council

on machinery products

{COM(2021) 202 final} - {SEC(2021) 165 final} - {SWD(2021) 83 final}

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Glossary

Term or acronym	*Meaning or definition*
AI	Artificial intelligence
CAGR	Compound average growth rate
CE	European conformity marking
CEN	European Committee for Standardization
Cenelec	European Committee for Electrotechnical Standardisation
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
EMCD	Electromagnetic Compatibility Directive
EN	European standards
ESO	European standardisation organisation
ETSI	European Telecommunications Standards Institute
EU	European Union
EU-28	EU-28 Member States (as of 1/12/2019)
FTE	Full-time equivalent
GDP	Gross domestic product
IIoT	Industrial internet of things
IoT	Internet of things
ISO	International standards
LD	Lifts Directive
LVD	Low-Voltage Directive
MD	Machinery Directive
ML	Machine learning
MS	Member State (of the EU)
MSA	Market surveillance authority
NACE	Statistical classification of economic activities in the EC
NBs	Notified bodies
n.e.c.	Not elsewhere classified
NGO	Non-governmental organisation
NLF	New legislative framework
OEM	Original equipment manufacturer
OJEU	Official Journal of the European Union
OND	Outdoor Noise Directive
OSHA	Occupational Safety and Health Administration
PCM	Partly completed machinery
PED	Pressure Equipment Directive
pp.	Percentage points
RED	Radio Equipment Directive
REFIT	Regulatory fitness and performance programme
SME	Small and medium-sized enterprises
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

The revision of the Product Safety Directive 2006/42/EC on Machinery ('the Machinery Directive' or 'the MD')[1] contributes to the digital transition and to the strengthening of the single market. It is part of the Commission's 2020 work programme under the priority 'A Europe fit for the digital age'. The Commission has been active in studying emerging technologies and their impact on safety legislation. For example, the Commission published a white paper on artificial intelligence in February 2020. The white paper was accompanied by the ***Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics***[2]. This report analysed the impact of emerging technologies and the challenges they pose to EU safety legislation. It concluded that **current product-safety legislation contains a number of gaps that need to be addressed. One such piece of product-safety legislation that contains gaps is the MD**. Addressing the gaps in this Directive is especially important for a sustainable recovery from the COVID-19 pandemic, since the machinery sector is an essential part of the engineering industry and one of the industrial mainstays of the EU economy.

The MD is the main piece of legislation regulating products made by the mechanical engineering industry. 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'. This definition applies to a great variety of products, from lawnmowers to 3D printers, and from powered hand-tools to robots or construction machinery. The MD applies across the whole value chain, from the design and manufacturing stages until the machinery is placed on the market (or put into service) for consumer and professional use. The machinery manufacturers must take the appropriate measures to ensure safety risk throughout the foreseeable lifetime of the machinery before it is placed on the market.

The MD lays down a regulatory framework for placing machinery on the single market, based on Article 114 of the TFEU (the approximation of laws). The MD was adopted on 17 May 2006 and implemented in 2009. It was the result of a comprehensive revision of previous legislation dating back to the first piece of legislation on this topic, Directive 89/392/EEC (which was reviewed in 1991 and 1993), replaced by a subsequent piece of legislation, Directive 98/37/EC. An amendment in 2009 to the current Directive 2006/42/EC added a 'protection of the environment' objective, although this amendment was limited to machinery used in pesticide applications.

The MD is a piece of product-safety legislation that aims to ensure a high level of protection for workers, consumers and other exposed people. It seeks to achieve this by focusing on the safety of machinery itself, and thus imposes obligations on machinery manufacturers to produce inherently safe machinery designs (safety by design). The general objectives of the MD are to: (i) ensure the free movement of machinery within the single market; and (ii) ensure a high level of protection for users and other exposed people. The MD imposes obligations on machinery manufacturers, but not on users.

The MD follows the 'new approach' principles of EU legislation. As opposed to the 'Old approach', where technical specifications are embedded in the legal text, the 'New approach' implies that the legal text, the MD in this case, is intentionally written to be 'technology neutral' by laying down the **essential health-and-safety requirements** (hereinafter '**safety requirements**') to be complied with, without prescribing any specific technical solution for complying with those requirements. The choice of the technical solution is a prerogative of manufacturers, which leaves space for innovation and the development of new designs.

[1] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery.
[2] Available at: https://ec.europa.eu/info/publications/commission-report-safety-and-liability-implications-ai-internet-things-and-robotics-0_en

The safety requirements are set out in Annex I of the MD. Some safety requirements are more general in nature, while others are specific to certain types of machinery. The manufacturers must make a risk assessment to determine what risks the machinery presents. Based on these risks, the manufacturers must identify the safety requirements with which the machine must comply. To help manufacturers prove that their machinery conforms to the requirements, and to allow inspection of conformity with the requirements, harmonised standards at EU level are commonly used (see Chapter 1.1 of this impact assessment). These standards are drawn up by private-law bodies and their use is voluntary. Manufacturers have the choice of implementing other technical solutions as long as they can prove that all relevant legal requirements are complied with. Compliant machinery is put on the market with a 'CE marking' affixed to it. This is a way for the manufacturer to declare that the product meets all the legal requirements and can be sold throughout the EU.

During the REFIT evaluation[3] of the MD, all interested parties confirmed that the MD is an essential piece of legislation necessary to guarantee: (i) the right level of safety for the wide range of products covered; and (ii) a level playing field in the machinery market. The evaluation was also positive about the MD's flexibility and openness to innovation. Nevertheless, the evaluation also identified a necessity to improve, simplify, and adapt the MD to the needs of the market. In particular, the evaluation concluded that a revision should aim to:

- address the risks stemming from emerging technologies while allowing for technical progress;
- improve the legal clarity of some major concepts and definitions in the current text of the MD;
- simplify the requirements for documentation by allowing digital formats, thus reducing administrative burden for businesses while also cutting environmental costs;
- ensure coherence with other directives and regulations for products and improve enforcement of the legislation through the alignment to the new legislative framework; and
- reduce the costs of transposition by converting the MD into a regulation.

Some members of the European Parliament's IMCO committee European Parliament's Committee on Internal Market and Consumer Protection (IMCO) expressed their support for the revision of the MD. In particular, they supported the idea of 'bringing the legislation into the 21st century' and promoting innovation for the EU economy.

1.1 The role of harmonised standards in the machinery sector

As indicated above, an important part of the application of the MD is the role of harmonised standards. These harmonised standards are developed by the European standardisation organisations (CEN/CENELEC and ETSI) following a standardisation request from the European Commission, according to Regulation (EU) No 1025/2012[4]. Machinery manufactured in conformity with a harmonised standard, the references to which have been published in the Official Journal of the European Union (OJEU), are presumed to comply with the requirements covered by such a harmonised standard.

The voluntary nature of the standards makes the framework flexible enough to: (i) enable innovation and technical development; and (ii) facilitate the placing on the market of new products for which a harmonised standard does not yet exist.

Under the MD, there are three types of standards: A, B and C. Type-A standards cover principles common to all machines. Type-B standards cover: (i) safety and ergonomic principles; (ii) safety

[3] Evaluation of the Machinery Directive: SWD (2018)160
[4] Regulation (EU) No 1025/2012 of 25 October 2012 on European standardisation, OJ L 316, 14.11.2012, pp. 12-33.

components; and (iii) devices. Type-C standards cover specific types or groups of machines. The references of harmonised standards are published in the OJEU. The most recent list comprising all three types of standards[5] includes a total of 1 112 standards relevant for the MD, of which 782 will still apply after 2022, meaning that 330 have been withdrawn or will be withdrawn by then.

The Commission may, within the limitations of the powers laid down in the Treaties, ask one or several European standardisation organisations (ESOs) to draft a European standard within a set deadline. European standards and European standardisation deliverables must: (i) be market-driven; (ii) take into account the public interest as well as the policy objectives clearly stated in the Commission's request; and (iii) be based on consensus. The Commission must determine the content requirements to be met by the requested document and set a deadline for its adoption[6].

1.2 The Machinery Directive in the broader EU legislative context

The MD is a piece of EU, harmonised, sectoral, product-safety legislation. As such, it is also part of the EU's body of law ('the *acquis*') dealing with product safety.

There are more general EU rules dealing with safety across different product types (i.e. the General Product Safety Directive[7] and the **new legislative framework**[8]) and sectoral rules for specific product types. The General Product Safety Directive is a safety-net legislation that applies to consumer products if: (i) there are not more specific provisions in harmonised, sectoral, product-safety legislation; and (ii) there are aspects and risks (or categories of risks) not covered by that sectoral product-safety legislation.

The MD covers all safety risks that manufacturers must address to be able to place their machinery on the EU market. The specificities of the products covered and their risks confirm the need for sectoral legislation. Therefore, because the safety requirements of the MD are more specific than the general safety requirements of the General Product Safety Directive, the MD takes precedence.

The MD ensures a high level of protection for machinery users and other exposed persons by ensuring the safety of machinery. It applies at the moment the machine is placed on the market (or put into service). Another directive, **EU Directive 2009/104/EEC**[9] lays down minimum safety and health requirements for the **use of work equipment**, after it has been placed on the market (or put into service). The two Directives are therefore complementary.

In some cases, depending on the machinery's characteristics, the MD may apply together with other pieces of legislation, such as: (i) the **Outdoor Noise Directive** (OND); (ii) the **Radio Equipment Directive** (RED); (iii) the Electromagnetic Compatibility Directive (EMCD); or (iv) Regulation (EU) 2016/1628 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery (recently amended by Regulation (EU) 2020/1040 in order to address the impact of the COVID-19 crisis). For instance, machinery with radio equipment may be subject to both the MD and the RED, while machines for use outdoors (such as in construction sites, road maintenance, gardening and forestry activities) may be subject to both the MD and the OND.

In other cases, the MD applies alternatively to other product-safety legislation, such as the **Low-Voltage Directive** (LVD), the **Pressure Equipment Directive** (PED), the **Lifts Directive** (LD) or the Medical Devices Directive. In such cases, some categories of machinery are explicitly

[5] Available at: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/machinery_en.
[6] Regulation (EU) No 1025/2012 of 25 October 2012 on European standardisation, OJ L 316, 14.11.2012, pp. 12-33.
[7] Directive 2001/95/EC the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, pp. 4-17).
[8] Regulation (EC) No. 2008/765 and Decision (EC) No. 2008/768.
[9] 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 (second individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), OJ L 260, 3.10.2009, pp. 5-19.

excluded from the scope of one of the legal acts, falling only under the scope of the other. For instance, certain machinery is excluded from the MD as listed in Article 1(2)(k) of the MD, and falls instead under the LVD. Other machinery is excluded from the PED (Category I products under PED) or the LD (lifting appliances whose speed is not greater than 0.15 m/s), and falls under the MD.

The Commission is also active in assessing artificial intelligence (AI), the internet of things (IoT), and other digital technologies and their implications for safety legislation. As mentioned in Introduction 1.1, the Commission published in February 2020 its *Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics*[10]. The report concluded that current product-safety legislation contains a number of gaps that need to be addressed, in particular in the MD. The revision of the MD is taking into account those recommendations.

The white paper on AI also outlined the Commission's objective to propose new legislation covering safety and fundamental requirements for AI systems. A new AI regulation is being drawn up in this area. The Commission intends to adopt proposals for both a new AI regulation and a revised MD in the second quarter of 2021. The link between a new AI regulation and the revised MD is further detailed in the policy options set out for AI. Coherence between this new AI regulation and the revised MD will be sought at the level of: (i) the safety requirements; (ii) the concepts and definitions used (e.g. the 'high-risk' concept); and (iii) the conformity-assessment procedure. This coherence is essential to ensure that no duplication or additional unnecessary burden is placed on businesses.

On cybersecurity, the MD is focused on product safety, and addresses only those risks that may have an impact on safety. This means that the revision of the MD should be limited to 'cyber safety' (related to the machine), rather than to cybersecurity in broad terms (related to the network).

On cybersecurity more broadly, the **Cybersecurity Act**[11] represents a point of reference as an existing market initiative on network security. The Cybersecurity Act is a voluntary, EU-wide certification framework for digital products, services and processes. It is based on a comprehensive set of rules, technical requirements, standards and procedures. Manufacturers can choose to follow this voluntary certification framework if they wish. The Cybersecurity Act also has the potential to cover emerging cybersecurity risks for machinery products that use emerging technologies, but only to a certain extent due to its voluntary nature. In addition, under the **RED**, preparatory work is under way for possible delegated acts addressing: (i) privacy; (ii) data protection; (iii) protection from fraud; and possibly (iv) protection to ensure that the equipment does not harm the network. Those delegated acts would apply to connected machines incorporating radio equipment.

The Commission is also taking a broader look at the impacts of EU regulation, paying attention to other aspects, such as environmental or circular-economy effects. The MD is a piece of pure **product-safety** legislation. It is true that the 2009 amendment added a 'protection of the environment' objective limited to machinery used in pesticide applications. Nevertheless, extending such an objective to the very wide range of machinery products would render the MD too broad and unmanageable. On **pollution and noise**, there is already specific legislation referred to above, namely the OND and Regulation (EU) 2020/1040 on engine emissions from mobile machinery. Some environmental and circular-economy effects are being taken into account in the revision of the MD where possible. Indeed, one of the improvements sought by the revision has a significant environmental benefit, namely to allow digital documentation which

[10] Available at: https://ec.europa.eu/info/publications/commission-report-safety-and-liability-implications-ai-internet-things-and-robotics-0_en.

[11] Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (Text with EEA relevance), OJ L 151, 7.6.2019, pp. 15-69.

would help save paper and decrease carbon emissions. In addition, some improvements proposed would favour the **circular economy**, such as the clarification of what constitutes a 'substantial modification', subject to which substantially modified machinery can be put on the market again with a new CE marking.

1.3 The machinery sector

The machinery and equipment sector is one of the major sectors of the EU's manufacturing industry. Detailed information on the machinery sector can be found in the *Impact assessment study on the revision of Directive 2006/42/EC on machinery*[12]. A snapshot of the main data[13] from that impact assessment study is set out in the following three bullet points.

- In 2017, the machinery sector recorded turnover of EUR 663 billion, production of EUR 609 billion, and a value added of EUR 191 billion.

- In 2017, the machinery sector employed 2.8 million people and comprised 82 239 enterprises. 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 people employed in manufacturing and accounted for 4.1% of all manufacturing enterprises.

- In 2017, total EU machinery and equipment exports amounted to EUR 503 billion, 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)[14].

Among the 82 239 enterprises registered in the machinery sector, only 1 703 (2%) are large companies, while 81 024 (98%) are SMEs. Although the sector has important large players, SMEs are its main driving force. For this reason, SMEs were extensively consulted for this report, as detailed in Annex 5: SME TEST. Impacts on SMEs have also been carefully analysed.

1.4 Digitalisation, robotics, the IoT and AI in the machinery sector

The uptake of emerging technologies in machinery depends on the type of machinery and the sector it is used in. One of the most relevant sectors for the uptake of emerging technologies is the factory-automation market. In 2018, the EU had the second largest factory-automation market after Asia-Pacific, putting it ahead of North America.

In the factory-automation market, we can distinguish between traditional and 'smart' manufacturing systems.

The **traditional manufacturing system** is based on two parts: humans and physical systems. In a traditional manufacturing system, machine-operation controls are completely manual. This traditional manufacturing system requires humans to complete tasks (e.g. information sensing, decision-making, operating and checking) and may therefore be defined as a human-physical system.

In comparison, there are three categories of **smart-manufacturing systems**. These three categories are presented in the bullet points below[15].

[12] Impact assessment study on the revision of Directive 2006/42/EC on machinery. Available at: https://data.europa.eu/doi/10.2873/423938.

13 https://ec.europa.eu/eurostat/statistics-explained/index.php/Industrial_production_statistics#Overview

14 UN COMTRADE.

[15] 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.

i) Digital manufacturing: This is sometimes called 'the third industrial revolution'. In digital manufacturing, physical systems continue to act as the 'executing body', but humans develop the underlying: (i) analysis; and (ii) methods and rules for computation and control models. The operation relies on the knowledge and experience of the operator. Industrial robots without advanced AI applications fall under this category.

ii) Digital-networked manufacturing: This adds the internet component to digital manufacturing. For instance, machine-tool manufacturers can engage with their suppliers in remote-operation maintenance of their products through networks.

iii) 'Next generation' smart manufacturing: This is sometimes called the 'fourth industrial revolution'. In this type of system, the knowledge in the cyber system is jointly built by humans and the self-learning/cognition module of the cyber system. Humans remain as the creators, managers and operators of intelligent machines. This stage is currently at the level of 'weak' or 'narrow' AI (used to accomplish a narrow set of goals).

The broad definition of 'smart manufacturing' covers many different technologies. Some of the key technologies in the smart-manufacturing movement include advanced robotics, industrial-connectivity devices, and machine learning (ML).

Robotics in the machinery sector

Robots can be defined and classified as set out in the figure below[16].

<table>
<tr><td colspan="3">A robot is an actuated mechanism programmable in two or more axes with a degree of autonomy, and moving within its environment to perform intended tasks.</td></tr>
<tr><td rowspan="2">Industrial robots are for use in industrial-automation applications (e.g. grinding, welding, assembling, handling or packaging).</td><td colspan="2">Service robots perform useful tasks for humans or equipment, excluding industrial-automation applications (e.g. floor-cleaning robots, robotic lawnmowers, and robots for entertainment).</td></tr>
<tr><td>Personal-service robots or service robots for personal use are used for a non-commercial task, usually by laypersons (e.g. domestic servant robots, automated wheelchairs, robots to assist with personal mobility, or pet-exercising robots).</td><td>Professional-service robots or service robots for professional use are service robots used for a commercial task, usually operated by a trained operator (e.g. cleaning robots for public places, delivery robots in offices or hospitals, etc.).</td></tr>
</table>

Industrial robots can bring great benefits for health and safety by substituting for people working in unhealthy or dangerous environments, or in other highly repetitive, risky or unpleasant tasks. **Europe accounts for** 18.5% of total global sales of industrial robots and is **the leading continent for the number of robots per 10 000 employees**. Germany ranks third globally for industrial robot density[17], while four more European countries make it into the top 10 (Sweden, Denmark, Belgium and Italy)[18].

Collaborative robots are a growing segment of the market. Also known as '**co-bots'**, these robots are intended for direct human-robot interaction within a shared space, as opposed to traditional industrial robots which are isolated from human contact. **A number of new robotics**

[16] https://www.iso.org/obp/ui/#iso:std:iso:8373:ed-2:v1:en
[17] Industrial robots per 10 000 employees in the manufacturing industry.
[18] www.ifr.org

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 co-bots. **The EU co-bots market** was worth EUR 343 million in 2019 and **is expected to grow at a rate of 41% annually between 2020 and 2026**[19]. Indeed, most established European robotics manufacturers have co-bots in their product portfolios, with key players including Comau, Festo, ABB, Bosch, Stäubli, and Mabi Robotic. **Of the key players in the global co-bots market, most are European companies**[20].

The global market for **non-industrial robotics** in the consumer sector is projected to reach an added value of USD 286 billion (EUR 260 billion) by 2025. Smaller markets will include robotics for use in agriculture and logistics, among others. Of the service robots for domestic use, 96% of sales are estimated to be vacuum and floor-cleaning robots, while 70% of the entertainment robots are estimated to be toy and hobby robots[21]. The International Federation of Robotics counts **700 registered companies that make service robots. Of these, 43% (300 manufacturers) are based in Europe.**

The IoT in the machinery sector

The IoT can 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[22]. For machinery, the IoT opens up the possibility of improving machine-to-machine communications in complex processes and operating work equipment remotely. Increased interconnectivity requires embedding software in a machine, which entails using some form of network such as the internet.

The industrial IoT (IIoT) is the use of smart sensors and actuators to enhance manufacturing and industrial processes. The 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'[23]. While the IIoT is still in its infancy, manufacturing is considered the largest market that will 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.

'Smart' manufacturing ranked fourth in terms of growth potential after smart energy, smart health and smart transport. And 'smart manufacturing' also ranked third in terms of the EU's industrial potential[24]. The IIoT is projected to increase global GDP by about USD 15 trillion (EUR 12 trillion) by 2030[25]. Although in 2014 only about 10% of industrial machines were connected, the projections indicate rapid growth in uptake of connectivity in the future. In comparison to the overall IoT, the number of IIoT connections is expected to increase by 70.5% from 2016 to 2025.

AI in the machinery sector

[19] Research And Markets (2020). Europe Collaborative Robots Market to Grow with a CAGR of 40.73% During the Forecast Period, 2020-2026.
[20] DG Research and Innovation (2020). Unlocking the potential of industrial human–robot collaboration.
[21] Statista. Let the robot do the cleaning. Estimated worldwide unit sales of robots for personal/domestic use (2017). Available at: https://www.statista.com/chart/9089/worldwide-personal-robot-sales-forecast/.
[22] The definition of the internet of things provided by the Recommendation ITU-T Y.2060 is available at https://www.itu.int/ITU-T/recommendations/rec.aspx?rec=y.2060.
[23] TechTarget (n.d.). Industrial internet of things (IIoT). Available at: https://internetofthingsagenda.techtarget.com/definition/Industrial-Internet-of-Things-IIoT.
[24] European Commission. Definition of a research and innovation policy leveraging cloud computing and IoT combination (2014). Available at: https://ec.europa.eu/digital-single-market/en/news/definition-research-and-innovation-policy-leveraging-cloud-computing-and-iot-combination.
[25] Ibid.

In the Commission's *White Paper on Artificial Intelligence - A European approach to excellence and trust*[26], AI systems are defined as follows.

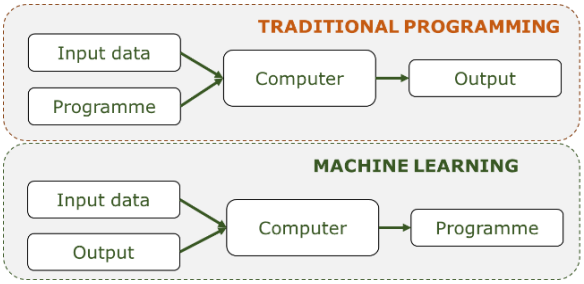
software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can 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.

AI can be categorised according to the following three stages of development[27].

i) Basic AI, or artificial narrow intelligence, is limited in scope and restricted to just one functional area (e.g. AlphaGo, a computer programme that plays the board game Go).

ii) Advanced AI, or artificial general intelligence (AGI), usually covers more than one field, such as the power of reasoning, abstract thinking, or problem solving on a par with human adults[28].

iii) Autonomous AI, or artificial super intelligence (ASI), is where AI surpasses human intelligence across all fields. This stage of AI is not expected to be fully developed for several decades[29].



Machine learning (ML) is the study of computer algorithms that improve automatically through experience and by the use of data. It is seen as a part of artificial intelligence. A traditional programmer would write computer code setting the rules needed to process data inputs to get an answer as output. In ML, the computer receives input data as well as the answers expected from the data, and the ML programme must then produce the rules itself. These rules can then be applied to new data to produce original answers. An ML-system is 'trained' rather than 'programmed'[30].

To date, the manufacturing sector is using AI in only a few ways, and AI is not yet considered to have come close to its full potential. The main applications of AI in the market are in ML. In robotics, these applications include[31]: **assembly** (AI combined with advanced vision systems to help with real-time remedying of errors in assembly); **packaging** (AI for quicker, lower-cost and more accurate packaging); **customer service (**AI natural-language-processing abilities to interact with customers); and **open-source robotics** (robotic systems sold as open-source systems with AI capability that enable users to teach their robots to carry out tasks based on their specific application).

[26] EU White Paper on Artificial Intelligence - A European approach to excellence and trust. Available at: Second quarterhttps://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf.
[27] IFC (2019, pp. 2-3). Artificial Intelligence: Investment trends and selected industry uses. 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.
[28] 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. Distributed, decentralized, and democratized artificial intelligence (2019). In: *Technological Forecasting & Social Change, 141*(April 2019), pp. 354-358.
[29] Note: other classifications and research found do not distinguish between AGI and ASI.
[30] JRC. Artificial Intelligence: A European Perspective (2018), available at: https://publications.jrc.ec.europa.eu/repository/bitstream/JRC113826/ai-flagship-report-online.pdf
[31] Robotics Industries Association. How artificial intelligence is used in today's robots (2018). Available at: https://www.robotics.org/blog-article.cfm/How-Artificial-Intelligence-is-Used-in-Today-s-Robots/117

One emerging market is the market for fully automated **self-driving robots**, also known as autonomous mobile robots (AMRs). AMRs can autonomously navigate in an uncontrolled environment by integrating sensors, 3D vision, and AI. They are often designed to interact and cooperate with humans. Due to the novelty of AMRs and the rapidly evolving market for these robots, there are no dependable figures on the market volume and adoption rate of self-driving robots. Despite this lack of data, analysts concur that the **annual growth rate of the self-driving robot market will remain high over the next 5 years, ranging between 12.9% and 21.5% per year**[32,33].

Another emerging market is driven by **ML applications in service robots for professional use**. The International Federation of Robotics estimates the combined value of the market for professional-service robots for the 2019-2021 period will be around EUR 34 billion[34]. Examples provided by the French Ministry of Agriculture include robots with ML capabilities to: (i) distinguish between crop plants and invasive plants (weeds); (ii) operate spray booms (so spraying stops in areas not contaminated by weeds); (iii) sort lettuces from foreign objects before bagging; (iv) sort general waste on a conveyor; and (v) follow an operator in a warehouse and 'learn' using smart sensors to memorise routes and obstacles while it transports loads.

Additional information on emerging technologies in the machinery sector is available in the *Impact assessment study on the revision of Directive 2006/42/EC on machinery*[35].

2. PROBLEM DEFINITION

2.1. What is/are the problems?

Problem 1: The MD does not sufficiently cover new risks originating from emerging technologies

The evaluation of the MD found that most stakeholders believe that the MD takes new innovations and technologies sufficiently into account either to a moderate or to a large extent. However, a number of stakeholders expressed their concern about: autonomous machines/systems, AI, collaborative robotics, mobile robotics, electrified machines, hybrid engines, smart appliances, wireless applications and cybersecurity. If accidents occur in these areas, trust in emerging technologies would be undermined. And unless the MD provides legal clarity about those technologies, existing gaps (as identified in the *Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics*[36]) could remove the level playing field for manufacturers. This would in turn impact the efficiency of the MD.

1. A first **source of potential risk is in human-robot collaboration**. Accidents at work related to industrial robots are not tracked at EU level. Some of these incidents may occur due to the robot malfunctioning, but others are due to human error, such as entering the fenced-off areas reserved for robots while the robots are operating. Industrial robots are designed to work autonomously, with safety ensured by isolation from human contact. However, co-bots are designed to work alongside human employees. Unlike industrial robots, co-bots are often lightweight and portable, which makes them ideal to use for multiple tasks within a factory. The safety of collaborative and autonomous robots may depend on: (i) designing them with lightweight construction materials and rounded edges; (ii) placing inherent limitations on their speed and force; or (iii) adding sensors and software to them to ensure their safe behaviour.

[32] Allied Market Research. Mobile Robotics Market - Global Opportunity Analysis and Industry Forecast, 2019-2026 ((2019)
[33] 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.
[34] International Federation of Robotics. World Robotics 2018 Service Robots report (2019).
[35] Impact assessment study on the revision of Directive 2006/42/EC on machinery. Available at: https://data.europa.eu/doi/10.2873/423938.
[36] Available at: https://ec.europa.eu/info/publications/commission-report-safety-and-liability-implications-ai-internet-things-and-robotics-0_en.

Annex 6 illustrates an example of a **collaborative robot** and its particularities, as well as the potential hazards of physical contact with co-bots.

A stakeholder consultation gathered some information on how to adapt the requirements for co-bots to better account for the risks of human-robot collaboration. Most stakeholders indicated that human-robot collaboration was not sufficiently covered by the MD. In particular, some authorities in charge of market surveillance for the MD considered that the MD's **Annex I requirements in Section 1.3.7. 'Risks related to moving parts'** could be problematic. For example, one of these requirements is 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'. Some authorities felt that these requirements **may not be sufficient in cases of human-robot coexistence in a shared space, or in cases where humans and robots are simultaneously working on something, or in cases where humans and robots are alternating in their work on something.**

Why did some stakeholders not consider that the current requirements sufficiently covered human-robot collaboration? Most industry associations and manufacturers cited concern over cybersecurity and the lack of physical separation between robots and humans. Notified bodies mostly said that the limits on force, speed, and energy in the current standards were not sufficient given the agility of interaction between humans and co-bots. Market-surveillance authorities also said that the current requirements did not sufficiently cover software traceability.

2. A second source of potential risk comes from connected machinery. Connected machinery may generate new risks such as: (i) a permanent loss of communication; (ii) intermittent connection; (iii) denial of service; or (iv) other situations when a sensor or camera capturing the physical world creates erroneous or still/frozen data. If data from the physical world (or the created and aggregated data) are incorrect or delayed, two problems are possible. Firstly, the analysis performed may not be correct depending on the extent of the delay. Secondly, the decision taken (such as stopping a machine to prevent overheating) may no longer be valid depending on the extent of the delay. The severity of safety issues due to incorrect control decisions taken based on erroneous sensorial data was highlighted by the analysis of accidents from the industrial-automation study conducted by the French Ministry of Ecology, Sustainable Development and Energy[37]. According to the study, sensor-related accidents were observed mostly in operations such as restarting, stopping and shutting down. Unlike standalone machinery, the safety of connected machinery requires consideration of all interactions between networked machinery assets. Malfunction accounted for more than 50% of accidents related to sensors, of which 66% were caused by human error, a lack of maintenance, insufficient connectivity or lack of cleaning.

Another cause for concern is the inclusion of communication devices to link the machine to the internet (IoT). This allows data on the machine's use and operation to be monitored or the machine to be started and controlled remotely. If an **unauthorised third party managed to upload code or software to a safety-critical piece of machinery**, this could have serious consequences for machinery users. For example, warning systems could be turned off or the functionality of the machinery could be changed to sabotage operations. For robotics, one study found that hackers could access co-bots, allowing them to stop safety programmes designed to protect the people working with the devices[38].

It is worth **distinguishing between cybersecurity, related to the network, and cyber safety, related to the machine**. It is also worth considering how and whether a machine enters into a 'safe mode' if it is subjected to a cyber attack. Although cybersecurity in broad terms does not

[37] 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.

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

fall under the scope of the MD, safety is well within its scope. For example, there is a **requirement in the current MD's** Annex I 1.2.1 on the 'Safety and reliability of control systems'. This requirement states that control systems 'must be designed and constructed in such a way that they can withstand the intended operating stresses and external influences'. An assessment should be made as to whether this requirement appropriately addresses cyber-safety risks. On this issue, several stakeholders and national authorities said it was unclear whether the notion of '**external influences' included cyber attacks.**

3. A third area of concern is the way **that software updates affect the 'behaviour' of the machinery after its placing on the market**. Nowadays, the functionality of a machine can be updated using standalone software. On modern machinery fleets, machines are designed in such a way that updates can be performed either on-site or remotely. This means that the resulting updated software is not embedded in the original product, but provided separately, sometimes by a third party different from the machine manufacturer. Such situations raise questions about the risks (and the management of these risks) emerging from **software updates that change the functionality and operation of machinery in unintended ways**. Some market-surveillance authorities that were consulted said they found it necessary to ensure: (i) that requirements are satisfied after the integration of independent software to any (standalone or networked) machinery. They also said it was necessary to ensure that software updates not considered in the initial manufacturer's risk assessment and that had an impact on safety should be considered as a substantial modification, thus requiring a new CE marking.

In addition, **software with a safety function that is placed independently on the market** is not considered a safety component under the current MD (see Annex V of the MD for an indicative list of the safety components). Most stakeholders consulted saw this as a gap in the current MD.

4. A fourth concern relates to the ability of original equipment manufacturers (OEMs) to conduct a **full risk assessment of ML applications before the product is placed on the market**. Chapter 1.4 of this report shows that narrow AI – and more specifically **ML applications** – are increasingly present in the machinery market. If the AI used for the machinery is set to learn and adapt as it is used, then its scope of operation could develop beyond what the designer took into account in their original risk assessment. With the development of collaborative robots that can move around and work closely with a person, these risks are much more difficult to control. These risks depend almost entirely on the safety of the AI programme running them, such as the quality of the computer's vision and image-recognition abilities.

In addition, some of the market-surveillance authorities interviewed said that the MD **lacks an explicit requirement for the manufacturer to provide test procedures/devices to maintain/adjust the relevant machinery**. Indeed, while there is such a requirement for automated machinery (see MD Annex I 1.6.1 'a connecting device for mounting diagnostic fault-finding equipment must be provided'), it is not clear whether the MD's wording sufficiently covers the specificities of the new generation of machines with learning capabilities.

Another key area is that of the 'control logic'. A control logic is a part of a computer programme that controls the operations of the programme. It can be highly complex, and is used to determine the learning process through which the machine uses the data sets to be trained on. **The current MD lacks requirements on control systems to prevent unsafe, unpredictable outcomes during the ML phase and during the use phase.** Combined with extensive and automated data collection, it can become very complicated to identify which data were used to reach certain decision outcomes, thus hindering the correction of faulty data or assumptions[39]. Some of the market-surveillance authorities consulted highlighted that **the current MD contains no**

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

obligations for source codes or programmed logics to be made available to the authorities, and that this does not facilitate the product-safety inspections.

5. Finally, there is the issue of **autonomous machines and remote supervisory stations**. The current MD assumes there is a driver or an operator responsible for the movement of a machine. The driver may be transported by the machinery or may accompany the machinery, or may guide the machinery by remote control. However, the MD does not consider the possibility that there might be no driver, and it sets **no requirements for autonomous machines**.

All the above problems may undermine the competitiveness of the machinery sector unless they are properly addressed. Legal uncertainty on the requirements that machinery with emerging theologies must comply would cause a distortion of competition in the market, with diligent manufacturers taking the necessary steps whereas other companies might take advance of this lack of precision in the legislation.

Problem 2: (i) Legal uncertainty due to a lack of clarity on the scope and definitions; and (ii) possible safety gaps in traditional technologies

The evaluation of the MD indicated the need for greater legal clarity in its scope and definitions. Both the scope and definitions generated some difficulties for manufacturers in understanding the correct legal framework they should apply.

In addition there are a number of requirements in the MD not related to emerging technologies that have been identified as either: (i) not clear or safe enough; or (ii) too prescriptive and potentially hindering innovation.

(i) Legal uncertainty due to a lack of clarity on the scope and definitions

- **The Low-Voltage Directive (LVD):** The evaluation of the MD indicated that the lack of clarity on scope was most common in the relationship between the LVD and the MD. Within the current MD, Article 1(2)(k) lists the categories of low-voltage electrical and electronic machinery that are excluded from the scope of the MD. As an example, one of the excluded categories is 'household appliances intended for domestic use', such as: refrigerators; freezers; ovens; dishwashers; washing machines and dryers; vacuum cleaners; irons; and toasters. These appliances thus fall under the LVD. A lack of consistency arises from the fact that these products are no longer excluded from the MD if they use radio equipment. If they contain radio equipment, these products shift from the LVD to the RED, which applies in addition to the MD. In 2018, the home-appliance industry in Europe generated EUR 53 billion turnover and comprised over 3 300 enterprises and more than 200 000 direct employees[40].

- **Exclusion of means of transport**: Tractors and other vehicles primarily intended for the transport of persons are excluded from the MD, since they fall under an ad-hoc EU type-approval legislation. Currently, the borderline is not clear enough, and allows that certain vehicles, such as multipurpose vehicles of the type All-Terrain Vehicles and Side-By-Side, can be considered as falling under the MD or under EU type-approval legislation, sometimes by the same manufacturer. In addition, recently proliferating light vehicles such as electrically power assisted cycles, hover boards or self-balancing scooters can be considered under the scope of the current MD, even if the MD is not meant and do not cover road circulation aspects. All this creates problematic distortions in the market.

- **Partly Completed Machinery (PCM):** As defined in Article 2 of the MD, PCM means an 'assembly which is almost machinery but which cannot in itself perform a specific

[40] https://www.applia-europe.eu/statistical-report-2018-2019/introduction/index.html

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'.

PCM is widely considered as a useful concept in the MD. The manufacturer of PCM determines with which health-and-safety requirements of Annex I of the MD it complies. According to the MD, the manufacturer only needs to specify in the declaration of incorporation those requirements that are actually relevant (in terms of the specified enabled applications of the machinery), and complied with. Buyers of such PCM thus often need to enter into specific private-law agreements to ensure the PCM's compliance with applicable requirements before purchase[41]. This incurs additional costs to solve any potential issues between supplier and customer in relation to PCM[42]. However, stakeholders have often stated that a clearer definition and/or further clarification would help buyers and sellers of PCM. Sometimes the definition is applied inconsistently by manufacturers, leading to incorrect classifications (e.g. products that are partly completed machines are defined as components) and/or to the incorrect CE marking of PCMs. This may generate safety issues or create an unlevel playing field in the market. Companies, particularly SMEs manufacturing or buying PCM, incur compliance expenses to obtain clarifications and legal certainty, by hiring external consultants or lawyers.

- **Substantial modification**: This problem relates to machinery that has undergone substantial changes. The *Guide to application of the Machinery Directive 2006/42/EC-Edition 2.2*[43] ('the Guide'), refers in paragraph 82 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 manufacturer's 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) and not foreseen or agreed by the manufacturer, the original manufacturer's CE marking becomes invalid and has to be renewed.

  The public consultation asked stakeholders about the potential issues resulting from substantially modifying machines. Just over a half (53.1%) of the stakeholders said they had modified their machines, of which 36.5% were companies. The large majority of respondents (78.3%) claimed they had not encountered any problems with the modification. Despite not encountering many problems, most of the respondents to the public consultation (61.2%) claimed that the MD should lay down the criteria for modifying machinery substantially. Otherwise, there a risk of different interpretations by market-surveillance authorities. This could potentially lead to uneven protection of safety across the EU and unequal terms for manufacturers, who may or may not be subject to costly conformity-assessment procedures, depending on the practices of the different national authorities[44].

(ii) Possible safety gaps in traditional technologies

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

[42] Assessment of the size of PCM market and number of companies affected was impossible due to lack of data. However, the problem was raised during the stakeholder consultations.

[43] Available at: https://ec.europa.eu/docsroom/documents/38022.

[44] Assessment of the size of the market for substantially modified machinery market was impossible due to lack of data. However, the problem was raised during the stakeholder consultations.

For a few types of machinery, a number of requirements have been identified as: (i) insufficient to ensure safety; or (ii) too prescriptive and potentially hindering innovation. These requirements are set out in the paragraphs below.

- **Installation of lifting appliances:** A lift under the Lifts Directive (LD) is considered to be placed on the market only after its installation, when it can be inspected and CE-marked. Lifting appliances under the MD (or so-called slow-speed lifts, the speed of which is not greater than 0.15 m/s) are often placed on the market and CE-marked by the manufacturer, and then installed by a third party following the manufacturer's instructions for installation. Issues have arisen in some Member States where installer and manufacturer consider the other party responsible for failures in installed lifts.

  The evaluation of the Lifts Directive in 2017 estimated the number of companies active in the lift market equal to 0.1% of all manufacturing-sector companies in the EU-28[45]. According to the European Lift & Lift Component Association, the estimated number of existing lifts in 2014 in the European Economic Area (EEA) was 5 361 896, although most of these fall under the scope of the LD rather than the MD[46].

- **Slow-speed lifts:** For slow-speed lifts, and the uncontrolled movement of objects in the carriers of slow-speed lifts, the MD states that 'the control devices for these movements must be of the hold-to-run type except where the carrier itself is completely enclosed'. Hold-to-run push buttons allow the platform to stop immediately once the button is released. Automatic controls may be used when the carriage is fully enclosed. Manufacturers claim this requirement limits innovative technologies such as light-barrier curtains. Also, some authorities consulted find it an anomaly that the MD, supposedly technologically neutral in its approach, prescribes a technical solution rather than a safety requirement.

  As indicated in the paragraph below, slow-speed lifts fall under the scope of the MD. In 2005, the EU stair-lift industry was estimated to have sold about 100 000 units (62 000 straight lifts and 38 000 curved lifts) and have turnover of EUR 188 million. The global market was also expected to grow. For example, the share of the US population owning a stair lift was expected to grow from 13% in 2005 to 19% in 2030[47].

- **Seating:** For 'ride-on' mobile machinery, such as excavators or agricultural sprayers, the current MD includes safety requirements for seating (Annex I 3.2.2.) that are seen as insufficient and hindering innovative solutions to prevent the risk of falling off. All stakeholder groups (national authorities, notified bodies, market-surveillance authorities, and workers' representatives), except for manufacturers agree that the health-and-safety requirements for seating should be revised and/or updated. According to these stakeholder groups, machines should be constructed in such a way as to prevent the worker from becoming unattached to the machinery. The current regulation in the MD requires a restraint system to be attached directly to the driver's seat, but this system is sometimes by-passed by users, thus increasing the risk of accidents. This requirement may also 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

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

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

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

(e.g. doors or door-bar systems). The EU market for mobile machinery is estimated to be worth EUR 90 billion in annual turnover[48].

- **Overhead power lines:** Overhead power lines have different heights in EU Member States. Accidents occur when vehicles or machinery make contact with overhead lines. If a vehicle or machine becomes 'live' by touching a power line then anyone touching the machine or vehicle is in mortal danger. Anyone in the cab of such a vehicle or machine may be in less danger, but they may still be threatened by the vehicle or machine catching fire. This may happen in a number of different scenarios, for example: (i) the equipment is tall enough to reach the line while driving along in its normal configuration; (ii) a trailer is tipped up, making contact with the line and rendering the entire vehicle 'live'; (iii) a hydraulic boom controlled from a cab makes contact with an overhead line, e.g. a crane lifting a load, etc. Because of the height of equipment used in agriculture, farmers and those using high agricultural equipment can be at risk if they hit an overhead line. In 2019, eight serious or fatal accidents were recorded in France resulting from contact between an agricultural machine and a live overhead power line. One of these accidents resulted in two deaths. The machines involved were irrigators, mobile elevating work platforms, trailers, grape harvesters, and combine harvesters[49]. In the former EU-28, the UK also reported several accidents of this nature. The French and other national authorities believe the requirements in the current MD to avoid or mitigate this risk are not sufficient. It was not possible to assess the more detailed market for other machinery which, because of its height, could potentially be impacted by this problem.

- **Protection against hazardous substances:** The current MD does not address the issue of protecting workers from exposure to hazardous substances. For example, many machines generate fine dust or metal micro parts, and these are considered very harmful to workers' lungs. Workers' associations and market-surveillance authorities believe it necessary to protect workers from hazardous substances, whereas consumer organisations and manufacturers do not find it necessary. According to workers' associations, the emissions of hazardous substances from machinery should be assessed and mitigated at design stage. On the other hand, manufacturers argue that the exposure of workers to hazardous substances is handled by Directive 89/391/EEC and is mainly the responsibility of the employer. Manufacturers also argue that they cannot address safety integration on their own in cases where employers often select machinery from multiple manufacturers for a final application. Consumer organisations agreed that there is other legislation in place that ensures workers' protection from hazardous substances[50].

- **Vibration from portable handheld and hand-guided machinery:** It is estimated that around 400 000 employees every year are exposed to vibrations from portable handheld and hand-guided machinery in Sweden[51]. An occupational injury caused by vibration can lead to painful and disabling conditions, which usually involve major limitations and inconveniences in everyday life for those affected. If the proportion of workers exposed to vibrations is the same in the rest of the EU, over 20 million workers in the EU could be exposed to vibrations from handheld and hand-guided machinery every year. The Swedish authorities, supported by other Member States, propose to ask manufacturers to better specify in the instructions for these kinds of machines the vibrations to which the hand-arm system is subjected, including continuous vibrations and the peak amplitude of the acceleration from repeated shock vibrations.

[48] Cost-benefit analysis study for impact assessment on road circulation of non road mobile machinery available at: https://op.europa.eu/en/publication-detail/-/publication/c0d598e2-17d8-11ea-8c1f-01aa75ed71a1/language-en.

[49] Machinery Working Group document:
WG-2020.35 - MD Revision_Accidents machines contact with OPL in France (agriculture) Year2019_February 2020_FR+EN.

[50] Assessment of the size of the market and number of companies affected was impossible due to the great variety of machines potentially involved and the lack of data availability.

[51] During at least 25% of an eight-hour working day. Machinery Working Group doc. WG-2020.46 - Swedish proposal on vibrations.

Problem 3: Insufficient provisions for high risk machines

The MD requires manufacturers to carry out a risk assessment for machinery they wish to place on the market. Manufacturers must determine which requirements are applicable, and therefore which measures must be taken to certify compliance. Compliance with the MD is primarily assessed through internal checks by the manufacturer and without the involvement of a third party. Nevertheless, there is an exception for a certain sub-category of machines: machines considered as presenting high risks that are listed in Annex IV. If these high-risk machines are not manufactured in full accordance with all relevant harmonised standards listed under the MD, or if there are no harmonised standards listed under the MD covering all applicable requirements for that machinery, then conformity through internal checks is not allowed, and a third party must be involved instead.

There is discussion about whether the **internal-checks option leads to safety concerns**. On this issue, the Rapid Alert System for Non-Food Dangerous Products (Safety Gate/RAPEX) has shown over the years that some of the products falling under Annex IV of the MD were identified as not being compliant with the requirements of the MD and the relevant European standards[52]. The products identified in Safety Gate/RAPEX include circular saws and vehicle lifts, which are part of Annex IV[53]. Some of these products were manufactured outside the EU.

Some market-surveillance authorities and notified bodies challenged the effectiveness of dealing with high-risk machines using a procedure that does not systematically impose a third-party conformity assessment. For these concerned stakeholders, third-party certification ensures higher quality and safer machinery, and minimises the need for surveillance authorities to intervene at later stages. However, since third partly involvement is costly, manufacturers of Annex IV machinery prefer to have the choice of involving or not a third party whenever they follow the relevant harmonised standards.

Another problem is that **the current list of high-risk machines in Annex IV was first drawn up 15 years ago**, and the market has developed greatly since then. Several market-surveillance authorities believe it is necessary to: (i) remove from Annex IV machines no longer considered high risk; and/or (ii) introduce new machines to Annex IV (such as machinery embedding AI systems which fulfil a safety function); and/or (iii) even re-arrange the high-risk machine list in categories of risks in a more efficient and comprehensive way. Disagreeing with this view, manufacturers of non-Annex IV machinery oppose any reclassification of their machines to the high-risk category, mainly due to the additional costs associated with third-party conformity procedures.

Problem 4: Monetary and environmental costs due to extensive paper-based documentation

Article 5 of the MD details the requirements for documentation. Before placing machinery on the market and/or putting it into service, manufacturers must:

- provide the necessary information, such as instructions;
- follow the appropriate procedures for assessing conformity in accordance with Article 12; draw up the EC declaration of conformity (DoC) in accordance with Annex II, part 1, Section A; and ensure that this declaration is included with the machinery; and
- ensure that the technical file referred to in Annex VII, part A is available.

Currently, the Guide clarifies that manufacturers must provide paper documentation for health-and-safety-related instructions and the conformity declaration. This is largely due to market

[52] It has not been possible to find out the percentage of non-compliant products, or the number of accidents caused.
[53] Non-compliant products in the high-risk machinery category reported in the Safety Gate/RAPEX system: since 2017, out of 138 machinery products in total, 43% belonged to Annex IV (37 brush cutters, 11 circular saws, 8 vehicle lifts and 4 log splitters).

characteristics during the early years of the MD's implementation, namely the lack of access to the internet and other digital formats. Thus, to ensure that every machine user had access to the instructions, providing a printed version was considered as the most viable option. Since then, however, the use of the internet and digital technologies has increased. Manufacturers state that the requirement to provide printed versions increases costs and administrative burden for economic operators and has a negative impact on the environment. On the other hand, some authorities and users (workers and consumer associations) have concerns about ending this requirement because of: (i) users that are less digitally savvy and that may prefer paper documentation; (ii) a lack of internet access in certain environments; and (iii) changes or updates to an online manual that might not match the version of an already purchased product.

The technical file and other information gathering foreseen in the MD other than the instructions and the DoC are already allowed in electronic formats.

Problem 5: Inconsistencies with other pieces of Union product-safety legislation

The new legislative framework (NLF) is a package of measures aimed at improving market surveillance and the quality of conformity assessments. It consists of Regulation (EC) 765/2008, Decision 768/2008 and Regulation (EC) 764/2008. A main objective of the Commission is to bring legislation on product-harmonisation in line with the reference provisions of Decision 768/2008/EC. While the MD is already a 'new approach' directive (as explained in Chapter 1 of this report), it is not yet aligned to the NLF.

One of the issues raised in the evaluation of the MD is the lack of appropriate enforcement. The evaluation also argued that aligning the MD to the NLF 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'[54].

In addition, the fact that the MD is not aligned to the NLF creates inconsistencies with other pieces of Union product legislation. For instance, there are differences:

- in the definitions of the economic operators and their obligations (including the conformity-assessment modules);
- in where the CE marking must be placed on the product;
- in the detailed information to be provided on the declaration of conformity (DoC)[55];
- in the format or layout required of the DoC and whether the DoC has to be provided along with the product or product documentation.

All this creates confusion for manufacturers and other economic operators whose products fall within the scope of more than one piece of product-safety legislation.

Contributors to the evaluation of the MD would like to see an alignment in the MD to ensure the coherence of its horizontal provisions. In particular they would like to see: (i) a harmonisation of the compliance documents (with the same DoC model and technical-file requirements as in other pieces of NLF legislation); (ii) the obligations of economic operators extended to importers and distributors; and (iii) enforcement of the requirements and conformity-assessment procedures in the wider EU legal framework and other NLF-aligned pieces of legislation.

In addition, the current MD presents a burdensome procedure for the management of the safeguard clauses, where the Commission needs always to intervene in the process, which is suboptimal. An alignment to the NLF would render the handling of safeguard clauses lighter and

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

[55] An EU declaration of conformity (DoC) is a mandatory document that a manufacturer must sign to declare that its products comply with the applicable EU law.

more efficient as the Commission will have to intervene only when a MS objects to the safeguard measure taken by another MS.

Currently, there are 23 pieces of product-safety legislation aligned to the NLF[56]. In the engineering and manufacturing sector, the MD is one of the few pieces of product-safety legislation not yet aligned to the NLF. Indeed, most of the product-safety legislation on machinery and equipment has already been aligned to the NLF, including the Low Voltage Directive, the Lifts Directive, the Radio Equipment Directive or the Pressure Equipment Directive. This means that all these pieces of legislation benefit from the following NLF improvements[57]:

- better coherence and consistency across the range of directives and regulations;
- improved market-surveillance rules to provide better protection for consumers and professionals from unsafe goods;
- a clarified notification process for conformity-assessment bodies;
- improved accreditation of conformity-assessment bodies;
- greater credibility and a clearer meaning for the CE mark;
- clarified obligations for importers and distributors where the manufacturer of the CE-marked product is based outside Europe.

Problem 6: Divergences in interpretation due to transposition

Differences in interpretation have arisen due to transposition. For instance there have been different definitions of PCM and 'safety component', and whether to consider software a safety component. Other differences occurred when one or several Member States consider that a product placed on the market does not comply with the essential health-and-safety requirements, although that product is available in many other Member States. This causes additional costs when the machine is traded in the single market, and thus poses an obstacle to the single market. These differences proved difficult to eliminate through many years of the MD's history. By preventing Member States' individual interpretation of the essential health-and-safety requirements, interpretation of technical solutions will also be prevented.

Furthermore, there have been delays in the transposition of the MD in some Member States[58].

A directive leaves Member States free to choose the means to comply with the legislative objectives. There have been cases in the past where, following to accidents, Member States have taken national measures, in theory on the basis of the MD but in praxis going beyond the MD.

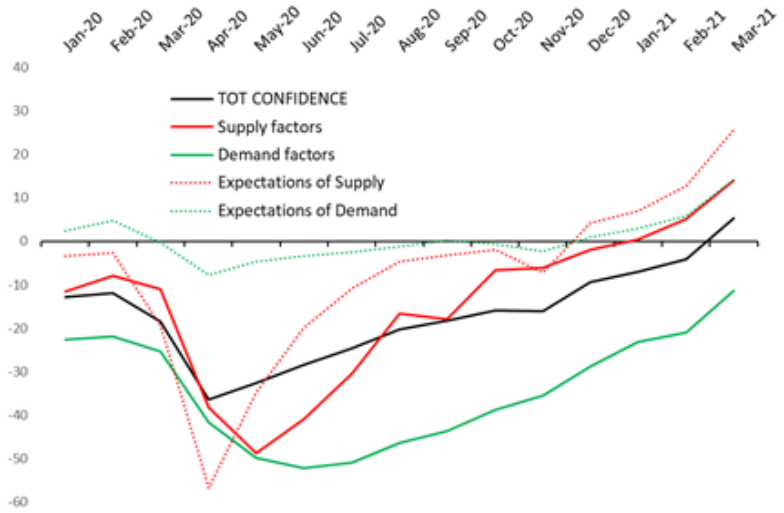
Impact of the COVID-19 pandemic on the machinery sector

The COVID-19 pandemic damaged the performance of the engineering industry, including the machinery sector. In the following graph, the main indicator for confidence in the machinery sector (C28) is calculated (black line) as a combination of recent supply and demand factors and expected supply and demand in the months ahead. This confirms the picture of a slow but steady recovery from COVID-19 during 2020:

[56] https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

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

[58] The Member State laws necessary to transpose and thus implement the MD were due to be passed 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. 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. Fifteen formal infringement procedures were opened against Member States for reasons other than 'non-communication' (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 (receipt of the letter of formal notice).



Source: GROW elaborations on data provided by the Joint Harmonised EU Programme of Business and Consumer Surveys.

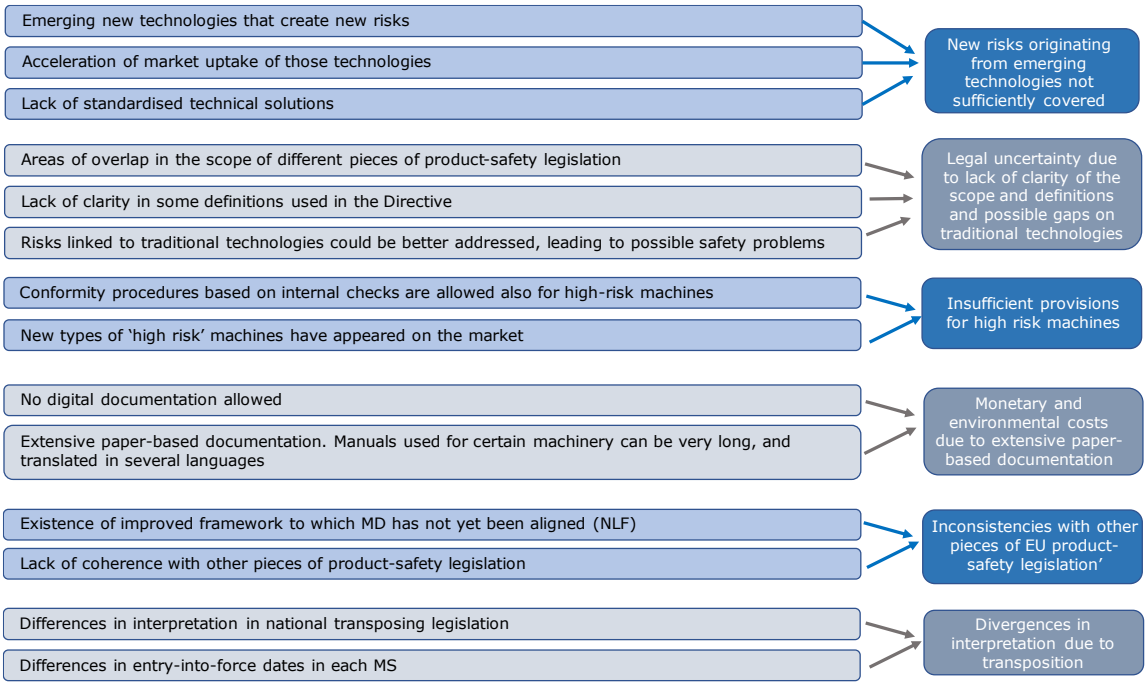
An analysis of the situation of this sector at the beginning of 2021 showed that:

- the biggest shock took place in April 2020 amid concerns about disruptions in the supply chain (supply factors went down, driven by very pessimistic expectations about supply);
- expectations of demand were stable throughout the year 2020 and until now;
- excessively weak demand is holding back recovery in this sector.

Just like the overall economy, this sector is suffering from the prolonged scarcity of aggregate demand, which is the lasting effect of the initial double shock (on both supply and demand).

2.2. What are the problem drivers?

The problem drivers were explained above together with the problems. A summary is presented below.



2.3. How will the problem evolve?

On the risks stemming from emerging technologies, the lack of appropriate requirements will likely lead to more non-compliant products coming onto the market, including imports from outside the EU. A lack of EU action would undermine user trust in machines that incorporate emerging technologies. Indeed, there is a danger that machines could be allowed onto the market that do not feature the necessary safety requirements. On the other hand, there is also a danger that manufacturers wanting to do the right thing might find their machinery development is hindered by the lack of legal clarity and guidance on what product types can or cannot be placed on the market. In this legal vacuum, Member States might decide to issue their own national rules. This could also create barriers in the single market, unfair competition, and a suboptimal level of safety.

On the lack of clarity in some areas of the MD, the room for different interpretations could generate additional costs and burden for manufacturers and market-surveillance authorities due to the need for clarifications. This could also disrupt the level playing field.

Without a reassessment of the concept of high-risk machines, high-risk machines could potentially be placed on the market without passing the appropriate conformity-assessment procedures, diminishing the level of safety for those types of machinery. The current list of high-risk machines, already outdated today, will become even more outdated with future market developments.

On documentation, unless digital documentation is allowed to a certain extent, the industry will keep incurring economic and environmental costs for the printing and handling of extensive documentation. This would mean the industry would lose the opportunity for greater digitalisation and fail to benefit from the advantages that digital formats can have for certain types of users and/or in certain environments (such as speed in finding information). Paper consumption will keep increasing unnecessarily, with the accompanying environmental damage and additional costs for industry that this brings.

On the lack of broader coherence with NLF legislation, the MD risks not taking advantage of the NLF's improved framework for market surveillance and therefore not benefiting from the related improvement in safety. Manufacturers might continue to be obliged to deal with different approaches in the various product-safety rules applying to their products. This burden would be even more difficult to bear for SMEs. Not taking action would also contradict the European Commission's commitment to aligning existing legislation to the NLF, where appropriate.

Finally, the current transpositions in the Member States have generated certain differences of interpretation that will create additional costs and burden. This is particularly true in cases where manufacturers and users are based in different EU countries.

Without further harmonisation of the market potentially brought by revising the MD, there is a risk that the opportunity to decrease the share of non-compliant products on the market might not be exploited. Moreover, not taking action would likely lead to Member States taking additional actions at national level (e.g. issuing additional requirements or providing clarifications of concepts that might differ from those of other Member States). This would further undermine the functioning of the single market and its level playing field. It could also potentially undermine the safety and health of machinery users and others exposed to machines.

3. WHY SHOULD THE EU ACT?

3.1. Legal basis

The MD is a 'total harmonisation' directive based on Article 114 TFEU (ex-Article 95 TEC) and follows the 'new approach' legislative technique. As explained in Chapter 1 of this report, under the 'new approach' principles, EU product legislation sets the 'essential health-and-safety requirements' (referred to in this report as 'safety requirements') which products must satisfy to benefit from the free movement of products across the internal market.

3.2. Subsidiarity: Necessity of EU action

This initiative addresses the issues identified in the evaluation of the MD, which was carried out as part of the Commission's regulatory fitness and performance (REFIT) programme. The evaluation concluded (see SWD (2018)160) that the MD is generally relevant, effective, efficient and coherent, and has EU added value, but that there was a need for specific improvements and simplification.

The machinery sector is a highly important part of the engineering industry and one of the industrial drivers of the EU's economy, exporting more than half its production. The MD is a key **driver of safety for machinery users** in the EU. The main objective of the MD is to ensure a high level of health-and-safety protection for these users, and to allow the free circulation of machinery in the EU. In particular, the MD helps to reduce social costs by preventing accidents that may be caused by the use of machinery. A key rationale for an EU-level machinery directive is to provide harmonisation across Member States based on Article 114 TFEU. Any changes to the scope or requirements of such a directive must be made at EU level to avoid distorting the market, creating barriers to the free movement of products, or undermining the protection of human health and well-being.

Proportionality of approach is ensured by the MD being technologically neutral (i.e. the MD lays down the safety requirements to be complied with, without prescribing any specific technical solution to comply with those requirements). It is also ensured by the Member States being responsible for the enforcement of the MD in their countries.

As explained in Chapter 1 of this report, the technical solutions to comply with the safety requirements set out in the MD are provided in European standards. These standards are developed by stakeholders, and the standards: (i) ensure interoperability and safety; (ii) reduce costs; and (iii) facilitate companies' integration into trade and the value chain. Further development of standards might pave the way to provide solutions to the problems outlined in Chapter 2. Given the widespread nature of these standardisation activities, any changes to the scope or requirements of the MD must be made at EU level to avoid: (i) distorting the market; (ii) creating barriers to the free movement of products; and (iii) undermining the protection of human health and well-being.

Without an EU-wide regulation, Member States could impose diverging safety requirements. This would lead to: (i) differences in the safety of products for users; (ii) inequalities in prices; and (iii) an increase in adaptation costs for manufacturers when trading machinery across different countries. For instance, some market-surveillance authorities consulted found it necessary to ensure that software updates not considered in the initial manufacturer's risk assessment and having an impact on safety would require the machine to go through a conformity-assessment procedure leading to a new CE marking. Unless these requirements are regulated in the revised MD, there is a risk of divergent Member State interpretations, with some imposing such procedures and others not.

A subsidiarity grid is provided in Annex 8 to this report.

3.3. Subsidiarity: Added value of EU action

A regulatory action at EU level would ensure coherent implementation of the safety requirements for machinery and thus a greater level of safety. It would also allow the free movement of machines within the EU. But all this would only happen if the regulatory action at EU level laid down EU-wide requirements for ensuring the health and safety of machinery users, and allowing market enforcement at the national level according to the NLF principles. Regulatory action of this sort would: (i) help develop the internal (and digital) single market; (ii) provide legal certainty and a level playing field for the industry; and (iii) build a high level of trust among machinery users.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives

There are two general policy objectives to be pursued when revising the MD to address the problems outlined above. These two general policy objectives are discussed in the paragraphs below and follow those of the original MD.

1. **General objective 1:** Keep ensuring a **high level of safety and protection** for users of machinery and other people exposed to it, **and build a high level of** trust in innovative digital technologies for consumers and users.

The EU has a competitive edge in world-leading industries such as manufacturing and robotics, producing more than a quarter of the world's industrial and professional-service robots. With the emergence of new digital technologies such as AI and the IoT, the EU must remain competitive in a transforming global market. Emerging digital technologies are increasingly gaining a foothold not only in consumer applications but also at commercial/industrial level, where they can bring new degrees of efficiency and productivity. With this general objective, the revision of the MD aims to ensure that the level of safety for traditional machinery is the same as that for machinery using emerging technologies which are being developed or will be developed in the future.

2. **General objective 2:** Keep ensuring the **good functioning of the single market, including the digital single market.** Create a **level playing field** for economic operators and preserve the **competitiveness** of the machinery sector in **global digital markets**.

This objective is natural to the MD as it is a 'total harmonisation' directive. The MD is based on Article 114 TFEU and on the 'new approach' that sets the safety requirements that products must satisfy to benefit from the free movement of products across the single market. The single market has brought benefits to businesses and the public through this free movement of products. Nevertheless, administrative obstacles and a lack of appropriate enforcement leave room for further improvement[59]. This second general objective for the revision of the MD is to implement uniform rules across the EU so that: (i) manufacturers and other economic operators exploit the full potential of the single market; and (ii) consumers and the public benefit from the same level of high safety protection across the EU.

4.2. Specific objectives

There are six specific objectives (SOs) for the revision of the MD, and they are set out in the paragraphs below.

- **SO1: Cover new risks related to emerging digital technologies**

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

The aim of this objective is to ensure that the MD covers any potential new risks stemming from emerging technologies used in machinery to improve product safety for users and others exposed to machinery. This will help build a high level of trust in innovative digital technologies among consumers and users. It will also improve the functioning of the single market and the digital single market by ensuring the free movement of machinery within the EU. A revised MD covering potential new risks will create a level playing field for economic operators and will preserve the competitiveness of the machinery sector in global digital markets. And addressing challenges stemming from the use of emerging technologies in machinery has another benefit: it can ensure the desired level of safety in both current market developments and future trends, making **the MD conducive to technological progress in digitalisation**.

- **SO2: Ensure coherent interpretation of the scope and definitions and improve safety for traditional technologies**

This specific objective aims at improving the legal clarity of some major concepts and definitions in the current text of the MD. This will: (i) guarantee that interpretations are consistent across the EU; and (ii) help create a level playing field for economic operators. It will also ensure the desired level of safety across the EU. Adapting certain definitions will help to reduce uncertainties in the implementation of the Directive, thus reducing cross-border trade barriers and compliance costs, among other benefits.

- **SO3: Reassess machines considered as 'high risk' and reassess related conformity procedures**

This specific objective relates in particular to the general objective of ensuring a high level of safety. It does so by reassessing the machines considered as high risk, and the conformity procedures that manufacturers of high-risk machines must follow.

- **SO4: Reduce paper-based requirements for documentation**

The aim of this objective is to ensure that the MD is as efficient as possible, minimising administrative burden where feasible. Revising the allowed format (from paper to digital) for manuals would entail **economic** benefits, such as savings on printing costs for manufacturers. It would also bring **environmental** benefits, such as reduced paper consumption and a decrease in carbon footprint.

- **SO5: Ensure coherence with other product-safety legislation**

Coherence with the wider EU legislative framework will improve enforcement of the legislation, thus leading to safety benefits. In addition, it will help economic operators to manage their activities more effectively and be more competitive in global markets. This improved coherence will provide further simplification, particularly for those machines that are covered by different NLF legislative acts. Together with the new mechanisms for enforcement and compliance provided for in the Commission's 'goods package'[60], a revised MD is expected to provide a clearer legal framework. Further simplification of the MD through its revision would decrease barriers to trade and cut the social costs of accidents by strengthening market-surveillance activities. It would also promote the removal of non-compliant machinery from the market.

- **SO6: Avoid divergences in interpretation derived from transposition**

This specific objective aims to reduce the shortcomings of different national transpositions of the MD in Member States, thus improving the legal clarity of the MD.

[60] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2017:787:FIN

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

Four policy options were considered. They are set out in the bullet points below.

- **Option 0 - Baseline**: The baseline scenario is 'no action'. This option would leave the standardisation process to develop as usual, without any particular focus on risks stemming from emerging technologies, and with no particular focus on areas for improvement related to traditional technologies. It would also include revision of the Guide following the ordinary process (discussions among stakeholders and decision taken only by consensus).

- **Option 1 - Self regulation by industry and changes to the Guide**: This option would make no changes to the current act. Instead, clarifications would be introduced in the Guide. The Commission would push for consensus on: (i) scope and definitions; (ii) reducing paper-based documentation; (iii) clarifications on existing high-risk machinery; (iv) better coherence with other pieces of NLF product-safety legislation; and (v) fewer divergences in interpretations in the various Member States. On this last point, this option would also involve setting up dedicated sessions of the Machinery Expert Group. New risks stemming from emerging technologies (as well as certain risks from traditional technologies) would be addressed by issuing a new Commission standardisation request, within the boundaries of the current legal text.

- **Option 2 - Burden minimisation:** This option would focus on clarifying the legal text and achieving simplification. To this end, this option would change the current MD to increase legal clarity in scope and definitions. It would also achieve simplification by: (i) allowing digital documentation in the legal text; (ii) aligning the MD to the NLF; and (iii) avoiding divergence in interpretations by converting the MD into a regulation. Changes to the current act would also include an empowerment to the Commission for reviewing in the future the list of high-risk machines under certain criteria. However, all this would be done without adaptations of the safety requirements for products, and thus with no changes in the manufacturers' obligations for designing and manufacturing the machinery. As a result, the following four annexes of the MD would remain unchanged: (i) Annex I: safety requirements; (ii) Annex IV: high-risk machinery; (iii) Annex V: indicative list of safety components; and (iv) Annex VII technical-file descriptions. The new risks stemming from emerging technologies (as well as certain risks from traditional technologies) would be addressed by issuing a dedicated Commission standardisation request, within the boundaries of the current legal text. This would be complemented by the issuance of a new Commission standardisation request, within the boundaries of the current safety requirements in legal text.

- **Option 3 - Burden minimisation and enhanced safety:** This option is the most ambitious and would strive for a better safety while taking advantage of all burden reduction possibilities. To this end, this option would change the current MD to increase legal clarity in scope and definitions. It would also achieve simplification by: (i) allowing digital documentation; (ii) aligning the MD to the NLF; and (iii) avoiding divergences in interpretations by converting the MD into a regulation. This option would also include an empowerment to the Commission for reviewing the current list of machines presenting high risks to new market developments in this area, remove the internal check option for the conformity assessment of the high risk machines, and make a first adaptation of the list of high risk machines. In addition, it would also adapt the safety requirements of Annex I with which manufacturers must comply when designing and manufacturing machinery, to address risks stemming from emerging technologies, as well as specific risks from traditional technologies. This would be complemented by the issuance of a new Commission standardisation request, taking into account any new and/or revised safety requirements in the legal text. Changes to the current act would also include: (i) a

limited update of the list of high-risk machines in Annex IV; (ii) making it possible to adopt a delegated act to further review the list in the future under certain criteria; and (iii) making mandatory the involvement of a third party in the conformity assessment for high-risk machines. Additional changes would be planned for Annex V: indicative list of safety components, and Annex VII: technical-file descriptions.

5.1. What is the baseline from which options are assessed?

Policy Option 0 is the current baseline scenario for the revision, against which the potential impacts of the policy options are measured. It consists in no EU action, meaning no change to the current regulatory framework. This option would include the usual standardisation process, without any particular focus on the gaps identified. It would also include the normal process of revision to the Guide, which requires consensus by all stakeholders and is therefore limited to minimum changes. This would lead to the continuation and consolidation of the shortcomings identified in the evaluation of the MD, and the effects of these shortcomings, as described in Chapter 2.3 of this report. The baseline option is not the current state but the state that would develop without any additional EU action.

5.2. Description of the policy options

Policy Options 0 to 3 address all specific objectives in ways that may gradually present higher compliance costs but that may also be more ambitious. These four options all tackle the problems to some extent. It could be said that they evolve from: (i) doing nothing (PO0); to (ii) purely 'soft law' (PO1); to (iii) a mix of 'soft law' and 'hard law' (PO2) that would revise the current act without changes to the obligations of manufacturers; to (iv) a 'hard law' option (PO3) that would revise the current act with some clarifications and additions of new obligations for manufacturers when designing and producing machinery. The 'hardest law' option (complete overhaul of the current act) was discarded from the beginning, as explained in Chapter 5.3.

Following this logic, each specific objective can be addressed from a 'softer' or a 'harder' approach. However, the extent to which these approaches meet the objectives may vary. The bullet points below set out different policy options that could be taken for each specific objective.

- SO1 – Cover new risks related to emerging digital technologies:
    - by the usual standardisation process (PO0);
    - by issuing a new Commission standardisation request (PO1, PO2);
    - by adapting the safety requirements in the MD, followed by a new Commission standardisation request (PO3).

- SO2 – Ensure coherent interpretation of the scope and definitions and improve safety for traditional technologies:*
    - by revising the Guide following the normal process (PO0);
    - by revising the Guide with a push for consensus (PO1);
    - by adapting the legal text (PO2, PO3).

` *Approaches for traditional technologies are the same as in SO1

- SO3 – Reassess machines considered as high risk and reassess related conformity-assessment procedures:
    - by revising the Guide following the normal process (PO0);
    - by revising the Guide with a push for consensus (PO1);
    - by adapting the legal text to allow a delegated act for reviewing in the future the list of high-risk machines under certain criteria (PO2);

- by updating the list of high-risk machines in Annex IV, allowing the adoption of a delegated act for future updates under certain criteria, and by making it mandatory to have third-party involvement in the conformity assessment (PO3).

- SO4 – Reduce paper-based requirements for documentation:
  - by revising the Guide following the normal process (PO0);
  - by revising the Guide with a push for consensus (PO1);
  - by adapting the legal text to allow digital documentation (PO2, PO3).

- SO5 – Ensure coherence with other product-safety legislation:
  - by revising the Guide following the normal process (PO0);
  - by revising the Guide with a push for consensus (PO1);
  - by adapting the legal text to align it to the NLF (PO2, PO3).

- SO6 – Avoid differences in interpretation derived from transposition:
  - by revising the Guide following the normal process (PO0);
  - by dedicated sessions of the Machinery Expert Group and the revision of the Guide with a push for consensus (PO1);
  - by adapting the legal text to convert it into a regulation (PO2, PO3).

The policy options are further explained in the following table:

Specific objectives (SOs)	PO0 – Baseline	PO1 – Self regulation by industry and changes to the Guide	PO2 – Burden minimisation	PO3 – Burden minimisation and improved safety
SO1 - Improve safety by covering new risks related to emerging digital technologies	**Standardisation as usual**	**Standardisation with focus on emerging technologies**		**Clarifications and targeted new provisions in Annex I safety requirements + standardisation**
Address risks derived from human-robot coexistence in a shared space with and without direct collaboration	Stakeholders tend to agree on narrower interpretations of the legal requirements. For this reason, whenever existing standards for different types of machinery are up for revision, such revised standards may or may not include the following areas depending on standardisers' interpretation of the MD's requirements on: • risks derived from human-robot coexistence • threats to cyber safety as external hazards • risks derived from ML capabilities.	A Commission standardisation request would be issued. However, stakeholders tend to agree on narrower interpretations of the legal requirements. Hence the extent to which actual improvements are required depends on how stakeholders involved in standardisation interpret the MD's current requirements on: • risks derived from human-robot coexistence • threats to cyber safety as external hazard • risks derived from ML capabilities.		Adapt Annex I requirements in the section on risks related to moving parts to specify that the prevention of risks of contact leading to hazardous situations must be also adapted to include human-robot coexistence.
Address machine cyber safety, i.e. the machine should be designed to go into 'safe mode' in the event of cyber attacks				Clarify that 'external hazards' include cyber threats and add requirements in Annex I sections 1.1.9 and 1.2.1. on protection against corruption and safety and reliability. Machinery certified under the Cybersecurity Act will be presumed to be in conformity with the revised MD in so far as those requirements are covered by the cybersecurity certificate or statement of conformity.
Address risks derived from ML capabilities and software updates potentially altering the behaviour of the machine				Clarify in Annex I that, for machines with ML capabilities, manufacturers must be able to plan out or at least frame in the initial risk assessment all potential future states of the machine. This will make it possible to ensure that safety is guaranteed at all times during the whole life cycle of the machine.
Explicitly cover software that has a safety function and is placed independently on the market	Bring for discussion a potential clarification in the Guide that: • 'logic units' include software • driverless machines are covered.	Push for consensus on clarifying in the Guide that: • 'logic units' include software • driverless machines are covered.		Software with a safety function that is placed independently on the market would be added to the list of safety components in Annex V.
Explicitly cover driverless machines (autonomous or remotely controlled)				To cover autonomous machines and remote supervisory stations, the definitions in Annex I are amended to consider the possibility of 'no driver'.

Specific objectives (SOs)	PO0 – Baseline	PO1 – Self regulation by industry and changes to the Guide	PO2 – Burden minimisation	PO3 – Burden minimisation and improved safety
SO2 – Ensure coherent interpretation of the scope and definitions and improve safety for traditional technologies	**Clarifications in the Guide following the normal process**	**Clarifications in the Guide with a push for consensus**	**Clarifying the legal text to provide legal certainty**	
Remove inconsistency in the exclusion of low-voltage products, specifically when such products are equipped with radio equipment	Bring for discussion a potential clarification in the Guide that: • in the same way that certain products are excluded from the MD and fall under LVD, equivalent products using radio equipment and falling under the RED would also be excluded; • there would be a potential enlargement in the exclusion of means of transport; • machines for which the specific applications are not activated until a piece of software is uploaded (e.g. non-pre-programmed robots) are not PCM; • new responsibilities when installing lifts are laid down; • the concept of substantial modification is defined.	Push for consensus on these topics in the Guide that: • in the same way that certain products are excluded from the MD and fall under LVD, equivalent products using radio equipment and falling under RED would also be excluded; • there would be a potential enlargement of the exclusion of means of transport; • machines for which the specific applications are not activated until a piece of software is uploaded (e.g. non-pre-programmed robots) are not PCM; • new responsibilities when installing lifts are laid down; • the concept of substantial modification is defined.	Make it explicit that in the same way that certain products are excluded from the MD and fall under the LVD, equivalent products using radio equipment that fall under the RED would also be excluded from the MD.	
Make more precise the exclusion of means of transport, currently limited only to means of transport by air, water and rail; and means of transport by road regulated in the EU type-approval legislation			Clarify in the legal text that means of transport whose only objective is the transport of goods or persons (e.g. light vehicles such as electric-power-assisted cycles, hover boards, self-balancing scooters and multipurpose vehicles such as all-terrain vehicles and side-by-sides) are out of scope, regardless of their speed limits.	
Harmonise interpretation of the concept of PCM			The legal text would clarify that those machines for which the specific applications are not activated until a piece of software is uploaded (e.g. non-pre-programmed robots) are not PCMs.	
Harmonise interpretation of responsibilities when installing lifts in some Member States			Clarify in the legal text that that where the machinery cannot be assembled on the manufacturer's premises, the appropriate measures must be taken at the place of use by the manufacturer 'or on the manufacturers' behalf'.	
Harmonise diverging approaches towards modifications of machinery during their use that are regarded as substantial, needing a new CE marking			Add the definition of 'substantial modification' in the legal text.	

Specific objectives (SOs)	PO0 – Baseline	PO1 – Self regulation by industry and changes to the Guide	PO 2 – Burden minimisation	PO3 – Burden minimisation and improved safety
SO2 – Ensure coherent interpretation of the scope and definitions and improve safety for traditional technologies	**Standardisation as usual**	**Standardisation with focus on identified gaps**		**Clarifications and targeted new provisions in Annex I safety requirements + standardisation**
Allow alternative innovative solutions to the hold-to-run control devices obligatory for not completely enclosed carriers on slow-speed lifts	Bring for discussion a clarification in the Guide that alternative solutions may be accepted if they provide an equivalent level of safety.	Push for consensus on a clarification in the Guide that alternative solutions may be accepted if they provide an equivalent level of safety.		Add the following to Annex I: if there is no risk to the people or the objects in the carrier of colliding or falling, and no other risks are added due to the upward and downward movements, then hold-to-run control devices may be replaced by other types authorising automatic stops at pre-selected positions.
Prevent serious or fatal accidents that happen when ride-on mobile machinery (e.g. ride-on lawn mowers) rolls or tips over (such as when cutting the grass on a hill) and the restraint systems are not attached by their operators	Stakeholders tend to agree on narrower interpretations of the legal requirements. Therefore, whenever existing standards for different types of machinery are up for revision, revised standards may or may not include the following areas depending on standardisers' interpretation of the MD's requirements on: • warnings for the driver when the restraint system is not activated; • avoiding overhead power lines; • protection against exposure of workers to hazardous substances; • vibration peaks.	A Commission standardisation request would be issued. However, stakeholders tend to agree on narrower interpretations of the legal requirements. Hence the extent to which actual improvements are required depends on how stakeholders involved in standardisation interpret the MD's current requirements on: • warnings for the driver when the restraint system is not activated; • avoiding overhead power lines; • protection against exposure of workers to hazardous substances; • vibration peaks.		Add the following to Annex I: if the restraint system must keep the people in their seats and/or in the protective structure, and if such a system is not active, some kind of warning to the driver should be activated. Standards will be revised to provide for technical solutions to fulfil this requirement.
Prevent serious or fatal accidents linked to mobile machinery hitting overhead power lines				Add a requirement in Annex I for mobile machinery to avoid overhead power lines.
Improve protection against exposure of workers to hazardous substances starting in the initial design phase of machinery				Add a requirement in Annex I to tackle chemical risks in Sections 1.7.4.2: Contents of the instructions; 2.2.1: Portable handheld and/or hand-guided machinery; and 3.5.3: Emissions of hazardous substances. This requirement to tackle chemical risks only applies when hazardous substances are part of the intended use of the machinery.
Prevent workers' sicknesses and medical costs due to exposure to vibration peaks when using portable machinery				Add a requirement in Annex I for portable handheld and hand-guided machinery in Annex I 2.2.1.1 Portable fixing and other impact machinery – General principles. The requirement is to ensure better measuring and declare values for vibration peaks.

Specific objectives (SOs)	PO0 – Baseline	PO1 – Self regulation by industry and changes to the Guide	PO2 – Burden minimisation	PO3 – Burden minimisation and improved safety
SO3 – Reassess machines considered as high risk and reassess related conformity-assessment procedures	**Clarifications in the Guide following the normal process. No changes to the conformity-assessment procedures**	**Clarifications in the Guide with a push for consensus. No changes to the conformity-assessment procedures**	**Revision of the legal text to allow the adoption of a delegated act for reviewing the list of high-risk machines under certain criteria. No changes to the conformity-assessment procedures**	**Revision of the legal text to allow the adoption of a delegated act for reviewing the list of high-risk machines under certain criteria. Removal of the conformity-assessment procedure based on internal-check options**
Clarify whether or not the concept of logic units includes all types of software including AI software. In addition, for types of machinery with a higher risk factor, a stricter certification procedure is desirable.	Bring for discussion in the regular process for revising the Guide whether item 21 in the list of high-risk machines ('logic units to ensure safety functions') includes software, and what types of software. This may be debatable. Changes to the Guide must be agreed by consensus. Changes are potentially reversible in future changes to the Guide (limited improvement of legal certainty). Conformity assessment of such software will require the involvement of a third party unless relevant harmonised standards exist and are applied by the manufacturer.	Push for consensus on revising the Guide, in particular to address whether item 21 in the list of high-risk machines ('logic units to ensure safety functions') includes software, and what types of software. Changes to the Guide must be agreed by consensus. Changes are potentially reversible in future changes of the Guide (limited improvement of legal certainty). Conformity assessment of such software will require the involvement of a third party unless relevant harmonised standards exist and are applied by the manufacturer.	The addition or removal of items from the list is not done immediately but later, once the Commission is empowered to amend the list. In the meantime, push for consensus on revising the Guide, in particular to address whether item 21 in the list of high-risk machines ('logic units to ensure safety functions') includes software, and what types of software.	Add two new items in Annex IV: 'software to ensure safety functions including AI systems' and 'machinery embedding AI systems ensuring safety functions'. The conformity assessment of such software will require the involvement of a third party in all cases due to the high-risk nature of the machinery included in Annex IV. In addition, for all other products in Annex IV, an obligation is set that a third party checks conformity.
Update the list of high-risk machines to keep up with market developments	Clarifications are discussed in the regular process for revising the Guide. However, categories cannot be added or removed.	Push for consensus on clarification in the Guide. However, categories cannot be added or removed.	The Commission will be empowered to amend the list, including by adding a new category of machinery or withdrawing an existing category of machinery, through delegated acts.	

Specific objectives (SOs)	PO0 – Baseline	PO1 – Self regulation by industry and changes to the Guide	PO2 – Burden minimisation	PO3 – Burden minimisation and improved safety
SO4 – Reduce paper-based requirements for documentation	**Allow (to a certain extent) instruction manuals in digital format, by amending the Guide following the normal process**	**Allow (to a certain extent) instruction manuals in digital format, by amending the Guide with a push for consensus**	**Allow (to a certain extent) instruction manuals in digital format, by amending the current act**	
Modernise the MD and minimise burden for manufacturers.	The current MD requires instructions to be included with the machinery, without determining the format of such instructions. The Guide further specifies that instructions must be on paper. Bring the possibility of digital instructions for discussion into the regular process for revising the Guide. Changes to the Guide must be agreed by consensus.	The current MD requires instructions to be included with the machinery, without determining the format of such instructions. The current version of the Guide specifies that instructions must be on paper. Push for consensus on revising the Guide as regards the documentation formats. Changes to the Guide must be agreed by consensus. Changes are potentially reversible in future changes to the Guide.	Allow in the legal text that instructions and declarations of conformity can be provided in a digital format. However, upon request at the time of the purchase of the machine, the instructions must be provided in paper format and free of charge. How to access the digital instructions must be marked on the machinery and in an accompanying paper, clearly stating which version of the instructions corresponds to the machinery model. The format provided must make it possible for the end-user to download the instructions and save them on his/her electronic device, if he/she needs access to the instructions during a breakdown of the machine.	

Specific objectives (SOs)	PO0 – Baseline	PO1 – Self regulation by industry and changes to the Guide	PO2 – Burden minimisation	PO3 – Burden minimisation and improved safety
SO5 – Ensure coherence with other product-safety legislation	**Clarifications in the Guide following the normal process**	**Clarifications in the Guide with a push for consensus**	**Align the current act with the NLF**	
In alignment with the NLF, include definitions and obligations of economic operators, which do not exist in the current MD (e.g. importer, distributor)	Bring the definitions of economic operators into discussions in the regular process for revising the Guide.	Push for consensus on adopting the complete definitions of economic operators in the Guide.	Add the NLF definitions/obligations on economic operators to the legal text.	
in alignment with the NLF, improve market-surveillance rules and streamline management of safeguard clauses	Bring the improvement of market-surveillance rules into discussions in the regular process for revising the Guide.	Push for consensus on improving market-surveillance rules in the Guide.	Aligning the MD to the NLF would bring the Information and Communication System for pan-European Market Surveillance (ICSMS) to the MD, enabling: (i) comprehensive exchange of information between all the market-surveillance bodies that is fast and works across borders; and (ii) streamlined management of safeguard clauses.	
SO6 – Avoid differences in interpretation derived from transposition	**Clarifications in the Guide following the normal process**	**Dedicated Machinery Expert Group sessions and clarifications in the Guide with a push for consensus**	**Convert current Directive into a Regulation**	
Due to the nature of a directive, Member States have a margin of flexibility in transposing it. This sometimes leads to a different interpretations of key concepts such as the definition of PCM. This in turn implies that some Member States will issue national standards to indicate how manufacturers must comply with the MD.	Bring the topic into discussion in the regular process for revising the Guide.	Discussion of this topic at dedicated Machinery Expert Group sessions. Push for consensus on revising the Guide on this topic.	Because regulations must be applied directly in Member States, this will prevent Member States from deviating from the legal text. This will in turn prevent the emergence of barriers to trade such as national standards.	

5.3. Options discarded at an early stage

Two other potential policy options or sub-options were discarded at an early stage. They are discussed in the two bullet points below.

- **A complete overhaul of the current act**, altering the current approach, which focusses on: safety requirements, no technical specifications, and technology neutrality. The evaluation of the MD, carried out as part of the Commission's regulatory fitness and performance (REFIT) programme, concluded that the MD was mostly fit for purpose. Large-scale revisions of the approach and requirements in the MD were seen as unnecessary. In addition, larger-scale revisions would lead to greater compliance costs for all stakeholder groups. The main expected costs would be one-off adaptation costs to deal with the changes. These costs would depend on the extent of the revision. A few manufacturers indicated in the public consultation that potential one-off costs could be up to 8% of annual turnover on average for major changes in requirements related to emerging technologies. Stakeholders involved in standardisation, and in CEN/Cenelec in particular, indicated that major changes to existing requirements would require checking the 800 harmonised standards that currently exist for machinery. This might slow down the process of revising and drafting new standards.

- **Repeal of the MD.** The evaluation of the MD also concluded that the MD is an essential driver for machinery safety in the market. All stakeholder groups agreed that the MD is generally relevant, effective, efficient and coherent. They also agreed that the MD has EU added value. In addition, repealing the MD would: (i) create a dramatic distortion of the single market for machinery; (ii) erect barriers to intra-EU trade; and (iii) undermine the competitiveness of the EU machinery industry both within the EU and globally. Most likely, Member States would create their own 27 national laws on machinery, since health-and-safety issues in machinery are too important to be left unregulated.

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

Economic, social and environmental impacts were considered in assessing the policy options. The analysis in this chapter focuses on these three options. It is quantitative whenever possible. Where it is not possible to be quantitative the analysis is qualitative. A brief summary of the three impacts are set out in the bullet points below.

Economic impacts (costs/benefits: one-off or recurrent, direct or indirect)

- For manufacturers:
  - savings (elimination of costs) due to improved legal clarity;
  - costs due to familiarisation with – and training on – the changes made to the Directive;
  - costs of conformity assessment (developing and updating technical files, internal testing activities, fees for notified bodies);
  - costs due to modifications to the design of the product;
  - savings of a share of the costs for printing, paper and shipping;
  - costs to develop and maintain the database for online manuals;
  - savings or costs due to innovation allowed or hindered;
  - improvement of industry competitiveness within the EU and globally.

- For national authorities:
    - costs due to familiarisation with – and training on – the changes made to the Directive;
    - time and burden to identify the correct digital manual and documentation;
    - savings (elimination of costs) for transposition.

- For notified bodies:
    - familiarisation with – and training on – the changes made to the MD.

- For standardisers:
    - additional work to review standards impacted by changes or draw up new standards.

- For users (workers and/or consumers):
    - potential increased costs of products if additional costs are moved down the value chain;
    - benefit of accessing innovative machinery in the market.

Social impacts

- For users (workers and/or consumers):
    - improved product safety;
    - access to products of the same level of safety on the market;
    - reduction in number of non-compliant products in the market;
    - advantages of e-manuals (e.g. non-paper instruction manuals, or manuals that can be better adapted for blind and partially sighted people) and disadvantages (e.g. lack of access to digital instructions in certain environments; changes or updates of the manual might not match version of a product).

- For national authorities
    - lower costs for the health system thanks to fewer accidents.

Environmental impacts

- For society:
    - saving of paper and a decrease in carbon footprint.

6.1. Policy Option 0 (PO0) – No change

This policy option is the baseline option. It entails no change to the current regulatory framework or to ways of working.

To address the risk stemming from emerging technologies, and possible gaps identified in traditional technologies, this option would rely on the usual standardisation process. It would not have any particular focus on the gaps identified. The European Standardisation Organisations (ESOs) would remain obliged to keep the registry of harmonised standards up to date. Currently, the ESOs propose standards for revision if they become obsolete, particularly whenever: (i) the state-of-the-art advances in a certain area; or (ii) a shortcoming is identified in a given standard (formal objection by a Member State[61] or other reason). Under this baseline option of Policy

61 When an EU Member State considers that a harmonised standard (see definition in Article 2(1)(c) of Regulation (EU) No 1025/2012) does not entirely satisfy the requirements which it aims to cover and which are set out in the relevant EU harmonisation legislation, it must inform the Commission thereof with a detailed explanation. This procedure is given in Article 11 of Regulation (EU) No 1025/2012. After such

Option 0, the proposed revisions could include any necessary updates covering emerging technologies applied to machinery such as: human-robot collaboration, AI, IoT and cybersecurity. The only condition is that stakeholders involved in standardisation (ESOs, industry, Member States, trade unions and consumer associations) must be of the view that the MD covers those areas. Indeed, stakeholders tend to agree on narrower interpretations of the legal requirements. This means that the standardisation process typically results in a compromise among stakeholders and provides the minimum level of quality necessary to comply with the requirements of the MD, without going beyond what the MD requires.

To give an example, the MD does not cover cybersecurity per se but only covers cybersecurity if it has an impact on safety. In Annex I, the MD stipulates that 'control systems must be designed and constructed in such a way that they can withstand the intended operating stresses and external influences'. Such 'external influences' may or may not be interpreted as including cyber attacks. If the interpretation of the standardisers is that cyber attacks are not included, then standards will not propose technical solutions to address them. However, if the legal text specifically states that external influences include cyber attacks, then only one interpretation is possible and standards will propose technical solutions so that the machine withstands such cyber attacks. Thus, Policy Option 0 addresses this problem, but only to a limited extent.

Policy Option 0 would follow the normal process of revising the Guide to: (i) ensure coherent interpretation of the scope and definitions; (ii) reassess high-risk machinery; (iii) reduce paper-based requirements for documentation; (iv) ensure coherence with other product-safety legislation; and (v) avoid differences in interpretation derived from transposition. However, Policy Option 0 has significant limitations in this area, for the following three reasons.

- It requires consensus from all stakeholders and is therefore generally limited to minimum changes. As an example, for many years the machinery community has debated the concept of substantial modification without reaching a consensus.
- Changes to the Guide are potentially reversible in future revisions, and this means that manufacturers face the risk of limited legal certainty.
- Changes to the Guide are limited to what the legal text allows. Changes cannot go beyond the legal text, otherwise they run the risk of being challenged in court.

This baseline option of Policy Option 0 is not the current state but the state that would develop without any additional EU action. This would lead to the continuation and consolidation of the shortcomings identified in the evaluation of the MD, and the effects of these shortcomings, as described in Chapter 2.3 of this report.

Under this baseline option of Policy Option 0, the problems identified will remain, and so will the costs derived from the existing lack of clarity. No significant impacts are expected. The vast majority of the respondents agreed that a revision of the MD is necessary, even if only a minor one. No stakeholder preferred this baseline option.

6.2. Policy Option 1 (PO1) – Self regulation by industry and changes to the Guide

- **PO1 – Specific objective (SO) 1: This option addresses new risks related to emerging digital technologies by self-regulation, and in particular, through standardisation activities.**

This policy option would include a new standardisation request issued by the Commission to the ESOs (CEN/Cenelec). The standardisation request would be focused on new standards covering emerging technologies applied to machinery such as: human-robot collaboration, AI, IoT and

objection, the Commission will, after consulting all EU members, adopt a decision which maintains, enables, restricts, or fully removes the references to the harmonised standards concerned in the Official Journal of the European Union (OJEU).

cybersecurity. The standardisation request would detail areas and deadlines for developing those standards.

Standards are developed by the ESOs. The industry, Member States, consumer associations and trade union representatives also participate in the development of standards. The Commission's role in the standardisation process consists of issuing standardisation requests to the ESOs. These standardisation requests detail the work areas, expected standards and delivery timeframes. When new standards (e.g. for a given type of machine) are proposed by ESOs to the Commission for publication in the OJEU, the Commission will publish those standards on condition that the standards address the relevant requirements of the legal act (Annex I of the MD) and the standardisation request. Only harmonised standards that are published in the OJEU provide presumption of conformity with the MD's relevant requirements.

The Commission has a validation role, but it does not have an active role in the drafting of standards. The Commission also does not have a voting right for approving new standards by the ESOs. In this respect, the Commission's lever for a correct standardisation process is making the legislation requirements (to which harmonised standards make reference) as clear as possible, so that they are not subject to different interpretations by standardisers when developing standards.

Harmonised standards provide the specifications and methods for testing the performance of a product for quality, safety or interoperability. For any machinery under the scope of the MD that is placed on the market according to a harmonised standard published in the OJEU, it is presumed that the machinery complies with the requirements of the European legislation, in this case the MD. Because 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, if manufacturers choose to use other appropriate technical solutions they must demonstrate the legal compliance of these solutions. 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: (i) innovation and technical development; and (ii) the placing on the market of new products for which a harmonised standard does not yet exist.

Industry associations, stakeholders working on standardisation, trade unions, and the European Economic and Social Committee (EESC) all agree that there is need for action on the way machinery safety is regulated. However, they would rather take action at the standardisation level. They consider that, because the MD is – and should stay – technologically neutral, no new safety requirements need to be added to the current act to cover emerging technologies. Policy Option 1 would take action only at the standardisation level, and thus would give time for emerging technologies to fully develop before further legal requirements are enacted. However, these groups that favoured only taking action at the standardisation level still found new safety requirements necessary in some areas. As an example, most of the stakeholders (56.8%) that participated in the public consultation (companies/business associations were the largest group that participated in the consultation) agreed that software that ensures a safety function and is placed independently on the market should explicitly be covered by the MD and therefore considered a safety component.

Member State authorities disagreed somewhat with industry associations, stakeholders working on standardisation, trade unions, and the EESC. This is because Member States believe that the MD must be the first area in which action is taken, and then the standards must follow. Member States argue that unless a requirement is specified in the legal act, it will not be properly developed in the standardisation process. Several market-surveillance authorities and consumer associations also believe that explicit provisions or adaptations to existing requirements are necessary to provide legal certainty for these emerging technologies that pose risks that were not considered when drafting the original requirements.

Although the MD is 'technology neutral' (which means that the wording in the requirements should not mention a specific technology) it must still ensure that the risks inherent to that technology are covered. In addition, harmonised European standards are drafted with the aim of providing presumption of conformity to certain requirements under EU acts. Therefore, it is the safety requirements included in those requirements (Annex I in the case of the MD) that drive the standardisation process. Moreover, many stakeholders with different perspectives and objectives are involved in this standardisation process (industry, consumers, public authorities, researchers and other interested parties). This means that the output of this process is often a compromise reached by those stakeholders that fulfils the strict minimum requirements laid down by the EU act without going beyond it. For this reason, the real 'lever' that product-safety legislators have to determine the necessary level of required safety are the requirements in the EU act themselves. Because this policy option would not involve any substantive changes to the MD itself, it would not address the 'gap' identified in the Commission *Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics*. This report stated that current product-safety legislation contains a number of gaps that need to be addressed, in particular in the MD.

[+/-] Costs and Benefits: PO1 meeting specific objective 1 presents no significant impacts on stakeholders, since it relies on the usual standardisation process. However potential costs may emerge due to the need for compliance with new standards. These costs would depend on the number and complexity of standards to be developed, and could not be quantified at this stage. However, it is worth noting that in case of absence of standards, there would be a cost of "not having a standard", since each company would need to develop its own.

- **PO1 – SOs 2, 3, 4 and 5: The Guide would bring some clarifications to the application of the MD on: (i) coherent interpretation of the scope and definitions; (ii) high-risk machines; (iii) digital documentation; and (iv) coherence with other pieces of NLF legislation.**

The Guide is an informative document published on the MD's Europa page in English only. It is a useful document, widely used by the machinery community, and quite extensive (450+ pages). Because the MD covers a wide range of machinery types, a significant amount of guidance is necessary. The Guide is regularly reviewed in concertation with all stakeholders involved. The current version was published in October 2019, and the previous version was published in July 2017.

Nevertheless, making clarifications in the Guide has its limitations. One limitation is that legal certainty will be limited, because it is a non-binding document that is regularly reviewed. Indeed, it should be stressed that only the MD and the texts implementing its provisions into national law are legally binding. Another limitation is that the Guide cannot go beyond what is written in the legal text. A further constraint is that the Guide is modified by consensus. This means that on many controversial issues it has not been possible to reach consensus, and it would take a very strong commitment by all interested parties to reach consensus on these issues.

On the coherent interpretation of the scope and definitions, the Guide could include clarifications on the scope and definitions. This could include clarifications as to what is or is not considered a substantial modification requiring a new CE marking. However, substantial modification has been discussed for years among machinery stakeholders, without ever reaching an agreement. It would therefore require a strong commitment from stakeholders to make progress in this area.

On the issue of high-risk machines, further clarification could be added to the Guide. The categories included or excluded in Annex IV could also be added to the Guide. As an example, Annex IV, Item 1 covers only 'circular saws for working with wood and analogous materials'. The Guide, in indent §388, states that 'Materials analogous to wood include, for example, chipboard, fibreboard, plywood (and also these materials when they are covered with plastic or

light alloy laminates/edges), cork, bone, rigid rubber or plastic. On the other hand, stone, concrete and similar materials requiring an abrasive type of cutting tool are not considered as materials analogous to wood'. This is an example of what can be clarified in the Guide. However, broader clarifications may be challenged by market-surveillance authorities if they go beyond what is written in the legal text. For instance, it would not be possible to use the Guide alone to add circular saws for working with stone and concrete to the list. Adding circular saws for working with stone and concrete to the list would require adapting the legal text.

On the issue of digital documentation, the Commission analysed whether the choice between digital and paper documentation might be product-related and not generalisable. However, the range of products covered by the MD is very wide, and it would be difficult to draw up and agree on criteria for allowing the use of e-manuals. One option could be to distinguish between consumer use and professional use and allow digital documentation for one of these uses but not the other. However, here again it would be difficult to determine what constitutes consumer use and what constitutes professional use. Therefore, one policy option would be to allow digital documentation for all machinery types. This policy option would specify in the Guide that the instruction manual and DoC[62] can be provided in digital form. It would state that the digital form must be such that a user can download the user manual to his/her own laptop, to ensure availability in environments where the internet may not always be available. However, the Guide would also specify that a free-of-charge paper copy must be provided in all cases if the customer asks for it at the time of purchase. Allowing e-manuals through a change in the Guide could be challenged in the future as not being in line with the legal text because it introduces the possibility of a lack of legal certainty.

Finally, to somewhat improve coherence with other NLF legislation, in this policy option, additional references to the 'Blue Guide' on the implementation of EU product rules[63] would be included in the Guide. Those references would have a limited effect, since real alignment would need to be done in the legal text.

On the gaps identified in the area of traditional technologies, the course of action and type and limited magnitude of the impacts are similar to those described for the emerging technologies in SO1. Since this policy option relies on the usual standardisation process also for traditional technologies, no significant impacts on stakeholders would be expected. However potential costs may emerge due to the need for compliance with new standards. These costs would depend on the number and complexity of standards to be developed, and could not be quantified at this stage. However, it is worth noting that in case of absence of standards, there would be a cost of "not having a standard", since each company would need to develop its own.

[+/-] Costs and Benefits: PO1 meeting specific objectives 2, 3 and 5 would have limited impacts on stakeholders. There would be additional costs for compliance with new standards on traditional technologies, and in relation to the likelihood that consensus is not reached for a change in the Guide. These costs could not be quantified. **PO1 meeting specific objective 4** brings an opportunity to **simplify** and **reduce net costs, mainly for manufacturers**. These benefits are quantified at the end of the PO1 section.

- **PO1 – SO6: On reducing possible divergences in interpretation derived from transposition, this policy option would: (i) identify inconsistencies with transposition of the current text through dedicated Machinery Expert Group sessions; and (ii) improve (to a certain extent) coherence in the Guide.**

The Machinery Working Group comprises: Member State authorities; the Commission; stakeholders from industry; standardisation bodies; notified bodies; consumer associations; and

[62] https://europa.eu/youreurope/business/product-requirements/compliance/technical-documentation-conformity/index_en.htm
[63] https://ec.europa.eu/growth/content/'blue-guide'-implementation-eu-product-rules-0_en

trade unions. It is used as a forum to the discuss problems in the practical application of the MD. The Machinery Working Group usually meets twice a year in Brussels. In 2021, this group will be converted into an expert group[64]. This policy option would identify inconsistencies with transpositions through a dedicated Machinery Expert Group workshop.

The Commission does not currently provide translations of the Guide into other EU languages, although a few Member States do translate the Guide into their language to benefit their own national machinery community. To better tackle specific objective 6, this policy option would see the Commission provide translations of the Guide into all the EU's languages. Overall, this policy option would make it possible to see if changes to the Guide are enough to solve the existing problems, before further legal requirements are enacted. However, making clarifications in the Guide has its limitations. One limitation is that legal certainty will be limited, because the Guide is a non-binding document that is regularly reviewed. Only the MD and the texts implementing its provisions into national law are legally binding. Another limitation is that the Guide cannot go beyond what is written in the legal text. And a further constraint is that the Guide is modified by consensus. This means that on a number controversial issues (e.g. substantial modification) it has not been possible to align positions so far, and it would take a very strong commitment by all interested parties to make it work.

[+/-] Costs and Benefits: PO1 meeting specific objective 6 presents no significant impacts on stakeholders. Cost savings from reducing clarification procedures between manufacturer and Member State authorities could be estimated at between EUR 100 and EUR 500 per instance. The number of instances could not be estimated. Some of these costs could be avoided if consensus is reached to make clarifications in the Guide.

Therefore, the biggest **cost and benefits of PO1** are linked to allowing some digital documentation by changing the Guide. This is the objective that this option is most likely to achieve, despite the legal uncertainty it would create by the prospect of possible future changes to the Guide. To estimate the potential additional costs and cost savings for stakeholders by switching to digital documentation, the following inputs have been assessed.

Machinery manuals can be very large, depending of the complexity of the machine. As an example, 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. Printing manuals imposes **costs** that include the **paper** itself, **storage**, **printing** and **postage**.

For manufacturers (an estimated 82 239 companies, of which 1 703 are large companies and 81 024 SMEs), **the net effect is clearly a benefit**.

[-] A change to the use of digital documentation could imply one-off costs for economic operators to purchase and set up a server, in addition to the recurring costs of maintaining this database and keeping the information on it up to date (A lower cost alternative would be renting server space, but for a more conservative estimate the purchase of a server has been considered). There are also other costs that might be added to provide other digital tools (e.g. CD-ROMs or USB sticks). On average, the purchasing costs of a server can be estimated at EUR 1 845[65] and the setup costs at EUR 115 per month server (EUR 1,960 per organisation). The costs of maintaining a server of maximum complexity are on average of EUR 272 per month (EUR 3,264 per year) for small businesses[66]. Costs for large manufacturers are likely to be lower. Some

[64] As per the Inter-Institutional Agreement on Better Regulation of 13 April 2016.
[65] Converted using European Commission's InforEuro, baseline 2019.
[66] Average cost for the purchase of a server of USD 2 000 (EUR 1 845) for small businesses. This average is taken for all equally, although costs for large manufacturers might be lower. Setup costs were indicated to be on average about USD 125 (EUR 115). Cost for maintenance of the data base are estimated at USD 295 (EUR 272) per month for systems with very high requirements. Cost estimates taken from https://www.servermania.com/kb/articles/how-much-does-a-server-cost-for-a-small-business/#Maintenance_Costs.

manufacturers or large companies might already possess a website including such a database due to their e-commerce activities. For these companies, the costs would be less than for other companies that would have to start from scratch. Within the machinery sector, 82% of manufacturers already use digital formats for documentation and/or manuals. Thus, the costs would apply to the remaining 18% in particular[67]. This would mean **one-off costs of EUR 1 960 and recurrent annual costs of EUR 3 264 per company,** which multiplied by 18% of the total number of companies (82 239) would lead to **one-off costs for the whole industry of EUR 29 million and recurrent annual costs of the whole industry of EUR 48 million across the EU-27.**

[+] Printing costs for user manuals have been estimated by different business associations and companies. Depending on the size of the manual and the number of products manufactured, printing costs were reported during consultations to account for 1-4% of companies' turnover per year. Taking into account the EUR 663 billion turnover in the machinery sector in 2017, this leads to an annual recurrent cost for the industry of between EUR 6.63 billion and EUR 26.5 billion. According to the answers to the public consultation, 62.7% of users would like to have the manuals only in digital form. This brings savings on printing costs for the industry to **between EUR 4 billion and EUR 16.6 billion** annual recurrent cost for the industry**,** which divided by the number of companies (82 239) would lead to **between EUR 48 000 and EUR 201 000 per company)**[68].

For **market-surveillance authorities** (71 or more) and notified bodies (137 or more) there would be:
[-] one-off costs for adaptation to change, which are not quantifiable;
[+] decreased storage costs for documentation, which are also not quantifiable.

For **users**, i.e. **workers** (of which there are an estimated 2 759 439) and **consumers** (of which there are an estimated 191 210 900), the benefits and costs would be as follows.
[-] Average EUR 0.4 of printing costs per manual[69](number of manuals not identified); a lack of internet access in certain environments; and changes or updates of the manual that might not match the version of a machine used by the user or worker.
Indeed, to estimate conservatively the costs and benefits, it should be considered an additional cost when users do not request the manual when purchasing the machinery, but decide to print it (or an extract of it) in one language subsequently.
[+] Some users might benefit from digital documentation (e.g. increased readability), but the number of such users is not quantifiable.

In addition, there are **environmental costs** associated with the paper documentation, ranging from sourcing through manufacturing to disposal. One key impact of printing is the use of primary material for papermaking: wood. Wood is critical for terrestrial carbon-dioxide storage. It must be considered that more than 40% of the industrial wood harvest is used for paper manufacturing, and that the paper industry is Europe's largest user of industrial-process water per tonne of end-product. The paper industry is also Europe's fourth-largest contributor to water pollution, and a lot of energy is needed to produce one sheet of paper[70].

[67] Results from consultations, n=22.
[68] EUR 4 billion (62.7% of 6.63 billion) and EUR 16.6 billion (62.7% of 26.5 billion). Divided by the number of companies (82 239) would lead to between EUR 48 000 and EUR 201 000 per company. (In the *Impact assessment study on the revision of Directive 2006/42/EC on machinery*, a more complex calculation method was used, based on the total number of machines sold, the average length of a machinery manual and the average costs per page. This method led to higher savings: EUR 129 billion across the industry (EUR 1.6 billion per organisation) in printing costs saved by switching to digital manuals and manuals printed on demand.)
[69] This cost is calculated from the total printing costs: average between 1% and 4% =2.5%, multiplied by turnover EUR 663 billion = EUR 26 520 000, divided then by 3.1 billion number of machinery units sold = EUR 8.5 per manual. The cost of printing one translation only is estimated by taking 1/23 of a manual based on the assumption that this manual contains all 23 EU languages. Therefore, supposing a user would only print his own language, costs of an individual printing would reach about EUR 0.4 per manual. No difference could be made on the number of manuals used by professional users in comparison to consumers.
[70] Smith, R., 'The Environmental Sustainability of Paper'. *Graduate Studies Journal of Organizational Dynamics*, (2011) Available at: https://repository.upenn.edu/cgi/viewcontent.cgi?article=1003&context=gsjod.

The table below shows the potential costs and cost savings for stakeholders from switching to digital documentation. The result of the switch would be a **net benefit for the most impacted stakeholder group, the manufacturers.** Nevertheless, the legal uncertainties of allowing digital documentation only through the Guide, without confirmation in the legal text, may lead to additional costs that could not be quantified. In fact, the Guide could be changed again to cancel the digital e-manuals in the future, thus eliminating the net benefit.

Potential costs and benefits of Policy Option 1

Stakeholder description		Companies			Administrations	Other organisations		Citizens/users	
Allowing digital documentation		**Large companies**	**SMEs**	**All**	**Market-surveillance authorities**	**Notified bodies**	**ESOs**	**People employed in the sector**	**Consumers**
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**	EUR 600 818[b] EUR 28 585 267[b] EUR 29 013 919[b] (These are the costs for setting up and creating a new website for e-manual downloads and complying with new standards) (not quantifiable)			Expected costs for adaptation to e-manuals (not quantifiable)	One-off costs for adapting to expected change (not quantifiable)	Compliance with new standards (not quantifiable)	-	
	Recurrent	EUR 1 000 547[e] EUR 47 603 220[e] EUR 48 317 057[e] (annually, for website maintenance) Costs due to limits and legal uncertainties related to the Guide not being binding, plus the risk of a lack of consensus to change the Guide (not quantifiable)			-	-	-	EUR 0.4[g] per manual if the user decides to print part of the manual (number of manuals not identified)	
2.2 Costs per organisation	**One-off**	EUR 1 960[c] (setting up and creating new website for downloading e-manuals)			-	-	-	-	
	Recurrent	EUR 3 264[d] (annually, for website maintenance) and costs due to legal uncertainties related to the Guide being not binding, plus the risk of a lack of consensus to change the Guide (not quantifiable)			-	-	-	-	-
3. Benefits	**Direct**	Between EUR 4 billion and EUR 16.6 billion (between EUR 48 000 and EUR 201 000 per company) savings on printing costs, excluding those who will keep using paper format			-	Some notified bodies might benefit from decreased storage costs for documentation (not quantifiable)	--	Some users might benefit from digital documentation e.g. because of increased readability, or because non-paper instruction manuals are better suited to the blind and partially sighted (not quantifiable)	
	Indirect	-	-	-	-	-	-	-	-

[a] Due to rounding differences in the Eurostat data, 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 the 18% of enterprises that do not yet use digital formats in the sector multiplied by the number of companies in the sector. These one-off costs are expected to be the same irrespective of the sub-option because servers would need to be purchased and set up in all sub-options.

[c] Based on an average of EUR 1 845 to purchase a server plus an average of EUR 115 to set up a server (EUR 1 960 per organisation).

[d] Based on an average of EUR 272 per month (EUR 3 264 per year) in costs to maintain 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 multiplied by the number of enterprises, large manufacturers, SMEs and the 18% of enterprises not yet using digital formats.

[f] Proxy used: number of households, Eurostat EU-27, 2016.

[g] Based on the estimation of costs of one manual at EUR 8.50 (Printing costs of one manual calculated by dividing the total printing costs (2.5% of turnover) by the total number of manuals (one per item of machinery at 3.1 billion machines). The cost of printing translations only was estimated by taking 1/23 of a manual based on the assumption that this manual contains all 23 EU languages. Respondents to the consultation expected only the translations to be printed, in which case the cost would only be EUR 0.4 for printing the relevant parts of their language per manual. No difference could be found in the number of manuals used by professional users compared to consumers.

6.3. Policy Option 2 (PO2) – Burden minimisation

- **PO2 – SO1: This policy option addresses new risks related to emerging digital technologies by adapting the current act to some extent (to make reference to the**

availability of source codes/programmed logics to authorities), although without making changes in the requirements. This adaptation to the current act would be complemented with the usual standardisation process.

As in PO1, PO2 would also include a new standardisation request issued by the Commission to the ESOs (for machinery CEN/Cenelec). This request would be focused on emerging technologies, detailing areas and deadlines for development of standards.

[+/-] The costs and benefits of PO2 meeting specific objective 1 consist of benefits for users thanks to a reduction in non-compliant products on the market. Potential costs may also emerge from the development of new standards as asked for in the new Commission standardisation request. These costs would depend on the number and complexity of standards to be developed, and could not be quantified at this stage.

- **PO2 – SO2: This policy option would adapt the current act on scope and definitions, such as the borderlines with LVD-RED, the exclusion of the means of transport, the PCM, the substantial modification, and the installation of lifting appliances, and also include any necessary further clarifications in the Guide.**

Article 1(2)(k) lists the categories of **low-voltage electrical and electronic machinery that are excluded from the scope of the MD**. These categories are: (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. Electrical machinery that is not in any of the categories listed in Article 1(2)(k) and that is not affected by one of the other exclusions falls in the scope of the MD, and the electrical risks are covered in Annex I 1.5.1 'Electricity supply'. When such machinery has an electrical supply within the voltage limits of the LVD (between 50 V and 1 000 V for alternating current or between 75 V and 1 500 V for direct current), it must fulfil the safety objectives of the LVD. As outlined in Chapter 2.1, the RED is not mentioned in this exclusion, which is not coherent. To tackle the inconsistency, this policy option would make it explicit that in the same way that certain products are excluded from the MD and fall under LVD, **equivalent products using radio equipment and falling under RED would also be excluded**.

The MD already excluded means of transport by air, water, rail networks, and means of transport by road regulated in the EU's type-approval legislation. By default, vehicles that were not regulated by that legislation were covered by the MD. Although a vehicle may fall under the definition of machinery, the purpose of the machinery legislation is to address the risks stemming from the machinery performing its function (such as excavator in a construction site), not the risks related to its circulation on the public roads. This option would make clear that the revised MD does not apply to means of transport, regardless of the speed limits, with the exception of machinery mounted on these means of transport. The means of transport includes all vehicles, the only objective of which is the transport of goods or persons. The following vehicles would therefore be excluded from the revised MD: (i) light vehicles, such as electrically power-assisted cycles, hover boards, or self-balancing scooters; and (ii) multipurpose vehicles such as all-terrain vehicles and side-by-sides.

As already mentioned, under Policy Option 2, the definition of **PCM** would be adapted to **exclude those machines** (e.g. non-pre-programmed robots) **for which the specific applications are not activated until a piece of software is uploaded**. In addition, the definition of PCM would also clarify that 'any device installed after the machinery on which it is assembled has been put into service is not deemed partly completed machinery'. This would make it possible to clearly distinguish between PCM and interchangeable equipment. The results from the public consultation show that most respondents (52.4%) support the changed definition of PCM and believe that further clarification would be beneficial. These respondents were not in favour of removing the concept of PCM from the MD. Removing this concept was expected to lead to

additional costs, including costs for: (i) negotiating the current PCM requirements for each delivery contract individually; (ii) filing these individual contracts and linking them to the technical file; (iii) court cases; and (iv) clarifications with market-surveillance authorities.

This policy option would add two things to the MD: (i) the concept of **'substantial modification'** as it exists in other NLF product-safety legislation; and (ii) the fact that a new CE marking is required for machinery substantially modified that is made available again on the market[71], unless it is meant for the manufacturer's own use. This addition would favour the **circular economy**, since substantially modified machinery could be put on the market again with a new CE marking.

To address the issues that arise where installer and manufacturer consider the other party responsible for failures in **installed lifts** which are intended to be **installed permanently**, a clarification would be added in Annex I. This clarification would specify that where the machinery cannot be assembled in the manufacturer's premises or in the premises of their authorised representative, the appropriate measures must be taken at the place of use by the manufacturer '**or on its behalf**'. For lifting machinery permanently installed in a building or a structure, the address where the machine is installed will be added in Annex II Declaration of Conformity.

[+/-] The costs and benefits of PO2 meeting specific objective 2 are mainly linked to: (i) the **addition of RED to the LVD exceptions in Article 1(2)(k); and (ii) the clarifications on the definition of PCM.** Clarifications in the MD allow the industry to save on guidance for interpretation or additional clarifications via commercial contracts. The table below shows the potential costs and benefits for stakeholders, although no quantification has been possible due to the lack of available data.

Costs and benefits of changing Article 1(2)(k)

Stakeholders' description		Companies			Administrations	Other organisations		Citizens/users	
ADAPTING THE LIST OF LOW-VOLTAGE PRODUCTS EXCLUDED		Large companies	SMEs	All	Market-surveillance authorities	Notified bodies	ESOs [b]	People employed in machinery sector	Users/ consumers
1. Number of affected stakeholders (EU-27)		360	17 645	18 005[a]	71 or more	137 or more	1	884 224[c]	191 210 900 [d]
2.1 Costs (total) / 2.2 Cost per organisation	One-off	Some costs for adapting to the changes are likely but these could not be reliably quantified			Some adaptation costs are likely but consultation participants expected these to be marginal	-	-	-	-
	Recurrent (annual)	Some recurrent costs expected by a few consultation participants but these recurrent costs could not be reliably quantified			-	-	-	-	-
Benefits	Direct	Some benefits are expected by a few consultation participants but these benefits could not be reliably quantified			Expected benefits from reducing legal uncertainty (not quantifiable)	-	-	Reduction of unsafe products (not quantifiable)	
	Indirect	-	-	-	-	-	-	-	-

[a] Based on Eurostat structural business statistics (EU-27) 2016, C28.23, C28.29, C28.95, C28.15.
[b] European standardisation organisations.
[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.

[71] In NLF legislation: (i) 'making available on the market' means any supply of machinery for distribution or use on the EU market in the course of a commercial activity, whether in return for payment or free of charge; and (ii) 'placing on the market' means the first making available of machinery on the EU market.

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, the cost cannot be reliably quantified. Proxy values are used when direct information is not available.

Potential costs and benefits of improving the definition of PCM

Stakeholders' description		Companies			Administrations	Other organisations		Citizens /users
CHANGING THE DEFINITION OF PARTLY COMPLETED MACHINERY		Large companies	SMEs	All	Market-surveillance authorities	Notified bodies	ESOs	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)/ 2.2 Costs per organisation	One-off	Costs for adapting to changes; these costs are not quantifiable but consultation participants expected them to be marginal			Costs for adapting to changes; these costs are not quantifiable but consultation participants expected them to be marginal	Costs for adapting to changes; these costs are not quantifiable but consultation participants expected them to be marginal	-	-
	Recurrent	No costs were identified			No costs were identified	No costs were identified	-	-
3. Benefits	Direct	Cost savings of roughly between EUR 5 000 and EUR 10 000 per instance [b)] (Number of instances was not identified)			Expected benefits include greater legal clarity (not quantifiable)	Some cost savings could stem from decreased efforts in solving problems of uncertainty (not quantifiable)	-	Cost savings of roughly between EUR 5 000 and EUR 10 000 per instance
	Indirect	-			-	-	-	-

[a)] Due to rounding differences in the Eurostat data, the total number of enterprises shown does not equal the sum of enterprises recorded per size class.
[b)] Based on consultation answers. An instance refers to one product being placed on the market by one manufacturer.
There are cases 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.

- **PO2 – SO3: Like in PO1, clarifications on the list of high-risk machines would be added to the Guide.**

This option includes the possibility for the Commission to be empowered to amend the list in the future, including by adding a new category of machinery or withdrawing an existing category of machinery, through delegated acts. In the meantime, as explained in PO1, clarification would include specifications as to what categories of machinery are included or not included, provided that enough consensus is found, and without going beyond what the legal text prescribes. New categories of machines could not be added or removed by a change in the Guide alone.

> The conformity assessment of such software will require the involvement of a third party in all cases due to the high-risk nature of the machinery included in Annex IV. In addition, for all other products in Annex IV, an obligation is set that a third party checks conformity.

[+/-] Costs and benefits: Like in PO1, **PO2 meeting specific objective 3 presents no significant impacts** to stakeholders.

- **PO2 – SO4: Like in PO1, this policy option would specify in the Guide that only 'safety' information must be included with the machinery in paper form; all other parts of the manual instructions can be provided in digital form (plus on paper and free of charge upon customer request).**

One of the results of the evaluation is that stakeholders, particularly the industry, thought it would be a good idea to include the option to provide documentation and user manuals in digital formats rather than on paper as is currently indicated in the Guide. This policy option would

require a change of the legal text in the MD, by specifying in the Annex I that the instruction can be provided either digitally or in paper, which would provide **legal certainty**, and would prevent this coming under question later on and being changed again in the Guide.

Under this policy option, the digital declaration of conformity (digital DoC) would be part of EU digital policy. Other pieces of EU product-safety legislation such as the Personal Protection Equipment Regulation[72] have already integrated this possibility of providing documentation in digital format. Furthermore, aligning the MD to the NLF would oblige Member States to implement the ICSMS, which offers fast and efficient communication for market-surveillance authorities to exchange information within a short space of time. The ICSMS allows information on non-compliant products (test results, product-identification data, photographs, economic-operator information, risk assessments, accident information, information on measures taken by surveillance authorities, etc.) to be quickly and efficiently shared between authorities. This means that Member States must already work with digital documentation on product compliance including the digital DoC.

[+/-] Costs and benefits: Like in PO1, **PO2 meeting specific objective 4** brings an opportunity for simplification and **net-cost reduction, mainly for manufacturers**. See table reported in PO1.

- **PO2 – SO5: By amending the legal text, this policy option would align the current act with the NLF.**

There are currently 23 pieces of product-safety legislation aligned to the NLF[73]. In the engineering and manufacturing sector, the MD is one of the few pieces of product-safety legislation not yet aligned to the NLF.

As mentioned previously, aligning the MD to the NLF would bring the following improvements[74].

i) It would improve coherence and consistency across the range of directives and regulations.
ii) It would improve market-surveillance rules to provide better protection for consumers and professionals from unsafe goods.
iii) It would clarify the notification process for conformity-assessment bodies.
iv) It would improve the accreditation of conformity-assessment bodies and improve the conformity-assessment procedures or modules.
v) It would clarify the meaning of the CE mark and increase its credibility.
vi) It would clarify the obligations of importers and distributors when the manufacturer of the CE-marked product is based outside Europe.

In other words, such an alignment would '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'[75]. Aligning the MD to the NLF would **bring the internet-supported ICSMS to the MD**. The ICSMS creates the basis for effective and efficient cooperation between market-surveillance bodies in Europe. Supported by the internet, the ICSMS enables the rapid, cross-border and comprehensive exchange of information between all the market-surveillance bodies. With this system, it is possible to implement efficient safety measures and consumer protection, and to ensure fair competition throughout the EU.

[72] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.
[73] https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en.
[74] 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.
[75] European Commission. Evaluation of the Machinery Directive, p. 105. (2018) Available at: https://op.europa.eu/en/publication-detail/-/publication/2b213537-25a8-11e8-ac73-01aa75ed71a1/language-en/format-PDF/source-68663524.

On the effectiveness of the MD, an **alignment to the NLF** would improve management of the safeguard clauses by using the ICSMS to involve all MS in the process before the Commission intervenes. Aligning the MD to the NLF and the 'goods package'[76] adopted by the Commission in 2018 will improve market surveillance and enforcement. It will also improve the conditions for accreditation of notified bodies and the monitoring of the performance of notified bodies because Decision No 768/2008/EC on a common framework for the marketing of products will apply.

There was **broad consensus** on the benefits of this alignment. Most respondents to the public consultation, across all stakeholder types, expressed support for this change.

Would you be in favour of aligning MD to the NLF?

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

Source: Public-consultation results (n=523)

Industry stakeholders said that, because manufacturers sometimes work under the rules of more than one piece of legislation, coherence would increase if all directives were aligned. Indeed, alignment is expected to ensure coherence of the horizontal provisions of the MD, especially in three areas: (i) compliance documents (there would be greater coherence as they would use the same DoC model and technical-file requirements as in other NLF legislation); (ii) the obligations of economic operators (greater coherence because these obligations would be extended to importers and distributors); (iii) and requirements and conformity-assessment procedures (greater coherence because these requirements and procedures would be aligned with the wider EU legal framework and other NLF-aligned pieces of legislation). This would result in significant simplification for the manufacturers.

National authorities considered that the alignment would lead to: (i) easier market surveillance; (ii) common rules among different products and (iii) more clarity in certain terms, transversal to several pieces of product-safety legislation, such as the concept of substantial modification. Similarly, notified bodies were of the view that the quality of the conformity assessment would increase through the alignment.

[+/-] Costs and benefits: PO2 meeting specific objective 5 would present benefits for all stakeholders, although quantification of these benefits was not possible due to the lack of available data. The table below shows the potential costs and benefits for stakeholders of aligning the MD to the NLF.

Costs and benefits of aligning the MD to the NLF

Stakeholders' description		Companies			Administrations	Citizens/users	
ALIGNMENT TO THE NLF		**Large companies**	**SMEs**	**All**	**Market-surveillance authorities**	**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) / 2.2 Costs per	**One-off**	Some adaptation costs likely, but consultation participants expected these costs to be marginal			Some adaptation costs likely but consultation participants expected	-	-

[76] See: (i) Regulation (EC) 765/2008 setting out the requirements for accreditation and the market surveillance of products; (ii) Decision 768/2008 on a common framework for the marketing of products, which includes reference provisions to be incorporated whenever product legislation is revised – in effect, Decision 768/2008 is a template for future product harmonisation legislation; and (iii) Regulation (EU) 2019/1020 on market surveillance and compliance of products (available at: https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en). In particular, the 'goods package': i) improves market surveillance rules to better protect both consumers and professionals from unsafe products, including those imported from outside the EU. In particular, this applies to procedures for products which can pose danger to health or the environment; ii) sets clear and transparent rules for the accreditation of conformity assessment bodies; iii) boosts the quality of and confidence in the conformity assessment of products through stronger and clearer rules on the requirements for the notification of conformity assessment bodies; iv) clarifies the meaning of CE marking and enhances its credibility; v) establishes a common legal framework for industrial products in the form of a toolbox of measures for use in future legislation. This includes definitions of terms commonly used in product legislation, and procedures to allow future sectorial legislation to become more consistent and easier to implement.

Stakeholders' description		Companies	Administrations	Citizens/users	
organisation			these costs to be marginal		
	Recurrent	-	-	-	-
3. Benefits	**Direct**	Benefits are expected through a harmonisation of 'new approach' directives under the same framework (not quantifiable)	Access to the 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 for professional products that accounted for 12% of the alerts registered in 2010-2019)	Harmonisation of market-surveillance procedures is expected to reduce the share of non-compliant products on the market (especially for consumer products that accounted for 88% of the alerts registered in 2010-2019)
	Indirect	-	-	Harmonisation 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 non-EU countries) Access to the ICSMS communication system for pan-European market surveillance will also be available to consumers (not quantifiable)	

[a] Due to rounding differences in the Eurostat data, 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.

- **PO2 – SO6: By amending the legal text, this policy option would convert the MD to a regulation.**

A directive leaves Member States to choose which means they will use to comply with the MD's legislative objectives. This has led to different interpretations of the MD's provisions, creating legal uncertainty and a lack of coherence throughout the single market. Furthermore, there have also been delays in the transposition of the MD in some Member States.

Converting the MD into a regulation will increase the uniformity of application. It will also reduce the scope for differences in interpretation, thus ensuring greater legal certainty and a level playing field for economic operators. Furthermore, it will synchronise the timing of the entry into force of regulations across the single market. Finally, costs from transposition will be avoided.

In addition, the MD is a 'total harmonisation' directive, which means that it requires a high level of safety, and does not allow the Member States to impose more restrictive obligations. In this respect, a regulation – by its legal nature – would better ensure that Member States do not impose national technical requirements that: (i) go beyond the safety requirements laid down in Annex I of the current Directive; and/or (ii) contradict those safety requirements. Therefore, the legal text fits best with a regulation approach rather than with a directive approach.

There was **broad consensus** across all stakeholder groups on the benefits of this conversion. A large majority of public-consultation respondents expressed support for this change.

Would you be in favour of having exactly the same rules on machinery safety applicable at the same time across the EU (converting the MD into a regulation)?

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

Source: Public-consultation results (n=523)

[+/-] Costs and benefits: PO2 meeting specific objective 6 would bring benefits to stakeholders. Manufacturers would save on administrative costs for clarifications on interpretation differences between Member States. These administrative costs are estimated to be

between EUR 100 and EUR 500 per instance[77] to write letters, print papers and resolve differences. Member States would also save administrative costs by not having to transpose the MD to national legislation. Differences in interpretation could be reduced by converting the MD into a regulation. The table below shows the potential costs and benefits for stakeholders.

Potential costs and benefits of converting the MD into a regulation

Stakeholders' description		Companies			Administrations	Other organisations	Citizens/users
CONVERTING THE MD INTO A REGULATION		**Large companies**	**SMEs**	**All**	**Market-surveillance authorities/Member States**	**Notified bodies**	**Users / consumers**
1. Number of affected stakeholders (EU-27)		**1 703**	**81 024**	**82 239**[a)]	**27 EU Member States to 71 market-surveillance authorities or more**	**137 or more**	**-**
2.1 Costs (total)	**One-off/ recurrent**	Some one-off adaptation costs are likely, but consultation participants expected these costs to be marginal. No expected recurrent costs.			Some adaptation costs are likely but consultation participants expected these costs to be marginal. No expected recurrent costs.	Some adaptation costs are likely but consultation participants expected these costs to be marginal. No expected recurrent costs.	-
3. Benefits-	**Direct**	EUR 100-500 per instance[b)] Cost savings in terms of clarification procedures between manufacturers and MSA authorities. Number of instances could not be estimated.			Benefits expected from avoiding transposition costs of the MD (not quantifiable)	Benefits expected through equal interpretation of the regulation across MS (not quantifiable)	Reduction of unsafe products
	Indirect	-	-	-	-	-	-

[a)] Due to rounding differences in the Eurostat data, the total number of enterprises shown does not equal the sum of enterprises recorded per size class.
[b)] Based on consultation answers. An instance refers to one product being placed in the market by one manufacturer.
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, the cost cannot be reliably quantified. Proxy values are used when direct information is not available.

[+/-] Costs and benefits: The overall effects on stakeholders of PO2 include: (i) a net benefit to manufacturers thanks to the switch to e-manuals; (ii) light adaptation costs due to the exclusion of **LVD products with embedded radio equipment** and the clarifications on **PCM**; and (iii) net benefits due to clarifications in the MD (thus allowing the industry to save on guidance for interpretation or the need for commercial contracts), the alignment to the **NLF**, and no longer needing any **transposition**. National authorities will also benefit from clarifications in the MD and avoiding transposition costs. Benefits for users and consumers derive from **fewer unsafe products**. The total costs and benefits for PO2 are summarised at the end of Chapter 6, in the table '**Comparison of impacts on stakeholder groups (costs/benefits)'**.

6.4. Policy Option 3 (PO3) – Burden minimisation and improved safety

- **PO3 – SO1: This policy option addresses new risks related to emerging digital technologies by adapting the current act, including the requirements with which manufacturers need to comply to place machinery on the market under the MD. In addition to the changes mentioned in PO2, it adapts the safety requirements in the legal text on: (i) standalone software with a safety function; (ii) human-robot interaction; (iii) ML test procedures and equipment; (iv) lack of connection or faulty connection; (v) cyber safety and external hazards; (vi) software updates; (vii) automated machines; and (viii) risk assessment. This adaptation to the current act would be complemented with the usual standardisation process.**

The machinery sector is developing rapidly, and potential risks to users might arise from machinery with new technology applications. For these reasons, Policy Option 3 – in addition to the changes mentioned in Policy Option 2 – also considers also some adaptation to existing requirements to address these concerns.

[77] An instance refers to one product being placed in the market by one manufacturer. The number of instances requiring clarifications could not be quantified.

The approach proposed in Policy Option 3 is coherent with the views of Member State authorities and other stakeholders active in implementation of the MD. The approach is also coherent with the on-going reflections at Commission level, which see advantages in combining horizontal legislation on crosscutting policy areas with more specific requirements that only sectoral legislation can accurately lay down for a given specific sector. As outlined in Chapter 1.4, the Commission *Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics*[78] reached two conclusions. The first conclusion was that **the emergence of new digital technologies like AI, the IoT and robotics raises new challenges in terms of product safety and liability such as: (i) connectivity; (ii) autonomy; (iii) data dependency; (iv) opacity; (v) the complexity of products and systems; (vi) software updates;** and (vii) more complex safety management and value chains. The report's second conclusion was that current product-safety legislation – including the MD – contains a number of **gaps that need to be addressed**. Addressing the concerns in the report, the changes planned for the MD will be coherent and will not affect the horizontal requirements to be laid down in a future AI regulation. This will help to avoid duplication and make the most of the advantages offered by the combination of horizontal and sectoral instruments.

The machinery sector is an important part of the engineering industry. It covers a broad range of products of different complexities. To ensure health and safety, and in particular the health and safety of workers and consumers (and where appropriate the health and safety of domestic animals and the safety of goods), machinery manufacturers must address the specific risks arising from the use of their machinery. For this purpose, the MD lays down the essential health-and-safety requirements of general application, e.g. lighting, ergonomics, operating positions, control systems, mechanical risks, hazardous substances, maintenance, and information. The MD also lays down a number of more specific requirements for certain categories of machinery e.g. foodstuff machinery, mobility machinery, and lifting machinery.

On AI, the future AI regulation will include safety requirements for high-risk applications. To assess the application of the AI regulation to products covered by the MD, it is important to consider the fact that machinery manufacturers must perform a risk assessment to ensure the safety of the machinery as a whole, including all parts of the machinery. This means that although AI developers will have to comply with the AI safety requirements, machinery manufacturers will have to assess the impact of AI systems on the safety of the whole machinery before it is placed on the market. Furthermore, the MD is 'technology neutral', which means that the risks stemming from emerging technologies must not be focused on one technology such as AI. Finally, the AI regulation will impose requirements only for high-risk applications. Considering the above criteria, the revised MD will refer to the AI regulation requirements: (i) when AI systems/components ensure safety functions; and (ii) for machinery containing AI systems with safety functions that are high-risk applications.

The impact assessment of the future AI regulation proposes the following approach[79].

***Regarding high-risk AI systems which are safety components of machinery**, the regulatory framework will integrate the enforcement of the new requirements into the revised MD so as to minimise additional burdens. This integration will take place following an appropriate transitional period before the new AI requirements become binding for operators under the revised MD. […] In particular:*

- ***Regarding high-risk AI systems covered by the revised MD**, existing NLF conformity assessment systems under the revised MD would be applicable for checking the compliance of the AI system with the new requirements. The application of the horizontal*

[78] Available at: https://ec.europa.eu/info/publications/commission-report-safety-and-liability-implications-ai-internet-things-and-robotics-0_en.
[79] Extract of impact assessment report on the AI regulation at the moment of finalisation of this impact assessment report on the revision of the MD. Where the original text mentions 'relevant NLF product legislation', this has been replaced by 'revised MD' to improve readability.

framework would not affect the logic, methodology or general structure of conformity assessment under the revised MD. [...] Obligations of economic operators and ex-post enforcement provisions (as described later in this text) of the horizontal framework will also apply to the extent they are not already covered under the revised MD.

To further clarify the interplay between the requirements of the revised MD and the AI regulation, the three paragraphs below discuss hypothetical cases where the two pieces of legislation could interact.

- When a standalone AI system fulfils a machinery-safety function, this standalone AI system is considered high-risk by both the revised MD and the AI regulation, and becomes a safety component under Annex V of the revised MD. The standalone AI must comply with the specific requirements of the AI regulation, and with any additional requirements under the MD necessary to ensure the standalone AI's proper integration in the machine for safe operation. The conformity assessment of the standalone AI system must be done under the revised MD.

- When an AI system embedded in the machinery fulfils a safety function, the machinery is considered high-risk by both the revised MD and the AI regulation, and belongs to the high-risk categories under Annex IV of the revised MD. The embedded AI system must comply with the specific requirements of the AI regulation, and the machinery must comply with any additional requirements under the revised MD necessary to ensure the AI system's proper integration in the machine for safe operation. The conformity assessment of the machinery containing the embedded AI system must be done under the revised MD.

- When a standalone piece of non-AI software fulfils a machinery-safety function, this standalone non-AI software does not fall under the scope of the AI regulation. The standalone non-AI software becomes a safety component under Annex V of the revised MD. In this case, only the revised MD applies.

Hence, Policy Option 3 best addresses the relationship with a future AI regulation, maximising legal clarity for manufacturers.

The following two paragraphs discuss the interplay between a revised MD and other directives.

General Product Safety Directive: On software with a safety function, the revision of the General Product Safety Directive intends to include software with a safety function under its scope. However, as explained in Section 1.2, the General Product Safety Directive does not apply when there are more specific provisions in harmonised, sectoral, product-safety legislation. As the MD will also cover software with a safety function addressing the specificities of the product, the safety requirements of the General Product Safety Directive will not apply.

Radio Equipment Directive: On cybersecurity requirements to secure connected products, delegated acts are being prepared under the RED to address data protection and privacy in some connected devices with Wi-Fi functions. These requirements will apply for machinery connected with Wi-Fi functions. For safety aspects, the revised MD will explicitly refer, in its essential health-and-safety requirements, to hazards caused by cyber attacks. This is to ensure the safety and reliability of machinery-control systems. The safety and reliability of machinery-control systems is discussed in more detail in this chapter, in the section on cyber safety.

Cybersecurity Act: In view of addressing the risks stemming from malicious third party actions that have an impact on the safety of machinery products, this policy option would include

essential health and safety requirements for which a presumption of conformity may be given to the appropriate extent by a certificate or statement of conformity issued under a relevant cybersecurity scheme adopted in accordance with Regulation (EU) 2019/881[80].

- In this policy option, **software with a safety function that is placed independently on the market would be added to the list of safety components** in Annex V.

Most stakeholders (56.8%) that participated in the public consultation agreed that software that ensures a safety function and is placed independently on the market should be explicitly covered by the MD and thus considered a safety component. Companies and business associations responding to the public consultation were mostly in favour of software to be considered a safety component. Considering software as a safety component would entail additional compliance costs for software companies specialising in safety, although this would be compensated by the increase in competitiveness that would come from being CE-marked under the MD. Because the AI software is used for wider purposes than just machinery, and software is transferable between domains, stakeholders consulted did not consider that these changes would: (i) result in consolidation of the software market; (ii) limit market access for smaller manufacturers; or (iii) lead the safety-software market to be absorbed by bigger manufacturers in AI.

Three case studies were carefully selected and conducted to provide practical, issue-based, and detailed insights on the implications and the developments related to emerging technologies in the machinery sector and the MD. Full details of these case studies can be found in the *Impact assessment study on the revision of Directive 2006/42/EC on machinery*[81]. A summary of these case studies is provided in Annex 7 of this report. In particular, the **second** case study confirmed the need for the addition of the above requirement on standalone software with a safety function.

- **On human-robot collaboration**, this option would adapt the requirements of Annex I in the section on risks related to moving parts. These adapted requirements would specify that preventing the risk of contact leading to hazardous situations must also be adapted to human-robot coexistence in shared spaces without direct collaboration and human-robot interaction (simultaneous or alternating work on a piece). Humans should always have control of the machinery. The detailed technical solutions to comply with this additional provision would be left to the standardisation process.

On the question of whether the existing requirements should be adapted or new requirements should be added to account for humans and robots in shared spaces, responses in the consultations were diverse between stakeholder groups.

Most manufacturers believed that the MD's existing requirements in combination with existing standards[82] already sufficiently cover robotic applications. The MD's current text states that the movable parts of machinery must be designed and constructed in such a way as to avoid any contact risks which may cause an accident. And the existing standards already lay down a range of security controls and measures (such as maximum permitted speeds, minimum separation levels, and the minimisation of sharp edges and projections) that reflect the state-of-the-art and the requirements of the MD. However, some manufacturers found that the MD's focus on blocking/stopping the machine as the main means of hazard prevention was insufficient. For co-bots, the objective is precisely to let humans and robot work together in a potentially dangerous environment. Technology can provide solutions here if the rules of the game are clear, so the requirements should be made clearer.

[80] Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (Text with EEA relevance), OJ L 151, 7.6.2019, pp. 15-69.
[81] Impact assessment study on the revision of Directive 2006/42/EC on machinery. Available at: https://data.europa.eu/doi/10.2873/423938.
[82] E.g. ISO 10218 and ISO/TS 15066.

Indeed, given **co-bots' higher degree of agility** and improved interactions with humans, both market-surveillance authorities and notified bodies found there is a lack of coverage of the protection objectives in the standards. For example, these standards do not refer to protection objectives in terms of force, speed, energy and interaction with people. The market-surveillance authorities and notified bodies believed that a clarification in the requirements was necessary. Generally, the groups in favour of adapting or adding new requirements were national authorities, consumer organisations, notified bodies, professional workers (including trade associations) and private users. Market-surveillance authorities found that, given the major developments in the field of robotics, the EU must make the necessary adjustments. For co-bots, revised safety requirement would trigger the revision/creation of standards which take into account the higher degree of agility in human/co-bot interactions mentioned above.

Among the **case studies** conducted and summarised in Annex 7 of this report, the **third** case study looked at the need to revise or add new requirements on human-robot collaboration.

- **On connectivity and cyber safety**, this option would adapt requirements in Annex I '1.2.1. Safety and reliability of control systems' to specify that the 'external influences' include **cyber threats**, and that, for cable-less control, a **failure of the connection or a faulty connection** must not lead to a hazardous situation. It will also add requirements in Annex I section 1.1.9 on **protection against corruption**. Machinery certified under the **Cybersecurity Act** will be presumed to be in conformity with the revised MD in so far as those requirements are covered by the cybersecurity certificate.

Connected machinery should be robust (the machinery should be able to withstand an attack) and resilient (capacity of the machinery to best react to an attack, preventing that the attack jeopardises the safety of the machinery). This means that when a machine receives signals from the outside world, it should be able to recognise and detect the authenticity of the input, and react to the input in a safe way. For example, air conditioning equipment should not be able to freeze an environment following a mischievous input.

Stakeholders were consulted to obtain information on the issue of cybersecurity and the MD. All stakeholder groups recognised a growing risk of malicious interference or hacking. On the question of whether the risk of cyber threats was sufficiently covered in the current MD, most consultation respondents indicated that it was not. A workshop on this issue was run by the German Commission for Occupational Health and Safety and Standardisation (KAN). The workshop concluded, after extensive discussions, that the MD covers cyber attacks (see Annex I, 1.2.1 'external influences', 'fault'). However, the fact that it took a long debate among experts with different views to reach this conclusion proves that the MD lacks clarity. Since this is a clarification of an already existing understanding of what is covered by the provision, no significant impacts are expected for manufacturers or market-surveillance authorities. However, clarification will ensure a level playing field in the market, for the benefit of manufacturers.

- On **ML capabilities and software updates potentially altering the safety of the machine after it is placed on the market/put into service**, Policy Option 3 would clarify that for the machine to be allowed on the market, it must be technically feasible to foresee in the initial **risk assessment** all potential risks arising during the whole life cycle of the machine.

This means the manufacturer must be able to appropriately anticipate or somehow limit the potential consequences derived from ML capabilities during the machine's whole life cycle. The manufacturer must also be able to do this for those machines that may change because of ML capabilities so they could place the machine on the market under the revised MD. Although this could be seen as hampering innovation, in reality it would guide innovation in the right direction so it is not detrimental to safety. Indeed, ML software can be safely tested in the research phases. There is also typically a learning phase, which should be done under the supervision of the

manufacturer whenever the ML affects the safety of the machinery. The MD applies only for the placing on the market of the machinery (hence after the research and testing phase has been completed), and at that moment the manufacturer must have taken all necessary precautions to ensure that the machine will not subsequently develop in a way that could harm users.

Similarly, a software update that may alter the behaviour of the machinery in a way that affects the compliance of the machinery would require a new conformity assessment. In this instance, the concept of substantial modification would come into play. However, standard updates that do not change the behaviour of the machinery would not require a new conformity assessment.

This clarification should not bring additional cost to manufacturers. However, it would bring benefits for users in the form of there being less non-compliant machinery on the market.

Among the case studies conducted and summarised in Annex 7 of this report, the **first case study** discusses the need for the addition of the above requirement on software updates to be included in the initial risk assessment for machinery with ML capabilities.

- On **autonomous machines** and remote supervisory stations, this option would amend the definition of 'driver' to consider the possibility of 'no driver'.

The proposed addition of a 'no driver' possibility will make it easier for new autonomous and remotely controlled machines to be put on the market in a compliant way. This clarification is therefore an enabler, but it does not add any specific costs to manufacturers. Technical solutions would be detailed in the relevant standards. As a result, some standards might need to be developed or revised following this change, or manufacturers might need to develop their own technical solutions and prove they are safe. A French manufacturer of autonomous robots for agricultural applications stated that their company was unable to place their product on the market, because they did not know how to make it compliant. This was because there were no dedicated requirements and standards for autonomous robots. As a result, the manufacturer was limiting themselves to supplying only a few prototype units.

The potential costs and benefits of covering new risks related to emerging digital technologies by adapting the safety requirements depend on the level of changes adopted. According to the experts consulted, the greater the changes, the higher the costs for industry in: design and manufacturing of the machinery; training for technical files; documentation; etc. However, because the MD is 'technology neutral', the changes to the requirements would mainly consist of: (i) adaptations to add legal clarity in certain areas; and (ii) certain targeted additions. In addition, documentation costs could be mitigated by: (i) keeping the numbering of the safety requirements in Annex I as close to the current version as possible; and (ii) providing a transposition table between the numbering of the revised requirement and the original, as was provided for in the last revision of the MD.

Most of the changes will only add legal clarity. A change in the wording for better legal clarity would impose some adaptation costs on manufacturers, although the experts expected these costs to be low. For these changes that add legal clarity, diligent manufacturers who perform complete risk assessments will not need to incur additional costs, other than the costs of familiarising themselves with a new legal text. Besides, ensuring legal certainty for emerging technologies in the MD will be more important due to the expected increase in use of those emerging technologies in the machinery sector, and the corresponding improvement in industry competitiveness. In addition, authorities will benefit from greater legal clarity when performing their market-surveillance activities, and users will benefit from greater safety in the market. It

would also result in some costs for revising related standards borne by CEN/Cenelec to ensure that the list of harmonised standards is up to date and fits the revised requirements[83].

There would also be a few targeted new safety requirements. For those, certain design, manufacturing and documentation costs will be incurred by manufacturers. In such cases the standard revision work borne by CEN/Cenelec will be more important, but only limited to the standards related to the affected machinery. The effects on (i) an improvement in industry competitiveness for manufacturers of such types of machinery and (ii) a greater safety in the market for users will also apply.

The new requirements and clarifications in the existing safety requirements set out in this policy option would be complemented by the usual standardisation process. Some harmonised standards exist today to cover some of these areas[84], but others must be developed. The Commission would issue a standardisation request to the ESOs (CEN/Cenelec in this case) to formally require the revision and drafting of any necessary new harmonised standards. These harmonised standards would detail the state-of-the-art technical solutions that ensure compliance with the MD. Priority should be given to carrying out this work at international level (ISO/IEC) to support the competitiveness of the EU industry.

There may be exceptional cases where: (i) no harmonised standards exist; and (ii) the Commission has asked one or more ESOs to draft a harmonised standard. In these exceptional cases, if there are undue delays in the standardisation procedure or if the request has not been accepted by any ESOs, the revised MD would **empower the Commission to adopt implementing acts laying down technical specifications** that meet the safety requirements of this regulation. However, this would only be a fall-back option.

[+/-] The **costs and benefits of PO3 meeting specific objective 1** are linked to standalone software with a safety function being added to the list of safety components. They are also linked to adaptation costs for: (i) revising the text on human-robot interaction; (ii) revised ML test procedures and equipment; (iii) addressing a lack of connection or a faulty connection; (iv) addressing cyber safety and external hazards; (v) software updates; (vi) addressing the issue of automated machines; and (vi) risk assessment. The table below shows the potential costs and benefits for stakeholders.

Potential cost and benefits of Policy Option 3 meeting specific objective 1

Stakeholders' description		Companies			Administrations	Other organisations		Citizens/users	
Net effect (+) NV not quantifiable		**Large companies**	**SMEs**	**All**	**Market-surveillance authorities**	**Notified bodies**	**ESOs[g)]**	**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**	One-off compliance costs and costs for adaptation to changes are likely			-	-	Review of up to 800	-	Not quantifiable,

[83] Harmonised standards have an annex where it is explained what requirements of the directive they fulfil. If the text of a requirement is redrafted to increase clarity, but the numbering and the scope/content stay the same, the related standard(s) do not need to be revised. If the text of a requirement is redrafted to impose a new obligation, harmonised standards that provide presumption of conformity to that requirement need to be potentially revised, but only those. Finally, if a new requirement is added, existing harmonised standards for machinery which is affected by the new requirement will need to be revised, but only those.

[84] EN ISO 10218-1:2011 Robots and robotic devices — Safety requirements for industrial robots — Part 1: Robots (ISO 10218-1:2011); EN ISO 10218-2:2011 Robots and robotic devices — Safety requirements for industrial robots — Part 2: Robot systems and integration (ISO 10218-2:2011); EN ISO 13482:2014 Robots and robotic devices — Safety requirements for personal care robots (ISO 13482:2014); EN 50636-2-107:2015 Safety of household and similar appliances — Part 2-107: Particular requirements for robotic battery-powered electrical lawnmowers (IEC 60335-2-107:2012 Modified) EN 50636-2-107:2015/A1:2018; EN ISO 18497:2018 Agricultural machinery and tractors - Safety of highly automated agricultural machines - Principles for design (ISO 18497:2018).

Stakeholders' description		Companies			Administrations	Other organisations		Citizens/users	
Net effect (+) NV not quantifiable		**Large companies**	**SMEs**	**All**	**Market-surveillance authorities**	**Notified bodies**	**ESOs[g)]**	**People employed in machinery sector**	**Users / consumers**
		(these include changes to: human-robot interaction; lack of connections or faulty connections; cyber safety and external hazards; software updates; automated machines; and risk assessment)[c)] (not quantifiable)					standards; no further quantification of efforts was possible [c)]		costs of changes could be pushed down the value chain
	Recurrent (annually)	-			-	-	-	-	-
2.2 Costs per organisation	**One-off**	One-off compliance costs and costs for adaptation to changes are likely (these include changes to: human-robot interaction; lack of connections or faulty connections; cyber safety and external hazards; software updates; automated machines; and risk assessment) (not quantifiable)			-	-	-	-	-
	Recurrent (annually)	-			-	-	-	-	-
3. Benefits	**Direct**	-			-	-	-	-	-
	Indirect[f)]	Increased competitiveness in and outside the EU; level playing field			Greater safety	-	-	Less non-compliant machinery on the market; greater safety	

[a)] Due to rounding differences in the Eurostat data, 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 time needed for larger revisions of the essential health-and-safety requirements. The revisions would entail an evaluation of the existing portfolio of harmonised standards and their applicability. Revised essential health-and-safety requirements could require adaptations.
[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 if all 137 notified bodies in the NANDO database used 10 FTEs.
[e)] Based on up to 1% of turnover for compliance costs for additional products covered by the Directive.
[f)] Some benefits might materialise quicker than others. For instance, benefits from legal clarity and digital documentation are likely to materialise quicker than benefits from changes in the requirements. Due to the differences in products covered in the MD and the proposed changes, the life cycles of machinery could not be taken as a proxy to estimate the potential timeline for benefits.
[g)] European standardisation organisations.
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.

- **PO3 – SO2: This policy option would adapt (i) the current act in scope and definitions such as the borderlines with LVD-RED, the exclusion of means of transport, the PCM, the substantial modification, and the installation of lifting appliances, and (ii) safety requirements on areas not related to emerging technologies, such as requirements for slow-speed lifts, for ride-on machinery on seating and avoidance of overhead power lines, for machinery dealing with hazardous substances, and hand-held machinery producing vibrations potentially harmful for workers. This would be complemented by any necessary clarifications in the Guide.**

In addition to the changes mentioned in PO2, PO3 would include the following **change to safety requirements not related to new digital technologies.**

- This option would add to '1.1.2. Principles of safety integration' an obligation for manufacturers to provide **test procedures and specific test equipment**, only when they are essential to enable the machinery to be adjusted, maintained and used safely. This does not include ordinary test equipment.

Although providing test procedures and specific test equipment may initially seem like an additional burden for manufacturers, it is not particularly burdensome. This is because diligent manufacturers already provide this equipment when it is necessary to adjust, maintain, and safely use machinery. Additional costs for those diligent manufacturers are therefore negligible. Manufacturers who do not already provide specific test procedures and equipment will have to bear a cost. This will improve the level playing field. However, some adaptation costs or additional training may be necessary for market-surveillance authorities.

- On lifting appliances, a clarification would be made for only those **lifting appliances intended to be permanently installed**. For these appliances, it would be clarified that the appropriate measures for correct installation must be taken at the place of use by the manufacturer **or on his behalf**, so that the manufacturer is responsible for the installation in all cases.

To estimate the potential number of affected companies, NACE C33.2 'installation of industrial machinery and equipment' was used. In 2018 in the EU-27, around 40 000 companies were registered, although this number includes not only lifting appliances, but also other industrial machinery and equipment that must be installed. No further quantification of the impact was possible.

- On **slow-speed lifts**, the obligation for **hold-to-run** control devices for carriers that are not completely enclosed would be **rephrased to make it technologically neutral** and allow other innovative solutions. Given the trends in the area of slow-speed lifts and the expected growth in their use, including among private users, it is essential to allow innovative solutions to enable products to be more efficient, safe and accessible to consumers. It is therefore crucial that the MD does not hinder such innovation and remains 'technology neutral' while ensuring safety. This change would not generate additional costs for manufacturers, since they could still use the current prescribed hold-to-run solution. However, it would be possible to innovate and propose other solutions with at least the same level of safety.

EU statistics on the manufacture of lifting and handling equipment[85] () provide information on the volume and value of lifting machinery sold in Europe. In 2018, 13 million of these units were sold at EU level. This accounted for about EUR 51 billion in revenues. However, not all these pieces of lifting and handling equipment fall under the MD. Based on Article 24 of the MD, slow-speed lifts are only included in the MD when the maximum speed does not exceed 0.15 m/s, otherwise the lifts fall under the scope of the Lifts Directive.

Based on PRODCOM data from 2014, the number of companies active in the lift market was equal to 0.1% of all manufacturing-sector companies in the EU-28. The estimated number of existing lifts in 2014 in the EEA was 5.4 million. In terms of market development, the overall turnover from the sales of new lifts and components was about EUR 5 billion in Europe in 2014, 3% lower than in 2013. However, it is likely 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. However in 2005, the EU stair-lift industry was estimated to sell about 100 000 units every year (62 000 straight lifts and 38 000 curved lifts) and be worth EUR 188 million in annual sales.

- To better protect machinery drivers, requirements for **restraint systems** would be clarified for **ride-on mobile machinery**. These clarified requirements would focus on cases where there was a risk that operators or other persons transported by the machinery might be crushed between parts of the machinery and the ground if the machinery rolled or tipped over. The clarified requirements would specify that for such cases: (i) machinery must be designed or equipped with a restraint system so as to **keep the**

[85] Eurostat PRODCOM code 28.22

persons in their seats and/or in the protective structure[86]; (ii) if such a system is not active, some kind of **warning** to the driver should be activated (visual, audible or other).

According to national authorities, notified bodies, and workers' representatives, machines should be constructed in such a way as to prevent the worker from becoming unattached. The current regulation prescribes the need for a restraint system attached directly to the driver's seat, and this restraint system is sometimes by-passed by users. Such a requirement may also 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.

Some manufacturers mentioned that, depending on the type of mobile machinery, product-type specific harmonised standards are a very good tool for adding this or similar requirements, when these features become common for this type/these types of machinery. Indeed, the proposed revised requirement on restraint systems for ride-on machinery would leave the ESOs to draw up the detailed technical solutions to comply with it. This would ensure that innovation could continue. Additional costs for this option are predicted only for manufacturers of ride-on mobile machinery, while the benefit would be an increase in safety for users.

- A requirement would be added in Annex I to reduce the risk of mobile machinery contacting **overhead power lines**.

According to the national authorities interviewed, the risk of contact with overhead power lines should be addressed in the MD's requirements. If a manufacturer sells a product across all Member States, differences between Member States – such as the height of power lines – must be taken into account during the design stage. This requirement would apply mainly to agricultural mobile machinery, but also to: (i) machines used in construction such as excavators or diggers; or (ii) other machinery such as self-propelled cranes or grabs. The main sector impacted by this change would be the agricultural machinery sector, in particular manufacturers of high machines. According to CEMA, the association representing the European agricultural machinery industry, the sector comprises about 7 000 manufacturers, producing more than 450 different types of machines (covering any activity in the field from seeding to harvesting) with an annual turnover of about EUR 40 billion (figures for the EU-28 for 2016) and 150 000 direct employees[87]. No further impact quantification was possible.

- A requirement would be added in Annex I to tackle **chemical risks** in: 1.7.4.2 'Contents of the instructions'; 2.2.1 'Portable handheld and/or hand-guided machinery'; and 3.5.3 'Emissions of hazardous substances'.

Stakeholders were asked whether the MD should address the protection of workers against exposure to hazardous substances starting in the initial design phase (through principles of safety integration). The stakeholders made the distinction between: (i) levels of **exposure** to hazardous substances, handled by Directive 89/391/EEC[88] and by means of personal protective equipment and other actions, and mainly the employer's responsibility; and (ii) the **emissions** of hazardous substances that can be addressed by the design of the machinery. If hazardous substances are a result of the intended use of the machinery (for example, where fine dust or metal micro parts are generated, both of which are considered very harmful for lungs), this is already a mandatory part of the risk analysis performed by the manufacturer. However, the revised MD would make clearer that, for those kind of machines, emissions should be assessed during risk assessment and should be mitigated by design.

[86] A protective structure can be a cabin or any other structure from which the driver should not be expelled in order to safeguard his/her own safety.
[87] https://www.cema-agri.org
[88] 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, pp. 1-8.

- A requirement for portable handheld and hand-guided machinery would be added in Annex I 2.2.1.1 'Portable fixing and other impact machinery – General principles, for better measuring and declaring **vibration peaks values'**.

The MD currently requires that manufacturers declare the vibration values in the instruction manuals of portable handheld and hand-guided machinery only when certain vibration limits are exceeded. Sweden, supported by other national authorities, proposes: (i) to remove those limits, so that that manufacturers declare the vibration values in all cases; and (ii) to add a requirement for manufacturers to declare in the instructions the machinery's peak vibration values, since repeatedly high peak values can be very harmful. A cost and benefit analysis was provided in the Swedish proposal[89] to the Machinery Working Group. The analysis estimated that, for declaring the mean peak value from repeated shock vibrations, manufacturers of handheld machines could expect a moderate increase in initial costs due to new measurement methods (e.g. new instrumentation and a slightly expanded test report). And for removing the limit for total continuous vibrations, there are no expected increased costs. Manufacturers today must already perform measurements to establish whether their machines exceed limits for total continuous vibrations or not. Therefore the costs or time needed for these more comprehensive measurements should not significantly increase the total cost for vibration measurements. Costs for users include the need for new handheld tools with better vibration dampening and a reduced vibration level. However, handheld tools have a limited lifetime and typically need to be replaced regularly. The benefits include **reduced social costs** for sick leave, fewer occupational injuries, fewer medical examinations, and less early retirement. These benefits would all be due to reduced vibration peaks in handheld machines, and have an estimated value of **EUR 15 million yearly**[90]. Low-vibration handheld and hand-guided machinery has a longer life span, and the tool accessories also last longer. This reduces costs and waste. Since vibration injuries are also a problem for countries outside the EU, the improved ability for employers and users to pinpoint dangerous vibrations with more reliable data will lead to an increased demand for handheld tools with lower vibration values. This will improve the competitiveness of EU manufacturers of handheld machinery, both within and outside the EU.

[+/-] The costs and benefits of PO3 meeting specific objective 2 (in addition to the RED clarification in the exceptions in Article 1(2)(k) and the clarifications on the definition of PCM presented in PO2) include: (i) **compliance and adaptation costs for manufacturers** (although these are not quantifiable); and (ii) the **net benefits for users** derived from the **declaration of vibration peak values**. Machinery **users** will benefit from **greater safety.**

- **PO3 – SO3: On Annex IV, this policy option would review the list of high-risk machines in Annex IV to include 'AI systems with a safety function' and/or machinery embedding them. It would also impose in Article 12 a requirement for manufacturers to systematically involve a third party to assess the conformity of Annex IV machines.**

Certain types of machinery (listed in Annex IV to the MD) are considered to present higher risks, and therefore must be subject to more stringent conformity-assessment procedures, involving a third party. Annex IV products currently include machines such as: (i) woodworking machinery; (ii) chainsaws; (iii) presses for the working of cold metal; (iv) manually loaded and unloaded compression moulding machines for plastics and rubber; (v) certain types of lifting equipment; and (vi) various safety components, among others.

Annex IV – list of machinery

[89] Machinery Working Group document 'WG-2020.46rev Swedish proposal and effects of a revision of the legal requirements in Annex 1, 2.2.1.1 on vibrations for handheld machinery'.

[90] Sweden would save on 100 medical examinations per year, at a price of EUR 3 000 each, which would mean EUR 300 000 per year in savings. These savings, extrapolated to the EU-27 based on the population ratio (ca. 50), would make for total EU savings of EUR 15 million per year.

Policy Option 3 would add two new types of machinery to the list of high-risk machines: (i) AI systems/components ensuring safety functions; and (ii) machinery containing AI systems with safety functions, in line with the categories of machinery that will be referred to in the AI regulation under preparation. Although AI application in machinery already exist, AI systems fulfilling safety functions or machinery embedding such systems are not yet considered to be in the market. Hence one-off costs of such AI systems or machinery embedding them for third party involvement will be borne by manufacturers, but are difficult to estimate. Nevertheless they are considered to be much lower than the costs incurred for the development of such products.

Without a reassessment of the high-risk machines, potentially high-risk machines could be placed on the market without the adequate conformity assessment procedures, diminishing the level of safety for those types of machinery. Furthermore, machines that are not high risk any more due to the technological progress could remain submitted to disproportionate conformity assessment procedures. To be able to adapt to future market developments, this policy option would include the possibility of implementing changes at a later stage via a **delegated or implementing act** in the revised MD. Additional revisions of the list should be backed up by relevant data and further discussed. Any addition of new categories to the current list of high-risk machines would potentially create additional costs for manufacturers. On the contrary, removal of categories from the current list would potentially diminish costs. These costs would need to be estimated for each type of machine added. Typically one-off costs for manufacturers are due to third party involvement and can be are estimated at EUR 25 000 per new product type, or more, depending on the type of machinery.

On the updating of Annex IV through revising the high-risk categories, there was a split in opinion in the consultation responses. Importers, notified bodies and professional workers were generally in favour of revising the categories. However, industry associations were opposed. The opinions of market-surveillance authorities were divided.

Annex IV – conformity assessment

Another subject for discussion is whether the conformity procedure for internal checks for Annex IV machines should stay as an option for machines that are put on the market according to harmonised standards covering all risks of the machinery and cited in the OJEU under the MD.

There is discussion about whether the **internal-checks option leads to safety concerns**. On this issue, the Rapid Alert System for Non-Food Dangerous Products (Safety Gate/RAPEX) has shown over the years that some of the products falling under Annex IV of the MD were identified as not being compliant with the requirements of the MD and the relevant European standards[91]. The products identified in Safety Gate/RAPEX include circular saws and vehicle lifts, which are part of Annex IV[92]. Some of these products were manufactured outside the EU.

Third-party involvement is perceived by economic operators as more effective in ensuring protection for users. However, economic operators said this third-party involvement also adds substantially to the costs and/or effort involved, when compared with the self-assessment option. By comparison, the main drawbacks to the self-assessment option are deemed to be: (i) the lack of reassurance and protection that might otherwise be provided by third-party involvement (which customers might expect/demand); (ii) the effort and expertise required internally to undertake the process; and (iii) the lack of relevant harmonised European standards to support the choice of self-assessment. Some stakeholders were concerned about an (unintentionally) incorrect application of the process by manufacturers and the lack of involvement/checks from a

[91] It has not been possible to find out the percentage of non-compliant products, or the number of accidents caused.
[92] Non-compliant products in the high-risk machinery category reported in the Safety Gate/RAPEX system: since 2017, out of 138 machinery products in total, 43% belonged to Annex IV (37 brush cutters, 11 circular saws, 8 vehicle lifts and 4 log splitters).

third party. For instance, manufacturers may just look to one harmonised standard, when in fact more than one standard has to be applied to properly assess a product.

According to the evaluation of the MD, the conformity assessments undertaken for machinery might be split approximately into: 80% self-assessment (non-Annex IV), 10% self-assessment (Annex IV), 8% EC-type examination, and 2% approval of full quality-assurance system. This suggests that half of the conformity assessments on Annex IV machines are done already with third party involvement. Purposes for this are: (i) to ensure or double check the quality of the product (ii) to increase competitiveness inside the EU and globally and (iii) to improve the brand reputation and recognition.

Given the nature of the risks involved in using machinery, procedures are often laid down for assessing the machinery's conformity to the essential health-and-safety requirements. These procedures should be devised based on the danger inherent in such machinery. Manufacturers should retain full responsibility for certifying the conformity of their machinery to the provisions of the MD. Nevertheless, for certain types of machinery with a higher risk factor, a stricter certification procedure is desirable.

The NLF, to which the MD is to be aligned, determines the appropriate conformity-assessment processes (these modules also include the manufacturer's DoC) to be applied. For products presenting high risks, a third party should check conformity, regardless of whether the manufacturer applies the relevant harmonised standards to prove conformity with the essential health-and-safety requirements. This is the case in other pieces of product-safety legislation aligned to the NLF, such as the Regulation on Personal Protective Equipment (PPE)[93].

[+/-] The costs and benefits of PO3 meeting specific objective 3 would include the third-party conformity-assessment costs for manufacturers of products in categories added to Annex IV, or savings if these products were removed from the list.

The evaluation of the MD also showed that obligatory third-party assessment does not add significant costs to industry. During the Commission evaluation of the internal market legislation for industrial products[94], economic operators indicated that, even though the obligation for mandatory third-party conformity assessment had been removed in the current version of the MD (until the last revision, the MD had required mandatory third-party conformity assessment for the categories of machinery in Annex IV), this had not necessarily led to a sudden reduction in demand for the services of notified bodies. Many manufacturers have continued to use the services of third parties 'voluntarily' for reputational reasons and to reassure their customers that their products are safe.

In the evaluation of the MD, industry provided estimates of the time and costs they incurred for their last conformity assessment relating to the MD. The average estimates were: (i) 1 393 days and EUR 105 000 in other costs for self-assessment; (ii) 33 days and EUR 275 000 for EC-type examination; and (iii) 4 days (no cost information given) for approval of full quality assurance (the last two needing the involvement of a third party).

On the costs of removing the internal-checks option, these costs are estimated by taking the difference between the compliance costs for manufacturers for both types of conformity assessments for the Annex IV products that are currently assessed via internal checks (10% of all machinery-conformity assessments currently carried out[95]). The total costs for all companies is

[93] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (Text with EEA relevance) OJ L 81, 31.3.2016, pp. 51-98.
[94] European Commission Staff Working Document part 1: Evaluation of the internal market legislation for industrial products (SWD/2014/023 final) (2014). Available at:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52014SC0023&from=SK&lang3=choose&lang2=choose&lang1=EN
[95] Evaluation of the Machinery Directive: SWD (2018)160.

estimated at EUR 202 million in one-off costs (EUR 2 467 per company, and up to EUR 25 000 or more for certain types of machinery). Some manufacturers argue that imposing a third-party assessment procedure for Annex IV machines will reduce manufacturers' interest in investing time and efforts to participate in the drafting of harmonised standards for those machines. However, harmonised standards will continue to provide presumption of conformity with the MD, the only difference is that compliance will be not self-certified by the manufacturer, but by a third party.

Removing the option for internal checks might lead to a higher degree of safety for the machinery. To assess the potential benefits of removing the option for internal checks, the evaluation of the MD is taken for a proxy. Here, the MD's role in protecting the health and safety of users in the market when Annex IV machinery is assessed through internal checks and 83% consider it effective-to-very-effective. This is compared to 94% when an EC-type examination is followed. Thus, removing the option of internal checks on Annex IV machinery has the potential to increase the effectiveness of the MD to protect health and safety by 13% for the 10% of assessments currently carried out through internal checks.

The total potential costs and benefits related to removing the internal-checks option under Annex IV are summarised in the table below.

Costs and benefits of removing the internal-checks option for Annex IV machinery

<table>
<tr><th colspan="2">Stakeholders' description</th><th colspan="3">Companies</th><th>Administrations</th><th colspan="2">Other organisations</th><th colspan="2">Citizens/users</th></tr>
<tr><td colspan="2">REMOVING THE OPTION FOR INTERNAL CHECKS FOR ANNEX IV MACHINERY</td><td>Large companies</td><td>SMEs</td><td>All</td><td>Market-surveillance authorities</td><td>Notified bodies</td><td>ESOs</td><td>People employed in machinery sector</td><td>Users / consumers</td></tr>
<tr><td colspan="2">1. Number of affected stakeholders (EU-27)</td><td>1 703</td><td>81 024</td><td>82 239[a)]</td><td>-</td><td>137 or more</td><td>-</td><td>2 759 439</td><td>446 000 000[b)]</td></tr>
<tr><td>2.1 Costs (total)</td><td>One-off</td><td colspan="3">EUR 202 895 485[c)]</td><td>-</td><td>Increased turnover EUR 202 895 485[c)]</td><td>-</td><td colspan="2">Not quantifiable, costs of changes could be pushed down the value chain</td></tr>
<tr><td>2.2 Costs per organisation</td><td>One-off</td><td colspan="3">Average 2 467[c)] (can be up to EUR 25 000 or more for certain types of machinery[g)])</td><td>-</td><td>One-off costs for adaptation are expected to require an average of 10 FTEs[e)] (not quantifiable)</td><td>-</td><td>-</td><td></td></tr>
<tr><td rowspan="2">3. Benefits</td><td>Direct</td><td colspan="3">A few consultation participants expected there to be some benefits from the changes but these benefits could not be reliably quantified (not quantifiable)</td><td>-</td><td>-</td><td>-</td><td colspan="2">MD's effectiveness in protecting the health and safety of users is expected to increase 13% for the 10%[d)] of machinery that currently undergoes internal checks (not quantifiable)</td></tr>
<tr><td>Indirect</td><td colspan="3">MD's effectiveness in facilitating the functioning of the internal market is expected to increase by 1%[f)] (not quantifiable)</td><td>-</td><td>Increased product portfolio among the 10% of machinery under Annex IV currently assessed through internal checks</td><td>-</td><td>-</td><td></td></tr>
</table>

[a)] Due to rounding differences in the Eurostat data, 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 undergo internal checks under Annex IV.
[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 MD and the difference in the MD's effectiveness in facilitating the functioning of the single market by type of conformity assessment.
[g)] From stakeholder interviews.
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.

- **PO3 – SO4: On digital documentation, this policy option would provide full legal clarity by amending requirement 1.7.4. (Instructions) to clarify that manual instructions can be provided in digital form (plus on paper and free of charge upon customer request).**

Similarly to PO2, this policy option would require a change of the legal text in the MD, by specifying in the Annex I that the instruction and declaration of conformity can be provided either digitally or in paper, which would provide **legal certainty**, and would prevent this coming under question later on and being changed again in the Guide.

[+/-] Costs and Benefits: Like in PO1 and PO2, **PO3 meeting specific objective 4** brings an opportunity to simplify and **reduce net costs, mainly for manufacturers.** See table reported in PO1.

- **PO3 – SO5: Like in PO2, by amending the legal text, this policy option would align the current MD with the NLF.**

As mentioned previously, aligning the MD to the NLF would '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'[96]. Aligning the MD to the NLF would **bring the ICSMS to the MD**. The ICSMS is the internet-supported information and communication system for pan-European market surveillance. As detailed in PO2, there was **wide consensus** on the benefits of this alignment; most respondents to the public consultation, across all stakeholder types, expressed support for this change.

[+/-] Costs and Benefits: PO3 meeting specific objective 5 would benefit all stakeholders, although quantification of these benefits was not possible due to the lack of available data. The table in PO2 shows the potential costs and benefits for stakeholders of aligning the MD to the NLF.

- **PO3 – SO6: Like in PO2, by amending the legal text, this policy option would convert the MD to a regulation.**

As detailed in PO2, there was **wide consensus** on the benefits of this conversion. Most public-consultation respondents, across all stakeholder types, expressed support for this change.

[+/-] Costs and benefits: PO3 meeting specific objective 6 would benefit stakeholders. Manufacturers would save on administration for clarifications on interpretation differences between Member States, which is estimated at between EUR 100 and EUR 500 to write letters, print papers and resolve differences[97]. The table in PO2 shows the potential costs and benefits for stakeholders.

Impacts of the policy option 3 on SMEs

As already mentioned, 98% of companies in the machinery sector are SMEs. Legal certainty will particularly favour SMEs since they have fewer resources to assess and interpret the legal text. For instance, legal certainty on the safety requirements will result on clearer harmonised standards, which will also be beneficial for SMEs that rely on harmonised standards to comply with the safety requirements. Standardisation on new technologies happens in alignment and reciprocal feedback with ISO/IEC (International Organization for Standardization/International Electrotechnical Commission) so that competitiveness in and outside the EU is maximised and export is facilitated (key aspect of the EU machinery sector, which exports 51% of their production to countries outside the EU, and this is the case for SMEs too).

Manufacturer of Annex IV high-risk machines are often SMEs. However, SMEs often prefer third party conformity assessment, due to lack of means e.g. laboratories/expertise or for

[96] Available at: https://ec.europa.eu/info/publications/commission-report-safety-and-liability-implications-ai-internet-things-and-robotics-0_en.
[96] Evaluation of the Machinery Directive: SWD (2018)160.
[97] An instance refers to one product being placed in the market by one manufacturer. The number of instances requiring clarifications could not be quantified.

competitiveness reasons, as a guarantee of quality, and in case of lack of brand recognition. According to the evaluation of the directive, 50% of the conformity assessment for Annex IV machines is already done with third party involvement.

On the burden reduction side, the following opportunities are favouring SMEs:

- Cost savings for manufacturers and favourable environmental impact by allowing digital instructions and digital declaration of conformity, applying to all machinery.

- The preferred option includes a definition of substantial modification in the legal text, and clarifies that the obligations of the company performing the substantial modification are limited to the part of the machinery affected by the modification (unless the substantial modification has an impact on the safety of the entire machinery). Companies modifying machinery are often SMEs.

- The alignment to the NLF means a better functioning of the directive and its enforcement, but also a burden simplification for manufacturers dealing with several product safety acts applying to their products (e.g. machinery to which both the machinery directive and the radio equipment directive apply). It streamlines the process of safeguard procedures, by involving manufacturers and Member States before the Commission is notified and triggers a Commission decision only in cases where there is disagreement between Member States.

- The complementarity between AI and machinery legal texts, where the AI regulation delegates the conformity assessment to the machinery, so that the risk assessment for machinery with AI systems is done only through the machinery directive.

The fact that the directive includes technology neutral requirements for new technologies drives the standardisation, which allows safe innovative solutions in the market. The objective is not to hinder innovation but to allow safe innovation. As far as high risk machines are concerned, the empowerment for a revision of the high risk categories in line with the market development will allow the directive to keep up to date in that sense.

As regards AI, research and development happen at an earlier stage. The MD applies when the machinery is put on the market, i.e. once the technology has become state of the art. Leaving the regulation of machine learning to the sole AI regulation would not ensure machinery safety. AI systems used in machinery need a risk assessment for the specific application of that machinery. This approach is coherent with the future AI regulation for continuously learning AI systems, which delegates the conformity assessment of the AI systems used in machinery to the machinery directive rules. In addition, it must be considered that development of AI software is more costly than other types of software. Costs derived from compliance to the directive would not be significant as compared to development costs.

Impacts of policy option 3 on innovation

The fact that the MD includes technology-neutral requirements for emerging technologies drives standardisation, which allows safe innovative solutions to come onto the market. The objective of standardisation is not to hinder innovation but to allow safe innovation. On the subject of high-risk machines, allowing a revision of the high-risk categories in line with market developments will allow the MD to keep up to date.

On AI, research and development happen at an early stage. The MD applies when the machinery is put on the market, i.e. once the technology has become commercialised. Leaving the regulation of ML solely to the AI regulation would not ensure machinery safety. AI systems used in machinery need a risk assessment for the specific application of that machinery. This approach is coherent with the future AI regulation for continuously learning AI systems, which will delegate

the conformity assessment of the AI systems used in machinery to the MD's rules. In addition, it must be considered that development of AI software is more costly than other types of software. Costs derived from ensuring AI software complies with the MD would not be significant compared to the costs of developing the software.

The following table summarises and compares the impacts (economic, social and environmental) of each policy option per stakeholder group.

[+/-] Costs and Benefits: The overall effects of PO3 on stakeholders include: (i) benefits for manufacturers thanks to the switch to e-manuals; (ii) benefits for society and users thanks to less exposure to peak vibrations; and (iii) net benefits generated by aligning the MD to the NLF and the legal clarity derived from a lack of transposition. Costs are predicted for manufacturers following the adaptation or introduction of new requirements. These costs are limited as there would only be a few cases where completely new requirements requiring re-design of products would be added. In most cases, new requirements would be applicable only to some types of machinery. Diligent manufacturers that already correctly perform the risk assessment may see cost savings from increased legal certainty. Greater legal clarity ensures a level playing field and would allow manufacturers to introduce emerging technologies.

On compliance costs, it must be stressed that the scope of the MD is very wide, and not all safety requirements in Annex I of the MD apply to all types of machinery. Manufacturers must make a risk assessment to determine the risks involved and the safety requirements relevant for their machinery. They need to ensure compliance only to those requirements relevant for their machinery. New or revised requirements proposed in this policy option are proportional and targeted, since they would be limited to certain types of machinery. For instance; (i) requirements on overhead power lines are relevant only to certain types of high mobile machinery; the (ii) declaration of peak vibration values is requested only for portable handheld and/or hand-guided machinery; and (iii) requirements on hazardous substances apply only to those machines whose operation implies emissions of those substances.

As outlined in Chapter 1.3 of this report, many machinery manufacturers are SMEs. Users (workers and consumers) will expect a similar level of product safety, regardless of the size of the company producing the machinery. The impacts of Policy Option 3 on SMEs include additional costs in a few cases where SMEs may need to adapt the design of their machinery to comply with new requirements. However, these additional costs would be targeted, and limited to certain machine types. Moreover, diligent manufacturers will be already implementing some of the revised requirements, and would thus already have a competitive advantage once the revised MD is in force. SMEs will particularly benefit from the legal clarity that the revised MD will bring. This legal clarity is important for them since SMEs typically have fewer resources to follow up and seek advice on legislation.

It must be also considered that, after the Commission adopts the regulation, negotiations with the European Parliament and Council take 2 years on average. After the new regulation on machinery products has entered into force, an additional transition period of 30 months will be given for the new provisions to be effective. This transitional period would allow manufacturers to prepare themselves for compliance with the new requirements. Often, manufacturers already take account of the new requirements while developing new models. For models already in production, if manufacturers want to keep putting them on the market after the end of the transitional period, they must modify those products so that they comply with the new regulation, where necessary. Market-surveillance authorities will face some adaptation costs for enforcing requirements linked to emerging technologies, but will benefit from an NLF alignment and the avoidance of transposition costs.

The following table summarises and compares the impacts (economic, social and environmental) of each of the policy options on every stakeholder group:

Comparison of impacts on stakeholder groups (costs/benefits/environmental benefits against baseline PO0)

Policy option	Companies	Notified bodies	ESOs	Member States	Citizens/Users (workers and consumers)	
Affected stakeholders	Up to 82 239 (EU-27); Up to 81 024 SMEs (EU-27); Up to 1 703 large companies (EU-27)	137 or more	CEN/ Cenelec	27 EU Member States (or more incl. EEA)	2 759 439 employees in the sector (EU-27)	Up to 446 000 000 EU citizens
PO1: Self regulation by industry and changes to the Guide	P1: Costs for compliance with new standards. P4: Costs for setting up and maintaining a server: one-off EUR 29 million (EUR 2 000 per company), annual EUR 48 million (EUR 3 000 per company); Reduction in printing costs of up to EUR 16.6 billion (EUR 201 000 per company). P2, 3, 5, 6: Legal uncertainty and lack of consensus for changes to the Guide.	P4: One-off costs for adaptation to change expected; Decreased storage costs for manuals.	P1: Compliance with new standards.	P4: One-off costs for adaptation to changes.	P4: EUR 0.4 per manual if user decides to print part of the manual after purchase; Increased readability, non-paper instructions manual more adapted for blind/partially sighted; Decreased use of paper and smaller carbon footprint.	
PO2: Burden minimisation	P1: Costs for compliance with new standards. P2: Some costs for adapting to changes on RED-LVD and PCM; Cost savings on PCM of about EUR 5 000 - EUR 10 000 per instance. P4: Costs for setting up and maintaining a server: one-off EUR 29 million (EUR 2 000 per company), annual EUR 48 million (EUR 3 000 per company); Reduction in printing costs of up to EUR 16.6 billion (EUR 201 000 per company). P5: Simplification thanks to Directives under the same framework. P6: Cost savings from fewer clarifications EUR 100 - EUR 500 per instance.	P4: One-off costs for adaptation to change expected; Decreased storage costs for manuals P6: Benefits from equal interpretation across Member States.	P6: Benefits through equal interpretation of regulation across Member States.	P2: Costs for adaptation to changes; increased legal clarity. P4: One-off costs for adaptation to changes. P5: Access to ICSMS P6: Saving on transposition costs.	P4: EUR 0.4 per manual if user decides to print part of the manual after purchase; increased readability, non-paper instructions manual more adapted for blind/partially sighted; Decreased use of paper and smaller carbon footprint. P5: Access to ICSMS. P6: Fewer unsafe products in the market.	
PO3: Burden minimisation and improved safety	P1: One-off costs for adaptation to changes on: (i) human-robot interaction; (ii) ML test procedures and equipment; (iii) a lack of connection or faulty connections; (iv) cyber safety and external hazards; (v) software updates; (vi) automated machines; (vii) risk assessment; and (viii) costs for compliance with new standards; Improved competitiveness and level playing field; Fewer barriers to market. P2: Some compliance costs and costs for adapting to changes (slow-speed lifts, seating, hazardous substances, overhead power lines, vibrations); Cost savings on PCM of EUR 5 000 – EUR 10 000 per instance. P3: EUR 202 million one-off overall costs (EUR 2 500 per company, EUR 25 000 or more for certain machine types) for removal of internal checks. P4: Costs for setting up and maintaining a server: one-off costs of EUR 29 million (EUR 2 000 per company), annual costs of EUR 48 million (EUR 3 000 per company); Savings on printing costs of up to EUR 16.6 billion (EUR 201 000 per company). P5: Simplification thanks to directives coming under the same framework. P6: Cost savings for fewer clarifications EUR 100 - EUR 500 per instance.	P3: Turnover increase: EUR 202 million for product portfolio of the 10% of machinery under Annex IV that is currently assessed through internal checks; P4: One-off costs expected for adapting to change; Decreased storage costs for manuals P6: Benefits through equal interpretation across Member States.	P1: Compliance with – and revision of – new harmonised standards P6: Benefits expected through equal interpretation of regulation across Member States.	P2: Costs from adapting to changes; increased legal clarity; reduced social costs for sick leave and occupational injuries (e.g. costs from vibrations are currently EUR 15 million annually). P4: One-off costs for adapting to changes. P5: Access to ICSMS. P6: Saving on transposition costs.	P1: Costs of changes pushed down the value chain; Less non-compliant machinery in the market; increased safety for workers and consumers; fewer occupational injuries for workers. P2: Increased safety thanks to clarifications; fewer occupational injuries for workers. P3: Costs pushed down the value chain; MD's; Higher effectiveness in protecting the health and safety of users expected to increase for machinery currently following internal checks. P4: EUR 0.4 per manual if user decides to print part of the manual after purchase; increased readability, non-paper instructions manual more adapted for blind and partially sighted; Decrease of use of paper and smaller carbon footprint. P5: Access to ICSMS. P6: Increased safety.	

7. HOW DO THE OPTIONS COMPARE?

The following tables provide information comparing the policy options in terms of effectiveness (how each option achieves the specific objectives), efficiency (cost-benefit analysis) and coherence with other pieces of EU law.

Comparison of policy options against the effectiveness criterion

	Cover new risks related to emerging digital technologies	Ensure coherent interpretation of the scope and definitions, and improve safety for traditional technologies	Reassess machines considered as high risk and reassess related conformity procedures	Reduce paper-based requirements for documentation	Ensure coherence with other product-safety legislation	Avoid divergences in interpretation derived from transposition	Net effect
PO0	It does not address any of the identified problems and does not fulfil any of the objectives						0
PO1	+	+	+	+	+	+	+
	It will rely on standards	It will add some clarity to the scope and definitions through the Guide, however to a very limited extent since not binding	It will add some clarity to high-risk machines through the Guide, however to a very limited extent since not binding	Digital instructions and DoC will be allowed through the Guide	It will add some coherence with the NLF through the Guide, however to a very limited extent since not binding	Workshops will be organised to clarify differences in interpretation due to transpositions, and clarifications will be added to the Guide	
PO2	+/++	+/++	+/++	+++	+++	+++	++
	It will add clarity to the scope and definitions in the current act, including the part of the current act related to risks stemming from emerging technologies, but with no changes to requirements	It will add clarity to the scope and definitions in the current act, but with no changes to requirements	It will add some clarity to the concept of high-risk machines through the Guide, however to a very limited extent since not binding	Digital instructions and DoC will be allowed in the legal text (full legal certainty)	Full alignment to NLF will be achieved	Reduction of costs and delays from transposition will be achieved	
PO3	+++	+++	+++	+++	+++	+++	+++
	It will add clarity to the scope and definitions in the current act including the part of the current act related to risks stemming from emerging technologies, and will adapt the requirements	It will add clarity to the scope and definitions in the current act, and will adapt the requirements	It will reassess and revise the list of high-risk machines in the legal text	Digital instructions and DoC will be allowed in the legal text (full legal certainty)	Full alignment to NLF will be achieved	Reduction of costs and delays from transposition will be achieved	

Comparison of policy options against the efficiency criterion

See table comparing the impacts on stakeholder groups (costs/benefits/environmental benefits against baseline PO0) at the end of Chapter 6.

In addition, the table below compares policy options against types of impacts.

Options	Social impacts	Environmental impacts
Policy Option 0	No change	No change
Policy Option 1	No change	Saving of paper Decrease of carbon footprint (with limited certainty)
Policy Option 2	Fewer non-compliant products on the market	Saving of paper Decrease of carbon footprint (with full certainty)
Policy Option 3	Fewer non-compliant products on the market Increased safety	Saving of paper Decrease of carbon footprint (with full certainty)

Comparison of policy options against the coherence criterion

Policy Options		Net effect
PO0	No coherence.	**0**
PO1	Very limited coherence in the implementation of the EU law for three reasons. Firstly, there would be no clarification on the exceptions due to borderline areas with LVD and RED. Secondly, there would not be any alignment to the NLF. Thirdly, the interplay with the AI regulation would not be ensured.	**0**
PO2	This option would allow a more coherent implementation of the EU law, by clarifying the borderline area with the LVD and RED and aligning the MD to the NLF but without covering the interplay with the future AI regulation.	+
PO3	This option would allow the most coherent implementation of the EU law, by: (i) clarifying the borderline area with the LVD and RED; (ii) aligning the MD to the NLF; and (iii) allowing full complementarity and interplay between the MR and the future AI regulation on high-risk machines with AI systems.	++

Overall comparison of policy options

	Effectiveness	Efficiency	Coherence
PO0	PO0 would not address any of the identified problems and would not fulfil any of the objectives. The standardisation process and revisions of the Guide would develop as usual, with limited ambition.	PO0 would have negative effects on industry competitiveness, the level playing field. Compliance, and safety in the market would decrease over time as a consequence of no action.	PO0 would not improve coherence with existing legislation and would not provide coherence with the new AI legislation nor with the Cybersecurity Act.

PO1	PO1 would obtain limited results in reaching the objectives. Emerging technologies would be covered to some extent through: (i) the issuance of a new standardisation request; and (ii) covering gaps in traditional technologies. Other objectives would be pursued by a push for consensus in the Guide.	PO1 would obtain limited results, and only mainly of the following areas: net benefits from the allowance of digital documentation in the Guide, although with limited certainty; but no avoidance of existing costs due to clarification of differences in interpretation. This option implies few costs for companies incurred for compliance with new standards, but less than if requirements were changed. There would be no significant benefits for users or other stakeholders.	PO1 would slightly improve coherence with existing legislation by clarifications in the Guide, but would not provide coherence with the new AI legislation nor with the Cybersecurity Act.
PO2	PO2 would address to a large extent all the identified problems through: (i) changes in the MD's scope and definitions; (ii) alignment to the NLF; (iii) conversion into a regulation; and (iv) allowance of digital documentation. The only identified problem it would not address is the level of safety.	PO2 would fully achieve some of the objectives, such as the allowance of digital documentation and related large savings on printing costs for companies, and the clarifications in scope definition and the avoidance of transposition, which would avoid costs for manufacturers due to clarification of differences in interpretation. One area where only limited results would be achieved is in the safety of new and traditional technologies and of high-risk machines.	PO2 would ensure full coherence with existing legislation by: (i) revising the current act in scope and definitions; (ii) aligning to the NLF. However, it would not provide coherence with the new AI legislation nor with the Cybersecurity Act.
PO3	PO3 would address to a large extent all the identified problems through: (i) changes in the MD's scope and definitions; (ii) alignment to the NLF; (iii) conversion into a regulation; and (iv) allowance of digital documentation. It would also improve the level of safety in the market. As a result, it would increase trust in emerging technologies, improve competitiveness, and ensure a level playing field.	PO3 would fully achieve all the objectives (with correspondingly greater impacts), including the improvement of safety. As a result, companies would bear costs for adapting to changes in requirements and complying with new standards. However, they would still make large savings from the allowance of digital documentation with full certainty and would avoid costs derived from differences in interpretation. Companies would also benefit from a better legal clarity, greater competitiveness and a more level playing field in the machinery market. - Users would benefit from safer machines in the market and lower cost of injuries and sickness at work.	PO3 would ensure full coherence with existing legislation by: (i) revising the current act in scope and definitions; and (ii) aligning to the NLF. PO3 would also ensure full coherence with the new AI legislation and with the Cybersecurity Act.

In a nutshell, the options could be summarised as follows.

Option 0: No action.

Option 1: Unambitious option that achieves limited results and does not prepare the MD for either the short-term or the medium/long term.

Option 2: This option boosts competitiveness by minimising burden for manufacturers. It brings economic benefits for industry by allowing digital documentation for all machinery. It also modernises the legislation by aligning it to the NLF. However, by not adapting the safety requirements on emerging technologies, it misses the opportunity to render the legislation future proof.

Option 3: This option boosts competitiveness by minimising the burden for manufacturers. It also improves safety by clarifying or adding requirements on emerging (and traditional) technologies. These additional or clarified requirements bring additional costs for compliance. Nevertheless, despite these extra costs, the additional or clarified requirements bring longer term benefits such as: (i) fewer unsafe products in the market; (ii) greater legal certainty (reducing private litigation); and (iii) a more level playing field for economic operators on the global market. This option also brings economic benefits for industry because it allows digital documentation. In addition, this option has benefits for the public and national healthcare systems, because it would lead to safer products on the market. As a result, there would be fewer injuries, less sick leave, and lower rehabilitation costs. This is also the most future-proof option.

8. PREFERRED OPTION

8.1. Preferred policy option: Option 3

In light of the data and the considerations in the previous chapters, the preferred policy option is Policy Option 3. This policy option addresses all identified problems in the most effective and efficient way, proposing a revised MD that is not only fit for purpose now, but also in the years to come. Policy Option 3 also ensures coherence with existing product-safety legislation and with the future AI regulation.

Policy Option 3 adds new requirements and clarifies existing ones: (i) in a targeted and proportional way; and (ii) only when necessary. These new requirements and clarifications are often applicable only to certain types of machinery. It adds legal clarity to the current act in its scope, definitions and requirements, including those requirements covering risk stemming from emerging technologies. In addition, this option will drive the standardisation activities in the machinery area, which will increase safety and ensure a higher level of trust and competitiveness in the market for machinery and digital machinery. This option also: (i) adapts high-risk machines to new market developments in this area; (ii) removes the internal-check option for the conformity assessment of high-risk machines; and (iii) ensures full coherence with the new AI regulation. This option proposes a burden-reduction measure that was widely requested by industry, and which partially allows digital documentation, while at the same time ensuring that end-users and consumers can have a printed version free of charge if they so request. Finally, the revised MD will gain in coherence and legal certainty by being aligned to the NLF and becoming a regulation. To ensure proportionality, this policy option includes: (i) the standardisation process with a new standardisation request issued by the Commission for detailed technical solutions; and (ii) the Guide for detailed clarification examples.

The preferred policy option complies with the principle of proportionality. The proposed changes to the safety requirements are targeted, and limited to the following machinery types: machinery including emerging technologies, specific machinery, and high-risk machinery. The burden-reduction measures are aimed at all machinery types. These burden-reduction measures include: (i) clarifications on what constitutes a substantial modification; (ii) digital documentation; (iii) alignment to the NLF; and (iv) conversion of the MD to a regulation. Proportionality is also ensured by the MD being technologically neutral. The proposed clarifications or additions to the safety requirements are kept to the strict minimum in the proposal. They will be complemented by a new standardisation request issued by the Commission to empower the standardisation bodies to develop voluntary technical solutions.

This policy option is coherent with the new regulation on artificial intelligence, which will address the risks having an impact on safety for high-risk AI systems embedded in a machinery or that are safety components under the machinery regulation. In addition, this option is coherent with the Union policy on cybersecurity, making the link with the future cybersecurity schemes pursuant to the Cybersecurity Act. Furthermore it contributes to simplification of the regulatory environment.

8.2. REFIT (simplification and improved efficiency)

REFIT cost savings – Preferred option – Option 3		
Description	***Amount***	***Comments***
Allowing digital instructions generates considerable economic benefits (printing and paper cost savings, etc.) that greatly outweigh the costs generated (purchasing, setting up and maintaining a server, etc.)	Printing saving costs up to EUR 16.6 billion (EUR 201 000 per company) in printing costs saved with digital instructions and DoC.	Benefits are mainly for manufacturers. End-users might benefit from price decreases if these price decreases are passed on to them. National authorities and notified bodies might benefit from decreased storage costs for documentation
Reduced social costs for sick leave and fewer occupational injuries thanks to reduced vibration peaks in handheld machines	EUR 15 million yearly	Benefits are mainly for consumers
Clarifications where there had previously been a lack of legal clarity or differences in interpretation between Member States	EUR 5 000 - EUR 10 000 per instance for clarifications of differences in interpretation between Member States	Benefits are for manufacturers and national authorities
Alignment to NLF	Not quantifiable	Beneficial to all stakeholders
Conversion to a regulation	Cost savings in terms of clarification procedures EUR 100 to EUR 500 per instance	Benefits are mainly for manufacturers

Impact calculation methodology is described in Annex 4: Analytical methods.

9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

This chapter proposes several indicators to monitor and evaluate the implementation of the changes. After the entry into force of the preferred option, the Commission will monitor the implementation, application and compliance of these new provisions to assess their effectiveness.

On **unsafe products and accident data**, monitoring would be based on: (i) the information that is made available by Member States in the **ICSMS** on safeguard clauses; (ii) the information that is made available by Member States in the **RAPEX** systems about unsafe products found on the market; and (iii) the safety concerns and related accident data regularly reported at both the **Machinery Administrative Cooperation Group's (AdCo)** twice yearly meetings (market-surveillance authorities and the Commission as observer) and the **Machinery Expert Group (MEG)** twice-yearly meetings (with all interested stakeholders: industry, trade unions, consumer associations, standardisation organisations, notified bodies, market-surveillance authorities and the Commission). Following the alignment of the revised MD to the NLF, the use of the ICSMS on defective products will facilitate and improve this reporting.

The capacity of the revised MD to deal with **new innovations and emerging technologies** could be monitored by the **many new and revised harmonised standards** positively assessed and cited by the Commission. These new and revised standards provide presumption of conformity with the new and revised safety requirements. In addition, the Commission could consult competent authorities and stakeholders for evaluation[98].

The **removal of the current uncertainties and lack of clarity** in the application of the MD will lead to lower compliance costs, especially in the administrative burden related to additional paperwork for clarifications and paper documentation. By three years after the regulation becomes applicable and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. These evaluation reports will analyse the effective and efficiency of the legislation.

On the **reassessment of high-risk machines**, one indicator of success would be the greater safety of high-risk products. To monitor this, there would be targeted **new reporting** obligations on Member States limited to high-risk machinery as criteria to determine whether the list needs modification, such as (i) an assessment of the risks; (ii) a cost-effectiveness analysis; (iii) machinery accident analysis; (iv) statistics on accidents caused by the machinery product during the preceding four years, based on information from the Information and Communication System for Market Surveillance (ICSMS), safeguard clauses, Rapid Alert System (RAPEX) and the Machinery Administrative Cooperation Group reporting. This obligation would be proportionate, since it would be limited to high-risk products.

The expected objectives and impacts of allowing **digital documentation** could be evaluated through **stakeholder consultations**.

On the effectiveness of the MD, **aligning the MD to the NLF** would improve the management of safeguard clauses through the ICSMS. **Fewer safeguard clauses** handled by the Commission[99] would be an indicator of success with respect to greater safety and legal clarity. The alignment to the NLF and the 'goods package'[100] adopted by the Commission in 2018 will improve market surveillance and enforcement. It will also improve the accreditation and monitoring of the performance of notified bodies because Decision No 768/2008/EC on a common framework for the marketing of products will apply.

The Commission will monitor the implementation, the application and the compliance to the revised MD to assess its effectiveness. The revised MD will request a regular Commission's evaluation and review and the submission of a public report to the European Parliament and to the Council.

[98] Current developments in digitalisation, IoT and AI could allow data collection relevant to the monitoring and evaluation of the MD. Such data gathering mechanisms could possibly be outlined in new requirements in the MD at EU level (e.g. on the adoption of digital identifiers of machines and automatic digital collection of data from machines of certain types). After reflection, such mechanisms were considered too burdensome and thus not proposed.

[98] The alignment to the NLF will entail a reduction of the Commission decisions whether to justify a measure taken by a Member State to withdraw a product from the market. Under the current MD provisions, when a Member State notifies such a measure to the Commission, there is an obligation on the Commission to issue a decision in all cases. Under the NLF, the Commission will be subject to that obligation only when another Member State objects to the national measure, or where the Commission considers a national measure to be contrary to EU legislation.

[99] Current developments in digitalisation, IoT and AI could allow data collection relevant to the monitoring and evaluation of the MD. Such data gathering mechanisms could possibly be outlined in new requirements in the MD at EU level (e.g. on the adoption of digital identifiers of machines and automatic digital collection of data from machines of certain types). After reflection, such mechanisms were considered too burdensome and thus not proposed.

[100] See: (i) Regulation (EC) 765/2008 setting out the requirements for accreditation and the market surveillance of products; (ii) Decision 768/2008 on a common framework for the marketing of products, which includes reference provisions to be incorporated whenever product legislation is revised (in effect, it is a template for future product-harmonisation legislation); and (iii) Regulation (EU) 2019/1020 on market surveillance and compliance of products. Available at: https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en.

A summary is included in the table below.

Stage	Indicator	Definition	Unit of measurement	Data source
Implementation	Evolution of harmonised standards	As in the Standardisation Regulation 1025/2012	Number of harmonised standards positively assessed by the Commission	ESOs, internal Commission databases
Implementation	Assessment of high-risk machines	Reports	Number of positive third-party inspections out of total inspections on newly added high-risk machine categories	Notified bodies
Implementation	Reassessment of high-risk machines	New reporting obligations on Member States	statistics on accidents caused by the machinery product during the preceding four years	ICSMS, safeguard clauses, RAPEX and the Machinery Administrative Cooperation Group
Implementation	Simplification through digital instructions	Reports	Annual cost savings from digital documentation	Stakeholder consultations
Enforcement	Alignment to the NLF	Safeguard clauses needing Commission intervention	Number of safeguard clauses needing Commission intervention	ICSMS
Enforcement	Statistics of market-surveillance or other EU authorities	Reports	Number of pieces of non-compliant machinery	RAPEX
Enforcement	Reports from market-surveillance authorities or other EU authorities	Reports from market-surveillance authorities at AdCo and MEG meetings	Accidents, ad hoc reporting when concerns arise. Shared twice a year (at twice-yearly AdCo or MEG meetings).	Member States

Annex 1: Procedural information

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

The 'Revision of the Machinery Directive 2006/42/EC' is part of the 2020 CWP as one of the REFIT initiatives the Commission in taking within the "A Europe fit for the Digital Age" priority.

The lead DG for this initiative is the DG for Single market, Industry, Entrepreneurship and SMEs (DG GROW). The Directorate in charge is Directorate H - Construction & Machinery.

The initiative is coded in Decide Planning with the reference PLAN/2018/2979.

2. ORGANISATION AND TIMING

The timing for adoption of the new act by the Commission is April 2021.

The Inter-service consultation took place in March/April 2021.

3. CONSULTATION OF THE RSB

This impact assessment was sent to the RSB on 18/11/2020.

A meeting with the RSB took place on 3/02/2021.

The RSB issued its opinion on 5/02/2021, following which this impact assessment was revised as follows:

RSB recommendations	Revisions introduced
(B) Summary of findings	
(1) The report does not provide sufficient evidence on the scope and magnitude of the problems (e.g. regarding safety requirements, legal instrument). It does not explain which the most affected segments of the machinery sector are.	Further evidence on the scope and magnitude of the problems and additional explanations on types of machinery most affected by changes have been added in section 2 of the report: - The type of machinery affected by each problem, when only some types of machinery are affected; - Market data whenever available; - Examples of issues reported by Member States; - RAPEX data on non-compliant products belonging to Annex IV (high-risk) machinery.
(2) The report is not sufficiently transparent on the content and foreseen functioning of the policy options. It does not bring out clearly enough the key differences between the options, and where the main decisions lie for the political level. It does not sufficiently explore alternatives to deal with specific issues, such as on machine learning.	The following have been added in section 5: - More detailed explanation of the policy options; - Tables detailing how and to what extent every policy option meets each specific objective. The following have been added in section 6: - A chapter on innovation has been added at the end of the impacts section in policy

	option 3.
(3) The report lacks sufficient clarity on the role of the standardisation process and how future-proofness would be ensured, given the evolving safety risk and technology landscape.	The role of the standardisation process has been better developed in sections 5 and 6, particularly in the description and impacts of policy option 1. How future-proofness would be ensured has been developed in sections 5 and 6, particularly in the description and impacts of policy option 3, which is the most future-proof option.
(4) The report does not compare the efficiency of options in a clear and informative manner. Trade-offs between the options in terms of efficiency and effectiveness are not sufficiently explained.	The efficiency and effectiveness table in section 7 has been clarified.
C) What to improve	
(1) The report should be more specific on the scope and magnitude of the problems, for instance by differentiating between problems that affect specific segments of manufacturers or users, and problems that affect the overall sector. It should better substantiate the identified key issues and be transparent where there is a lack of, or only limited evidence available.	The following have been added in section 2: - The type of machinery affected by each problem, when only some types of machinery are affected; - Market data whenever available; - Examples of issues reported by Member States; - RAPEX data on non-compliant products belonging to Annex IV (high-risk) machinery.
(2) The report should provide more information on divergent transposition and interpretations across Member States, and the related problems that might justify a change in legal instrument. It should explain to what extent the reliance on harmonised standards can help mitigate such divergences.	Divergent transposition and interpretations across Member States have been better explained in section 2 (problem 6) and in section 6 (policy option 2 dealing with specific objective 9).
(3) The report should provide a comprehensive description of the content and functioning of the options in its options chapter. It should bring out more clearly their key differences, including by better justifying why certain provisions feature in certain policy options and not in others. It should explain if any alternative measures, or combinations thereof, were considered and, if so, why they were discarded. Where relevant, the report should further explore such alternative options. This should be the case for machine learning throughout the product life cycle, where alternative measures should be considered that might hamper innovation to a lesser extent while adequately ensuring safety.	The following have been added in section 5: - More detailed explanation of the policy options; - Tables detailing how and to what extent every policy option meets each specific objective. The following have been added in section 6: - A chapter on innovation has been added at the end of the impacts section in policy option 3.
(4) The report should clarify how some of the options would function. It should better explain why and for which types of machinery or new technologies the safety requirements or components (including in the annexes) would be changed under the preferred option. It should describe how this would affect current and future standardisation work. The report should better assess the future proofness of options, including the implications of dealing with upcoming new risks through standardisation.	The following have been added in section 5: - More detailed explanation of the policy options; - Tables detailing how and to what extent every policy option meets each specific objective. The following have been added in section 6: - A chapter on innovation has been added at the end of the impacts section in policy option 3.
(5) Overall, the quantitative analysis should be complemented by a qualitative explanation and assessment. The report should elaborate further the analysis of economic impacts, including on SMEs	The following have been added in section 6: - More complete reference to competitiveness; - A section on burden minimisation,

and competitiveness. It should present more clearly which provisions would contribute to simplifying the Machinery Directive.	particularly for SMEs, has been added at the end of the impacts section in policy option 3.
(6) The comparison of the efficiency of options should be improved to provide a more transparent overview of the expected costs and benefits. This should also help to better explain trade-offs between options in terms of efficiency and effectiveness.	The following have been added in section 5: - Tables detailing how and to what extent every policy option meets each specific objective. The following have been added in section 6: - A clearer and more transparent comparison of the options.
(7) The report should discuss possible solutions to solve data limitations in the future monitoring framework.	In section 9, the report proposes ways for future monitoring, but avoids imposing burdensome obligations to companies on data gathering.
Other changes as suggested in the check list received from the RSB on 29/01/2021 have been incorporated to the report.	The following impacts have been recalculated and better explained in section 6: - Savings for companies of printing costs linked to digital documentation; - Costs for companies for buying, setting up and maintaining a server; - Costs for users to print parts of the instructions; - Savings of medical costs due to workers exposure to vibration peaks when using hand held machinery.

4. EVIDENCE, SOURCES AND QUALITY

The Evaluation[101] of the directive identified the key areas for the revision. A study[102] supporting this impact assessment was carried out by an external contractor. The Commission's consultants carried out a number of interviews, analysed the data from the public and the targeted consultations, complementing them through desk research and three targeted case studies.

Evidence was also gathered in the Machinery Working Group, interviews with stakeholders and through public or targeted consultations. Another contribution to this impact assessment comes from the European Economic and Social Committee (EESC), which issued an Information Report[103] on this initiative.

Sources have been chosen as reliable as possible. Whenever quantitative information has been found, EU sources were preferred. When not available, other sources were also considered. Similar data were cross-checked whenever possible. It is acknowledged that some data are estimates; in order to compensate for possible inaccuracies, throughout this document benefits have been estimated in a conservative manner.

It has been consistently attempted to quantify impacts, but sometimes limitations of data have made possible only a qualitative analysis:

- As regards emerging technologies, accident data are not available because of the lack of penetration in the machinery market of emerging technologies performing safety functions.

[101] SWD (2018) 160 final, Evaluation of the Machinery Directive.
[102] Impact assessment study on the revision of Directive 2006/42/EC on machinery. Available at: https://data.europa.eu/doi/10.2873/423938
[103] https://www.eesc.europa.eu/en/our-work/opinions-information-reports/information-reports/revision-machinery-directive

- Limitations on accidents data: Safety incidents on a consumer level are not recorded. On occupational safety, Eurostat European Statistics on Accidents at Work (ESAW) general data are compulsory, but recording the causes and circumstances, which are the most interesting for an in-depth analysis, is not compulsory and hence not consistently reported. This has been mitigated by the reports from Member States, which have a good overview of the risks in their markets.
- A lack of granularity in the categorisation of the machinery sub-sectors in the structural business statistics, where NACE codes do not allow a high degree of accuracy. In such cases, proxy were used when possible.

Annex 2: Stakeholder consultation

Annex 2.1 Introduction

In the context of the impact assessment on the revision of the MD 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, a public consultation and a targeted online survey.

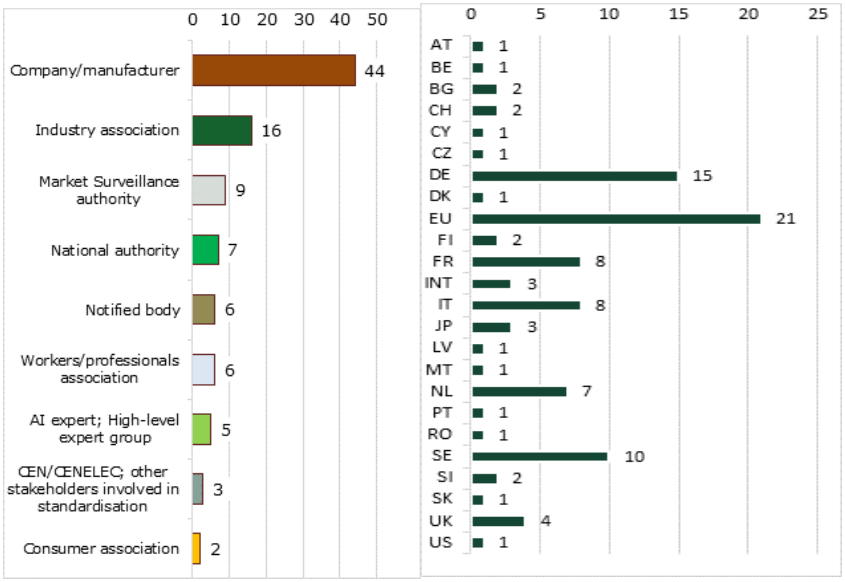
Annex 2.2 Overview of participants

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.

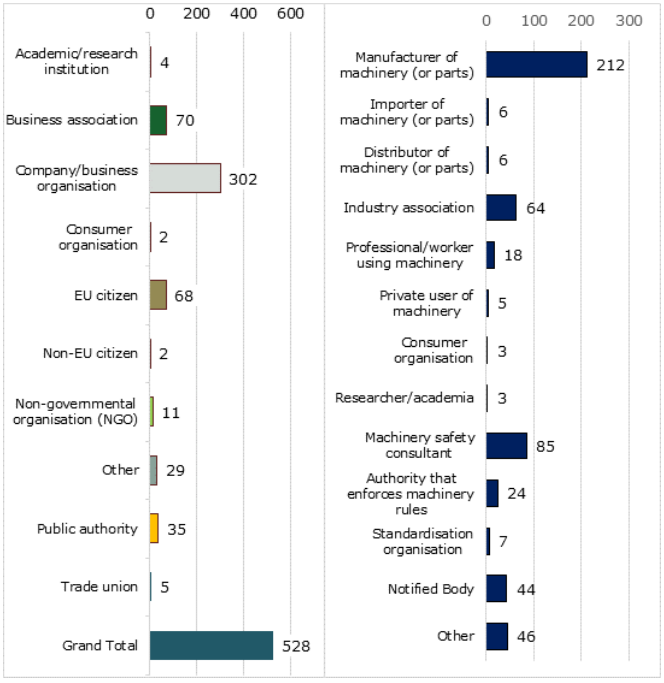
Over the course of the impact assessment, 98 stakeholders were interviewed. The majority of the interviewees were representatives from the industry, such as manufacturers and industry associations. The graphs below summarise the participation of the different stakeholder groups in the semi-structured interviews and the country of origin. The majority of the interviewed stakeholders were EU-level based associations, followed by Germany.

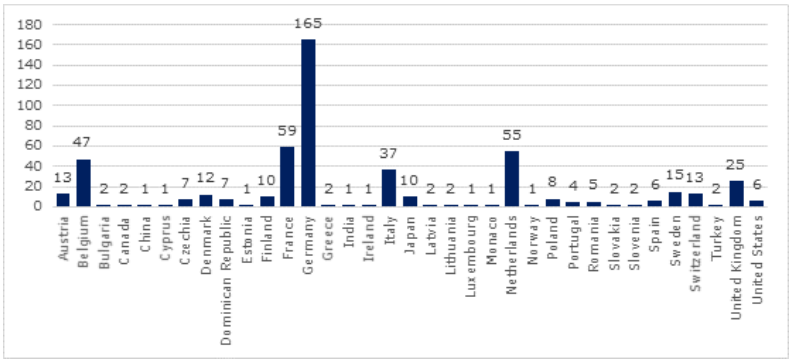
Participants in the semi-structured interviews



The 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 public consultation 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 Public Consultation and their country of origin.

Participants in the Public Consultation





The targeted online survey was conducted during November 2019. The aim was to close certain information gaps identified. A total of 24 stakeholders participated in the survey: i) companies/manufacturers (22); ii) notified bodies (1); and Experts on emerging technologies (1).

Annex 2.3 Summary of results

- **Specific Objective 1: Cover new risks related to digital emerging technologies**

The consultation activities asked stakeholders whether they have experienced or are aware of any safety incidents with machinery using emerging technologies, which types of emerging technologies they own and for manufacturers, what the expected trend for employing emerging technologies is.

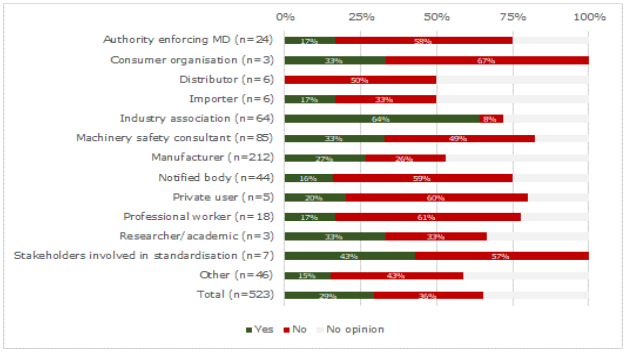
In general, most stakeholders of all groups participating in the 98 semi-structured interviews did not report any instances of health and/or safety incidents resulting from the use of machinery with AI or IoT implementations. Of the respondents to the public consultation, the majority had not encountered (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 emerging 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 emerging technologies should be addressed in the MD 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 emerging 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 public consultation 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.

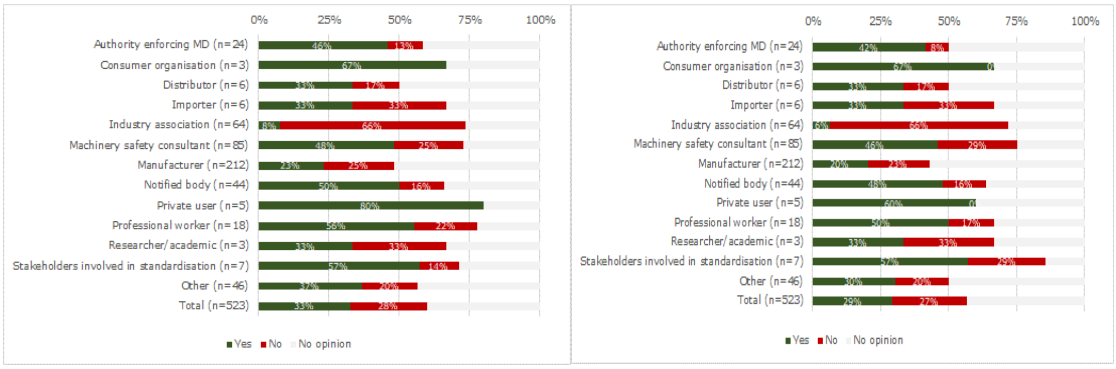
On the question as to whether the current requirements sufficiently covers the safety **of human-robot collaboration,** the majority of public consultation respondents answered negatively (36%), compared to 29% positive responses. The only stakeholder group that considered the current requirements to suffice were industry associations. Again, more respondents indicated a preference towards adapting the current requirements 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 requirements (29%) than not (27%). With regards to the interview responses, many stakeholders, in particular manufacturers, referred to the limitations of the current requirements in 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.

Does the MD sufficiently cover human-robot collaboration?

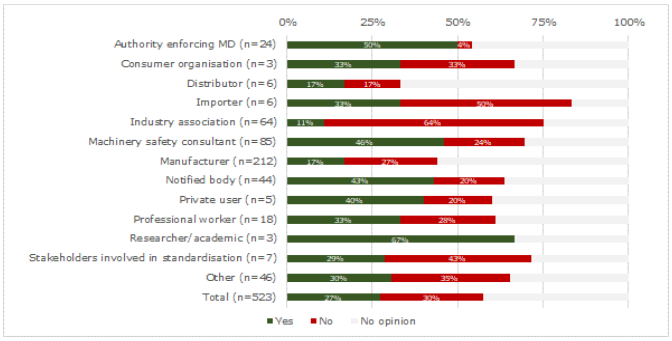


Opinions on adapting or adding new requirements on human-robot collaboration

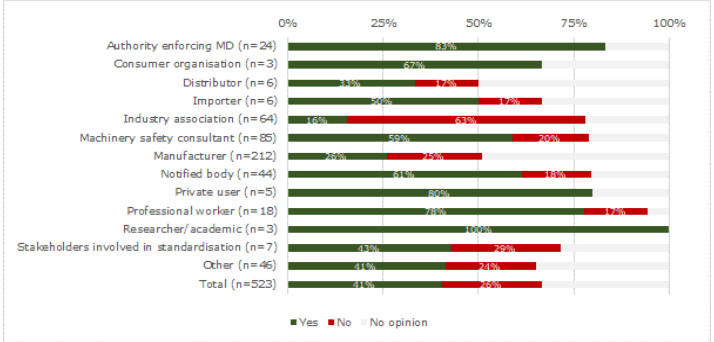


On risks of **AI and ML**, the responses are varied across stakeholder groups and specific aspects on AI and ML. First, on transparency of algorithms and datasets, more respondents to the public consultation negated that this should be addressed in the MD (30%), compared to those that agreed it should (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 public consultation 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%).

The MD should explicitly address transparency of algorithms and datasets

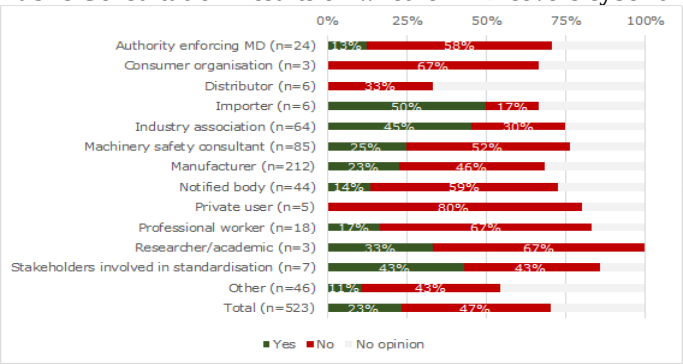


The MD should specifically address software updates



Finally, 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 public consultation 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 public consultation 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 requirements 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.

Public Consultation Results on whether MD covers cyber threats affecting safety



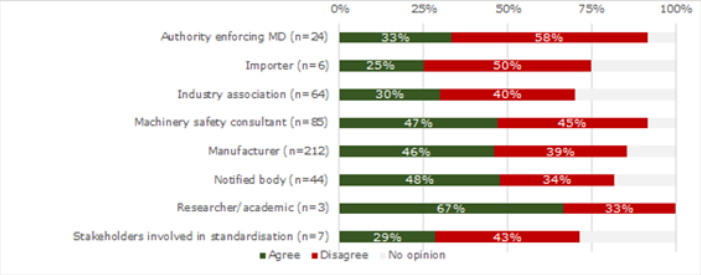
- **Specific objective 2: Ensure coherent interpretation of the scope and definitions and improve safety for traditional technologies**

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 public consultation answered that it did not (58%). Most of the offered alternatives were not preferred by most industry respondents to the public consultation, 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.

Respondents' opinion on differentiating between consumer and professional products for Art. 1.2(k), by stakeholder group

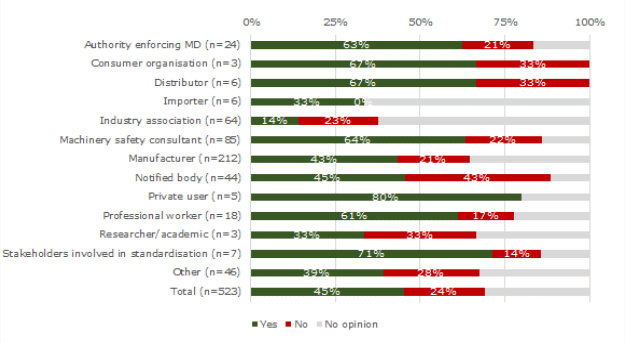


Importers of machinery (50%) and manufacturers (27%) could also imagine a removal of the exclusion of low voltage machinery in Art. 1.2(k), so that the machinery whose risks are mainly of electrical origin are covered exclusively by the LVD. Most stakeholder groups, however, were not in favour of a removal of the exclusion.

Finally, on **the definition of partly completed machinery**, the majority of stakeholders did not experience any problems with the definition, according to the public consultation 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.

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.

The requirements for carriers or run-controls for slow-speed lifts should be revised



- **Specific objective 3: Reassess machines considered as high risk and reassess related conformity procedures**

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 public consultation, 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.

- **Specific objective 4: Reduce paper-based requirements for documentation**

On allowing digital formats for documentation, the public consultation 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%).

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%

	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
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 i 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%

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.

- **Specific objective 5: Ensure coherence with other NLF legislation**

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, in particular manufacturers and market surveillance authorities. 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.

- **Specific objective 6: Reduce possible divergences in interpretation derived from transposition**

This objective focuses on the potential of converting the Directive into a Regulation. Most of the stakeholders that participated in the public consultation 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%).

Further information on all consultation activities performed can be found in the in the 'Impact assessment study on the revision of Directive 2006/42/EC on machinery'[104].

[104] Impact assessment study on the revision of Directive 2006/42/EC on machinery. Available at: https://data.europa.eu/doi/10.2873/423938

Annex 3: Who is affected and how?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

First, changes to the requirements will lead to additional direct compliance costs borne by manufacturers in terms of adaptation to the changes, training and familiarity with the new text. Standardisation bodies will also be affected by the necessity to review the transferability of the revised requirements to the list of harmonised standards in the OJEU. 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. However, the impacts generated by a change of requirements can be mitigated by keeping the numbering of the new or adapted requirements close to the existing list or by providing a reference table between the current requirements and the new ones. Machinery users and consumers will benefit from safer products in the market, at a potentially higher price if manufacturers pass the higher costs on. Machinery users will benefit from safer products in the market, at a potentially higher price if manufacturers pass the higher costs on to them. Society will benefit from a significant reduction of public health systems costs across the EU.

In relation to the compliance costs, it must be stressed that the scope of the MD is very wide, and not all safety requirements in Annex I of the MD are applicable for all types of machinery. Manufacturers need to make a risk assessment, to determine the risks involved and the safety requirements relevant for their machinery, and they need to ensure compliance only to those. New or revised requirements proposed in this policy option are proportional and targeted, since limited to certain types of machinery. For instance, requirements on overhead power lines are relevant only to certain high mobile machinery types, declaration of peak vibration values is requested for portable hand-held and/or hand-guided machinery, and requirements on hazardous substances are applicable only to machines whose operation implies emissions of those.

As outlined in chapter 1.3 of this report, many machinery manufacturers belong to the SME category. Users (workers and consumers) will expect a same level of product safety, independently of the size of the company producing it. Impacts of policy option 3 on SMEs include additional costs in few cases where they may need to adapt the design of their machinery to comply with new requirements, although those would be targeted, and limited to certain machine types. On the other hand, diligent manufacturers will be already implementing some of the revised requirements and in such cases they would have a competitive advantage once the revised MD is in force.

Secondly, clarifications in scope and definitions may be beneficial for manufacturers who will not need to seek advice or resort to private contracts for clarification. SMEs will particularly benefit from the legal clarity that the revised MD will bring, important for them since SMEs have typically less resources to follow up and seek advice on legislation. Further legal clarity will have an effect on the reduction of uncompliant products in the market, for the benefit of machinery users (workers and consumers).

Thirdly, a revised list of high-risk machinery (Annex IV of the MD) will lead to additional direct compliance costs for third party involvement borne by manufacturers of products newly added to it, and potential savings for products removed. 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, although notified bodies will increase their turnover and market surveillance authorities will be backed by the notified bodies work. Machinery users and consumers will benefit from safer products in the market, although at a potentially higher

price if manufacturers pass the higher costs on to them. A removal of the internal checks option for conformity assessments of Annex IV machinery would bring additional costs for third party involvement to manufacturers, but is expected to increase the effectiveness of the Directive to ensure the protection of health and safety of users.

Fourthly, allowing digital documentation will bring cost savings to manufacturers, as well as an environmental benefit derived from the reduction in paper consumption and waste. Additional costs for manufacturers derived from the setting up of proper digital traceability systems will be offset by far by the economic benefits. In some cases, market surveillance authorities will need to adapt and put in place new market surveillance procedures related to digital documentations. Under the existing NLF product legislation, market surveillance authorities have already been adapted to digital documentation e.g. ICSMS. Machinery users and consumers will benefit from a free of charge paper version of the manual instructions should they require it.

Fi**nally, an alignment to the NLF and a conversion of the directive to a regulation** represents an opportunity to harmonise the market surveillance process, clarify the economic operators' obligations and decrease costs of compliance borne by manufacturers through a reduction of differences in interpretation across Member States. The work of the market surveillance authorities will be likewise facilitated. Machinery users and consumers will benefit from a lower number of uncompliant machinery in the market.

2. SUMMARY OF COSTS AND BENEFITS

This table summarises the potential costs and benefits of all the potential changes. 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 (Policy Option 3)		
Description	**Amount**	**Comments**
Direct benefits		
Administrative cost reductions	Printing saving costs up to EUR 16.6 billion (EUR 201 000 per company)	printing costs saved with digital instructions and DoC
Social benefits	EUR 15 million yearly	Reduced social costs for sick leave and occupational injuries, medical examinations and early retirement, by reduced vibration peaks in handheld machines
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	EUR 100 to EUR 500 per instance	A change of the requirements in terms of emerging technologies can lead to improved legal certainty and maintain a level playing field, particularly for manufacturers
Indirect benefits		
Safety of products on the market	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, as well as from new/revised targeted safety requirements through a reduction of non-compliant products on the market and increased safety. This benefit will be reinforced by the alignment of the MD to the NLF

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). Stakeholder group main recipient of the benefit in the comment section is indicated. For reductions in regulatory costs, details as to how the saving arises (e.g. reductions in compliance costs, administrative costs, regulatory charges, enforcement costs, etc.) are provided.

II. Overview of costs – Preferred option (Policy Option 3)							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Specific Objective 1	Direct costs		Higher prices in the market if passed on by companies	Compliance and adaptation to changes		Compliance and adaptation to changes	

II. Overview of costs – Preferred option (Policy Option 3)							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
	Indirect costs						
Specific Objective 2	Direct costs		Higher prices in the market if passed on by companies	Compliance and adaptation to changes		Compliance and adaptation to changes	
	Indirect costs						
Specific Objective 3	Direct costs		Increased costs of products if additional costs are moved down the value chain	Familiarisation with new legal text (one-off).	If the internal checks procedure is removed: Increased costs for third parties conformity assessment /Annual EUR 202 million overall		
	Indirect costs						
Specific Objective 4	Direct costs		EUR 0.4 per manual if user decides to print part of the manual (number of manuals not identified)	EUR 29 million (EUR 1 960 in average per company)	EUR 48 million (EUR 3 264 in average per company)	Increased costs of adaptation to new procedure.	
	Indirect costs						
Specific Objective 5 and 6	Direct costs			Some adaptation costs likely but expected to be marginal		Some adaptation costs likely but expected to be marginal	
	Indirect costs						

Estimates are provided with respect to the baseline. Costs are provided for each identifiable action/obligation of the preferred option otherwise for all retained options when no preferred option is specified. If relevant and available, information on costs according to the standard typology of costs (compliance costs, regulatory charges, hassle costs, administrative costs, enforcement costs, indirect costs) is provided.

Annex 4: Analytical methods

This Annex presents a general overview of the methodological approach taken during this impact assessment. In order to provide an exhaustive and systematic answer to all evaluation questions, data and information from a wide range of sources have been collected.

This impact assessment is supported by a study [105] carried out through a range of data collection methods. A **desk research and literature review** from statistical databases, reports and studies, a **stakeholder consultation** comprising semi-structured interviews (68 interviews), a **public consultation** (528 replies), **follow-up interviews** (30) and three **use cases** on emerging technologies (digital transformation, product optimisation and self-driving robots) were performed.

In addition, regular Machinery Working Group meetings have been held with all stakeholders has allowing all stakeholder groups to express their views, also when evolving in light of deeper discussions. A contribution was also received from the European Economic and Social Committee (EESC), by means of an Information Report issued on this initiative [106]. Finally, constant exchanges with all stakeholders by the Commission services has allowed a wide and extensive consultation process at all levels which has left no voice unheard.

Overview of the assessment tools and methods

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.

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. Moreover, a **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.

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

[105] Impact assessment study on the revision of Directive 2006/42/EC on machinery. Available at: https://data.europa.eu/doi/10.2873/423938
[106] https://www.eesc.europa.eu/en/our-work/opinions-information-reports/information-reports/revision-machinery-directive

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 analysis.

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 (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.

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.

Methodology for calculation of impacts

Methodology for calculation of reduced social costs of EUR 15 Million for sick leave and occupational injuries medical examinations thanks to changes in requirements for declaration of peak vibration in hand held machinery:

- In Sweden, there are 400 000 exposed vibrations from hand held machinery. The medical examinations of vibration injuries cost around EUR 3 000. It is reported that the requirement proposed would improve the situation and avoid 100 medical visits per year. This means that a reduction of the number of performed medical examinations by 100 per year would lessen the costs in Sweden by EUR 300 000 every year. These savings, extrapolated to the EU27 based on the population ratio (ca. 50), would make a total EU saving of EUR 15 Million. (Source: Machinery Working Group document 'WG-2020.46rev Swedish proposal and effects of a revision of the legal requirements in annex 1, 2.2.1.1 on vibrations for handheld machinery'.)

Methodology for calculation of impacts for manufacturers of Annex IV machines if the internal checks procedure is removed:

- Increased costs for third parties hired for the conformity assessment /Annual EUR 202 895 485 (recurring): 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. (Source: 'Impact assessment study on the revision of Directive 2006/42/EC on machinery'.)

Methodology for calculation of impacts on digital documentation:

Savings in printing costs by companies:

- Printing costs are reported to reach 1-4% of companies' turnover per year. Taking in to account EUR 663 billion turnover in the machinery sector in 2017, this leads to an annual recurrent cost for the industry of up to between EUR 6.63 billion and EUR 26.5 billion. According to the public consultation on the preferences of the form of documentation,

62.7% would like to have it always digital, bringing the estimate of the annual recurrent savings for the industry to between EUR 4 billion and EUR 16.6 billion. Dividing these amounts by the number of companies 82 239, this savings can be estimated at between 48 000 and 201 000 per company.

Costs for developing and maintaining the database for online manuals by companies:

- EUR 1 960: 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)

- EUR 29 013 919: Based on average costs of purchasing and setting up a server for small business od EUR 1 960, multiplied by the number of companies 82 239 and multiplied by 18% of companies not yet using digital formats.

- EUR 3 264: Based on average of EUR 272 per month (EUR 3 264 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.

- EUR 48 317 057: Based on the yearly costs of maintaining a server times EUR 3 264 the number of companies 82 239 and multiplied by 18% of enterprises not yet using digital formats.

User costs for printing digital manuals by users of EUR 0.4 per manual is calculated as follows:

- Total printing costs: average between 1% and 4% =2.5%, multiplied by turnover EUR 663 billion = EUR 26 520 000

- EUR 26 520 000 divided by 3.1 billion number of machinery units sold = EUR 8.5 per manual

- 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. Therefore, supposing a user would only print his own language, costs of an individual printing would reach about EUR 0.4 per manual. No difference could be made on the number of manuals used by professional users in comparison to consumers.

Methodology for calculation of impacts from transposition

- Cost savings in terms of clarification procedures between manufacturer and Member State authorities. EUR 100 to EUR 500 per instance. Based on consultation answers. The number of instance could not be estimated.

Data limitations and mitigation

As regards accidents data, key data limitations should be considered. First, safety incidents on a consumer level are not recorded. Second, availability of data differs depending on the variable of Eurostat European Statistics on Accidents at Work (ESAW). 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. This has been mitigated by the information that is

made available by Member states in the ICSMS and RAPEX systems about unsafe products found in the market, and the safety concerns and related accident data regularly reported at the at the Machinery Administrative Cooperation Group (AdCo) biannual meetings (market surveillance authorities and the Commission as observer) and also at the Machinery Working Group biannual meetings (with all interested stakeholders: industry, trade unions, consumer associations, standardisations organisations, notified bodies, market surveillance authorities and Commission).

Another limitation is the categorisation of the machinery sector in the structural business statistics, where 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 low-voltage products. In such cases, a proxy was used.

Annex 5: SME TEST

Preliminary assessment of businesses likely to be affected

According to the stakeholder consultations, no specific business sector were mentioned as being particularly or disproportionally affected by the policy options.

Consultation with SMEs representatives

SMEs taking part in the public consultation 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 Requirements (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.

Public consultation with SME representatives produced the following results about the specific objectives:

- **Specific Objective 1: Cover new risks related to digital emerging technologies**

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 public consultation 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 public consultation also do not have an opinion on whether requirements should be adapted to cover the human-robot collaboration (n=115). 30.4% of SMEs on the hand believes that requirements should be adapted in order to account human and robots in shared space. 26.1% of SMEs believe that new requirements should be added to cover human-robot collaboration (n=115). According to the 45% of the consulted SMEs in the public consultation report that changes made to the requirements in order to take into 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 (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).

- **Specific objective 2: Ensure coherent interpretation of the scope and definitions and improve safety for traditional technologies**

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 (48.7%) does not have an opinion whether the changes to the safety requirements covering speed lifts should be made. 34.8% of SMEs however believes that safety requirements should be changed (n-115). Large majority of SMEs (88.1%) believes that if changes to the safety requirements covering speed lifts were to be made, there would be no changes in costs (neither increase nor decrease of costs) (n=67).

- **Specific objective 3: Reassess machines considered as high risk and reassess related conformity procedures**

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 public consultation 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.

- **Specific objective 4: Reduce paper-based requirements for documentation**

61.3% of users which are 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).

- **Specific objective 5: Ensure coherence with other NLF legislation**

53.9% of SMEs agree with the alignment of MD to the New Legislative Framework (n=115).

- **Specific objective 6: Reduce possible divergences in interpretation derived from transposition**

Majority of SMEs participating in the public consultation (78.3%) would support the conversion of the Directive into regulation (n=115).

Annex 6: Example of a collaborative robot

The collaborative robot AURA is a relevant example from a regulatory perspective. Aura is marketed as Partly Completed Machinery.

Aura as advertised on Comau's website[107]

AURA **can automatic switch from 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[108], 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, operators can stop the AURA at any time. While the MD 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.[109]

In addition, 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[110]. 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[111]. 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 risk assessments before being deployed on the factory floor[112].

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[107] https://www.comau.com/en/our-competences/robotics/automation-products/collaborativerobotsaura

[108] COMAU (n.d.) AURA: Advanced use robotic arm. Available at: https://www.comau.com/Download/our-competences/robotics/Automation_Products/Folder_Aura%20Doppie.pdf

[109] 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

[110] COMAU (n.d.) AURA: Advanced use robotic arm. Available at: https://www.comau.com/Download/our-competences/robotics/Automation_Products/Folder_Aura%20Doppie.pdf

[111] Although the specific mode in which the AURA currently operates is signalled through a bright LED lamp

[112] DG Research and Innovation (2020). Unlocking the potential of industrial human–robot collaboration

Hazards for Physical Contacts with Crowdbot[113]

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

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

Annex 7: Case studies on emerging technologies

Three case studies were conducted in order to provide practical, issue-based, and detailed insights on the implications and the developments related to emerging technologies in the machinery sector and the Directive. Full details on these case studies can be found in the Impact assessment study on the revision of Directive 2006/42/EC on machinery[114]. The conclusions are reported here below.

- **1. 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 safety requirements are satisfied following software updates and that the relevance and accuracy of required documentation (manuals, requirements 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.

- **2. 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 ML 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.

- **3. 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.

[114] Impact assessment study on the revision of Directive 2006/42/EC on machinery. Available at: https://data.europa.eu/doi/10.2873/423938

Case Study 1 - Digital transformation of machinery

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 improved safety (e.g. re-assessment of risk in case of a major update and updating the requirements 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 requirements 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 software that ensures a safety function and is placed independently on the market as safety component yielded positive responses by the majority of respondents.

Summary of challenges and potential changes to the Directive – Case study 1

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 the requirements. • 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 system of machinery raises issues of cybersecurity.	• Defining requirements 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.

Case Study 2 - Production optimisation

The scope of this case study was to assess the challenges limited to existing technologies related to sensor-based control, ML 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 systems.

The MD should facilitate the innovation of emerging technologies and help in strengthening the position of EU as the leader in ML 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 requirements 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 ML 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.

Summary of challenges and potential changes to the Directive – Case study 2

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.

Case Study 3 - Self-driving robots

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.

This case study 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.

Summary of challenges and potential changes to the Directive – Case study 3

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 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 requirements requiring that specific safety 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 8: Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?
1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?
Article 114 TFEU, according to which the EU may adopt measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the single market
1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?
In the case of product safety legislation for the single market, the Union's competence is shared (Article 4 of the TFEU)
*Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU[115]. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU[116] sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU[117] sets out the areas for which the Unions has competence only to support the actions of the Member States.*
2. Subsidiarity Principle: Why should the EU act?
2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[118]: - Has there been a wide consultation before proposing the act? - Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?
The consultation activities performed include an inception impact assessment over a four week period, a 12-week public consultation in 23 languages on the Commission's central public consultation webpage, targeted consultations to follow and build on the results of the public consultation, and regular consultations with stakeholders, experts, workers/users and other interested parties at EU level. In particular, the following entities were consulted: • **the Machinery Committee (Member states authorities and Commission)** • **the Machinery Working/Expert Group (all interested stakeholders: industry, trade unions, consumer associations, standardisations organisations, notified bodies, market surveillance authorities and Commission) – biannual meetings** • **The Machinery Administrative Cooperation (AdCo) group (market surveillance authorities) - biannual meetings** • **The European Economic and Social Committee issued an information report** • **The Advisory Committee on Safety and Health at Work (ACSH) Working party** • **The EP Internal Market Committee (IMCO)** **The explanatory memorandum and the impact assessment (chapter 3) contain a section on the principle of subsidiarity. In addition, chapter 9 of the IAR proposes several indicators to monitor and evaluate the implementation of the changes.**

[115] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN
[116] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN
[117] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML
[118] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

A regulatory action at the EU level, laying down EU-wide requirements for ensuring the health and safety of machinery users, and allowing market enforcement at the national level according to the New Legislative Framework (NLF) principles, ensures a coherent implementation of the safety requirements for machinery, thus an improved level of safety, and allows the free movement of machines within the EU. This contributes to the development of the Internal (and Digital) Single Market, provides legal certainty and a level playing field for the industry, and establishes a high level of trust among machinery users.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

The proposed action cannot be achieved by the Member States acting alone as this would likely lead to different health and safety requirements in each Member State. This would create barriers in the single market, additional administrative burden on manufacturers, and a loss of competitiveness of the European mechanical industry also outside the EU. The Machinery Directive is a full harmonisation directive that ensures a same level of essential health and safety requirements and the free circulation of machinery across the EU, impacting manufacturers that place machinery in the EU market and protecting users of machinery in all Member States. The Machinery Directive is enforced by each Member State following common market surveillance rules.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

The Machinery Directive is a full harmonisation directive and play a fundamental role in ensuring the free circulation of machinery intra EU. In 2017, the machinery sector recorded a turnover of EUR 663 billion, production of EUR 609 billion and a value added of EUR 191 billion. In that same year, the total EU machinery and equipment exports amounted to EUR 503 billion, 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). [119]

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[120] or significantly damage the interests of other Member States?

National action or the absence of the EU level action would create an important gap in the single market.
As regards the risks stemming from emerging technologies, a lack of EU action would undermine the users trust on machines incorporating emerging technologies. Machines could be allowed on the market without being imposed the necessary safety requirements. Manufactures might find their machinery development hindered by the lack of legal clarity and guidance on what products types can or not be placed on the market. In this legal vacuum Member States may decide to issue their own national rules. All that could also create barriers in the single market, unfair competition and a suboptimal level of safety. In relation to the lack of clarity in some areas of the directive, the room for different interpretations by different manufacturers would generate

[119] UN COMTRADE

[120] https://europa.eu/european-union/about-eu/eu-in-brief_en

additional costs and burden for manufacturers and market surveillance authorities due to the need for clarifications, and would prevent a level playing field. Without a further harmonisation of the market potentially brought by the MD revision, the opportunity of decreasing the share of non-compliant products on the market might not be exploited. The Evaluation of the Machinery Directive showed that all stakeholder groups value the Machinery Directive and were in agreement with a revision, maintaining its current architecture and technological neutrality approach.
(c) To what extent do Member States have the ability or possibility to enact appropriate measures?
The Machinery Directive has been transposed into all EU Member States legislation. Member States are responsible for its enforcement, following common market surveillance rules. Without clear requirements for emerging technologies, Member States could try to fill the gap, or allow machinery in the market without the necessary safety level. The level of safety could become different from one EU country to another, altering the functioning of the single market and the level of trust of machinery users.
(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?
The Machinery Directive is a product safety legislation whose implications are the same at all levels of the EU and is enforced by each Member State following common market surveillance rules. Each Member State applies these common market surveillance rules according to their own national allocation of competencies. Germany, the biggest machinery producer in the EU, 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; they are further followed by the Netherlands, Sweden, Austria, Denmark and Spain. All EU countries are users of machinery.
(e) Is the problem widespread across the EU or limited to a few Member States?
The Machinery Directive is a product safety legislation that tackles machinery manufactured and placed on the market/put into service across the EU. The share of 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%). As outlined in (d), all EU countries are users of machinery.
(f) Are Member States overstretched in achieving the objectives of the planned measure?
The revision of the Machinery Directive all introduce some simplification for Member States, namely the alignment to the NLF will improve and bring the market surveillance activities in line with those existing under other product safety legislation already aligned, including the ICSMS (Information and Communication System for the pan-European Market Surveillance). Member States authorities have been active participants to the consultation and have made concrete proposals for the revision of the Machinery Directive. They are supportive of the changes proposed, which in some cases are clarifications that will facilitate their market surveillance and enforcement work.
(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?
The Market Surveillance Authorities may be national or regional depending on political systems and competencies allocation in each Member State. Authorities enforcing the

Machinery Directive agree in that the Machinery Directive need revision. The new Regulation on machinery products proposed by the commission has overall the support of a majority of the Member States, as demonstrated through the several consultations held (public consultation, targeted interviews, dedicated committee meeting with Member States authorities, and dedicated working group sessions with the wider machinery stakeholder group. Diverging views were found on few proposals, for which a minimum compromise has been made.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

The Machinery Directive is a harmonised product safety piece of legislation, already acting at EU level, which ensures a high level of safety and protection for users of machinery and other people exposed to it, as well as the well-functioning of the digital single market, which allows economies of scale at the manufacturer's level. The revised Directive will add clarity to the current act in its scope, definitions and requirements, including those covering risk stemming from emerging technologies (such as e.g. artificial intelligence and autonomous robots).

(a) Are there clear benefits from EU level action?

The Machinery Directive is a harmonised product safety piece of legislation, thus acting at EU level already. The Evaluation of the Machinery Directive (SWD (2018)160) concluded that the Directive is generally relevant, effective, efficient and coherent, and has EU added value, but that there was a need for specific improvements and simplification. As a result from the revision, new risks related to digital emerging technologies (AI, IoT, robotics) will be adequately covered, ensuring the well-functioning of the (digital) single market and establishing a high level of trust in digital innovative technologies for consumers and users. The revision will also ensure a coherent interpretation of the scope throughout the EU; reassess machines considered as high risk and their related conformity procedures and increase coherence with other NLF legislation, ensuring a high level of safety and protection for users of machinery and other people exposed to it. It will also bring a reduction of paper-based requirements for documentation leading to environmental and economic benefits (recurrent EUR 79 m net savings for manufacturers annually).

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

There are economies of scale at the manufacturer's level, since they can sell their machinery in all EU countries, as long as it complies with the Machinery Directive.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

This was already done when the first Machinery Directive was adopted (Directive 89/392/EEC). Since then, this and any subsequent directives have played an essential role in ensuring a harmonised set of safety requirements to protect machinery users and other exposed persons and has ensured a proper functioning of the single market for machinery. Both the Evaluation and the Impact Assessment consultations have confirmed the benefit of the Machinery Directive for all stakeholders and most particularly for manufacturers and users of machinery (workers and consumers).

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at

national, regional and local levels)?

An EU-level action is the most efficient way to ensure the objectives sought by the revised directive:

- Keep ensuring a high and the same level of safety and protection for users of machinery and other people exposed to it in the EU, and establish a high level of trust in digital innovative technologies for consumers and users; and
- Keep ensuring the well functioning of the (digital) single market. Create a level playing field for economic operators and preserve the competitiveness of the machinery sector in global digital markets.

(e) Will there be improved legal clarity for those having to implement the legislation?

The proposed revised Machinery Directive will add legal clarity to the current act in its scope, definitions and requirements, including those covering risk stemming from emerging technologies. In addition, the revised Machinery Directive will gain in coherence by aligning to the NLF and becoming a Regulation.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

Several policy options were considered for the revision of the Machinery Directive. A complete overhaul of the Directive imposing major new requirements to address the risk stemming from emerging technologies was considered not proportional and discarded from the beginning. The non-revision of the Directive, or the revision only in scope and definition was considered insufficient. The revision of the directive including clarifications to scope, definitions and minor necessary adaptation to the essential health and safety requirements was considered proportionate and not exceeding what it necessary to achieve the objectives.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The initiative is limited to the setting of product safety requirements, that are better dealt with at EU level to ensure a harmonised product safety and the free circulation of machinery, leaving the enforcement to the Member States. Those requirements are formulated in a technologically neutral way, so that innovation is allowed to adopt the best technical solutions according to the state of the art for each type of machinery. The revised text takes the form of a regulation to minimise differences in interpretation and avoid costs and delays of transposition. The benefits of this initiative offset the costs incurred.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

The initiative sets out the essential health and safety requirements the manufacturers of machinery need to comply with when designing and manufacturing their machines for the EU market. Only taken at EU level can this action create a harmonised product safety and allow the free circulation of machinery within the EU. Member States are responsible for the enforcement of the Directive, which is better dealt with at national level.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?
The instrument proposed for the revision of the Machinery Directive is a regulation, since it is seen as the most effective and efficient solution, for it minimises the potential differences in interpretation and avoids costs and delays of transposition. There is a wide consensus on the benefits of the conversion of the directive to a regulation. 79% of 523 public consultation respondents, across all stakeholder types, expressed support for this change, and also all Member States authorities supported this choice of instrument.
(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)
The Machinery Directive is a fully harmonised piece of legislation; hence, Member States cannot alter the requirements laid down in the directive. However, this is the basis for achieving an EU wide level of safety for machinery users and the free circulation of machinery across EU countries. However, since the Machinery Directive is technologically neutral, it leaves space for manufacturers to meet the safety requirements via harmonised standards cited in the OJEU, or to propose alternative solutions as long as they demonstrate conformity to the requirements of the directive.
(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?
The initiative create additional costs in some areas (costs for manufacturers of software with a safety function that is put independently in the market) and other adaptation costs for manufactures and authorities, but bring overall more benefits (e-manuals brings saving of printing costs for manufacturers, vibration requirements allow savings of social costs for reduced sick leave and occupational injuries). In addition, clarifications in the directive allow the industry to save on guidance for interpretation or additional clarifications via commercial contracts, and ensure fair competition in the EU market. The changes to the Machinery Directive in this revision are the minimum necessary to achieve the objectives, and are commensurate with those objectives, complemented with clarifications in the Guide to application of the Machinery Directive and with the standardisation process.
(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?
No special circumstances apply to any individual Member State in the frame of this initiative have been identified.