

Ensuring machine safety in the digital age

Revision of the Machinery Directive

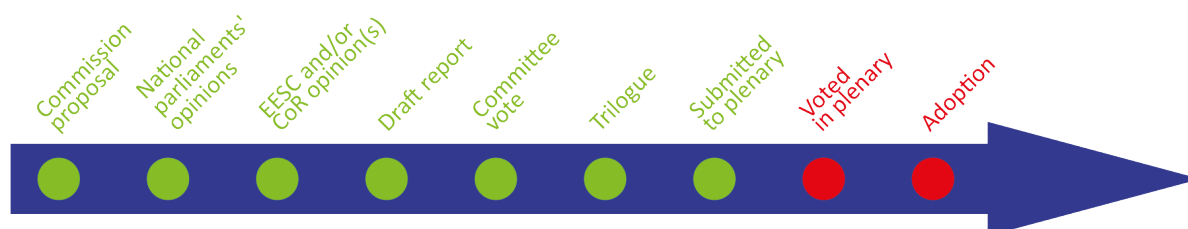
OVERVIEW

The current Machinery Directive (Directive 2006/42/EC) was designed to allow the free movement of machinery within the internal market, while ensuring a high level of user health and safety. To reduce the occurrence of accidents, it promotes the inherently safe design and construction of machinery, and proper installation and maintenance.

On 21 April 2021, the Commission put forward a proposal for a regulation on machinery products, as part of a wider 'artificial intelligence package'. The need for an update stemmed in particular from recent developments in digital technologies, such as artificial intelligence, the internet of things, and robotics, which have raised new safety challenges. The proposed revision also intends to ensure more coherent interpretation of the scope and definitions, enhance safety for traditional technologies, reassess machines considered as 'high risk' and the conformity assessment procedures, reduce paper-based requirements for documentation, ensure coherence with other product safety legislation and avoid divergences in interpretation stemming from transposition.

The Parliament and Council reached a provisional agreement on the new regulation on 15 December 2022. In the Council, the Permanent Representatives Committee approved the agreement on 25 January 2023. In the Parliament, the Committee on Internal Market and Consumer Protection (IMCO) approved the agreement on 2 March 2023 by 36 votes in favour and one abstention. The vote in plenary on Parliament's first reading position will take place in April.

Proposal for a regulation of the European Parliament and of the Council on machinery products		
<i>Committee responsible:</i>	Internal Market and Consumer Protection (IMCO)	COM(2021)202
<i>Rapporteur:</i>	Ivan Štefanec (EPP, Slovakia)	21.4.2021
<i>Shadow rapporteurs:</i>	Adriana Maldonado López (S&D, Spain) Svenja Hahn (Renew, Germany) David Cormand (Greens/EFA, France) Marco Campomenosi (ID, Italy) Carlo Fidanza (ECR, Italy) Kateřina Konečná (The Left, Czechia)	2021/0105(COD) Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')
<i>Next steps expected:</i>	Vote in plenary on first reading position	



Introduction

The major economic transformations that have unfolded since the first industrial revolution have been driven largely by the increasing uptake of machines, such as [machine tools](#) or robots. Machines can, however, be a source of accidents. The current [Machinery Directive](#) (Directive 2006/42/EC) has been applicable since 29 December 2009. It has a dual objective: a) to allow the free movement of machinery within the internal market, while ensuring a high level of protection of health and safety of users; b) to reduce the occurrence of accidents by promoting inherently safe design and construction of machinery, and proper installation and maintenance.

The EU co-legislators have amended the Machinery Directive. The need for an update stemmed in particular from recent developments in digital technologies, such as artificial intelligence (AI), the internet of things (IoT, which is based on networks of interconnected objects) and robotics. These emerging technologies have transformed the features of a wide range of machines, and raised new safety challenges.

Existing situation

The Machinery Directive is part of EU legislation on product safety. It focuses on ensuring the inherent safety of machines and obliges machinery manufacturers to take safety into account when designing and constructing machinery ('safety by design'). Regarding machinery used in pesticide applications, the directive also aims to protect the environment. The directive defines machinery as an assembly of components, at least one of which moves, joined together for a specific application, the drive system being powered by energy other than human or animal effort. The products covered include **construction machinery, lawnmowers, 3D printers and robots**. In addition to machinery in the strict sense, the scope covers other related products, such as safety components or partly completed machinery.

The Machinery Directive relies on a regulatory method known as the 'new approach to technical harmonisation and standards'. The legislation sets out the **mandatory 'essential health and safety requirements'** (EHSRs) that machinery products placed on the EU market must fulfil (listed in Annex I). The manufacturer conducts a **risk assessment** to determine the EHSRs that apply to the specific machinery product. The machinery product must be designed and built to prevent and minimise all relevant risks.

The directive also sets out the mandatory procedures for assessing the conformity of machinery with the EHSRs ('**conformity assessment procedures**') to be used to demonstrate that the machine fulfils these requirements. Demonstrating compliance with the requirements can be done through the application of European harmonised standards, which include detailed technical specifications for fulfilling these EHSRs, or another solution that demonstrates a similar level of safety. The use of standards remains voluntary, but when references for harmonised standards are published in the Official Journal of the EU, application of their specifications confers a presumption of conformity with the EHSRs they cover. The voluntary nature of harmonised standards is intended to prevent standards from being an obstacle to the placing on the market of machinery incorporating innovative solutions. [CEN and CENELEC](#) are involved in the development of standards supporting the Machinery Directive. Since 1 December 2018, [references for harmonised standards](#) have been published in, and withdrawn from, the Official Journal of the EU by means of Commission implementing decisions.

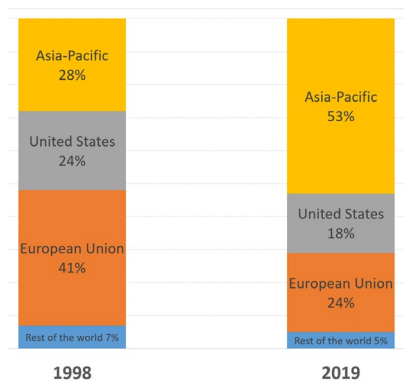
The various conformity assessment procedures are set out in Annexes VIII, IX and X. The **rules for their selection** are given in Article 12. If the machinery is **not referred to in Annex IV (i.e. machinery not presenting higher risks)**, the manufacturer has to apply the procedure for assessment of conformity with internal checks on the manufacture of machinery (Annex VIII). This procedure **does not include an obligation to involve the intervention of a third party**. However, the manufacturer is free to seek any independent advice or assistance to carry out the conformity

assessment of the machinery. For categories of machinery **listed in Annex IV (i.e. machinery presenting higher risks)** designed and constructed in accordance with harmonised standards, three alternative conformity assessment procedures may be applied. One of them is identical to the one applied to non-Annex IV machinery, but may only be used if three conditions are fulfilled.¹ If any of the three conditions is not met, the conformity assessment procedure for Annex IV machinery **must involve a third party (i.e. a 'notified body')**.

Furthermore, the directive requires manufacturers to produce a **technical file**, sign a **declaration of conformity** and affix the **'CE' marking** to the machinery. The CE marking indicates that the machinery product meets the relevant EHSRs and can be traded without restriction in the internal market. Member States are responsible for carrying out market surveillance, to identify non-compliant products and to enforce corrective measures.

Context

Figure 1 – Production of machinery by region, globally (1998 and 2019)



Source: [European Commission](#), 2021.

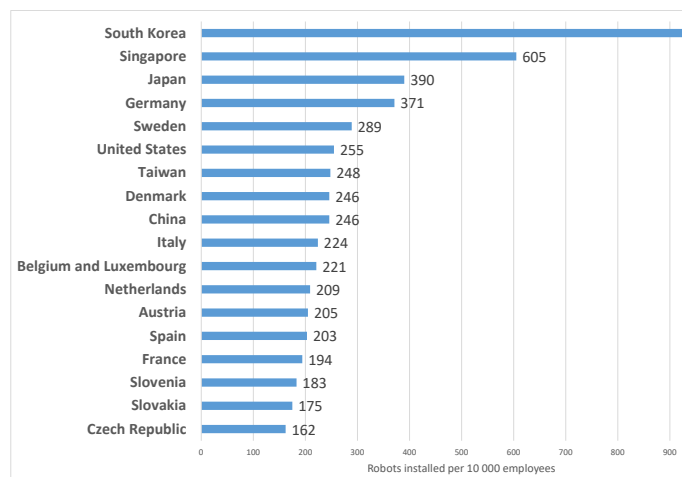
The machinery industry is one of the major manufacturing sectors within the EU. The [EU machinery industry](#) has an annual turnover of €700 billion. The sector comprises around 80 000 companies, employing about 3 million workers. [Two thirds](#) of companies in the sector are micro-enterprises (i.e. they employ fewer than nine people).

The EU's machinery industry accounts for 9.4 % of manufacturing turnover, 11.2 % of its value added and employs around 10 % of all persons employed in manufacturing.

Machinery manufacturers from the EU and the United States have dominated the global machinery market for decades, but Asian companies have gained in importance over the past few decades (Figure 1).

In the machine tool segment, Germany (15 % of global market share) and Italy (8 %) are among the top five producers, together with China (28 %), Japan (14 %) and the United States (6 %).

Figure 2 – Robot density in the manufacturing industry (2020)



Source: [International Federation of Robotics](#), 2021.

The use of industrial robots in factories has shot up, as [robot density has nearly doubled](#) globally over the past five years, reaching 126 robots per 10 000 employees in 2020.

The EU's most automated Member State is Germany (Figure 2), ranking fourth worldwide. Germany belongs to the [top five largest robot markets in the world](#), with China, Japan, the United States and South Korea. In 2020, it accounted for 33 % of total robot installations in the EU, followed by Italy with 13 % and France with 8 %.

Parliament's starting position

In its [resolution](#) of 16 February 2017 (previous parliamentary term) with recommendations to the Commission on civil law rules on robotics, Parliament pointed to the potential of robotics to generate new risks, owing to the increasing number of human-robot interactions in the workplace, and stressed the need to guarantee health and safety in the workplace. In its [resolution](#) of 20 October 2020, with recommendations to the Commission on a framework of ethical aspects of AI, robotics and related technologies, Parliament noted that the Commission should examine the existing legal framework and its application, including product safety legislation, to identify legal gaps and to address the new challenges posed by the emergence of AI, robotics and related technologies.

In its [resolution](#) of 25 November 2020 on addressing product safety in the single market, Parliament stressed the need to adapt product safety rules to the new market realities and the digital transition, by tackling emerging risks and threats. More specifically, it asked the Commission to identify and close gaps within the Machinery Directive, ensuring a consistent approach towards product safety in all sectoral legislation. Parliament also insisted, in its [resolution](#) of 12 February 2019, on a comprehensive European industrial policy on AI, to ensure that some rules addressed the risk of accidents resulting from the interaction of AI technologies developed for manufacturing with humans. Moreover, the further promotion, development and improvement of common standards on safety, reliability, or security for robotics and AI should be among the EU's priorities.

In its [resolution](#) of 3 May 2022 on AI in a digital age, Parliament stressed that there is a need to establish a risk-based legal framework for AI, combined with product safety provisions, fostering AI uptake and innovation. Parliament also noted that, in order to increase product safety and improve the identification of faults, the developers of high-risk AI should ensure that accessible logs of algorithmic activity are maintained securely. Furthermore, developers should design high-risk AI systems with embedded mechanisms – 'stop buttons' – for human intervention to safely and efficiently halt automated activities at any moment and ensure a human-in-the-loop approach. The AI system's output and reasoning should always be comprehensible to humans.

Preparation of the proposal

In May 2018, the Commission released an [evaluation](#) of the Machinery Directive, based on the findings of an [external study](#) published by Technopolis group in September 2017. It concluded that the directive was generally relevant, effective, efficient, coherent and had EU added value. It nevertheless identified a number of issues, for example concerning the monitoring and enforcement of the directive and the need for better legal clarity. It also pointed to the need for clarification of its interaction with other legislation. Furthermore, the evaluation highlighted that the directive was sufficiently flexible to allow technological developments in a digital era, but stressed that further innovation in fields such as AI and IoT may test the directive's effectiveness in the future. In particular, AI robots could pose much higher risks than purely software AI systems, owing to their mechanical moving parts.

On 10 January 2019, the Commission published an [inception impact assessment](#). A public consultation was open between 7 June and 30 August 2019. A Commission [report](#) on the safety and liability implications of AI, the IoT and robotics, released in 2020, stressed that these new digital technologies raised new product safety challenges for machines, because they were: more interconnected (they can be hacked); autonomous; dependent on data (that may be faulty); opaque (decisions taken by AI systems learning from experience may be difficult to understand ('black box effect')); and rely on software that requires regular updates. The report concluded that current EU product safety legislation, including Directive 2006/42/EC, contained a number of gaps in this respect that needed to be addressed.

An [impact assessment study](#) on the revision of the directive, carried out by Valdani Vicari & Associati, Deloitte, the Vienna Institute for International Economic Studies and Ecorys, was published in August 2020. The [impact assessment](#) prepared by the Commission was released together with the [proposal](#) for a regulation on machinery products. [Feedback](#) on the Commission proposal was open between 26 April and 2 August 2021.

On 17 July 2021, EPRS published an [implementation appraisal](#) on the operation of the Machinery Directive, providing an overview of publicly available material on the implementation, application and effectiveness to date of the directive. It stresses that the European Commission's regulatory fitness and performance programme (REFIT) evaluation of 2018 had concluded that the Machinery Directive had generally remained relevant and effective. However, it pointed to certain shortcomings in the enforcement of the directive (mainly related to market surveillance, a Member State responsibility). It also found that the directive might not sufficiently cover new risks stemming from emerging technologies (in particular, robots using artificial intelligence technologies).

On 2 July 2021, EPRS published an [initial appraisal of the Commission impact assessment](#). It found that the assessment was mostly qualitative, and explained openly the analytical methods and data limitations. Furthermore, it stressed that the scale of problems and the efficiency aspect in the comparison of the policy options could have been explained further. Moreover, the briefing pointed out that the impact assessment could have been more informative concerning the stakeholder consultations. It also questioned whether the [SME test](#) (an assessment of potential impacts of the proposal on SMEs) had been duly conducted.

The changes the proposal would bring

On 21 April 2021, the Commission put forward a [proposal](#) for a regulation on machinery products. The proposal was part of an '[AI package](#)' that included, in particular, a [proposal](#) for a regulation laying down harmonised rules on AI ('AI act').² The proposal is designed to cover new risks relating to the use of new digital technologies; ensure coherent interpretation of the scope and definitions; enhance safety for traditional technologies; reassess machines considered as 'high risk' and the related conformity assessment procedures; decrease paper-based requirements for documentation; ensure consistency with other product safety legislation; and avoid divergences in interpretation stemming from transposition.

Principles

Change of legal instrument: from a directive to a regulation

The proposal would repeal and convert the current directive into a regulation. This is designed to avoid delays and erroneous, or diverging, interpretation of the directive across the Member States, stemming from transposition (i.e. incorporation of the provisions of the directive into national legislation). The choice of a regulation is also intended to avoid the risk of 'gold-plating' in Member States (e.g. the setting-up of requirements that go beyond those required by the directive).

As [highlighted by the Commission](#), transposition of the Machinery Directive has led to different interpretations of key concepts across Member States, such as those of 'partly completed machinery' or 'safety components'. Furthermore, the Commission has identified cases of diverging interpretations of the EHSRs, which have created obstacles to the single market (e.g. cases where one or several Member States consider that a machine does not comply with the EHSRs, although the machine is available in other Member States).

Alignment with the new legislative framework (NLF)

The proposal seeks to increase consistency with other pieces of EU product-safety legislation by aligning the Machinery Directive with the [new legislative framework](#) (NLF). The NLF is a package of measures³ adopted in 2008 to improve the functioning of the single market for goods and to improve the quality of conformity assessment of products. While 23 other pieces of legislation have

been aligned with the NLF (e.g. the [Low Voltage Directive](#) (Directive 2014/35/EU), the [Radio Equipment Directive](#) and the [Lifts Directive](#)), this is not yet the case for the Machinery Directive. This alignment aims to prevent confusion for manufacturers and other economic operators whose products fall within the scope of more than one piece of product-safety legislation. It is also expected that this alignment would improve enforcement of the Machinery Directive.

The proposal therefore adapts the provisions of the Machinery Directive to the NLF reference provisions. For instance, the proposal introduces, in Article 3 (whose scope corresponds to ex-Article 2 of the Machinery Directive), some NLF definitions that were not in the current directive (e.g. importer, distributor and economic operator). It also incorporates a chapter on obligations for economic operators (Chapter II), clarifying e.g. manufacturers' obligations (Article 10). The proposal also includes the NLF provisions on safeguard procedures, to ensure the conformity with Union legislation of national measures dealing with machinery products presenting a risk (Chapter VI, Articles 41 to 44). Moreover, it incorporates the NLF provisions on the notification of conformity assessment bodies; the NLF conformity assessment modules are introduced in Annexes VI, VII, VIII and IX.

Digitalisation of documentation

In order to reduce paper-based requirements for documentation, the proposal specifies in Annex I (item 1.7.4) that the instructions can be provided either digitally or on paper.⁴ Nevertheless, they must be provided free of charge in paper format upon the purchaser's request, at the time of the purchase of the machinery product (this may be useful for users that are less digitally savvy and for those who lack internet access in certain environments, such as forests). Economic operators had complained about the costs and administrative burden linked to paper documentation. Furthermore, the Commission pointed to some environmental benefits deriving from the reduction in paper use resulting from these new provisions.

Adapted current elements

Clarification of scope, and new (or adapted) definitions

The proposal aims to clarify the scope and definitions included in the directive; the objective is to reduce legal uncertainty. Uncertainty stems from the fact that the directive may in some cases apply *together* with other pieces of legislation (e.g. with the [Radio Equipment Directive](#)), while in other cases the directive applies *alternatively* to other legislation (e.g. to the [Low Voltage Directive](#)). The proposal therefore clarifies some exclusions: the electrical and electronic products that are listed in Article 2(2)m would now be excluded from the directive insofar as they fall under the Low Voltage Directive (e.g. household appliances for domestic use – e.g. dishwashers) or the Radio Equipment Directive, to cover e.g. dishwashers with built-in Wi-Fi.

Furthermore, due to some uncertainties concerning means of transport covered by the Machinery Directive, the proposal clarifies (Article 2(e)) that means of transport whose objective is to transport people or goods are excluded from the scope of the regulation (such as electric-power-assisted cycles or hover boards). In addition, the proposal adapts some definitions or introduces new ones (such as those of importer, distributor and economic operator, in line with the NLF).

Partly completed machinery (PCM) is a machinery product that must undergo further construction in order to be able to perform its specific application. Not all requirements of the Machinery Directive apply to PCM. The proposal clarifies the definition of PCM, as the current definition has been applied inconsistently by manufacturers, which could have led to incorrect classification of products as components instead of PCM, and to incorrect CE marking of PCM. To take into account the growing use of software in machinery, the proposal adds a new indent in the definition of machinery (Article 3(1)b), stating that an assembly missing only the upload of software intended for its specific application is machinery and not PCM (meaning e.g. that non-pre-programmed robots are machinery).

Moreover, the proposal adds a definition of 'substantial modification' of machinery (Article 3(16)), also in order to avoid different interpretations across the EU (a new CE marking is required for machinery having undergone such a modification). In addition, Article 3(3) now clearly states that a safety component can be digital.

Furthermore, low-speed lifts (whose speed is not greater than 0.15 m/s) fall within the scope of the Machinery Directive (e.g. lifting appliances for persons with impaired mobility), as they are excluded from the scope of the [Lifts Directive](#). These lifts are often installed by an installer following the manufacturer's instructions. However, unclear responsibility in cases of failures in installed lifts has been identified as a weakness of the current directive. The proposal aims to harmonise the interpretation of responsibility when installing such lifts (EHSR 4.1.3).

Improved safety of traditional machinery

The proposal adapts or introduces a number of EHSRs concerning the design and construction of traditional machinery products, located in Annex III of the proposed regulation. In order to prevent serious or fatal accidents, the current EHSRs (3.2.2.) for 'ride-on' mobile machinery (e.g. excavators, ride-on lawn mowers and agricultural sprayers) are considered insufficient to prevent the risk of falling off when machinery rolls or tips over. The proposal updates this EHSR to specify that a visual or audible signal must be provided at the driving position alerting the driver when the restraint system is not active. Furthermore, a new EHSR (3.5.4) on risk of contact with live overhead power lines has been added, as several accidents linked to mobile machinery hitting such power lines have occurred over the past few years.

Moreover, several EHSRs have been updated in order to improve protection of workers against exposure to hazardous substances: a new indent has been added in EHSR 1.7.4.2 (w), specifying that instructions should provide information on emissions of hazardous substances from the machinery product. Another indent is added in EHSR 2.2.1 (e), stating that portable hand-held and/or hand-guided machinery should have a device or a connected exhaust system, with an extraction connection outlet or equivalent system to capture or reduce emissions of hazardous substances. EHSR 3.5.3 has also been updated so that ride-on mobile machinery whose main function is the spraying of products shall be equipped with filtration cabs or equivalent safety measures.

In addition, in order to prevent injuries stemming from vibrations from handheld and hand-guided machinery, EHSRs 2.2.1.1 and 3.6.3.1 (instructions) have been updated so that instructions should give information on the vibration total value from continuous vibrations to which the hand-arm system is subjected (no longer only if it exceeds 2.5 m/s^2) and on the mean value of the peak amplitude of the acceleration from repeated shock vibrations, to which the hand-arm system is subjected.

The proposal also adapts EHSR 6.2 on control devices with the aim of promoting innovation: if there is no risk to the people or the objects in the carrier of colliding or falling, and no other risks are added on account of the upward and downward movements, then hold-to-run control devices may be replaced by other types authorising automatic stops at pre-selected positions (in the current directive, hold-to-run control devices were obligatory for not completely enclosed carriers on slow-speed lifts).

Substantial modification of a piece of machinery

The current directive does not address situations where machinery is modified by distributors without the manufacturer's agreement. The machinery may then no longer be in conformity with the EHSRs. Therefore, the proposal introduces a definition of 'substantial modification' (when machinery products are modified by physical or digital means in a way that is not envisaged by the manufacturer, and that may imply that it is no longer in conformity with the EHSR). The person that carried out the substantial modification becomes manufacturer and is required to perform a new conformity assessment before placing the modified machinery product on the market (only for aspects of the machinery product that are impacted by the modification).

Commission empowerment to develop technical specifications

The proposal empowers the Commission to adopt technical specifications for the EHSRs (Article 17(3)), to facilitate the manufacturer's obligation to comply with these requirements. The Commission would use this possibility only if harmonised standards were absent (e.g. when the standard request had not been accepted by any of the standardisation organisations or when the standardisation process was blocked).

New elements

'High-risk' machinery products

In the current directive, as explained above, for certain types of machinery presenting a higher risk (listed in Annex IV), a stricter certification procedure is to be applied. The proposal aims to reinforce the provisions for these machinery products. The title of Annex I (former Annex IV) now clearly refers to 'high-risk machinery products'. Furthermore, the proposal updates the list of high-risk machinery, adding two new items: software ensuring safety functions, including AI systems; and machinery embedding AI systems ensuring safety functions. There would be 25 categories of machinery products in total in this annex. Furthermore, with the current directive, the list of high-risk machinery could only be updated through the ordinary legislative procedure. The proposal empowers the Commission to adopt delegated acts to update this list (Article 5(2)), to take scientific and technical progress into account more quickly. The proposal also lays out criteria to be taken into account when assessing the risk posed by a machinery product (e.g. the number of people potentially affected) (Article 5(3)).

Importantly, the proposal removes the internal check option for the conformity assessment for high-risk machines. It therefore introduces the obligation to involve a third party in the conformity assessment for all high-risk machinery (Article 21(2)).

Improved safety by covering new risks relating to new digital technologies

The proposal updates the general principles in Annex III on EHSRs. More specifically, when carrying out risk assessments to select the EHSRs applying to a machinery product, manufacturers must identify the **hazards that may be generated during its lifecycle**, owing to its **evolving behaviour** or logic, as a result of the machinery product operating with some degree of autonomy. Furthermore, to take into account changes in **human-machinery interaction** arising from the emergence of digital technologies, particularly as machines may resemble humans and be more autonomous, the proposal updates a number of EHSRs.

For instance, for EHSR 1.1.6 on **ergonomics**, when designing machinery, manufacturers must reduce to a minimum operators' stress by adapting the human-machinery interface to the operator's characteristics, including when machines have evolving behaviour and a certain degree of autonomy. In addition, manufacturers must make sure that such machines are able to respond to operators verbally or not verbally, and to communicate on their planned actions.

EHSR 1.3.7 on **risks related to moving parts and psychological stress** has been updated to include mention of the need for machines with evolving behaviour and a certain degree of autonomy to respond to people and to communicate on their planned actions.

EHSR 1.2.1 on **safety and reliability of control systems** is updated to state that a machinery product with evolving behaviour or logic that is designed to operate with varying levels of autonomy must be designed not to cause the machinery product to perform actions beyond its defined task and movement space; and so that it shall be possible at all times to correct the machinery product in order to maintain its inherent safety. In order to improve traceability and facilitate conformity assessment and market surveillance, the tracing log of the data generated in relation to an intervention and of the versions of safety software uploaded after the machinery product has been placed on the market or put into service, would be enabled for five years.

Recording of data on the safety-related decision-making process after the machinery product has been placed on the market or put into service would be enabled and such data should be retained for one year after its collection, to demonstrate the conformity of the machinery product with the annex following a request from a competent national authority.

Annex IV (former Annex VII) on technical documentation for machinery products would be updated so that technical documentation would include the source code or programmed logic of the safety-related software to demonstrate the conformity of the machinery product with the regulation, further to a request from a competent national authority, provided that is necessary in order for those authorities to be able to check compliance with the EHSRs.

The proposal also adds **software ensuring safety functions**, including AI systems placed independently on the market, to the indicative list of safety components in Annex II (Annex V of the current directive). The proposal empowers the Commission to use delegated acts to adapt the indicative list of safety components in Annex II, to take into account technical progress and new knowledge or scientific evidence.

Safety issues linked to **cyber-attacks** are also addressed in the proposal, which introduces a new EHSR (1.1.9) on **protection against corruption**. Manufacturers must design machinery products so that connection to them by another device does not lead to a hazardous situation, and a hardware component for connection must be designed so that it is protected against corruption. The proposal also clarifies EHSR 1.2.1 on **safety and reliability of control systems**. More specifically, failure of the connection or a faulty connection must not lead to a hazardous situation. Machinery products that have been certified or for which a statement of conformity has been issued under a relevant cybersecurity scheme adopted in accordance with the [Cybersecurity Act](#) (Regulation (EU) 2019/881) would be presumed to be in conformity with EHSRs 1.1.9 and 1.2.1, as regards protection against corruption and safety and reliability of control systems (Article 17(5)).

Driverless mobile machines (autonomous or remotely controlled) are now covered explicitly through the amendment of Annex III (EHSR 3.1): the definition of a driver now includes a person who may remotely supervise the autonomous mobile machinery product regardless of the distance and the means of control communication.

Advisory committees⁵

The legal basis of the proposal (Article 114 TFEU) requires consultation of the European Economic and Social Committee (EESC). In its [opinion](#) of 22 September 2021 (rapporteur: Martin Böhme, Diversity Europe – Group III, Germany), the EESC welcomed the Commission proposal, not least for taking into account the impact of digital technologies.

The EESC put forward a number of recommendations. It added derogations to mandatory third-party conformity assessment for high-risk machinery products in duly justified cases (e.g. if the AI software cannot evolve on its own or make decisions). The EESC also added new provisions to promote the involvement of workers' representatives in the procedure for the purchase and installation of new machinery products.

The EESC opinion calls for clear definition of the responsibilities of natural or legal persons in the event of an accident, particularly when AI is concerned. It also recommends increasing legal clarity by specifying in Article 50 which rules should be applied during the transitional period in the move from the Machinery Directive to the new Machinery Regulation. The EESC suggests keeping the same numbering of the annexes as in the Machinery Directive. It also recommends that the Commission and stakeholders monitor implementation of the new regulation continuously (by means of a dedicated administrative board). The EESC particularly welcomed the introduction of the possibility for the Commission to draw up technical specifications in the absence of appropriate harmonised standards.

National parliaments

National parliaments had [until 13 September 2021](#) to submit reasoned opinions to the Commission on the grounds of subsidiarity. Only the [Czech Chamber of Deputies](#) submitted a written opinion (concerning the whole AI package), which did not raise any subsidiarity issues.

Stakeholder views⁶

The consultation was open between 26 April and 2 August 2021 and the Commission received [115 contributions](#) from stakeholders.

In a July 2021 position [paper](#), ANEC (European Association for the Coordination of Consumer Representation in Standardisation) recommended: including fairground and amusement park equipment within the scope; either including e-bikes and e-scooters or addressing them with specific legislation; including escalators on the list of high-risk machinery products; and 'revitalising' the [European Injury Database](#) to assess whether a machine poses a high risk for consumers.

In a [statement](#) released on 4 October 2021, 17 business organisations (including BusinessEurope, Orgalim and Digital Europe) welcomed the conversion of the directive into a regulation, alignment with the NLF framework and the possibility to provide digital format documentation. They opposed the introduction of mandatory third-party conformity assessment for high-risk machinery, claiming that the Commission had underestimated the associated costs, that it would hamper innovation and that there was no proof that this new provision would enhance safety. They also expressed their opposition to the adoption of technical specifications by the Commission in the absence of harmonised standards, except in some cases. Furthermore, these organisations stressed that essential requirements should remain technology-neutral. The business organisations also called for clear provisions on the transition period between the Machinery Directive and the new regulation.

Legislative process

European Parliament

In the European Parliament, the file was allocated to the Committee on Internal Market and Consumer Protection (IMCO), with the Committee on Employment and Social Affairs (EMPL) as an opinion-giving committee. Ivan Štefanec (EPP, Slovakia) was appointed rapporteur in IMCO.

The final report, as well as the decision to [enter into interinstitutional negotiations](#), with the committee [report](#) as the mandate (including 179 amendments), were both [adopted](#) by 38 votes in favour and 7 against, on 3 May 2022. The plenary endorsed that decision on 20 May 2022, opening the way for the committee to start interinstitutional negotiations with the Council.

Council

In the Council, discussions on the proposal started on 26 April 2021 in the [Working Party on Technical Harmonisation](#). The Council adopted its [mandate for negotiations](#) with the Parliament on 24 June 2022.

Agreement on the new Machinery Regulation

Trilogues took place on 12 July 2022, 17 November 2022, and on 15 December 2022, when the [provisional agreement](#) on the new Machinery Regulation was [reached](#) by the Parliament and the Council (20 months after the publication of the Commission proposal). The Council and Parliament then initiated the process towards formal adoption of the new Machinery Regulation. In the Council, the Permanent Representatives Committee [approved](#) the agreement on 25 January 2023. In the Parliament, IMCO [approved](#) the [provisional agreement](#) on 2 March 2023 by 36 votes in favour, none against, and 1 abstention. The vote in plenary on the Parliament's first reading position is expected to take place in April. The agreement builds particularly on the following provisions:

The new Regulation covers e-bikes, e-scooters and other personal mobility devices that are not subject to EU type approval under [Regulation \(EU\) No 167/2013](#), or under [Regulation \(EU\) No 168/2013](#), as mentioned in recital 15.

The text agreed splits Annex I (initially referring to 'high-risk' machinery products) into two parts: the first (part A), includes only six categories of machinery that will be subject to mandatory third-party certification (compared to 25 in the proposal): (i) removable mechanical transmission devices including their guards; (ii) guards for removable mechanical transmission devices; (iii) vehicle servicing lifts; (iv) portable cartridge-operated fixing and other impact machinery; (v) safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions; and (vi) machinery embedding systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only of those systems.

For the 19 categories of machinery listed in a new second part (Part B) in Annex I, the manufacturer can decide to carry out the conformity assessment itself (self-assessment of conformity).

The agreement also specifies in Article 5 that the Commission has to consult stakeholders and the views of the relevant expert groups nominated by the Member States before adopting delegated acts changing the content of Annex I. In addition, the agreed text includes a list of factors (e.g. known accidents) that the Commission must take into account when assessing the seriousness of the inherent potential risk posed by a category of machinery for the purpose of changing the list of categories of machinery in Annex I. The Commission must adopt implementing acts on a template for the collection of the data and the information provided by the Member States in this exercise. The Commission must also adopt delegated acts setting up a common methodology on the data and information to be collected (e.g. on the methods for their collection and compilation).

Furthermore, the agreed text deletes the reference to 'AI systems' and replaces it by references to 'self-evolving behaviour using machine learning approaches' (for instance, in Annex I, Part A).

The newly introduced definition of substantial modification (Article 3) is further specified: such modification affects the safety of machinery by creating a new hazard or by increasing an existing risk which requires the addition of guards or protective devices to that machinery or the adoption of additional protective measures.

The agreed text further specifies the provisions concerning PCM. For instance, it includes a new article concerning obligations of PCM manufacturers (Article 10a), stating e.g. that it must be constructed in accordance with the relevant EHSR and be accompanied by the assembly instructions.

The agreement also confirms that the instructions may be provided in a digital format and specifies the obligations of manufacturers, e.g. the manufacturer must mark on the machinery and on the packaging or in an accompanying document how to access the digital instructions (Article 10a). The manufacturer must provide the instructions in paper format free of charge within one month, if requested by the user at the time of the purchase. When the machinery is used by non-professional users, the manufacturer must provide in paper format the safety information that is key for putting the machinery or related product into service and for using it safely.

The agreed text specifies that notified bodies have to take into account the specific interests and needs of SMEs when setting the fees for conformity assessment (Article 21(4)), as supported by the Parliament, while the Council intended to delete this specific provision.

The agreement maintains the empowerment of the Commission to adopt technical specifications for the EHSRs, to facilitate the manufacturer's obligation to comply with these requirements. For instance, the agreement specifies that the Commission must take into account the views of relevant bodies and the expert group and duly consult all relevant stakeholders in the process (Article 17). When the reference of a harmonised standard is published in the Official Journal of the EU, the Commission must repeal the implementing act containing the technical specifications.

The agreed text gives 6 more months (compared to the proposal) for the Commission to submit a report on the evaluation and review of the regulation (5 years after the date of entry into force of the regulation) (Article 51). The current directive will be repealed one year later than initially proposed by the Commission (3.5 years after entry into force of the current regulation) (Article 49).

Once the final act has been signed, the regulation will enter into force on the 20th day following that of its publication in the Official Journal of the EU. It will apply 42 months (3.5 years) after the date of its entry into force (one year later than initially proposed), with some exceptions (Article 52).

EUROPEAN PARLIAMENT SUPPORTING ANALYSIS

[Machinery Directive: Revision of Directive 2006/42/EC – Implementation Appraisal](#), EPRS, European Parliament, September 2021.

[Revising the Machinery Directive – Initial Appraisal of a European Commission impact assessment](#), EPRS, European Parliament, July 2021.

OTHER SOURCES

[Regulation on machinery products](#), Legislative Observatory (OEL), European Parliament.

ENDNOTES

- ¹ 1) Harmonised standards covering the type of machinery concerned are available; 2) The harmonised standard or standards concerned cover all of the EHSRs that are applicable to the machinery, as determined by the risk assessment; 3) The manufacturer of the machinery concerned has applied the relevant harmonised standards.
- ² The AI act should establish harmonised rules for the development, placement on the market and use of AI systems, following a risk-based approach. It addresses the safety risks of AI systems, while the proposal on machinery products focuses on the safe integration of AI systems into machinery.
- ³ The NLF consists of [Regulation \(EC\) 765/2008](#) (as amended by [Regulation \(EU\) 2019/1020](#)) laying down rules on the organisation and operation of accreditation of conformity assessment bodies), and [Decision No 768/2008/EC](#) setting out general principles and reference provisions for the drawing up of EU legislation harmonising the conditions for the marketing of products (provisions on definitions, obligations for economic operators, conformity of the product, notification of conformity assessment bodies or safeguard procedures).
- ⁴ As explained in the [guide](#) to application of the Machinery Directive, its current Section 1.7.4 does not specify the form of the instructions, but it is generally agreed that all health and safety-related instructions must be supplied in paper form. The situation is the same for the declaration of conformity, which is included in the instructions.
- ⁵ The European Committee of the Regions did not adopt an opinion on the proposal.
- ⁶ This section aims to provide a flavour of the debate and is not intended to be an exhaustive account of all different views on the proposal. Additional information can be found in related publications listed under 'European Parliament supporting analysis'.

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