Machinery Directive
Revision of Directive 2006/42/EC

This briefing is one in a series of implementation appraisals produced by the European Parliamentary Research Service (EPRS) on the operation of existing EU legislation in practice. Each briefing focuses on a specific EU law that is likely to be amended or reviewed, as envisaged in the European Commission’s annual work programme. Implementation appraisals aim at providing a succinct overview of publicly available material on the implementation, application and effectiveness to date of specific EU law, drawing on input from EU institutions and bodies, as well as external organisations. They are provided by the Ex-Post Evaluation Unit of the EPRS to assist parliamentary committees in their consideration of new European Commission proposals, once tabled.

SUMMARY

The Machinery Directive establishes a regulatory framework for mechanical engineering industry products. It regulates the harmonisation of essential health and safety requirements for machinery in order to ensure the free movement of machinery products within the internal market on the one hand, and a high level of protection for machinery users on the other. The European Commission’s Regulatory Fitness and Performance Programme (REFIT) evaluation of 2018 concluded that the directive has generally remained relevant and effective. However, it pointed at certain shortcomings in the enforcement of the directive (mainly related to market surveillance, a Member State responsibility), and found that despite its technology-neutral design, the directive might not sufficiently cover new risks stemming from emerging technologies (in particular robots using artificial intelligence technologies). Furthermore, it identified the potential for administrative simplification. The Commission issued its new proposal for a regulation on machinery products (COM(2021) 202) on 21 April 2021, as part of the ‘artificial intelligence package’. In particular, the change of instrument (regulation instead of a directive) aims at ensuring a uniform implementation in the Member States and avoiding the risk of ‘gold plating’.

Background

The Machinery Directive (Directive 2006/42/EC) is the EU’s regulatory framework covering mechanical engineering industry products. Based on Article 114 TFEU (approximation of laws for the functioning of the internal market), its main objectives are:

- to ensure the free circulation of new machinery in the internal market; and
- to protect the health and safety of machinery users and other exposed persons; this is achieved through safe design and construction on the one hand, and proper installation and maintenance on the other hand.¹

An additional objective, limited to the machinery used in pesticide application, is to protect the environment.
The directive is part of the EU product harmonisation legislation and follows the 'new approach to technical harmonisation and standards'. Under this regulatory method, the directive defines the mandatory essential health and safety requirements (EHSR) that machinery products must fulfil to be placed on the European market, as well as the procedures for assessing their conformity, while the technical details are mainly provided through (non-binding) European harmonised standards elaborated by European standards organisations. Machinery produced in conformity with harmonised standards is presumed to comply with the essential health and safety requirements. Alternatively, manufacturers can also reach EHSR compliance through other procedures laid down in the directive, namely either EC-type examination or full quality assurance. In terms of administration, the directive requires manufacturers to prepare a technical file, draw up the EC Declaration of Conformity and affix the 'CE' marking to the product. The CE marking indicates that the machinery product meets the health and safety requirements in place and can be traded without restriction in the internal market. The Member States are responsible for carrying out market surveillance to identify non-compliant products and to enforce corrective measures. While most product harmonisation legislation was aligned with the new legislative framework (NLF) as from 2008, this is not (yet) the case for the Machinery Directive.

Scope

The geographical scope of the Machinery Directive goes beyond the EU; it includes the European Free Trade Association (EFTA) countries, Switzerland and Turkey. The directive applies to all new machinery placed on the market for the first time, regardless of its origin, i.e. whether manufactured within or outside the EU. Its scope of application is very broad, encompassing a vast array of machinery for industrial and private use, including construction machinery, lawnmowers, powered hand-tools, as well as certain modern machinery, including 3D printers, e-bikes, robots and drones. In addition, the directive also applies to specific machinery-related products, such as safety components, lifting accessories, chains and ropes, removable mechanical transmission devices, as well as partly completed machinery.

Product categories exempted from the scope of the directive are listed in Article 1(2). These include, inter alia:

- weapons and firearms;
- various means of transport, notably:
  - agricultural and forestry tractors (with the exception of equipment mounted on the vehicles, such as telescopic booms; digging equipment; cutting devices);
  - motor vehicles and their trailers (including two or three-wheel motor vehicles);
  - aircraft or means of water-borne transport, including hovercraft;
- household appliances;
- equipment for use in fairgrounds and/or amusement parks;
- machinery for nuclear purposes;

However, the legal text leaves some margin of interpretation as to whether a specific product or component is covered by the Machinery Directive. Detailed guidance in this respect (partly even
including illustrations) is provided in the Commission's Guide to application of the Machinery Directive, which was last updated in October 2019.

Successive amendments to Directive 2006/42/EC to date

The Machinery Directive has a long history, with its original version dating from 1989 (89/392/EEC). The current Directive 2006/42/EC consolidates and updates previous versions. In 2009, the directive's scope of application was extended through Directive 2009/127/EC to include machinery used for applying pesticides. This type of machinery includes, for instance, large sprayers used in farming and smaller, portable equipment for gardeners. The amendment inserted a specific environmental protection provision, requiring the design of the machinery to ensure minimum dispersal of pesticides into the environment.

Two minor amendments followed: Regulation 167/2013 explicitly excluded agricultural and forestry tractors from the scope of the Machinery Directive, with the exception of machinery mounted on those vehicles. Finally, Directive 2014/33/EU (the Lift Directive) repealed Article 24 of the Machinery Directive.

Transposition and implementation

Directive 2006/42/EC was adopted on 17 May 2006, under the co-decision procedure. Member States had to transpose the directive by 29 June 2008, and apply its provisions as from 29 December 2009. The Commission initiated infringement procedures against 12 Member States, mostly for non-communication of transposition measures. While most cases were resolved at an early stage of the procedure, two were referred to the European Court of Justice (ECJ):

- In Case C-127/10 Commission v Greece, the Court found Greece in breach of EU law.
- Case C-246/10 Commission v Luxembourg was removed from the Court's register, following the Commission's withdrawal from the proceedings.

Member States are responsible for the implementation, correct application and enforcement of the directive at the national level. They are in charge of market surveillance and are expected to appoint competent authorities ('notified bodies') to assess and certify machinery's conformity with the directive for its placing on the market (or putting into service). They also need to take action in case of non-compliant products.

At EU level, various fora and working groups exist to ensure the directive's implementation. In particular, the Machinery Committee, set up in accordance with Article 22 of the Directive and composed of Member State representatives, assists the Commission with implementing measures. In comparison, the Machinery Working Group brings together representatives of all stakeholder categories to discuss the practical application of the directive. The latter group is also involved in the continuous work on the Guide to the application of the Machinery Directive, which aims at promoting uniform interpretation and application of the directive.

EU machinery industry: key data

According to the latest Eurostat data (2018 for EU-27), in the EU, the machinery and equipment sector employs 3 million people in 80 000 enterprises, a majority of which are small and medium-sized enterprises (SMEs). The total production of the sector is valued at €670 billion, with Germany and Italy accounting for more than half.

Some 60 % of EU machinery and equipment was exported to other EU countries and thus remained within the internal market (2015 data).

European Commission reports


The European Commission’s REFIT evaluation (SWD(2018) 160), published in May 2018, examined the operation of the directive in all relevant machinery categories throughout 2010-2016. It paid particular attention to emerging digital technologies such as artificial intelligence (AI), robotics and the internet of things (IoT), which are transforming traditional manufacturing processes, as well as machinery products and value chains. The evaluation was supported by a study (conducted for the Commission by Technopolis), and public and targeted stakeholder consultation.

It concluded that the initial objectives of the directive – safe design and construction of machinery, and EU-wide harmonisation in safety legislation and certification to facilitate trade – have remained highly relevant and that the directive has generally attained these objectives. In this vein, manufacturers and other economic operators generally expressed high satisfaction with the Machinery Directive. While the evaluation found that the directive’s technology-neutral design (relying on the ‘new approach’ principles) has proven to be sufficiently flexible to cope with technological innovations, it nonetheless raised concerns that further innovations in digital technologies ‘may come to test limits of the existing product safety framework’ (p. 30). The evaluation pointed specifically at human-machine interaction as potentially posing higher risks (due to their mechanical moving parts and self-learning capabilities). Similarly, it identified remotely controlled processes and other IoT and AI powered systems as a growing threat, due to their vulnerability to cyberattacks.

According to evaluation findings, stakeholders rate the impact of the directive on the operation of the internal market for machinery as largely positive, in particular with regard to the range of products, turnover and profitability of the sector, international competitiveness, and volume and value of machinery trade. There is also a broad consensus on the effectiveness of the conformity assessment options available and the fulfilment of requirements ensuring the free movement of machinery. Nonetheless, some factors hampering the effectiveness and notably the enforcement of the directive were observed, pertaining in particular to shortcomings in the area of market surveillance (a Member State responsibility), which is ‘generally seen as insufficient and ineffective’ (p. 27). It appears that the number and extent of market surveillance activities varies greatly from country to country, as does the approach taken in case of non-compliant machinery (voluntary measures, restrictive measures or sanctions). It should be noted that, in the meantime (thus after the evaluation), Regulation (EU) 2019/1020 on market surveillance and compliance of products has been adopted, which aims at improving the functioning of the internal market by strengthening the market surveillance of products covered by EU harmonisation legislation. This regulation applies to a set of 70 EU acts, including the Machinery Directive. However, as the new regulation only fully applies since 16 July 2021, it remains to be seen how much of an improvement it will effectively entail.

Stakeholders generally praised the effectiveness of harmonised European standards – 780 exist in the machinery area alone (providing presumption of conformity to the Machinery Directive), a third of which are derived from international standards.’ However, they also pointed at a lack of specific standards in a number of areas, such as additive manufacturing machinery (e.g. 3D printers), and indicated that harmonised standards for innovative products were lagging behind.

The evaluation also pointed to certain data limitations. These concern, for instance, the availability of disaggregated statistics on accidents and injuries related to machinery use; data related to the update and use of harmonised European standards, and on the number of non-compliant products; market surveillance activities; and costs related to the application of the Machinery Directive. The evaluation sought to mitigate the data gap to the extent possible through surveys and interviews,
but these efforts cannot compensate for a lack of systematic data collection over time. Against the background that the directive precisely seeks to improve machinery safety, it appears rather a shortcoming that no statistics on machinery-related accidents are gathered, even more so as Recital 2 of the directive explicitly refers to the ‘social cost of the large number of accidents caused directly by the use of machinery’.

Finally, stakeholders highlighted the relatively high costs of standards as an issue for SMEs. It appears that manufacturers, and notably SMEs, find the administrative costs arising from time and resources spent on documentation to be ‘disproportionate’ (p. 32). Specific issues mentioned in this context pertain to translations of manuals and the mandatory supply of instructions in paper format. Generally, however, stakeholders perceive that the benefits of the directive far outweigh the costs.

Report on the safety and liability implications of artificial intelligence, the internet of things and robotics (2020)

The challenges emerging from new digital technologies in terms of product safety and liability (such as connectivity, autonomy, data dependency, opacity, the complexity of products and systems, software updates and more complex safety management and value chains), have been explored in greater detail in a dedicated Commission report (COM(2020) 64). It concluded that the current product safety legislation contains a number of gaps that need to be addressed, in particular in the General Product Safety Directive, Machinery Directive, the Radio Equipment Directive and the NLF. The report emphasised that future work on the adaptation of legislation in this framework will be carried out ‘in a consistent and harmonised manner’ (p. 16).

European Parliament activities

Recent European Parliament resolutions

**Resolution of 25 November 2020 on product safety in the single market**

This resolution, based on an own-initiative Internal Market and Consumer Protection Committee (IMCO) report (rapporteur: Marion Walsmann, EPP, Germany), addressed the need to adapt product safety legislation to the digital age and to close gaps in existing legislation, including the Machinery and the Radio Equipment directives. Against the background that AI and other emerging technologies embedded into products can modify their purpose and hence impact on product safety once placed on the market (e.g. through software updates or self-learning technology), Parliament called on the Commission to revisit the approach, to guarantee safety at the moment of a product being placed on the market. Parliament instead advocated a switch to continued responsibility for products to conform with product safety legislation. Moreover, it reiterated its call for a harmonised, risk-based assessment framework regarding products with embedded new technologies and for the effectiveness of market surveillance to be enhanced.

**Resolution of 12 February 2020 on automated decision-making processes: ensuring consumer protection and free movement of goods and service**

In this resolution, based on an oral question to the Commission put forward by the IMCO committee, the European Parliament noted that rapid progress in the areas of AI and automated decision-making processes affects all sectors of the internal market. While Parliament generally welcomed the potential of these new technologies, it voiced concerns regarding the safety and liability of products with automated decision-making capabilities, since those ‘may evolve and act in ways not envisaged when first placed on the market’. Parliament thus urged the Commission to bring forward proposals to adapt the EU’s specific product safety rules that set harmonised...
requirements, including inter alia the Machinery Directive, to safeguard the protection of users on the one side and to provide clarity for manufacturers about their obligations on the other.

Furthermore, Parliament stressed the need for a risk-based approach to regulation. In this vein, it called on the Commission to develop a risk assessment scheme for AI and automated decision-making, in order to ensure a consistent approach to the enforcement of product safety legislation in the internal market. In addition, Parliament asked Member States to develop harmonised risk management strategies for AI in the context of their national market surveillance strategies.

Resolution of 20 October 2020 with recommendation to the Commission on a framework of ethical aspects of AI, robotics and related technologies

In this resolution, based on a legislative own-initiative report (rapporteur: Ibán García del Blanco, S&D, Spain), Parliament called on the Commission to examine the existing legal framework and its application, including the consumer law acquis, product liability legislation, product safety legislation and market surveillance legislation, in order to identify legal gaps, as well as existing regulatory obligations in the light of the challenges posed by AI, robotics and related technologies. In particular, Parliament suggested requiring 'developers and deployers of high-risk technologies to, where a risk assessment so indicates, provide public authorities with the relevant documentation on the use and design and safety instructions', which might include source code, development tools and data used by the system.

Resolution of 12 February 2019 on a comprehensive European industrial policy on artificial intelligence and robotics

Against the backdrop that AI applies to a variety of sectors where standardisation is of high relevance, e.g. smart manufacturing, this resolution (based on an own-initiative report drawn up by Ashley Fox, ECR, UK), advocates further promotion and development of common standards for robotics and AI. To this end, it called on the Commission, in cooperation with EU standardisation bodies, 'to continue to engage proactively with international standardisation bodies on improving standards in this field'.

Selected parliamentary questions

Since its entry into force, the Machinery Directive has been the subject of dozens of parliamentary questions posed by Members to the Commission. The following section summarises selected questions put forward since the beginning of the eighth parliamentary term.

Unsurprisingly, a number of parliamentary questions pertain to artificial intelligence and robotics. Members addressed technological progress in machinery products with regard to robotics and artificial intelligence, and notably the lack of an EU legal framework in that field (e.g. E-006570/2016 posed by Roberta Metsola (EPP, Malta) and E-006127/2017 by Jérôme Lavrilleux (EPP, France)). Question E-000028/2019, put forward by Miroslav Mikolášik (EPP, Slovakia), touched upon liability in the event that robots make mistakes. He inquired what approach the Commission had endorsed vis-à-vis liability in the evaluation of both the Machinery and the Product Liability directives, following the publication of the Commission's 2018 communication on AI for Europe and the coordinated plan on AI. Commissioner Elżbieta Bieńkowska replied that both evaluations included 'questions related to emerging digital technologies' and concluded that, while the overall regulatory framework for machinery and product liability was sound, 'there may be a need for some clarifications'. Overall, the Machinery Directive would allow 'for technological developments in a digital era'.

Members were also interested in various aspects regarding the safety of electric vehicles, such as e-bikes and e-scooters:

E-005895/2018, posed by Maria Gabriela Zoană (S&D, Romania), referred to electric scooters available for hire in cities. She asked whether the Commission intended to come up with a strategy and safety-related legislation for e-scooters. Commissioner Bienkowska stated that although these vehicles are not subject to EU rules on type-approval, they will still have to comply with the Machinery Directive 2006/42/EC, which sets out harmonised requirements related to the safety aspects of their design, manufacture and placing on the market.

Dita Charanzová (ALDE, Czechia) addressed the level of competence regarding lightweight electric vehicles, and in particular e-scooters (question E-000778-19). In her response, then Commissioner Violeta Bulc, explained that electric self-balancing vehicles (e-scooters, but also segways, hoverboards and monowheels) would touch upon safety, type-approval and traffic competences. She clarified that, in terms of market approval and safety aspects, these vehicles fall under the scope of Directive 2006/42/EC, which sets out harmonised requirements related to the safety aspects of their design, manufacture and placing on the market.

The Commission’s answer to question E-003051/2019 (put forward by Seán Kelly (EPP, Ireland)) confirmed that electric bicycles (e-bikes) with a continuous rated power of less than or equal to 250 W and a maximum speed of 25 km/h are excluded from type-approval and are covered by the Machinery Directive and European standard EN 15194.

A set of parliamentary questions related to health and safety aspects. Question E-003988/2020, posed by Jutta Paulus and Anna Cavazzini (Greens, Germany and Italy, respectively), asked the Commission to take action to mitigate health risks related to laser printer emissions into ambient air, in particular hazardous compounds contained in the toner. In his reply, Commissioner Virginijus Sinkevičius pointed to Annex I of the Machinery Directive, which already includes EHSR covering the concerned type of risks posed by industrial and 3D printers. In addition, he referred to the chemicals strategy for sustainability and to a new voluntary industry agreement on printers.

Priority question P-010059/2015 dealt with the protection of workers exposed to pesticides during crop spraying. Constance Le Grip (EPP, France) asked whether crop treatment machinery fitted with a cab (motor vehicles, tractors) would fall under the Machinery Directive’s safety requirements. In her reply, Commissioner Bienkowska recalled the amendment to the Machinery Directive regulating machinery for pesticide application and pointed more generally to the EU legislative framework on occupational safety and health. She stressed that Member States need to ensure that machinery placed on the market is safe. If national authorities undertake insufficient or inadequate market surveillance, the Commission might carry out an investigation, which could lead to an infringement procedure against the Member State concerned.

Following severe incidents, question E-004041/2019 (Theodoros Zagorakis, EPP, Greece) addressed amusement park safety standards. Fairground and amusement park equipment is not regulated at EU level and is explicitly exempted from the scope of application of Directive 2006/42/EC. It is merely covered by a European Standard (EN 13814:2004), which was last revised in May 2019. In his answer, Commissioner Thierry Breton stated that the impact assessment study preparing the revision of the Machinery Directive would analyse the possibility of bringing this kind of equipment under the scope of the new directive. The Commission’s impact assessment study suggests that most stakeholders think ‘that the exclusion on specific equipment for use in fairgrounds and/or amusement parks should be removed’ (p.134). Nonetheless, the new Commission proposal maintains the status quo and the exclusion of ‘the specific equipment for use in fairgrounds or amusement parks’ from the scope of the proposed regulation (Article 2(2)b).

Finally, some Members have sought clarification from the Commission as to whether specific industrial engineering products are subject to the Machinery Directive. For instance, Mairead McGuinness (EPP, Ireland) asked whether the directive applied to wind turbines (question E-005937-19), which Commissioner Bienkowska confirmed.
Economic and Social Committee (EESC)

In June 2020, the EESC presented an information report on the revision of the Machinery Directive, requesting that the basic approach of this 'very important and successful instrument for European industry' is left unchanged. The report deemed the directive 'fit for purpose', and argued that 'massive changes', in particular regarding the essential health and safety requirements, would negatively impact on the work of developing harmonised standards.

The EESC warned against undertaking a major revision of the directive 'before resolving the chronic understaffing, underfunding and poor performance of machinery inspections and controls (either before or after putting machinery into service)', arguing that 'insufficient market surveillance would make any improvement and change unenforceable'. The report noted great variation in the performance of market surveillance across the EU Member States. It observed that little proactive control work was carried out, and highlighted the negative effects this might entail, such as an increasing amount of defective machinery in circulation; non-conformity with the legislative requirements; an increased likelihood of accidents; and unfair competition for law-abiding companies.

The EESC report rejected the argument that challenges arising from progress in digital technologies would necessitate a revision of the directive. The report recommended maintaining regulation of cybersecurity – and the related risks – within a separate, horizontal EU act, to which the revised Machinery Directive should merely include a reference. Furthermore, while recognising the rapid evolution of AI, it deemed the directive's methodology in controlling risks suited to accommodating this technology, 'because the principles of Risk Assessment and Risk Reduction (RA&RR) – in which the Machinery Directive is rooted' – would remain constant. In this respect, the EESC argued that the RA&RR principles are technology-neutral and the directive would be 'perfectly able to differentiate between compliant and non-compliant digital applications by means of RA&RR'.

The EESC report included a number of concrete recommendations for the Commission, it:

- suggested improving the text of the Machinery Directive with regard to ergonomic risks, such as musculoskeletal problems, deeming the current section on ergonomics (Annex I, §1.1.6) to be insufficient, in the sense that it would not prevent 'chronic harm caused by poor ergonomic design'. In this regard, it proposed to involve the Machinery Administrative and Cooperation Group, a group of national labour inspectors.
- stressed the need for 'a clearer connection' between the Machinery Directive and the Use of Work Equipment Directive 2009/104/EC, in order to reduce ambiguity regarding the manufacturers, employers, market surveillance authorities and labour inspectors risk assessment duties in respect of machinery. The two acts would complement each other in regulating safe design and safe use of machinery.
- invited the Commission to involve the social partners (machinery users), market surveillance authorities and SMEs in standardisation work, arguing that their inclusion would contribute to the ‘acceptance and uptake of harmonised standards’.
- insert definitions for the concepts 'state of the art' and 'reasonable foreseeable misuse' into the directive to improve clarity.
- invited the Commission to work on the format of the Guide supporting the application of the directive, by adding a web-based version, which would be easier to consult and update.

European Court of Justice

Apart from the infringement procedures the Commission launched against Greece and Luxembourg, the case-law database of the European Court of Justice (ECJ) lists three proceedings relating to Directive 2006/42/EC:
All three pertain to the safeguard clause procedure under Article 11 of the Machinery Directive. Under this procedure, Member States must withdraw CE-marked machinery deemed unsafe (i.e. non-compliant with the EHSR) from the market, or prohibit their placing on the market. Any such measure must be notified to the Commission, together with a justification. Following consultations with the parties concerned, the Commission adopts a decision as to whether it considers the measure justified. It may then require all Member States to withdraw the non-compliant machinery (and any other machinery with the same defect) from the market, or impose specific restrictions to its usage. Manufacturers have the right to appeal against the Commission decision by seeking its annulment before the ECJ. Member States regularly issue safeguard notifications concerning national measures taken for unsafe CE-marked machinery. According to the Commission evaluation, the Commission received 45 such notifications in 2010-2016. In the three above cases, the machinery manufacturers challenged the Commission’s decisions – all of them supporting the safeguard measures taken by Member States – before the ECJ.

In Case T-337/13 CSF v Commission, the plaintiff sought annulment of the Commission decision prohibiting an item of multi-purpose earthmoving machinery. The Court dismissed the manufacturer’s appeal.

Similarly, in Case T-168/16 Grizzly Tools v Commission, the Court upheld the Commission’s implementing decision to ban a portable pressure washer from the market. In this case, the Commission followed the reasoning of the Member State that had initially taken the measure and considered the machinery in question as an appliance of dual use – namely as both a portable and hand-held appliance – even if it was not intended for hand-held use by the manufacturer. Consequently, the Commission argued, the machinery would require a higher level of safety.

In Case T-474/15 GGP Italy v Commission, the manufacturer sought to appeal against a Commission decision prohibiting the placing on the market of a lawnmower. In this ruling, the Court annulled the Commission’s decision, arguing the Commission had ‘committed an error of law’.

**Stakeholder positions**

**Consultations**

The European Commission sought stakeholder input at different stages of the revision process, to:

- inform the evaluation (September to December 2016);
- inform the impact assessment (January to February 2019);
- confirm the issues identified by the evaluation and to indicate areas to be improved and/or simplified in the Machinery Directive (June to August 2019);
- and, finally and most recently, a consultation on the new Commission proposal COM(2021) 202 took place from April to August 2021.

With regard to the REFIT evaluation, the Commission undertook public and targeted consultations to gather stakeholder feedback. These yielded over 400 responses from various stakeholder categories, including national authorities, notified bodies, industry associations, businesses (roughly half of which were SMEs), workers and consumers (and their representative organisations), consultancies and service providers for machinery safety, as well as standardisation bodies.

According to the Commission’s synopsis report, stakeholders commented overwhelmingly positively on the general objectives of the Machinery Directive. A large majority of businesses found that the current Machinery Directive reduced costs. Moreover, stakeholders cited clear benefits, such as the recognition of the CE mark beyond EU borders; the effectiveness of European
harmonised standards; and lower certification costs achieved through self-certification. Further specific issues not yet, or only marginally, addressed in the chapter on the evaluation include:

- alignment of the Machinery Directive with the NLF;
- simplification of the risk assessment procedure;
- improving the demarcation between different types of machineries;
- a rise in non-compliant machinery on the market, particularly from outside the EU.

Position papers

The following section presents selected position papers published by representative organisations during the revision process.

**Orgalim**, the organisation representing Europe’s technology industries, considers the Machinery Directive ‘a core piece of product legislation enabling companies to place state of the art and safe machinery on the single market’ that is ‘performing as it should’. It therefore recommends keeping modification of the directive to a minimum and leaving the basic philosophy untouched. With regard to information and communication technologies (ICT), robotics, cybersecurity and hacking, the organisation considers the current directive fit for purpose, as it defines the EHSR and leaves the manufacturer the choice to use any specific technology reflecting the ‘state of the art’. Furthermore, it does not see a need to simplify the risk assessment procedures, flagging instead a ‘lack of uniform approach among notified bodies’ as an issue. Finally, it calls for more effective market surveillance.

Similarly, **CEMA**, an association representing the European agricultural machinery industry, deems the Machinery Directive ‘very robust legislation and fit for purpose for upcoming technologies’. It suggests addressing new emerging technologies in the form of standards, rather than through legislation.

Conversely, **Eurosmart**, which represents digital security industry manufacturers, deems artificial intelligence and the internet of things ‘game-changing technologies which make an evolution of the Machinery Directive a necessity’.

The International Federation of Inspection Agencies (IfIA) and the International Confederation of Inspection and Certification Agencies (CEOC International), representing the independent testing, inspection and certification sector and having meanwhile merged into the TIC Council, issued a joint position paper. They strongly advocate the alignment of the Machinery Directive with the NLF, arguing that the NLF’s risk-based approach is more flexible than the current system under Directive 2006/42. They also favour revising certain definitions to enhance legal clarity (e.g. the boundaries between completed machinery and partly-completed machinery is not always clear, as is illustrated by the example of robots without end effectors). Other issues raised include conformity assessment procedures with regard to process manufacturing (e.g. production lines, where machines operate as part of a system) and substantial retrospective modifications (by operators) to machinery after it has been brought into service. Moreover, they support the transformation of the legal framework into a regulation, arguing this would fully harmonise the application of the legislative act and create a level playing field for economic operators.

Revision of the Machinery Directive

The European Commission announced the revision of the Machinery Directive in its 2020 and 2021 work programmes. Drawing on the findings of the REFIT evaluation, broad stakeholder consultation and external studies, on 21 April 2021, the Commission put forward a new proposal for a regulation on machinery products ([COM(2021) 202]) as part of the wider ‘AI package’. The proposal was accompanied by an impact assessment ([SWD(2021) 82]). The Commission justified the proposed change of instrument (regulation instead of a directive) by its simplification of the regulatory environment, as well as the need to ensure uniform implementation throughout the EU,
which also helps to avoid ‘gold plating’ (i.e. over-implementation of EU legislation at the national level).

The new proposal seeks to tackle the following problems identified in the evaluation and the impact assessment on the Machinery Directive:

- Insufficient coverage of new risks stemming from the new digital technologies;
- Legal uncertainty due to a lack of clarity regarding the scope and definitions and possible safety gaps in traditional technologies;
- Insufficient provision for high-risk machines;
- Costs due to extensive paper-based documentation;
- Inconsistencies with other pieces of EU product safety legislation;
- Divergences in interpretation due to transposition (hence the regulation).

The proposal maintains the 'new approach' architecture, while seeking to enhance the enforcement of the legal act through the alignment to the NLF.

The proposal also addresses the safe integration of AI systems into the overall provisions for machinery. A separate proposal (also included in the AI package) for a regulation laying down harmonised rules on artificial intelligence (the proposed 'AI act', (COM(2021) 206)), aims at setting harmonised rules for the development, placement on the market and use of AI systems, following a risk-based approach.

In the European Parliament, the IMCO Committee is responsible for the legislative proposal for machinery products; Ivan Štefanec (EPP, Slovakia) has been appointed rapporteur for the file.
MAIN REFERENCES


ENDNOTES

1 It should be noted that the safe use of machinery in the workplace is governed by a separate act: Directive 2009/104/EC concerning the minimum safety and health requirements for the use of work equipment by workers at work.
3 These are notably the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI).
4 More specifically, machinery that complies with the Machinery Directive benefits from free movement in Iceland, Liechtenstein and Norway (Agreement on the European Economic Area (EEA)), Switzerland (Mutual Recognition Agreement with the EU), and Turkey, Andorra and San Marino (respective Customs Union Agreements between the EU and these countries).
5 Article 24 of the Machinery Directive (repealed) had amended the former Lift Directive 95/16/EC.
6 The Commission’s annual reports on monitoring the application of EU law for 2008, 2009, 2010 and 2013, recap the infringement procedures mentioned.
7 Figures according to CEN and CENELEC.
9 The results of the consultation (‘synopsis report’) were published as Annex 4 of the Commission’s evaluation (pp. 51-57).

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