



Basic information	
<b>2021/0105(COD)</b> COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Regulation on machinery products  <b>Subject</b>  2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 3.40.08 Mechanical engineering, machine-tool industry 4.15.15 Health and safety at work, occupational medicine 4.60.04.02 Consumer security  <b>Legislative priorities</b>  <a href="#">Joint Declaration 2021</a> <a href="#">Joint Declaration 2022</a> <a href="#">Joint Declaration 2023-24</a>	

Key players				
European Parliament	Committee responsible		Rapporteur	Appointed
	IMCO	Internal Market and Consumer Protection	ŠTEFANEC Ivan (EPP)	27/05/2021
			Shadow rapporteur  MALDONADO LÓPEZ Adriana (S&D)  HAHN Svenja (Renew)  CORMAND David (Greens /EFA)  FIDANZA Carlo (ECR)  KONEČNÁ Kateřina (The Left)	
	Committee for opinion		Rapporteur for opinion	Appointed
	EMPL	Employment and Social Affairs	VIND Marianne (S&D)	01/12/2021
Council of the European Union				
European Commission	Commission DG		Commissioner	
	Communications Networks, Content and Technology		BRETON Thierry	

## Key events

Date	Event	Reference	Summary
21/04/2021	Legislative proposal published	COM(2021)0202 	Summary
07/06/2021	Committee referral announced in Parliament, 1st reading		
03/05/2022	Vote in committee, 1st reading		
03/05/2022	Committee decision to open interinstitutional negotiations with report adopted in committee		
05/05/2022	Committee report tabled for plenary, 1st reading	A9-0141/2022	Summary
18/05/2022	Committee decision to enter into interinstitutional negotiations announced in plenary (Rule 71)		
06/06/2022	Committee decision to enter into interinstitutional negotiations confirmed by plenary (Rule 71)		
02/03/2023	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE742.409 GEDA/A/(2023)000924	
18/04/2023	Decision by Parliament, 1st reading	T9-0097/2023	Summary
18/04/2023	Results of vote in Parliament		
22/05/2023	Act adopted by Council after Parliament's 1st reading		
14/06/2023	Final act signed		
29/06/2023	Final act published in Official Journal		

## Technical information

Procedure reference	2021/0105(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Treaty on the Functioning of the EU TFEU 114
Mandatory consultation of other institutions	<a href="#">European Economic and Social Committee</a>
Stage reached in procedure	Procedure completed
Committee dossier	IMCO/9/05874

## Documentation gateway

## European Parliament





Document type	Committee	Reference	Date	Summary
Committee draft report		PE697.614	20/10/2021	
Amendments tabled in committee		PE699.191	10/11/2021	

Committee opinion	EMPL	PE703.051	08/03/2022	
Committee report tabled for plenary, 1st reading/single reading		A9-0141/2022	05/05/2022	Summary
Text agreed during interinstitutional negotiations		PE742.409	25/01/2023	
Text adopted by Parliament, 1st reading/single reading		T9-0097/2023	18/04/2023	Summary

#### Council of the EU

Document type	Reference	Date	Summary
Coreper letter confirming interinstitutional agreement	GEDA/A/(2023)000924	25/01/2023	
Draft final act	00006/2023/LEX	14/06/2023	

#### European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2021)0202 	21/04/2021	Summary
Document attached to the procedure	SEC(2021)0165 	22/04/2021	
Document attached to the procedure	SWD(2021)0082 	22/04/2021	
Document attached to the procedure	SWD(2021)0083 	22/04/2021	
Commission response to text adopted in plenary	SP(2023)260	05/07/2023	

#### National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	CZ_CHAMBER	COM(2021)0202	11/06/2021	

#### Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES2559/2021	22/09/2021	

#### Additional information

Source	Document	Date
EP Research Service	Briefing	06/07/2022

**Meetings with interest representatives published in line with the Rules of Procedure**

## Rapporteurs, Shadow Rapporteurs and Committee Chairs

Transparency				
Name	Role	Committee	Date	Interest representatives
ŠTEFANEČ Ivan	Rapporteur	IMCO	21/06/2022	FEM aislb
ŠTEFANEČ Ivan	Rapporteur	IMCO	20/06/2022	Amazon Europe Core SARL
ŠTEFANEČ Ivan	Rapporteur	IMCO	14/06/2022	Orgalim – Europe's Technology Industries
CORMAND David	Shadow rapporteur	IMCO	07/01/2022	TÜV Rheinland AG
CORMAND David	Shadow rapporteur	IMCO	22/10/2021	The European Consumer Voice in Standardisation
HAHN Svenja	Shadow rapporteur	IMCO	20/10/2021	Hauptverband der Deutschen Bauindustrie e.V.
CORMAND David	Shadow rapporteur	IMCO	19/10/2021	Confederation of the European Bicycle Industry ASBL
HAHN Svenja	Shadow rapporteur	IMCO	11/10/2021	TÜV-Verband e. V.
CORMAND David	Shadow rapporteur	IMCO	05/10/2021	CECE - Committee for European Construction Equipment European Materials Handling Federation Orgalim – Europe's Technology Industries The European Consumer Voice in Standardisation TÜV Rheinland AG
HAHN Svenja	Shadow rapporteur	IMCO	05/10/2021	ORGALIM FEM CECE ANEC TÜV
HAHN Svenja	Shadow rapporteur	IMCO	02/07/2021	FEM aisbl (European Materials Handling Federation)
HAHN Svenja	Shadow rapporteur	IMCO	23/06/2021	Committee for European Construction Equipment (CECE)
HAHN Svenja	Shadow rapporteur	IMCO	15/06/2021	Orgalim

## Other Members

Transparency		
Name	Date	Interest representatives
DE MEO Salvatore	24/06/2021	Confindustria

Final act
<p>Corrigendum to final act 32023R1230R(01) OJ L 169 04.07.2023, p. 0035</p> <p>Regulation 2023/1230 OJ L 165 29.06.2023, p. 0001</p> <p style="text-align: right;"><a href="#">Summary</a></p>

## Regulation on machinery products

**PURPOSE:** to improve and adapt the existing Machinery Directive to the new needs of the market and risks origination from emerging technologies.

**PROPOSED ACT:** Regulation of the European Parliament and of the Council.

**ROLE OF THE EUROPEAN PARLIAMENT:** the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

**BACKGROUND:** as part of the Commission Work Programme 2020 under the priority 'A Europe fit for the Digital Age', the Commission plans to revise the [Machinery Directive](#) ('the MD', Directive 2006/42/EC). This revision contributes to both the digital transition and to the strengthening of the single market.

In order to boost the trust in new digital technologies such as direct human-robot (co-bot) collaboration, connected machinery, 3D printers, the MD needs to provide legal certainty as regards those technologies, existing gaps could hinder a level playing field for manufacturers, which would impact the efficiency of the MD.

The fact that the current machinery legislation is a Directive leaving Member States to choose the means to comply with the legislative objectives, has led to different interpretations of the MD provisions creating legal uncertainty and lack of coherence throughout the single market.

The Commission suggests that the proposal should take the form of a Regulation as this would better ensure that Member States do not impose national technical requirements that go beyond the safety requirements laid down in Annex I of the current Directive and/or contradict those safety requirements.

**CONTENT:** this draft regulation proposed by the Commission responds to market needs by bringing greater legal clarity to the current provisions, simplifying the administrative burden and costs for companies by allowing digital formats for documentation and adapting conformity assessment fees for SMEs, while ensuring coherence with the EU legislative framework for products.

The proposed new regulation will ensure the safe integration of artificial intelligence (AI) systems into machines and thus encourage innovation.

### ***Specific provisions of the proposal***

#### ***Scope and definitions***

While the scope of the proposed regulation remains the same, the definition of safety component has been clarified to include non-physical components such as software. There is also a new definition of substantial modification to ensure that machinery, placed on the market and/or put into service, that suffers substantial modifications is in conformity with the essential health and safety requirements in Annex III.

#### ***Exclusions***

The exemption of the means of transport on road is extended beyond the Union type approval legislation to increase the legal certainty. The reason is to prevent that vehicles not covered by that legislation are covered by default by the machinery legislation, as this legislation is not meant to regulate risks other than those stemming from the machinery function (such as sawing, excavating, etc.), and not the risks exclusively related to its transport function of persons or goods.

#### ***High-risk machinery***

The proposal sets up classification rules for high-risk machinery empowering the Commission to adopt delegated acts to adapt the list of high-risk machinery in Annex I. This list is obsolete and needs to be adapted to the technical progress and new type of machinery presenting high risks such as machinery with Artificial Intelligence ensuring safety functions.

#### ***Obligations of economic operators***

The proposal incorporates obligations for manufacturers, importers and distributors to be aligned with the New Legislative Framework Decision.

#### ***Conformity assessment***

The proposal keeps the manufacturer internal check option for machinery that is not classified as high risk. However, for high-risk machinery, considering that Annex I will be adapted to the technological progress when needed and the NLF alignment, only third-party certification will be accepted, even when manufacturers apply the relevant harmonised standards.

#### ***Notified bodies***

Proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and for the confidence of all interested parties in the New Approach system. Therefore, the proposal sets out requirements for national authorities responsible for conformity assessment bodies (notified bodies). It leaves the ultimate responsibility for designating and monitoring notified bodies with the individual Member State.

## **Regulation on machinery products**

The Committee on the Internal Market and Consumer Protection adopted the report by Ivan ŠTEFANEC (EPP, SK) on the proposal for a regulation of the European Parliament and of the Council on machinery products.

The committee recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure be amended as follows:

#### ***Subject matter and scope***

Member stated that the Regulation lays down requirements for the design and construction of machinery products to allow the making available on the market or putting into service of machinery products and establishes rules on the free movement of machinery products in the Union, **ensuring a high level of protection for Union consumers and professional operators.**

The following should be **excluded** from the scope of the Regulation:

- vehicles which have as their only objective the transport of goods, persons or animals by air, water or rail except for machinery mounted on those vehicles;
- motor vehicles and their trailers, as well as systems, components and separate technical units, parts and equipment designed and constructed for such vehicles, which fall within the scope of application of Regulation (EU) 2018/858, except for machinery mounted on those vehicles;
- motor vehicles intended exclusively for competition.

Machinery mounted on two- or three-wheel vehicles and quadricycles as well as on agricultural and forestry tractors should be covered by Regulation (EU) 2018/858.

#### ***Clarification of definitions***

The report proposed to clarify certain definitions, such as 'safety component', 'substantial modification' and 'manufacturer', and suggested adding new definitions, namely 'machine and related products', 'safety function', 'technical documentation' and 'lifetime', to make the scheme more understandable.

Members also considered it necessary to make a clearer distinction between the definitions that apply to 'partly completed machinery' and those that apply to other categories of machinery and related products.

#### ***High-risk machinery and related products***

Members proposed to replace the term 'high-risk machinery and related products' with '**categories of machinery and related products subject to the specific conformity assessment procedure**' (Annex I, Part A).

The Commission could adopt delegated acts to amend Annex I, after consulting the relevant stakeholders, by adding a new machine or related product to the list of categories of machinery and associated products in Annex I, or by removing a machine or related product from that list. Where a new machine or related product is added to the list in Annex I, the Commission should ensure that economic operators have sufficient time to comply with their obligations under the Regulation.

Machinery and related products which present a risk to human health taking into account their design, intended purpose and any foreseeable use would be added to the list of categories of machinery and related products in Annex I.

A machinery product that is established as posing a risk to human health should be included in the list of categories of machinery products in Annex I, Part A, if at least one of the following conditions is fulfilled:

- no harmonised standards or technical specifications covering all the relevant essential health and safety requirements exist for the category of the machinery product in question;
- residual risks due to shortcomings of protective measures exist and information communicated to the Commission in accordance with paragraph 4 demonstrates a recurrence of serious or fatal accidents or damage to health in relation with these residual risks;
- statistics on accidents referred to in paragraph 4 demonstrate either shortcomings in the relevant harmonised standards or technical specifications or a recurring incorrect application of the relevant harmonised standards or technical specifications;
- the degree of uncertainty of the potential risk related to new types of machinery or technologies.

A machine or related product that is found to present a risk to human health and that does not fulfil any of these conditions should be included in the list of categories of machinery and related products in Annex I, Part B.

#### ***Partly completed machinery***

Partly completed machinery should only be made available on the market if it complies with the relevant essential health and safety requirements set out in Annex III, and if the manufacturer has declared this to be the case in the EU Declaration of Incorporation.

#### ***Documents***

All relevant technical documentation, assembly instructions and declarations should be available in paper form or electronically and, where electronic, should be accessible throughout the life cycle of the machinery or related product.

### ***Presumption of conformity of machinery and related products***

If harmonised standards covering the essential health and safety requirements set out in Annex III are developed and references to these standards are published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, the relevant technical specifications should no longer apply.

### ***Procedure applicable at national level***

Where the market surveillance authorities of a Member State have sufficient reason to believe that a machine or related product does not comply with the requirements set out in the Regulation or presents a risk to the health or safety of persons and, where appropriate, domestic animals or to property and, where applicable, the environment, they should carry out an evaluation in relation to the machinery product concerned covering all relevant requirements laid down in this Regulation.

Where the relevant economic operator does not take corrective action referred to in the Regulation, within the specified period or where the non-compliance or the risk persists, the market surveillance authorities should ensure that the machinery product concerned is withdrawn or recalled, or that making available on the market is prohibited or restricted, and that the public, the Commission and the other Member States are informed accordingly without delay.

### ***Deadlines and transitional arrangements***

The report proposes to extend the deadline for repealing Directive 2006/42/EC from 30 to 48 months after the date of entry into force of the new Regulation. Member States should not prevent the making available on the market of machinery that has been placed on the market in accordance with Directive 2006/42/EC before the date of application of the Regulation.

The deadline for the Commission to submit its first report on the evaluation of the Regulation would be extended from 54 to 72 months. Lastly, the date of application of the regulation has been postponed from 30 to **48 months** after its entry into force.

## **Regulation on machinery products**

2021/0105(COD) - 29/06/2023 - Final act

**PURPOSE:** to ensure that machinery placed on the market meets the requirements to provide a high level of protection of the health and safety of persons and, where appropriate, domestic animals and property.

**LEGISLATIVE ACT:** Regulation (EU) 2023/1230 of the European Parliament and of the Council on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC.

**CONTENT:** the new legislation updates the 2006 Machinery Directive and transforms it into a Regulation.

### ***Subject matter and scope***

The new regulation lays down **health and safety requirements for the design and construction of machinery, related products and partly completed machinery** to allow them to be made available on the market or put into service while ensuring a high level of protection of the health and safety of persons, in particular consumers and professional users, and, where appropriate, of domestic animals and property, and, where applicable, of the environment. It also establishes rules on the free movement of products within the scope of this regulation in the Union.

The regulation applies to machinery and the following related products: (a) interchangeable equipment; (b) safety components; (c) lifting accessories; (d) chains, ropes and webbing; (e) removable mechanical transmission devices.

It also applies to partly completed machinery.

### ***Conformity requirements***

The regulation makes conformity assessment by a third-party compulsory for six categories of machinery (listed in Annex I, Part A) with a higher risk factor, namely:

1. Removable mechanical transmission devices including their guards.
2. Guards for removable mechanical transmission devices.
3. Vehicle servicing lifts.
4. Portable cartridge-operated fixing and other impact machinery.
5. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions.
6. Machinery that has embedded 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.

The Commission will assess the seriousness of the inherent potential risk presented by a category of machinery or related product for the purpose of determining whether to add that category of machinery or related product to Annex I or to withdraw that category of machinery or related product from Annex I. That assessment will be established based on the combination of the probability of occurrence of harm and the severity of that harm.

When conducting the assessment, the Commission will consider the following elements:

- indications of harm that have been caused in the past by machinery or related products which have been used for their intended use or following any reasonably foreseeable misuse;
- information about safety defects detected in the course of market surveillance, and material possibly available in the information systems administered by the Commission;
- information about known accidents and serious 'close calls', including the characteristics of those accidents or 'close calls';
- data on accidents or damage to health caused by the machinery or related product for at least the preceding four years.

A category of machinery or related product will be included in Annex I, Part A, if, according to the assessment and taking into account the available information, it presents a serious inherent potential risk, and if specific conditions are fulfilled.

#### ***Common technical specifications***

The Commission will be able to adopt implementing acts laying down common specifications for the essential health and safety requirements of the Regulation, provided that in doing so it duly respects the role and functions of standardisation organisations, as an **exceptional fall back solution** to facilitate the manufacturer's obligation to comply with those health and safety requirements, when the standardisation process is blocked or when there are delays in the establishment of appropriate harmonised standards.

#### ***Documentation requirements***

Safety information will need to be provided for each product but, in line with the digital transition, the regulation states that **digital instructions will be the default option**. Paper instructions will remain an option for customers who request them.

Economic operators will ensure that all relevant documentation, such as the instructions for use, while containing precise and comprehensible information, is **easily understandable** and available in a language which can be easily understood by users, as determined by the Member State concerned, takes into account technological developments and changes to user behaviour, and is as up to date as possible.

No later than 14 July 2028 and every four years thereafter, the Commission will present a report on the evaluation and review of the Regulation to the European Parliament and the Council. The reports will be made public.

ENTRY INTO FORCE: 19.7.2023.

APPLICATION: from 14.1.2027.

## **Regulation on machinery products**

2021/0105(COD) - 18/04/2023 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 595 votes to 7, with 30 abstentions, a legislative resolution on the proposed for a regulation of the European Parliament and of the Council on Machinery products.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission's proposal as follows:

#### ***Subject matter***

This Regulation lays down **health and safety requirements** for the design and construction of machinery, related products and partly completed machinery to allow them to be made available on the market or put into service while ensuring a high level of protection of the health and safety of persons, in particular consumers and professional users, and, where appropriate, of domestic animals and property, and, where applicable, of the environment. It also establishes rules on the free movement of products within the scope of this Regulation in the Union.

In order to ensure that the scope of this Regulation is sufficiently clear, a distinction should be made between machinery, related products and partly completed machinery. Moreover, related products should be understood as comprising interchangeable equipment, safety components, lifting accessories, chains, ropes and webbing, and removable mechanical transmission devices, which are all products within the scope of this Regulation.

#### ***Scope of application***

The purpose of this Regulation is to address the risks stemming from machinery function and not from the transport of goods, persons or animals. Consequently, this Regulation should not apply to means of transport by air, on water and on rail networks although it should still apply to the machinery mounted on those means of transport.

Means of transport by road that are not yet covered by a specific Union legal act should be regulated by this Regulation except in respect of risks that might arise from circulation on public roads. This means that vehicles, including e-bikes, e-scooters and other personal mobility devices that are not



subject to EU type approval under Regulation (EU) No 167/2013 of the European Parliament and of the Council or Regulation (EU) No 168/2013 of the European Parliament and of the Council or approval under Regulation (EU) 2018/858 of the European Parliament and of the Council(10) are covered by this Regulation.

### ***Protection of persons during installation or use of machinery or related products***

Member States may lay down requirements to ensure that persons, including workers, are protected when installing or using machinery or related products, provided that such rules do not allow for the modification of machinery or a related product in a way that is not compatible with this Regulation.

### ***List of products***

The new Regulation changes the structure of the list of machinery or products, which is set out in Annex I of the Commission proposal. Machinery and related products falling under the categories listed in Annex I, Part A and Part B should be subject to **specific conformity assessment procedures**. The European Commission, after consulting the relevant stakeholders, should adopt delegated acts to **update** this list of products.

The Commission should **assess the seriousness of the inherent potential risk** presented by a category of machinery or related products for the purpose of determining whether to add that category of machinery or related products to Annex I or to withdraw that category of machinery or related product from Annex I.

When conducting the assessment, the Commission should consider the following elements:

- indications of harm that have been caused in the past by machinery or related products which have been used for their intended use or following any reasonably foreseeable misuse;
- information about safety defects detected in the course of market surveillance, and material possibly available in the information systems administered by the Commission;
- information about known accidents and serious 'close calls', including the characteristics of those accidents or 'close calls';
- data on accidents or damage to health caused by the machinery or related product for at least the preceding four years.

A category of machinery or related product should be included in Annex I, Part A, if, according to the assessment and taking into account the available information, it presents a serious inherent potential risk, and if certain conditions are fulfilled.

### ***Common technical specifications***

The Commission should adopt **implementing acts** laying down common specifications for the essential health and safety requirements of the Regulation, provided that it respects the role and functions of the standardisation organisations, as an **exceptional fall back solution** to facilitate the fulfilment of the manufacturer's obligation to comply with those requirements, where the standardisation process is blocked or where there is a delay in establishing appropriate harmonised standards. If such a delay is due to the technical complexity of the standard in question, the Commission should take this into account before contemplating the establishment of common specifications. The Commission should involve relevant stakeholders in the process.

### ***Instructions***

The new Regulation strikes a balance between digital and paper documentation. Manufacturers should ensure that machinery or related products are accompanied by the instructions and information set out in Annex III. The instructions should be provided in **digital format**. These instructions and information must clearly describe the product model to which they correspond.

When the instructions for use are provided in digital format, the manufacturer should make them accessible online during the expected lifetime of the machinery or related product and for at least 10 years after the placing on the market of the machinery or related product. However, at the request of the user at the time of the purchase, the manufacturer should **provide the instructions for use in paper format free of charge within one month**.

The instructions for use, the safety information and the information set out in Annex III should be in a language which can be easily understood by users, as determined by the Member State concerned, and shall be clear, understandable and legible.