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Machinery: from the Directive to the new Regulation, what changes?

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Machinery: From the Directive to the new Regulation, what changes?

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Created in 1991 within the French Social Security system, EUROGIP is an observatory and resource centre on issues relating to accidents at work and occupational diseases at international level.

EUROGIP's mission is to analyse international, and particularly European, developments in the field of insurance and prevention of occupational injuries, but also to put forward the point of view of the French occupational injury insurance on these issues to the relevant Community bodies and national organizations.
It carries out various activities:

- Comparative surveys on occupational risks in Europe
- Projects of Community interest
- Information sharing and communication: monthly newsletter (Eurogip infos), publication of survey reports and thematic notes, organization of events, social networks (Twitter, LinkedIn), etc.
- Secretariat of the coordination of notified bodies for the regulatory certification of personal protective equipment and machinery (delegation of the French Ministries of Labour and Agriculture)
- Coordination of the network of 70 experts from the French occupational health and safety insurance scheme, chosen for their technical skills, who participate in European and international standardization work in the field of occupational health and safety.

EUROGIP was set up in the form of a public interest grouping between the French National Health Insurance Fund (CNAM) and the National Research and Safety Institute for the Prevention of Occupational Injuries (INRS).

The European Trade Union Institute is the independent research and training centre of the European Trade Union Confederation (ETUC). It uses its expertise to promote the interests of workers at European level and to strengthen the social dimension of the European Union.

The ETUI is composed of two Departments: A Research Department, which includes three units (Europeanisation of Industrial Relations; Economic, Social and Employment Policies; Working Conditions, Health and Safety) and an Education Department.
The ETUI conducts studies on socio-economic and industrial relations issues and monitors European policy developments of strategic importance to the world of work. It builds bridges between academia, the research community and the trade union movement in order to encourage independent research on topics of key importance to the world of work.
The ETUI encourages training, education and learning activities. It provides the ETUC and its affiliates with programmes and exchanges that strengthen the European trade union identity.
The ETUI provides technical assistance in the field of health and safety to achieve a high level of protection at work for workers throughout Europe.
A foresight unit is responsible for studying the long-term challenges for the European trade union movement and its implications for the functioning of the Institute.
The ETUI is an international non-profit association under Belgian law, employing a staff of about 70 people from all over Europe. It receives financial support from the European Union.

Preface

Marian Schaapman
ETUI

Raphaël Haeflinger
EUROGIP

"At ETUI, we are convinced that European legislation should be subject to constant public debate so that the degree of accountability, transparency and competence of the European Institutions can be measured at any time.

At EUROGIP, our task is among others to improve understanding of the decisions and actions implemented at Community level regarding health and safety at work.

Thus, this work would not have been possible without the joint contribution of the ETUI and EUROGIP, longstanding partners in the promotion of health and safety at work in Europe.

It has made it possible to co-sign this publication and thus provide an indispensable tool for assessing the quality and relevance of the changes proposed by the European Commission in 2021 between the Machinery Directive and the new regulation.

The "line-by-line" comparison format devised by authors Pierre Belingard and Stefano Boy, and the associated colour coding, greatly facilitates the task of stakeholders involved in the design, purchase, use and conformity assessment of new machinery placed on the market.

We hope that this publication will help to move from words to action, so that the machinery regulation can be interpreted, implemented and enforced in the best possible way in the years to come."

Authors

Pierre Belingard, EUROGIP

Pierre is an electro-technical engineer. He has been in charge of testing and validation of products in different industrial fields for over ten years before joining EUROGIP. With its expertise in the fields of system evaluation in the automotive or in the defence and security sectors, he is responsible for the French coordination of Notified Bodies for the Machinery Regulation and the Personal Protective Equipment Regulation, under delegation from the French authorities. In close collaboration with the French Ministry of Labour and the French Ministry of Agriculture, he has collaborated in the elaboration of the guidance for modification of machines and in the prevention guidance for manufacturers and users for the implementation of robotized collaborative applications. He also participates in standardization activities in the machinery sector and represent the positions of the prevention actors.

Stefano Boy, ETUI

Stefano, a nuclear engineer, held various positions during his ten-year career in the oil and gas sector, starting as an operator controlling machines and ending it as health and safety manager in charge of quantified risk assessment studies. Before joining the ETUI in 2000, he worked for the European Commission's Joint Research Centre carrying out accident investigations of industrial sites. As a member of the Machinery Expert Group and the CEN-CENELEC Safety of Machinery Advisory Nucleus, he was one of the members of CEN/TC 114/ SG Ad Hoc Group for the revision of EN 292 and CEN/TC 114/WG 4 Rules for the preparation and presentation of safety standards (CEN Guide 414). Stefano also contributed to the negotiations of the Machinery Directive 2006/42/EC and the Regulation 1025/2012 on European standardisation. He is co-author of CEN/TR 16710-1:2015 Ergonomics methods - Part 1: Feedback method - A method to understand how end users perform their work with machines.

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Comparison between the Directive 2006/42/EC and the new Machinery Regulation (EU) 2023/1230 of 14 June 2023[1]

For the purpose of this document the following colour code have been used in order to facilitate the reading comparison of both new machinery regulation and "old" machinery Directive 2006/42/EC.

Meaning of the colours and highlights introduced in the text

- **The red colour** indicates the new words/sentences introduces in the new regulation
- **The yellow highlighting** indicates the words/sentences of the old directive no longer present in the new regulation.
- **The grey highlighting** indicates the new words/sentences that have similar position in the new and old regulation, and/or that convey similar or different meaning: open to interpretations
- **The blue colour** indicates old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation. The corresponding texts of the two regulations have been compared using the colour/highlighting convention as above.

[1] **DIRECTIVE 2006/42/EC** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast)
https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32006L0042&qid=1688049029612

REGULATION (EU) 2023/1230 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC
https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32023R1230

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
Chapter I ***GENERAL PROVISIONS***		
Article 1 **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.		
Article 2 **Scope** (1) This 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; This Regulation also applies to partly completed machinery. For the purposes of this Regulation, machinery, the related products listed in the first subparagraph and partly completed machinery shall together be referred to as 'products within the scope of this Regulation'.	*Article 1* **Scope** 1. This Directive applies to the following products: (a) machinery; (b) interchangeable equipment; (c) safety components; (d) lifting accessories; (e) chains, ropes and webbing; (f) removable mechanical transmission devices; (g) partly completed machinery.	Rewording but equivalent.

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
(2) This Regulation does not apply to:	2. The following are excluded from the scope of this Directive:	
(a) safety components that are intended to be used as spare parts to replace identical components and are supplied by the manufacturer of the original machinery, related product or partly completed machinery;	(a) safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery;	
(b) specific equipment for use in fairgrounds or amusement parks;	(b) specific equipment for use in fairgrounds and/or amusement parks;	
(c) machinery and related products specially designed for use within or used in a nuclear installation and whose conformity with this Regulation may undermine the nuclear safety of that installation;	(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;	
(d) weapons, including firearms;	(d) weapons, including firearms;	
	(e) the following means of transport:	
(e) means of transport by air, on water and on rail networks except for machinery mounted on those means of transport;	— means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport;	
(f) aeronautical products, parts and equipment that fall within the scope of Regulation (EU) 2018/1139 of the European Parliament and of the Council and the definition of machinery under this Regulation, insofar as Regulation (EU) 2018/1139 covers the relevant essential health and safety requirements set out in this Regulation;		
(g) motor vehicles and their trailers, as well as systems, components, 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 and their trailers covered by Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers [(2)] with the exclusion of machinery mounted on these vehicles,	On Directive, the indent refers to: (2) OJ L 42, 23.2.1970, p. 1. Directive as last amended by Commission Directive 2006/28/EC (OJ L 65, 7.3.2006, p. 27).
(h) two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, that fall within the scope of application of Regulation (EU) No 168/2013, except for machinery mounted on those vehicles;	— vehicles covered by Directive 2002/24/EC of the European Parliament and of the Council of 18 March 2002 relating to the type-approval of two or three-wheel motor vehicles [(3)], with the exclusion of machinery mounted on these vehicles,	On Directive, the indent refers to: (3) OJ L 124, 9.5.2002, p. 1. Directive as last amended by Commission Directive 2005/30/EC (OJ L 106, 27.4.2005, p. 17).

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
(i) agricultural and forestry tractors, as well as systems, components, separate technical units, parts and equipment designed and constructed for such tractors, that fall within the scope of application of Regulation (EU) No 167/2013 with the exception of machinery mounted on those tractors;	— agricultural and forestry tractors for the risks covered by Directive 2003/37/EC, with the exclusion of machinery mounted on these vehicles,	
(j) motor vehicles exclusively intended for competition;	— motor vehicles exclusively intended for competition, and	
(k) seagoing vessels and mobile offshore units and machinery installed on board such vessels or units;	(f) seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;	
(l) machinery or related products specially designed and constructed for military or police purposes;	(g) machinery specially designed and constructed for military or police purposes;	
(m) machinery or related products specially designed and constructed for research purposes for temporary use in laboratories;	(h) machinery specially designed and constructed for research purposes for temporary use in laboratories;	
(n) mine winding gear;	(i) mine winding gear;	
(o) machinery or related products intended to move performers during artistic performances;	(j) machinery intended to move performers during artistic performances;	
(p) the following electrical and electronic products, insofar as they fall within the scope of application of Directive 2014/35/EU or Directive 2014/53/EU:	(k) electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits [1]:	On Directive, the indent refers to: (1) OJ L 77, 26.3.1973, p. 29. Directive as amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).
(i) household appliances intended for domestic use which are not electrically operated furniture;	— household appliances intended for domestic use,	
(ii) audio and video equipment;	— audio and video equipment,	
(iii) information technology equipment;	— information technology equipment,	
(iv) ordinary office machinery, except additive printing machinery for producing three-dimensional products;	— ordinary office machinery,	
(v) low-voltage switchgear and control gear;	— low-voltage switchgear and control gear,	
(vi) electric motors;	— electric motors;	
(q) the following high-voltage electrical products:	(l) the following types of high-voltage electrical equipment:	
(i) switchgear and control gear;	— switch gear and control gear,	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
(ii) transformers.	— transformers.	
Article 3 **Definitions** For the purposes of this Regulation, the following definitions shall apply: (1) 'machinery' means: (a) an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application; (b) an assembly referred to in point (a), missing only the components to connect it on site or to sources of energy and motion; (c) an assembly referred to points (a) and (b), ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure; (d) assemblies of machinery referred to in points (a), (b) and (c) or partly completed machinery which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole; (e) an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort; (f) an assembly as referred to in points (a) to (e) missing only the uploading of the software intended for the specific application foreseen by the manufacturer.	*Article 2* **Definitions** For the purposes of this Directive, 'machinery' designates the products listed in Article 1(1)(a) to (f). The following definitions shall apply: (a) 'machinery' means: — an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application, — an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion, — an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure, — assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point (g) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole, — an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
(2) 'interchangeable equipment' means a device which, after the putting into service of machinery or an agricultural or forestry tractor, is assembled with that machinery or agricultural or forestry tractor by the operator in order to change its function or attribute a new function to it, provided that the device is not a tool;	(b) 'interchangeable equipment' means a device which, after the putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool;	
(3) 'safety component' means a physical or digital component, including software, of a product within the scope of this Regulation which is designed or intended to fulfil a safety function and which is independently placed on the market, the failure or malfunction of which endanger the safety of persons, but which is not necessary in order for that product to function or for which normal components may be substituted in order for that product to function;	(c) 'safety component' means a component: — which serves to fulfil a safety function, — which is independently placed on the market, — the failure and/or malfunction of which endangers the safety of persons, and — which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.	
(4) 'safety function' means a function that serves to fulfil a protective measure designed to eliminate, or, if that is not possible, to reduce, a risk, which, if it fails, could result in an increase of that risk;		
(5) 'lifting accessory' means a component or equipment not attached to the lifting machinery, which enables the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market, including slings and their components;	(d) 'lifting accessory' means a component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market; slings and their components are also regarded as lifting accessories;	
(6) 'chains' means chains designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;	(e) 'chains, ropes and webbing' means chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;	
(7) 'ropes' means ropes designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;		
(8) 'webbing' means webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
(9) 'removable mechanical transmission device' means a removable component for transmitting power between self-propelled machinery or a tractor and another machinery or related products by joining them at the first fixed bearing. When it is placed on the market with a guard, the device and the guard are to be regarded as one item;	(f) 'removable mechanical transmission device' means a removable component for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one product;	
(10) 'partly completed machinery' means an assembly which is not yet machinery as it cannot in itself perform a specific application and which is only intended to be incorporated into or assembled with machinery or other partly completed machinery or equipment, thereby forming machinery;	(g) 'partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies;	
(11) 'making available on the market' means any supply of a product within the scope of this Regulation for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;		
(12) 'placing on the market' means the first making available of a product within the scope of this Regulation on the Union market;	(h) 'placing on the market' means making available for the first time in the Community machinery or partly completed machinery with a view to distribution or use, whether for reward or free of charge;	Deleted information from Directive are given in the Blue Guide §2.2
(13) 'putting into service' means the first use, for its intended purpose, in the Union, of machinery or related products;	(k) 'putting into service' means the first use, for its intended purpose, in the Community, of machinery covered by this Directive;	
(14) 'essential health and safety requirements' means mandatory provisions, set out in Annex III, relating to the design and construction of the products within the scope of this Regulation to ensure a high level of protection of the health and safety of persons, and, where appropriate, domestic animals and property, and, where applicable, of the environment;	(m) 'essential health and safety requirements' means mandatory provisions relating to the design and construction of the products subject to this Directive to ensure a high level of protection of the health and safety of persons and, where appropriate, of domestic animals and property and, where applicable, of the environment. The essential health and safety requirements are set out in Annex I. Essential health and safety requirements for the protection of the environment are applicable only to the machinery referred to in section 2.4 of that Annex.	
(15) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
(16) 'substantial modification' means a modification of machinery or related product, by physical or digital means after that machinery or related product has been placed on the market or put into service, which is not foreseen or planned by the manufacturer, and which affects the safety of that machinery or related product, by creating a new hazard or by increasing an existing risk, which requires: (a) the addition of guards or protective devices to that machinery or related product the processing of which necessitates the modification of the existing safety control system, or (b) the adoption of additional protective measures to ensure the stability or mechanical strength of that machinery or related product; (17) 'instructions for use' means the information, provided by the manufacturer when the machinery or related product is placed on the market or put into service, to inform the user of the machinery or related product, of the intended and proper use of that machinery or related product, as well as information on any precautions to be taken when using or installing the machinery or related product, including information on the safety aspects, and on how to keep that machinery or related product safe, and to ensure that it remains fit for purpose during its entire lifetime;		
(18) 'manufacturer' means any natural or legal person who: (a) manufactures products within the scope of this Regulation or who has those products designed or manufactured, and markets those products under its name or trademark or (b) manufactures products within the scope of this Regulation, and puts those products into service for its own use;	(i) 'manufacturer' means any natural or legal person who designs and/or manufactures machinery or partly completed machinery covered by this Directive and is responsible for the conformity of the machinery or the partly completed machinery with this Directive with a view to its being placed on the market, under his own name or trademark or for his own use. In the absence of a manufacturer as defined above, any natural or legal person who places on the market or puts into service machinery or partly completed machinery covered by this Directive shall be considered a manufacturer;	In Machinery regulation, other stakeholders' obligation than manufacturer and its authorized representative are detailed. For example, specific requirements are now given to importers, which were before considered as manufacturer due to the fact they were the "natural or legal person who places on the market or puts into service machinery or partly completed machinery".

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
(19) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his or her behalf in relation to specified tasks;	(j) 'authorised representative' means any natural or legal person established in the Community who has received a written mandate from the manufacturer to perform on his behalf all or part of the obligations and formalities connected with this Directive;	
(20) 'importer' means any natural or legal person established within the Union who places a product within the scope of this Regulation from a third country on the Union market;		
(21) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product within the scope of this Regulation available on the market;		
(22) 'economic operator' means the manufacturer, the authorised representative, the importer or the distributor;		
(23) 'technical specifications' means a document that prescribes technical requirements to be fulfilled by products within the scope of this Regulation;		
(24) 'harmonised standard' means a harmonised standard as defined in Article 2, point 1 (c) of Regulation (EU) No 1025/2012;	(l) 'harmonised standard' means a non-binding technical specification adopted by a standardisation body, namely the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), on the basis of a remit issued by the Commission in accordance with the procedures laid down in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services[(1)];	On Directive, the indent refers to: (1) OJ L 204, 21.7.1998, p. 37. Directive as last amended by the 2003 Act of Accession.
(25) 'CE marking' means a marking by which the manufacturer indicates that machinery or a related product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;		
(26) 'accreditation' means accreditation as defined in Article 2, point (10) of Regulation (EC) No 765/2008;		
(27) 'national accreditation body' means a national accreditation body as defined in Article 2 point (11) of Regulation (EC) No 765/2008;		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
(28) 'conformity assessment' means the process for demonstrating whether the applicable essential health and safety requirements in this Regulation relating to machinery or related products have been fulfilled; (29) 'conformity assessment body' means a body that performs conformity assessment activities, including calibration, testing, certification and inspection; (30) 'notified body' means a conformity assessment body notified in accordance with this Regulation; (31) 'market surveillance authority' means a 'market surveillance authority' as defined in Article 3, point (4), of Regulation (EU) 2019/1020; (32) 'recall' means any measure aimed at achieving the return of a product within the scope of this Regulation that has already been made available to a user; (33) 'withdrawal' means, for a product, any measure aimed at preventing a product within the scope of this Regulation that is in the supply chain from being made available on the market; (34) 'lifetime' means the period from the moment that machinery or a related product is placed on the market or put into service until the moment that it is discarded, including the effective time when the machinery or related product is capable of being used and the phases of transport, assembly, dismantling, disabling, scrapping or other physical or digital modifications foreseen by the manufacturer; (35) 'source code' means the currently installed version of the software of a product within the scope of this Regulation, written in a programming language, so that it is unambiguous and understandable to humans; (36) 'professional user' means a natural person who uses or operates machinery or a related product in the course of his or her professional activity or work.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
Article 4 **Free movement** 1. Member States shall not impede, for reasons relating to the aspects covered by this Regulation, the making available on the market of products within the scope of this Regulation or the putting into service of machinery or related products which comply with this Regulation. 2. At trade fairs, exhibitions and demonstrations or similar events, Member States shall not prevent the display of a product within the scope of this Regulation which does not comply with this Regulation, provided that a visible sign clearly indicates that it does not comply with this Regulation and will not be made available on the market until it has been brought into conformity. During demonstrations, adequate measures shall be taken to ensure the protection of persons.	*Article 6* **Freedom of movement** 1. Member States shall not prohibit, restrict or impede the placing on the market and/or putting into service in their territory of machinery which complies with this Directive. 2. Member States shall not prohibit, restrict or impede the placing on the market of partly completed machinery where the manufacturer or his authorised representative makes a declaration of incorporation, referred to in Annex II, part 1, Section B, stating that it is to be incorporated into machinery or assembled with other partly completed machinery to form machinery. 3. At trade fairs, exhibitions, demonstrations, and such like, Member States shall not prevent the showing of machinery or partly completed machinery which does not conform to this Directive, provided that a visible sign clearly indicates that it does not conform and that it will not be made available until it has been brought into conformity. Furthermore, during demonstrations of such non-conforming machinery or partly completed machinery, adequate safety measures shall be taken to ensure the protection of persons.	
Article 5 **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.	*Article 15* **Installation and use of machinery** This Directive shall not affect Member States' entitlement to lay down, in due observance of Community law, such requirements as they may deem necessary to ensure that persons, and in particular workers, are protected when using machinery, provided that this does not mean that such machinery is modified in a way not specified in this Directive.	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
Article 6 **Categories of machinery and related products listed in Annex I subject to relevant conformity assessment procedures** 1. Machinery and related products that fall within the categories listed in Annex I, Part A, shall be subject to the specific conformity assessment procedures referred to in Article 25(2), and machinery and related products that fall within the categories listed in Annex I, Part B shall be subject to the specific conformity assessment procedures referred to in Article 25(3). 2. The Commission is empowered to adopt delegated acts in accordance with Article 47 to amend Annex I, after consulting the stakeholders concerned, in the light of technical progress, advances in knowledge or new scientific evidence by adding to the list of categories of machinery and related products in Annex I a new category of machinery or related products, withdrawing an existing category of machinery or related products from that list or moving a category of machinery or related products from one Part of Annex I to another Part of that Annex, in accordance with the criteria and the procedures laid down in paragraphs 4, 5 and 7 of this Article. 3. Before adopting a delegated act, the Commission shall seek the views of experts in the relevant expert group in accordance with article 47(4). 4. The Commission shall 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 shall be established based on the combination of the probability of occurrence of harm and the severity of that harm. In determining the probability and severity of harm, the following criteria shall, where relevant, be taken into account: (a) the nature of the hazard inherent to the function of the category of machinery or related product, taking into account the intended use and any reasonable foreseeable misuse;		

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(b) the severity of harm which a person would suffer, including the degree of reversibility of that harm; (c) the number of persons potentially affected by the harm; (d) the frequency and the duration of the exposure to the hazard that a person would be exposed to in the course of the intended use or any reasonably foreseeable misuse of the category of machinery or related product; (e) the possibilities of avoiding or limiting harm; (f) in the case of safety components, the likelihood of serious consequences for the safety of the persons exposed to harm in the event of their failure. 5. When conducting the assessment referred to in paragraph 4, the Commission shall consider the following elements: (a) 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; (b) information about safety defects detected in the course of market surveillance, and material possibly available in the information systems administered by the Commission; (c) information about known accidents and serious 'close calls', including the characteristics of those accidents or 'close calls'; (d) data on accidents or damage to health caused by the machinery or related product for at least the preceding four years. In particular, information obtained, inter alia, from the Information and Communication System on Market Surveillance (ICSMS), safeguard clauses, Safety Gate Rapid Alert System, the European Injury Database (EU-IDB), Eurostat's European Statistics on Accidents at Work (ESAW) and the Machinery Administrative Cooperation Group (AdCo).		

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In addition to points (a) to (d) of this paragraph, the Commission shall take into account any other information available that is relevant to the assessment referred to in paragraph 4. 6. The data and information referred to in paragraph 5, points (a) to (d), shall be provided by Member States in accordance with paragraph 9. 7. A category of machinery or related product shall be included in Annex I, Part A, if, according to the assessment referred to in paragraph 4, and taking into account the available information, including the data referred to in paragraph 5, it presents a serious inherent potential risk, and one or more of the following conditions is fulfilled: (a) there is a lack of harmonised standards or common specifications covering the relevant essential health and safety requirements; (b) residual risks exist, including those which, according to the manufacturer, could be reduced by particular training or personal protective equipment, and the data and information referred to in paragraph 5, demonstrate the recurrence of similar serious or fatal accidents or damage to health in connection with those residual risks; (c) data and information exist which according to the Commission demonstrate recurring wrongful application of the relevant harmonised standards or common specifications and for which the market surveillance activities that were carried out have not led to major improvements of the market situation, in a reasonable period; (d) there is a degree of uncertainty in the existing risk assessment methods related to new categories of machinery or technologies. Any other category of machinery or related product that, according to that assessment, presents a serious inherent potential risk but does not fulfil one or more of the conditions in points (a) to (d) shall be included in Annex I, Part B.		

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8. A Member State which has concerns about a category of machinery or related product being listed or not in Annex I shall immediately inform the Commission of those concerns and provide reasons in support thereof. The Commission shall conduct the assessment referred to in paragraph 4 immediately after being informed by a Member State. After making that assessment, the Commission may initiate the procedure laid down in paragraph 2. 9. By 20 July 2025 and every five years thereafter, Member States shall provide the data and information referred to in paragraph 5, including information to the effect that none of the events referred to in paragraph 5 has occurred, for every category of machinery or related products which is included in Annex I or which is not included in Annex I where that non-inclusion is a cause of concern for the Member State. 10. The Commission shall adopt implementing acts setting out and, where necessary in the light of technological and market development, updating a template concerning the collection by Member States of the data and the information referred to in paragraph 5, points (a) to (d). When adopting those implementing acts, the Commission shall issue guidance to Member States on the collection and transmission of comparable, high-quality data and information. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3). The first such implementing act shall be adopted not later than 20 July 2024.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
11. If necessary after the Commission report referred to in Article 53(3), the Commission shall adopt delegated acts in accordance with Article 47 to supplement paragraph 5 of this Article by specifying the obligations of Member States to provide data and information required pursuant to this Article through the establishment of a common methodology concerning the data and information to be collected, including the methods for their collection and compilation, and the procedures for their transmission, as well as the relevant definitions, in order to ensure that sufficient and comparable data is available for the Commission to carry out the assessment referred to in paragraph 4.		
Article 7 **Safety components** 1. An indicative list of safety components is set out in Annex II. 2. The Commission is empowered to adopt delegated acts in accordance with Article 47 to amend Annex II in the light of technical progress and knowledge or new scientific evidence by including a new safety component in the indicative list of safety components or withdrawing an existing safety component from that list.	*From Article 2 section (c):* An indicative list of safety components is set out in Annex V, which may be updated in accordance with Article 8(1)(a); *Article 8* **Specific measures** 1. The Commission may take any appropriate measure relating to the following: (a) updating the indicative list of safety components in Annex V referred to in Article 2(c); (b) restricting the placing on the market of machinery referred to in Article 9. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3). 2. The Commission, acting in accordance with the advisory procedure referred to in Article 22(2), may take any appropriate measure connected with the practical application of this Directive, including measures necessary to ensure cooperation of Member States with each other and with the Commission, as provided for in Article 19(1).	Restriction in placing on the market requirement is more detailed in regulation Article 41 section 4. See regulation Article 46 for more details on cooperation between Member States

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
3. A Member State which has concerns about a safety component being listed or not listed in Annex II shall immediately inform the Commission of its concerns and provide reasons in support thereof.		
Article 8 **Essential health and safety requirements for products within the scope of this Regulation** Machinery or related products shall only be made available on the market or put into service if, where properly installed and maintained and used for their intended use or under conditions which can reasonably be foreseen, they meet the essential health and safety requirements set out in Annex III. Partly completed machinery shall only be made available on the market if it meets the relevant essential health and safety requirements set out in Annex III.		
Article 9 **Specific Union harmonisation legislation** Where, for a certain product within the scope of this Regulation, the risks addressed by the essential health and safety requirements set out in Annex III are wholly or partly covered by Union harmonisation legislation that is more specific than this Regulation, this Regulation shall not apply to that product to the extent that specific Union legislation covers such risks.	*Article 3* **Specific Directives** Where, for machinery, the hazards referred to in Annex I are wholly or partly covered more specifically by other Community Directives, this Directive shall not apply, or shall cease to apply, to that machinery in respect of such hazards from the date of implementation of those other Directives.	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
Chapter II ***OBLIGATIONS OF ECONOMIC OPERATORS***		
Article 10 **Obligations of manufacturers of machinery and related products** 1. When placing machinery or a related product on the market or putting it into service, manufacturers shall ensure that it has been designed and constructed in accordance with the essential health and safety requirements set out in Annex III. 2. Before placing a machinery or related product on the market or putting it into service, manufacturers shall draw up the technical documentation set out in Annex IV, Part A and carry out the relevant conformity assessment procedure referred to in Article 25 or have it carried out. Where compliance of a machinery or related product with the essential health and safety requirements laid down in Annex III has been demonstrated by that conformity assessment procedure, manufacturers shall draw up the EU declaration of conformity in accordance with Article 21 and affix the CE marking in accordance with Article 24.	*Article 5* **Placing on the market and putting into service** 1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall: (a) ensure that it satisfies the relevant essential health and safety requirements set out in Annex I; (b) ensure that the technical file referred to in Annex VII, part A is available; (c) provide, in particular, the necessary information, such as instructions; (d) carry out the appropriate procedures for assessing conformity in accordance with Article 12; (e) draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery; (f) affix the CE marking in accordance with Article 16. 3. For the purposes of the procedures referred to in Article 12, the manufacturer or his authorised representative shall have, or shall have access to, the necessary means of ensuring that the machinery satisfies the essential health and safety requirements set out in Annex I.	Authorised representative requirements are set out in Regulation Article 12. Directive requirement (c) is covered in Regulation Article 10 section 8 (see below).

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
	4. Where machinery is also the subject of other Directives relating to other aspects and providing for the affixing of the CE marking, the marking shall indicate that the machinery also conforms to the provisions of those other Directives. However, where one or more of those Directives allow the manufacturer or his authorised representative to choose, during a transitional period, the system to be applied, the CE marking shall indicate conformity only to the provisions of those Directives applied by the manufacturer or his authorised representative. Particulars of the Directives applied, as published in the Official Journal of the European Union, shall be given on the EC declaration of conformity.	Requirement covered in Regulation Article 19 related to CE marking rules.
3. Manufacturers shall keep the technical documentation and the EU declaration of conformity at the disposal of the market surveillance authorities for at least 10 years after the machinery or the related product has been placed on the market or put into service.	*From Annex VII part A section 2 1st paragraph:* 2. The technical file referred to in point 1 must be made available to the competent authorities of the Member States for at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced. *From Annex II section 2 1st paragraph:* The manufacturer of machinery or his authorised representative shall keep the original EC declaration of conformity for a period of at least 10 years from the last date of manufacture of the machinery.	The requirement linked to the duration of keeping technical documentation and EU declaration of conformity was split in the directive on Annex VII and Annex II.
Where relevant, the source code or the programming logic included in the technical documentation shall, upon a reasoned request, be made available to the competent national authorities, if that source code or programming logic is necessary in order for them to be able to check compliance with the essential health and safety requirements set out in Annex III.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
4. Manufacturers shall ensure that procedures are in place in order that machinery or related products that are part of a series production remain in conformity with this Regulation. Adequate account shall be taken of changes in the production process or in the design or characteristics of the machinery or related product, and changes in the harmonised standards, in other technical specifications, or in the common specifications referred to in Article 20 by reference to which the conformity of the machinery or related product is declared. When deemed appropriate with regard to the risks presented by machinery or related products, manufacturers shall, in order to protect the health and safety of users, carry out sample testing of machinery or related products made available on the market and investigate their results. If necessary, manufacturers shall keep a register of complaints, of non-conforming machinery or related products and machinery or related product recalls, and shall keep distributors informed of any such monitoring.		
5. Manufacturers shall ensure that the machinery or related product which they place on the market or put into service bears at least a designation of the machinery or related product model, series or type, the year of construction, namely the year in which the manufacturing process was completed, and any batch or serial number or other element allowing its identification that exists, or, where the size or nature of the machinery or related product does not allow this, that the required information is provided on the packaging or in a document accompanying the machinery or related product.	*From Annex 1, 1.7.3. Marking of machinery:* All machinery must be marked visibly, legibly and indelibly with the following minimum particulars: […] — designation of the machinery, […] — designation of series or type, — serial number, if any, — the year of construction, that is the year in which the manufacturing process is completed.	Complementary to EHSR 1.7.3 Machinery Directive.

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
6. Manufacturers shall indicate their name, registered trade name or registered trade mark, and the postal address and the website, e-mail address or other digital contact at which they can be contacted on the machinery or related product or, where that is not possible, on its packaging or in a document accompanying the machinery or related products. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by users and market surveillance authorities. 7. Manufacturers shall ensure that the machinery or related products are accompanied by the instructions for use and the information set out in Annex III. The instructions may be provided in a digital format. Such instructions and information shall clearly describe the product model to which they correspond. When the instructions for use are provided in digital format, the manufacturer shall: (a) mark on the machinery or related product, or, where that is not possible, on its packaging or in an accompanying document, how to access the digital instructions; (b) present them in a format that makes it possible for the user to print and download the instructions for use and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the machinery or related product; this requirement also applies where the instructions for use are embedded in the software of the machinery or related product; (c) 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 shall provide the instructions for use in paper format free of charge within one month.	*From Annex 1, 1.7.3. Marking of machinery:* — the business name and full address of the manufacturer and, where applicable, his authorised representative, […] — the CE Marking (see Annex III), […]	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
In the case of machinery or a related product intended for non-professional users or that can, under reasonably foreseeable conditions, be used by non-professional users, even if not intended for them, the manufacturer shall provide, in paper format, the safety information that is essential for putting the machinery or related product into service and for using it in a safe way.		
The instructions for use, the safety information and the information set out in Annex III shall 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.	*From Annex 1, 1.7.4. Instructions, first paragraph:* All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service.	
	From Article 5, section 1: (e) draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery;	First part of this Directive requirement is covered on Article 10, section 2 second paragraph of the regulation.
8. Manufacturers shall ensure that the machinery or related products is accompanied by the EU declaration of conformity set out in Annex V, Part A or, or alternatively, manufacturers shall provide the internet address or machine-readable code where that EU declaration of conformity can be accessed in the instructions for use and the information set out in Annex III. Digital EU declarations of conformity shall be made accessible online for the expected lifetime of the machinery or related product and in any event for at least 10 years after the placing on the market or the putting into service of the machinery or related product.		
9. Manufacturers who consider or have reason to believe that machinery or a related product, which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that machinery or related product into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the machinery or related product presents a risk to the health or safety of persons, and, where appropriate, domestic animals or to property, and, where applicable, to the environment, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the machinery or related product available on the market, or in which they put it into service, to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
10. Manufacturers shall, further to a reasoned request from a competent national authority, provide that authority with all the information and documentation, in paper or digital format, necessary to demonstrate the conformity of the machinery or related products with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks presented by the machinery or related products, which they have placed on the market or put into service.		This detailed requirement was introduced in Directive under market surveillance prerogatives (see Annex VII section A.3; Annex IX section 7)
Article 11 **Obligations of manufacturers of partly completed machinery** 1. When placing partly completed machinery on the market, manufacturers shall ensure that it has been designed and constructed in accordance with the relevant essential health and safety requirements set out in Annex III. 2. Before placing partly completed machinery on the market, manufacturers shall draw up the technical documentation set out in Annex IV, part B. Where compliance of partly completed machinery with the relevant essential health and safety requirements set out in Annex III has been demonstrated in the technical documentation set out in Annex IV, Part B, manufacturers shall draw up the EU declaration of incorporation in accordance with Article 22.	*Article 13* **Procedure for partly completed machinery** 1. The manufacturer of partly completed machinery or his authorised representative shall, before placing it on the market, ensure that: (a) the relevant technical documentation described in Annex VII part B is prepared; […] (c) a declaration of incorporation described in Annex II, part 1, Section B has been drawn up. *From Article 5, section 2:* 2. Before placing partly completed machinery on the market, the manufacturer or his authorised representative shall ensure that the procedure referred to in Article 13 has been completed.	Authorised representative requirements are set out in Regulation Article 12. Directive Article 13 refers to the draw up of technical documentation, assembly instruction and declaration of incorporation. Authorised representative requirements are set out in Regulation Article 12.

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
3. Manufacturers shall keep the technical documentation and the EU declaration of incorporation at the disposal of the market surveillance authorities for at least 10 years after the partly completed machinery has been placed on the market.	*From Annex VII section B, 2nd before last paragraph:* The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to the competent authorities of the Member States. It does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. It must be capable of being assembled and presented to the relevant authority by the person designated in the declaration for incorporation. *From Annex II section 2, 2nd paragraph:* The manufacturer of partly completed machinery or his authorised representative shall keep the original declaration of incorporation for a period of at least 10 years from the last date of manufacture of the partly completed machinery.	Authorised representative requirements are set out in Regulation Article 12.
Where relevant, the source code or the programming logic included in the technical documentation shall, upon a reasoned request, be made available to the competent national authorities, if that source code or programming logic is necessary in order for them to be able to check compliance with the relevant essential health and safety requirements set out in Annex III. 4. Manufacturers shall ensure that procedures are in place for partly completed machinery that is part of a series production to remain in conformity with this Regulation. Adequate account shall be taken of changes in the production process, or in the design or characteristics of the partly completed machinery, and changes in the harmonised standards or other technical specifications, or in the common specifications referred to in Article 20, by reference to which the conformity of the partly completed machinery is declared or verified.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
5. Manufacturers shall ensure that the partly completed machinery which they place on the market bears at least the designation of the partly completed machinery, the year of construction, namely the year in which the manufacturing process was completed, model and series or type and any batch or serial number or other element allowing its identification that exists, or, where the size or nature of the partly completed machinery does not allow this, that the required information is provided on the packaging or in a document accompanying the partly completed machinery.		Complementary to EHSR 1.7.3 Machinery Directive.
6. Manufacturers shall indicate their name, registered trade name or registered trade mark, and the postal address and website, email address or other digital contact at which they can be contacted, on the partly completed machinery or, where that is not possible, on its packaging or in a document accompanying the partly completed machinery. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by the person who incorporates the partly completed machinery into machinery and by market surveillance authorities.		Complementary to EHSR 1.7.3 Machinery Directive.
	From Article 13 section 1, point (b):	
7. Manufacturers shall ensure that the partly completed machinery is accompanied by the assembly instructions set out in Annex XI.	(b) assembly instructions described in Annex VI are prepared;	
The assembly instructions may be provided by the manufacturer in digital format.		
When the assembly instructions are provided in digital format, the manufacturer shall:		
(a) mark on the partly completed machinery, or, where that is not possible, on its packaging or in an accompanying document, how to access the digital assembly instructions;		
(b) present them in a format that makes it possible for the person who incorporates the partly completed machinery to print and download the assembly instructions and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the partly completed machinery; this requirement also applies where the assembly instructions are embedded in the software of the partly completed machinery;		

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(c) make them accessible online for at least 10 years after the placing on the market of the partly completed machinery. However, at the request of the person who incorporates the partly completed machinery at the time of purchase, the manufacturer shall provide the assembly instructions in paper format free of charge within one month. The assembly instructions shall be in a language which can be easily understood by the person who incorporates the partly completed machinery, as determined by the Member State concerned and shall be clear, understandable, intelligible and legible.		
8. Manufacturers shall ensure that the partly completed machinery is accompanied by the EU declaration of incorporation set out in Annex V, Part B or, alternatively, manufacturers shall provide the internet address or machine readable code where that EU declaration of incorporation can be accessed in the assembly instructions set out in Annex XI. Digital EU declarations of incorporation shall be made accessible online for at least 10 years after the placing on the market of the partly completed machinery.	*From Article 13, section 2:* 2. The assembly instructions and the declaration of incorporation shall accompany the partly completed machinery until it is incorporated into the final machinery and shall then form part of the technical file for that machinery.	
9. Manufacturers who consider or have reason to believe that partly completed machinery which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that partly completed machinery into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the partly completed machinery presents a risk as regards the relevant essential health and safety requirements, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the partly completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.		This detailed requirement was introduced in Directive under market surveillance prerogatives (see Annex II section B.5; Annex VII section B second last paragraph; Annex IX section 7)

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Article 12 **Authorised representatives** 1. A manufacturer of a product within the scope of this Regulation may, by a written mandate, appoint an authorised representative. The obligations laid down in Article 10(1) and Article 11(1) and the obligation to draw up the technical documentation set out in Annex IV shall not form part of the authorised representative's mandate. 2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following: (a) keep the technical documentation and the EU declaration of conformity of machinery and related products or the EU declaration of incorporation of partly completed machinery at the disposal of the national market surveillance authorities for the expected lifetime of the machinery or related product for at least 10 years after the product has been placed on the market; (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the product within the scope of this Regulation. It could be either in paper or digital format; (c) cooperate with the competent national authorities, at their request, on any actions taken to eliminate the risks presented by a product within the scope of this Regulation covered by the authorised representative's mandate.		
Article 13 **Obligations of importers of machinery and related products** 1. Importers shall place only compliant machinery or related products on the market.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
2. Before placing machinery or a related product on the market, importers shall ensure that the appropriate conformity assessment procedures referred to in Article 25 have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation set out in Annex IV, Part A, that the machinery or related product bears the CE marking referred to in Article 23 and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 10(5), (6) and (8). Where an importer considers or has reason to believe that machinery or a related product is not in conformity with this Regulation, the importer shall not place it on the market until it has been brought into conformity. Furthermore, where the machinery or related product presents a risk to the health and safety of persons and, where appropriate, domestic animals and property, and, where applicable, to the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect. 3. Importers shall indicate their name, registered trade name or registered trade mark, and the postal address and website, email address or other digital contact at which they can be contacted, on the machinery or related product or, where that is not possible, on its packaging or in a document accompanying the machinery or related product. The contact details shall be in a language easily understood by users and market surveillance authorities. 4. Importers shall ensure that the machinery or related product is accompanied by the instructions for use and information set out in Article 10(7). 5. Importers shall ensure that, while the machinery or related product is under their responsibility, the storage or transport conditions do not jeopardise conformity with the essential health and safety requirements set out in Annex III.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
6. When deemed appropriate with regard to the risks presented by machinery or a related product, importers shall, in order to protect the health and safety of persons, and where appropriate, domestic animals and property, and, where applicable, the environment carry out sample testing of machinery or related products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming machinery or related products and machinery or related product recalls, and shall keep distributors informed of any such monitoring. 7. Importers who consider or have reason to believe that machinery or a related product, which they have placed on the market, is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that machinery or related product into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the machinery or related product presents a risk to the health and safety of persons and, where appropriate, domestic animals and property, and, where applicable, to the environment, importers shall immediately inform the competent national authorities of the Member States in which they made the machinery or related product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken. 8. Importers shall, for at least 10 years after the machinery or related product has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation set out in Annex IV, Part A, can be made available to those authorities upon request. Where relevant, the source code or the programming logic included in the technical documentation shall, upon a reasoned request, be made available to the competent national authorities, if that source code or programming logic is necessary in order for them to be able to check compliance with the essential health and safety requirements set out in Annex III.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
9. Importers shall, further to a reasoned request from a competent national authority, provide that authority with all the information and documentation, in paper or digital format, necessary to demonstrate conformity of the machinery or related products with this Regulation in a language that can be easily understood by that authority. Importers shall cooperate with that authority, at its request, on any action taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property, and, where applicable, to the environment presented by machinery or related products which they have placed on the market.		
Article 14 **Obligations of importers of partly completed machinery** 1. Importers shall place only compliant partly completed machinery on the market. 2. Before placing partly completed machinery on the market, importers shall ensure that the manufacturer has drawn up the technical documentation set out in Annex IV, Part B, that the partly completed machinery is accompanied by the required documents and that the manufacturer has complied with the requirements set out in Article 11(5), (6) and (8). Where an importer considers or has reason to believe that partly completed machinery is not in conformity with this Regulation, the importer shall not place it on the market until it has been brought into conformity. Furthermore, where the partly completed machinery presents a risk as regards the relevant essential health and safety requirements, the importer shall inform the manufacturer and the market surveillance authorities to that effect. 3. Importers shall indicate their name, registered trade name or registered trade mark, and the postal address and website, email address or other digital contact at which they can be contacted, on the partly completed machinery or, where that is not possible, on its packaging or in a document accompanying the partly completed machinery. The contact details shall be in a language easily understood by the person who incorporates the partly completed machinery and by the market surveillance authorities.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
4. Importers shall ensure that the partly completed machinery is accompanied by the assembly instructions set out in Article 11(7). 5. Importers shall ensure that, while the partly completed machinery is under their responsibility, the storage or transport conditions do not jeopardise the conformity with the relevant essential health and safety requirements set out in Annex III. 6. Importers who consider or have reason to believe that partly completed machinery which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that partly completed machinery into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the partly completed machinery presents a risk as regards relevant essential health and safety requirements, importers shall immediately inform the competent national authorities of the Member States in which they made the partly completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken. 7. Importers shall, for at least 10 years after the partly completed machinery has been placed on the market, keep a copy of the EU declaration of incorporation at the disposal of the market surveillance authorities and ensure that the technical documentation set out in Annex IV, Part B can be made available to those authorities upon request. 8. Importers shall, further to a reasoned request from a competent national authority, provide that authority with all the information and documentation, in paper or digital format, necessary to demonstrate the conformity of the partly completed machinery with this Regulation in a language that can be easily understood by that authority. Importers shall cooperate with that authority, at its request, on any action taken to eliminate the risks as regards the relevant essential health and safety requirements presented by a partly completed machinery, which they have placed on the market.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
Article 15 **Obligations of distributors of machinery and related product** 1. When making a machinery or related product available on the market, distributors shall act with due care in relation to the requirements of this Regulation. 2. Before making a machinery or related product available on the market, distributors shall verify that: (a) the machinery or related product bears the CE marking; (b) the machinery or related product is accompanied by the EU declaration of conformity referred to in Article 10(8); (c) the machinery or related product is accompanied by the instructions for use and the information referred to in Article 10(7), and that they are in a language which can be easily understood by users, as determined by the Member State in which the machinery or related product is to be made available on the market; (d) the manufacturer and the importer have complied with the requirements referred to in Article 10(5) and (6) and Article 13(3) respectively. 3. Where a distributor considers or has reason to believe that machinery or a related product is not in conformity with this Regulation, the distributor shall not make the machinery or related product available on the market until it has been brought into conformity. Furthermore, where the machinery or related product presents a risk to the health and safety of persons and, where appropriate, domestic animals and property, and, where applicable, to the environment, the distributor shall inform the manufacturer or the importer as well as the market surveillance authorities to that effect. 4. Distributors shall ensure that, while machinery or a related product is under their responsibility, the storage or transport conditions do not jeopardise conformity with the essential health and safety requirements set out in Annex III.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
5. Distributors who consider or have reason to believe that machinery or a related product which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective actions necessary to bring that machinery or related product into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the machinery or related product presents a risk to the health and safety of persons and, where appropriate, domestic animals and property, and, where applicable, to the environment, distributors shall immediately inform the competent national authorities of the Member States in which they have made the machinery or related product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken. 6. Distributors shall, further to a reasoned request from a competent national authority, provide that authority with all the information and documentation, in paper or digital format, necessary to demonstrate the conformity of the machinery or related product with this Regulation in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property, and, where applicable, to the environment presented by machinery or a related product which they have made available on the market.		
Article 16 **Obligations of distributors of partly completed machinery** 1. When making a partly completed machinery available on the market, distributors shall act with due care in relation to the requirements of this Regulation. 2. Before making a partly completed machinery available on the market, distributors shall verify that: (a) the partly completed machinery is accompanied by the by the EU declaration of incorporation set out in in Article 11(8);		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
(b) the partly completed machinery is accompanied by the assembly instructions referred to in Article 11(7), and that they are in a language which can be easily understood by the person who incorporates the partly completed machinery as determined by the Member State in which the partly completed machinery is to be made available on the market; (c) the manufacturer and the importer have complied with the requirements referred to in Article 11(5) and (6) and Article 14(3) respectively. 3. Where a distributor considers or has reason to believe that partly completed machinery is not in conformity with this Regulation, the distributor shall not make the partly completed machinery available on the market until it has been brought into conformity. Furthermore, where the partly completed machinery presents a risk as regards relevant essential health and safety requirements, the distributor shall inform the manufacturer or the importer as well as the market surveillance authorities to that effect. 4. Distributors shall ensure that, while a partly completed machinery is under their responsibility, the storage or transport conditions do not jeopardise conformity with the relevant essential health and safety requirements set out in Annex III. 5. Distributors who consider or have reason to believe that partly completed machinery which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective actions necessary to bring that partly completed machinery into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the partly completed machinery presents a risk as regards the relevant essential health and safety requirements distributors shall immediately inform the competent national authorities of the Member States in which they have made the partly completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
6. Distributors shall, further to a reasoned request from a competent national authority, provide that authority with all the information and documentation, in paper or digital format, necessary to demonstrate the conformity of the partly completed machinery with this Regulation. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks as regards the essential health and safety requirements presented by partly completed machinery which they have made available on the market.		
Article 17 **Cases in which obligations of manufacturers apply to importers and distributors** An importer or distributor shall be considered to be a manufacturer for the purposes of this Regulation, and shall be subject to the obligations of the manufacturer set out in Articles 10 and 11, where that importer or distributor places a product within the scope of this Regulation on the market under its name or trademark or modifies a product already placed on the market in such a way that compliance with the applicable requirements might be affected.		
Article 18 **Other cases in which obligations of manufacturers apply** A natural or legal person that carries out a substantial modification of machinery or a related product shall be considered to be a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 for that machinery or related product or, if the substantial modification has an impact on the safety of only machinery or a related product that is part of an assembly of machinery, for that affected machinery or related product, as demonstrated in the risk assessment.		

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The person who carries out the substantial modification shall in particular, but without prejudice to other obligations set out in Article 10, ensure and declare on its sole responsibility that the machinery or related product concerned is in conformity with the applicable requirements of this Regulation and shall apply the relevant conformity assessment procedure as provided in Article 25 (2), (3) and (4) of this Regulation. A non-professional user who carries out a substantial modification to his or her machinery or related product, for his or her own use, shall not be considered to be a manufacturer for the purposes of this Regulation and shall not be subject to the obligations on the manufacturer set out in Article 10.		
Article 19 ***Identification of economic operators*** 1. Economic operators shall, on request, identify the following to the market surveillance authorities: a) any economic operator who has supplied them with a product within the scope of this Regulation (b) any economic operator to whom they have supplied a product within the scope of this Regulation 2. In order to be able to comply with the obligation in paragraph 1, economic operators shall retain the information referred to in that paragraph for at least 10 years after they supplied or were supplied with the products within the scope of this Regulation.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
Chapter III ***CONFORMITY OF PRODUCTS WITHIN THE SCOPE OF THIS REGULATION***		
Article 20 **Presumption of conformity of products within the scope of this Regulation** 1. A product within the scope of this Regulation which is in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those standards or parts thereof. 2. The Commission shall, as provided in Article 10(1) of Regulation (EU) No 1025/2012, request one or more European standardisation organisations to draft harmonised standards for the essential health and safety requirements set out in Annex III. 3. The Commission may adopt implementing acts establishing common specifications covering technical requirements that provide a means to comply with the essential health and safety requirements set out in Annex III for products within the scope of this Regulation. Those implementing acts shall only be adopted where the following conditions are fulfilled: (a) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements set out in Annex III and: (i) the request has not been accepted; or (ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or (iii) the harmonised standards do not comply with the request; and	*Article 7* **Presumption of conformity and harmonised standards** 2. Machinery manufactured in conformity with a harmonised standard, the references to which have been published in the *Official Journal of the European Union*, shall be presumed to comply with the essential health and safety requirements covered by such a harmonised standard.	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
(b) no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex III has been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3). 4. Before preparing the draft implementing act referred to in paragraph 3, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 3 have been fulfilled. 5. When preparing the draft implementing act referred to in paragraph 3, the Commission shall take into account the views of relevant bodies or the expert group and shall duly consult all relevant stakeholders. 6. A product within the scope of this Regulation which is in conformity with the common specifications established by implementing acts referred to in paragraph 3, or parts thereof, shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those common specifications or parts thereof. 7. Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the *Official Journal of the European Union*, the Commission shall assess the harmonised standard in accordance with Regulation (EU) 1025/2012. When reference of a harmonised standard is published in the *Official Journal of the European Union*, the Commission shall repeal the implementing acts referred to in paragraph 3, or parts thereof which cover the same essential health and safety requirements as those covered by that harmonised standard.	3. The Commission shall publish in the Official Journal of the European Union the references of the harmonised standards. 4. Member States shall take the appropriate measures to enable the social partners to have an influence at national level on the process of preparing and monitoring the harmonised standards.	

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8. When a Member State considers that a common specification does not entirely satisfy the essential health and safety requirements set out in Annex III, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question. 9. Machinery and related products that have been certified or for which a statement of conformity has been issued under a cybersecurity certification scheme adopted in accordance with Regulation (EU) 2019/881 the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III, sections 1.1.9 and 1.2.1, as regards protection against corruption and safety and reliability of control systems insofar as those requirements are covered by the cybersecurity certificate or statement of conformity or parts thereof.		
Article 21 **EU declaration of conformity of machinery and related products** 1. The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex III has been demonstrated. 2. The EU declaration of conformity shall have the model structure set out in Annex V, part A, and shall contain the elements specified in the relevant modules set out in Annexes VI, VIII, IX, and X. It shall be continuously updated and shall be translated into the language or languages required by the Member State in which the machinery or related product is placed on the market, is made available on the market or put into service.	*From Article 7 section 1:* 1. Member States shall regard machinery bearing the CE marking and accompanied by the EC declaration of conformity, the content of which is set out in Annex II, part 1, Section A, as complying with the provisions of this Directive. *From Article 5, section 1 (e):* (e) draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery; *From Annex II, section 1.A, first paragraph:* This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex I, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
3. Where machinery or related product is subject to more than one Union legal act that requires an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union legal acts concerned, including their publication references. 4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the machinery or related product with the requirements laid down in this Regulation. .	*From Article 5:* 4. Where machinery is also the subject of other Directives relating to other aspects and providing for the affixing of the CE marking, the marking shall indicate that the machinery also conforms to the provisions of those other Directives. However, where one or more of those Directives allow the manufacturer or his authorised representative to choose, during a transitional period, the system to be applied, the CE marking shall indicate conformity only to the provisions of those Directives applied by the manufacturer or his authorised representative. Particulars of the Directives applied, as published in the Official Journal of the European Union, shall be given on the EC declaration of conformity.	
Article 22 **EU declaration of incorporation of partly completed machinery** 1. The EU declaration of incorporation shall state that the fulfilment of the relevant essential health and safety requirements set out in Annex III has been demonstrated 2. The EU declaration of incorporation shall have the model structure set out in Annex V, part B. It shall be continually updated and shall be translated into the language or languages required by the Member State in which the partly completed machinery is placed on the market or is made available on the market.	*From Article 13 section 1, point (c):* (c) a declaration of incorporation described in Annex II, part 1, Section B has been drawn up. *From Annex II, section B, first paragraph:* This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex 1, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
3. Where partly completed machinery is subject to more than one Union legal act requiring an EU declaration of conformity, the EU declaration of incorporation shall include a sentence declaring the conformity with such acts. That declaration shall contain the identification of the Union legal acts concerned, including their publication references. 4. By drawing up the EU declaration of incorporation, the manufacturer shall assume responsibility for the compliance of the partly completed machinery with the requirements laid down in this Regulation.		
Article 23 **General principles of the CE marking** The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.	*Article 16* **CE marking** 1. The CE conformity marking shall consist of the initials 'CE' as shown in Annex III.	
Article 24 **Rules for affixing the CE marking to machinery and related products** 1. The CE marking shall be affixed visibly, legibly and indelibly to the machinery or related product. Where that is not possible or not warranted on account of the nature of the machinery or related product, it shall be affixed to the packaging and to the documents accompanying the machinery or related product. 2. The CE marking shall be affixed before the machinery or related product is placed on the market or put into service.	2. The CE marking shall be affixed to the machinery visibly, legibly and indelibly in accordance with Annex III. *From Article 5 section 1:* 1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall: […] (f) affix the CE marking in accordance with Article 16.	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
3. Where the conformity of machinery or related products is assessed in accordance with the conformity assessment procedure referred to in Article 25 (2) points (a), (b) and (c) and in article 25 (3) points (b), (c) and (d), the CE marking shall be followed by the identification number of the notified body involved in that procedure. The identification number of that notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or the manufacturer's authorised representative.	From Annex II last paragraph: Where the full quality assurance procedure referred to in Article 12(3)(c) and 12(4)(b) has been applied, the CE marking must be followed by the identification number of the notified body.	For third party evaluation, identification number of the notified body shall now be affix to the CE marking, and not only for full quality assurance procedure.
4. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or any other marking indicating a special risk or use.	*From Article 16, section 3:* 3. The affixing on machinery of markings, signs and inscriptions which are likely to mislead third parties as to the meaning or form of the CE marking, or both, shall be prohibited. Any other marking may be affixed to the machinery provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.	
	Article 17 **Non-conformity of marking**	Non-conformity of marking in Directive have been also introduced in Regulation Article 46 Formal non-compliance.
5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.	1. Member States shall consider the following marking not to conform: (a) the affixing of the CE marking pursuant to this Directive on products not covered by this Directive; (b) the absence of the CE marking and/or the absence of the EC declaration of conformity for machinery; (c) the affixing on machinery of a marking, other than the CE marking, which is prohibited under Article 16(3).	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
Chapter IV **CONFORMITY ASSESSMENT**		
Article 25 **Conformity assessment procedures for machinery and related products**	*Article 12* **Procedures for assessing the conformity of machinery**	
1. The manufacturer or the natural or legal person referred to in Article 18 shall apply one of the conformity assessment procedures referred to in paragraphs 2, 3 and 4.	1. The manufacturer or his authorised representative shall, in order to certify the conformity of machinery with the provisions of this Directive, apply one of the procedures for assessment of conformity described in paragraphs 2, 3 and 4.	
2. Where the category of machinery or related product is listed in Annex I, part A, the manufacturer or the natural or legal person referred to in Article 18 shall apply one of the following procedures: (a) EU type-examination procedure (module B) set out in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII; (b) Conformity based on full quality assurance (module H) set out in Annex IX. (c) Conformity based on unit verification (module G) set out in Annex X.		Evaluation procedures evolving notified bodies only.
3. Where the category of machinery or related product is listed in Annex I, part B, the manufacturer or the natural or legal person referred to in Article 18 shall apply one of the following procedures: (a) internal production control (module A) set out in Annex VI; (b) EU type-examination (module B) set out in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII; (c) conformity based on full quality assurance (module H) set out in Annex IX;	3. Where the machinery is referred to in Annex IV and manufactured in accordance with the harmonised standards referred to in Article 7(2), and provided that those standards cover all of the relevant essential health and safety requirements, the manufacturer or his authorised representative shall apply one of the following procedures: (a) the procedure for assessment of conformity with internal checks on the manufacture of machinery, provided for in Annex VIII; (b) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3; (c) the full quality assurance procedure provided for in Annex X.	Evaluation procedures with possibly evolving notified bodies.

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
(d) conformity based on unit verification (module G) set out in Annex X.		New evaluation module available
	From Article 12 section 3:	
If a manufacturer applies the internal production control procedure referred to in point (a), it shall design and construct the machinery or related product in accordance with the harmonised standards or common specifications specific to that category of machinery or related product covering all the relevant essential health and safety requirements.	3. Where the machinery is referred to in Annex IV and manufactured in accordance with the harmonised standards referred to in Article 7(2), and provided that those standards cover all of the relevant essential health and safety requirements, […]	
Where the category of machinery or related product is listed in Annex I part B and the machinery or related product was not designed and constructed in accordance with the harmonised standards or common specifications specific to that category of machinery or related product covering all the relevant essential health and safety requirements for that category of machinery or related product, the manufacturer, including a natural or legal person referred to in Article 18, shall apply one of the procedures referred to in points (b), (c) or (d) of this paragraph.	4. Where the machinery is referred to in Annex IV and has not been manufactured in accordance with the harmonised standards referred to in Article 7(2), or only partly in accordance with such standards, or if the harmonised standards do not cover all the relevant essential health and safety requirements or if no harmonised standards exist for the machinery in question, the manufacturer or his authorised representative shall apply one of the following procedures: (a) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3; (b) the full quality assurance procedure provided for in Annex X.	
4. Where the category of machinery or related product is not listed in Annex I, the manufacturer, including a natural or legal person referred to in Article 18 shall apply the internal production control procedure (module A) set out in Annex VI.	2. Where the machinery is not referred to in Annex IV, the manufacturer or his authorised representative shall apply the procedure for assessment of conformity with internal checks on the manufacture of machinery provided for in Annex VIII.	
5. Notified bodies shall take into account the specific interests and needs of small and medium sized enterprises when setting the fees for conformity assessment.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
Chapter V **NOTIFICATION OF CONFORMITY ASSESSMENT BODIES**		
Article 26 **Notification** Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks in accordance with this Regulation.	*Article 14* **Notified bodies** 1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the assessment of conformity for placing on the market referred to in Article 12(3) and (4), together with the specific conformity assessment procedures and categories of machinery for which these bodies have been appointed and the identification numbers assigned to them beforehand by the Commission. Member States shall notify the Commission and other Member States of any subsequent amendment.	Other information from Article 14 section 1 in Directive are specified in Regulation Article 35 (notification procedure).
Article 27 **Notifying authorities** 1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 32. 2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body as defined in Regulation (EC) No 765/2008 in accordance with that Regulation.	2. The Member States shall ensure that the notified bodies are monitored regularly to check that they comply at all times with the criteria set out in Annex XI. The notified body shall provide all relevant information on request, including budgetary documents, to enable the Member States to ensure that the requirements of Annex XI are met. 3. Member States shall apply the criteria set out in Annex XI in assessing the bodies to be notified and the bodies already notified.	

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3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body, which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 28. In addition, that body shall have arrangements to cover liabilities arising out of its activities. 4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.		
Article 28 **Requirements relating to notifying authorities** 1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs. 2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities. 3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment. 4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform, nor shall it offer or provide consultancy services on a commercial or competitive basis. 5. A notifying authority shall safeguard the confidentiality of the information it obtains. 6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
Article 29 **Information obligation on notifying authorities** Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto. The Commission shall make that information publicly available.	4. The Commission shall publish in the Official Journal of the European Union, for information, a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.	Directive Article 14 section 4 is also covered in Regulation Article 35.
Article 30 **Requirements relating to notified bodies** 1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11. 2. A conformity assessment body shall be established under the national law of a Member State and have legal personality. 3. A conformity assessment body shall be a third-party body that is independent of the organisation or of the machinery or related product that it assesses. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacture, provision, assembly, use or maintenance of machinery or related products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a conformity assessment body.	**ANNEX XI** **Minimum criteria to be taken into account by Member States for the notification of bodies**	

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4. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, importer, distributor, installer, purchaser, owner, user or maintainer of machinery or related products, that they assess, nor shall it fulfil any of those roles in relation to partly completed machinery that has been incorporated into the assessed product or be the representative of any of those parties. This shall not preclude the use of assessed machinery or related products that are necessary for the operations of the conformity assessment body or the use of machinery or related products for personal purposes.	1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of machines which they inspect, nor the authorised representative of any of these parties.	
A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, import, distribution, manufacture, marketing, installation, use or maintenance of those machinery or related products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services. A conformity assessment body shall ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of its conformity assessment activities.	They shall not become involved, either directly or as authorised representatives, in the design, construction, marketing or maintenance of the machines. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.	
5. A conformity assessment body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence its judgement or the results of its conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.	2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.	
6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes VII, IX and X and in relation to which it has been notified, regardless of whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.		

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At all times, and for each conformity assessment procedure and each kind of machinery or related products for which it has been notified, a conformity assessment body shall have at its disposal the necessary:	3. For each category of machinery for which it is notified, the body must possess […]	
(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;	[…] personnel with technical knowledge and sufficient and appropriate experience to perform a conformity assessment. […]	
(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures;		
(c) appropriate policies and procedures to distinguish between tasks that it carries out as a notified body and other activities;		
(d) procedures for the performance of conformity assessment activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the machinery or related product technology in question and the mass or serial nature of the production process.		
A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.	[…] It must have the means necessary to complete the technical and administrative tasks connected with implementation of the checks in an appropriate manner; it must also have access to the equipment necessary for the exceptional checks.	
7. The personnel responsible for carrying out conformity assessment tasks shall have the following:	4. The staff responsible for inspection shall have:	
(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;	— sound technical and vocational training,	
(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;	— satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,	
(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex III, of the applicable harmonised standards and common specifications referred to in Article 20, and of the relevant provisions of Union harmonisation legislation and of national legislation;		

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(d) the ability to draw up certificates, records and reports demonstrating that conformity assessments have been carried out.	— the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.	
8. The impartiality of a conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.	5. The impartiality of inspection staff shall be guaranteed. […]	
The remuneration of the top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not depend on the number of conformity assessments carried out or on the results of those assessments.	[…] Their remuneration shall not depend on the number of tests carried out or on the results of such tests.	
9. A conformity assessment body shall take out liability insurance unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.	6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.	
10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out the conformity assessment tasks in accordance with Annexes VII, IX and X, except in relation to the competent authorities of the Member State in which its tasks are carried out. Proprietary rights, intellectual property rights and trade secrets shall be protected.	7. The staff of the body shall be bound to observe professional secrecy with regard to all information obtained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.	
11. A conformity assessment body shall participate in, or ensure that its personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 42 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.	8. Notified bodies shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or ensure that they know the situation in respect of relevant standards.	
	9. Member States may take all necessary measures they regard as necessary in order to ensure that, in the event of cessation of the activities of a notified body, the files of its customers are sent to another body or are made available to the Member State which has notified it.	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
Article 31 **Presumption of conformity of notified bodies** Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Article 30 insofar as the applicable harmonised standards cover those requirements.	*From Article 14 section 5:* 5. Bodies meeting the assessment criteria laid down in the relevant harmonised standards, the references of which shall be published in the Official Journal of the European Union, shall be presumed to fulfil the relevant criteria.	
Article 32 **Use of subcontractors and subsidiaries by notified bodies** 1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary; it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 30 and shall inform the notifying authority accordingly. 2. A notified body shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever those are established. 3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client. 4. A notified body shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes VII, IX and X.		
Article 33 **Application for notification** 1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.		

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2. The application for notification shall be accompanied by a description of the conformity assessment activities, of the conformity assessment procedures set out in Annexes VII, IX and X and of the kinds or categories of machinery or related products for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 30. 3. Where the conformity assessment body concerned cannot provide an accreditation certificate as referred to in paragraph 2, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 30.		
Article 34 **Notification procedure** 1. A notifying authority shall notify only conformity assessment bodies which have satisfied the requirements laid down in Article 30. 2. The notifying authority shall send a notification to the Commission and the other Member States, using the electronic notification tool developed and managed by the Commission. 3. The notification referred to in paragraph 2 shall include the following: (a) full details of the conformity assessment activities to be performed; (b) an indication of the conformity assessment module or modules and the kinds or categories of machinery or related products concerned; (c) the relevant attestation of competence.	*From Article 14 section 1:* 1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the assessment of conformity for placing on the market referred to in Article 12(3) and (4), […] […] together with the specific conformity assessment procedures and categories of machinery for which these bodies have been appointed and the identification numbers assigned to them beforehand by the Commission. […]	Identification number requirement from Article 14 is detailed in Regulation Article 35.

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4. Where a notification is not based on an accreditation certificate referred to in Article 33(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 30. 5. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of the validation of the notification where it includes an accreditation certificate referred to in Article 33(2), or within two months of the notification where it includes documentary evidence referred to in paragraph 4 of this Article. Only such a body shall be considered a notified body for the purposes of this Regulation. 6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification referred to in paragraph 2.	*From Article 14 section 1, last sentence:* […] Member States shall notify the Commission and other Member States of any subsequent amendment.	
Article 35 **Identification numbers and lists of notified bodies** 1. The Commission shall assign an identification number to a notified body. It shall assign a single such number even where the body is notified under several Union acts. 2. The Commission shall make publicly available the list of bodies notified under this Regulation including the identification numbers that have been assigned to them and the conformity assessment activities for which they have been notified. The Commission shall ensure that the list is kept up to date.	From Article 14 section 1: 1. […] and the identification numbers assigned to them beforehand by the Commission. […] *From Article 14 section 4:* 4. The Commission shall publish in the Official Journal of the European Union, for information, a list of the notified bodies and their identification numbers and the tasks for which they have been notified. […] […] The Commission shall ensure that this list is kept up to date.	

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Article 36 **Changes to notifications** 1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 30, or that it is failing to fulfil its obligations as set out in Article 38 the notifying authority shall restrict, suspend or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly. 2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.	*From Article 14 section 8:* 8. A Member State which has notified a body shall immediately withdraw its notification if it finds: (a) that the body no longer meets the criteria set out in Annex XI; or (b) that the body seriously fails to fulfil its responsibilities. The Member State shall immediately inform the Commission and the other Member States accordingly.	
Article 37 **Challenge of the competence of notified bodies** 1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject. 2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned. 3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.		

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4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including the withdrawal of the notification if necessary. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 48(2).		
Article 38 **Operational obligations of notified bodies** 1. A notified body shall carry out conformity assessments in accordance with the conformity assessment procedures set out in Annexes VII, IX and X. 2. A notified body shall perform its activities in a proportionate manner, avoiding unnecessary burdens for economic operators, and taking due account of the size of an undertaking, the sector in which the undertaking operates, the structure of the undertaking, the degree of complexity of the technology in question and the mass or serial nature of the production process. In so doing, the notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the machinery or related product with the requirements of this Regulation.		

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	From Article 14 section 6:	
3. Where a notified body finds that the essential health and safety requirements set out in Annex III, or corresponding harmonised standards or common specifications referred to in Article 20 have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective actions and shall not issue an EU-type examination certificate, adopt a quality system approval decision or issue a unit verification certificate.	6. If a notified body finds that relevant requirements of this Directive have not been met or are no longer met by the manufacturer or that an EC type-examination certificate or the approval of a quality assurance system should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate or the approval issued or place restrictions on it, giving detailed reasons, unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. […]	
4. Where, in the course of the monitoring of conformity following the issue of an approval decision according to Annex IX, a notified body finds that machinery or a related product no longer complies, it shall require the manufacturer to take appropriate corrective actions and shall suspend or withdraw the approval decision, if necessary. Where corrective actions are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any approval decisions, as appropriate.	[…] In the event of suspension or withdrawal of the certificate or the approval or of any restriction placed on it, or in cases where intervention by the competent authority may prove necessary, the notified body shall inform the competent authority pursuant to Article 4. The Member State shall inform the other Member States and the Commission without delay. An appeal procedure shall be available.	
Article 39 **Appeals against decisions of notified bodies**		
	From Annex IX section 5, last sentence:	
A notified body shall ensure that a transparent and accessible appeals procedure against its decisions is available.	5. […] An appeal procedure must be available.	
Article 40 **Information obligation on notified bodies**		
	From Annex IX section 5, second sentence:	
1. A notified body shall inform the notifying authority of the following:	5. […] It shall inform […] the Member State which notified it. […]	

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	From Annex IX section 5, firs sentence:	
(a) any refusal, restriction, suspension or withdrawal of a certificate or approval decision;	5. If the type does not satisfy the provisions of this Directive, the notified body shall refuse to issue the applicant with an EC type-examination certificate, giving detailed reasons for its refusal. […]	
(b) any circumstances affecting the scope of, or the conditions for, its notification;		
(c) any request for information which it has received from market surveillance authorities regarding its conformity assessment activities;		
	From Annex IX section 7, second sentence:	
(d) on request, any conformity assessment activities performed within the scope of its notification and any other activity performed, including cross-border activities and subcontracting.	7. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC type-examination certificates. On reasoned request, the Commission and the Member States may obtain a copy of the technical file and the results of the examinations carried out by the notified body.	
	From Annex IX section 5, second sentence:	
2. A notified body shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same kinds of machinery or related products with relevant information on issues relating to negative and, on request, positive conformity assessment results.	5. If the type does not satisfy the provisions of this Directive, the notified body shall refuse to issue the applicant with an EC type-examination certificate, giving detailed reasons for its refusal. It shall inform […] the other notified bodies […]. […]	
Article 41 **Exchange of experience** The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.	*From Article 14, section 7:* 7. The Commission shall provide for the organisation of an exchange of experience between the authorities responsible for appointment, notification and monitoring of notified bodies in the Member States, and the notified bodies, in order to coordinate the uniform application of this Directive.	Directive Article 14, section 7 coordination requirement for Notified Bodies is moved to Regulation Article 42.

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Article 42 **Coordination of notified bodies** The Commission shall ensure the establishment and good functioning of appropriate coordination and cooperation between bodies notified under this Regulation in the form of a sectoral group of notified bodies. Notified bodies shall participate in the work of that group, directly or by means of designated representatives.	*From Article 14, section 7:* 7. The Commission shall provide for the organisation of an exchange of experience between the authorities responsible for appointment, notification and monitoring of notified bodies in the Member States, and the notified bodies, in order to coordinate the uniform application of this Directive.	
CHAPTER VI **UNION MARKET SURVEILLANCE AND UNION SAFEGUARD PROCEDURES**		
Article 43 **Procedure at national level for dealing with products within the scope of this Regulation presenting a risk** 1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a product within the scope of this Regulation presents a risk to the health or safety of persons, and, where appropriate, domestic animals or property, and, where applicable, to the environment, they shall carry out an evaluation in relation to the product concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.	*Article 11* **Safeguard clause** 1. Where a Member State ascertains that machinery covered by this Directive, bearing the CE marking, accompanied by the EC declaration of conformity and used in accordance with its intended purpose or under conditions which can reasonably be foreseen, is liable to compromise the health and safety of persons and, where appropriate, domestic animals or property, it shall take all appropriate measures to withdraw such machinery from the market, to prohibit the placing on the market and/or putting into service of such machinery or to restrict free movement thereof.	Measures of restrictions to non-compliant products (withdrawal from the market, prohibition of the placing on the market or putting into service, etc.) are moved to regulation Article 43 section 4.

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	From Article 11 section 5:	
Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the product within the scope of this Regulation does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take appropriate and proportionate corrective action, as provided for in Article 16(3) of Regulation (EU) 2019/1020, to bring the non-compliance to an end or to eliminate hazards or, if that is not possible, minimize the risk specified by the market surveillance authorities within a reasonable period which is commensurate with the nature of the risk referred to in the first subparagraph. The market surveillance authorities shall inform the relevant notified body accordingly.	5. Where machinery does not conform and bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the marking and shall so inform the Commission. The Commission shall inform the other Member States.	
	From Article 11 section 2:	List of specific attention points are moved to regulation Article 43 section 5.
2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.	2. The Member State shall immediately inform the Commission and the other Member States of any such measure, indicating the reasons for its decision and, in particular, whether the non-conformity is due to: (a) failure to satisfy the essential requirements referred to in Article 5(1)(a); (b) incorrect application of the harmonised standards referred to in Article 7(2); (c) shortcomings in the harmonised standards themselves referred to in Article 7(2).	
3. The economic operator shall ensure that all appropriate corrective action is taken in respect of the products within the scope of this Regulation concerned that the economic operator has made available on the market, throughout the Union.		

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	From Article 11 section 1, end sentence:	
4. Where the relevant economic operator does not take the corrective action referred to in paragraph 1, second subparagraph, within the specified period or where the non-compliance, referred to in paragraph 1, second subparagraph, or the risk referred to in paragraph 1, first subparagraph, persists the market surveillance authorities shall ensure that the product concerned is withdrawn or recalled, or that making it available on the market is prohibited or restricted. In such cases, the market surveillance authorities shall ensure that the public, the Commission and the other Member States are informed accordingly, without delay.	1. […] it shall take all appropriate measures to withdraw such machinery from the market, to prohibit the placing on the market and/or putting into service of such machinery or to restrict free movement thereof.	
	From Article 11 section 2:	
5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant product within the scope of this Regulation, the origin of that product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to any of the following:	2. […], in particular, whether the non-conformity is due to:	
(a) the failure of the product to meet the requirements relating to the essential health and safety requirements set out in Annex III;	(a) failure to satisfy the essential requirements referred to in Article 5(1)(a);	
	(b) incorrect application of the harmonised standards referred to in Article 7(2);	
(b) shortcomings in the harmonised standards referred to in Article 20(1);	(c) shortcomings in the harmonised standards themselves referred to in Article 7(2).	
c) shortcomings in the common specifications referred to in Article 20(4).		
6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the product within the scope of this Regulation concerned, and, in the event of disagreement with the adopted national measure, of their objections.		

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7. Where, within three months of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed to be justified. 8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the product, are taken in respect of the product within the scope of this Regulation concerned without delay.		
Article 44 **Union safeguard procedure** 1. Where, on completion of the procedure set out in Article 43(4), (6) and (7) objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation acts, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not. The Commission shall address its decision to all Member States and shall without delay communicate it to them and to the relevant economic operator or operators. 2. If the national measure is considered to be justified, all Member States shall ensure that appropriate restrictive measures, such as withdrawal, are taken in respect of the non-compliant product within the scope of this Regulation, and shall inform the Commission accordingly.	*From Article 11 section 3:* 3. The Commission shall enter into consultation with the parties concerned without delay. The Commission shall consider, after this consultation, whether or not the measures taken by the Member State are justified, and it shall communicate its decision to the Member State which took the initiative, the other Member States, and the manufacturer or his authorised representative. *From Article 11 section 6:* 6. The Commission shall ensure that Member States are kept informed of the progress and outcome of the procedure. *From Article 11 section 4:* 4. Where the measures referred to in paragraph 1 are based on a shortcoming in the harmonised standards and if the Member State which instigated the measures maintains its position, the Commission or the Member State shall initiate the procedure referred to in Article 10.	

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If the national measure is considered unjustified, the Member State concerned shall withdraw that measure. 3. Where the national measure is considered to be justified and the non-compliance of the product within the scope of this Regulation is attributed to shortcomings in the harmonised standards referred to in Article 43(5), points (b), of this Regulation, or common specifications referred to in Article 43(5), points (c), of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 or in Article 20(8) of this Regulation.	*Article 10* **Procedure for disputing a harmonised standard** Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission or the Member State shall bring the matter before the committee set up by Directive 98/34/EC, setting out the reasons therefor. The committee shall deliver an opinion without delay. In the light of the committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union.	The procedure for disputing a harmonized standard is define in Article 13 of Regulation (EU) No 1025/2012.
Article 45 **Compliant products within the scope of this Regulation which present a risk** 1. Where, having carried out an evaluation under Article 43(1), a Member State finds that although a product within the scope of this Regulation is in compliance with the essential health and safety requirements set out in Annex III, it presents a risk to the health and safety of persons and, where appropriate, domestic animals or to property and, where applicable, to the environment, it shall require the relevant economic operator to take all appropriate measures to ensure that the product concerned, when placed on the market, no longer presents that risk, to withdraw that product or to recall it within a reasonable period which is commensurate with the nature of the risk. 2. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the products within the scope of this Regulation concerned that the economic operator has made available on the market throughout the Union.	*Article 9* **Specific measures to deal with potentially hazardous machinery** 1. When, in accordance with the procedure referred to in Article 10, the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery with technical characteristics presenting risks due to the shortcomings in the standard or to make such machinery subject to special conditions. From Article 17, section 2: 2. Where a Member State ascertains that marking does not conform to the relevant provisions of this Directive, the manufacturer or his authorised representative shall be obliged to make the product conform and to put an end to the infringement under conditions fixed by that Member State.	

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3. The Member State shall immediately inform the Commission and the other Member States about the product which presents a risk, as referred to in paragraph 1. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of that product, the nature of the risk involved and the nature and duration of the national measures taken.		
4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not and, where necessary, order appropriate measures.	When, in accordance with the procedure referred to in Article 11, the Commission considers that a measure taken by a Member State is justified, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery presenting the same risk by virtue of its technical characteristics or to make such machinery subject to special conditions.	
	2. Any Member State may request the Commission to examine the need for the adoption of the measures referred to in paragraph 1.	
That implementing act shall be adopted in accordance with the examination procedure referred to in Article 48(3).		
On duly justified imperative grounds of urgency relating to the protection of the health and safety of persons, the Commission shall adopt an immediately applicable implementing act in accordance with the procedure referred to in Article 48(4).	3. In the cases referred to in paragraph 1, the Commission shall consult the Member States and other interested parties indicating the measures it intends to take, in order to ensure, at Community level, a high level of protection of the health and safety of persons.	
5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operator or operators.	Taking due account of the results of this consultation, it shall adopt the necessary measures in accordance with the procedure referred to in Article 22(3).	

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Article 46 **Formal non-compliance**	*Article 4* **Market surveillance**	
1. Without prejudice to Article 43, where a Member State makes one of the following findings with regard to a machinery or related product, it shall require the relevant economic operator to put an end to the non-compliance concerned:	1. Member States shall take all appropriate measures to ensure that machinery may be placed on the market and/or put into service only if it satisfies the relevant provisions of this Directive and does not endanger the health and safety of persons and, where appropriate, domestic animals or property, when properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen.	
(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 24 of this Regulation;		Requirement also present in Machinery Directive Article 17 (Non-conformity of marking).
(b) the CE marking has not been affixed;		
(c) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 24(3) or has not been affixed;		
(d) the EU declaration of conformity has not been drawn up or has not been drawn up correctly;		Requirement also present in Machinery Directive Article 17 (Non-conformity of marking).
	From Annex VII part A section 3:	
(e) the technical documentation is either not available or not complete;	3. Failure to present the technical file in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the machinery in question with the essential health and safety requirements.	
(f) the information referred to in Article 10(6) or Article 13(3) is absent, false or incomplete;		
(g) any other administrative requirement provided for in Article 10 or Article 13 is not fulfilled.		
2. Without prejudice to Article 43, where a Member State makes one of the following findings with regard to partly completed machinery, it shall require the relevant economic operator to put an end to the non-compliance concerned:	2. Member States shall take all appropriate measures to ensure that partly completed machinery can be placed on the market only if it satisfies the relevant provisions of this Directive.	
(a) the EU declaration of incorporation has not been drawn up or has not been drawn up correctly;		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
(b) the technical documentation is either not available or not complete; (c) the information referred to in Article 11(5) or Article 14(3) is absent, false or incomplete; (d) any other administrative requirement provided for in Article 11 or Article 14 is not fulfilled.	*From Annex VII part B last paragraph:* Failure to present the relevant technical documentation in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the partly completed machinery with the essential health and safety requirements applied and attested.	
2. Where the non-compliance referred to in paragraph 1 and 2 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the product within the scope of this Regulation concerned being made available on the market or ensure that it is recalled or withdrawn from the market.	From Article 17: 3. Where non-conformity persists, the Member State shall take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedure laid down in Article 11. 3. Member States shall institute or appoint the competent authorities to monitor the conformity of machinery and partly completed machinery with the provisions set out in paragraphs 1 and 2. 4. Member States shall define the tasks, organisation and powers of the competent authorities referred to in paragraph 3 and shall notify the Commission and other Member States thereof and also of any subsequent amendment.	Dedicated requirements related to organization and powers of market surveillance authorities are defined in specific regulations (see. Regulation (EU) 2019/1020, Regulation (EU) No 167/2013, etc.)
	Article 19 **Cooperation between Member States** 1. Member States shall take the appropriate measures to ensure that the competent authorities referred to in Article 4(3) cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly. 2. The Commission shall provide for the organisation of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive.	Requirements are covered in specific union legislation dedicated to market surveillance.

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
	Article 20 **Legal remedies** Any measure taken pursuant to this Directive which restricts the placing on the market and/or putting into service of any machinery covered by this Directive shall state the exact grounds on which it is based. Such a measure shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time limits to which such remedies are subject.	Requirement dispatched in regulation Articles of Chapter VI.
	Article 21 **Dissemination of information** The Commission shall take the necessary measures for appropriate information concerning the implementation of this Directive to be made available.	
CHAPTER VII ***DELEGATED POWERS AND COMMITTEE PROCEDURE***		
Article 47 **Exercise of the delegation** 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article. 2. The power to adopt delegated acts referred to in Articles 6(2), 6(11) and 7(2) shall be conferred on the Commission for a period of five years from 19 July 2023. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
3. The delegation of power referred to in Articles 6(2), 6(11) and 7(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force. 4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. 5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council. 6. A delegated act adopted pursuant to Articles 6(2), 6(11) or 7(2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.		
Article 48 **Committee procedure** 1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011. 2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply. 3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	*Article 22* **Committee** 1. The Commission shall be assisted by a committee, hereinafter referred to as the 'Committee'. 2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. 3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
Where the committee delivers no opinion regarding the draft implementing act as referred to in Article 20(3), Article 5(4), third subparagraph, of Regulation (EU) No 182/2011 shall apply. 4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply. 5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legal act. The committee may furthermore examine any other matter concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.	4. The Committee shall adopt its rules of procedure.	
CHAPTER VIII ***CONFIDENTIALITY AND PENALTIES***		
Article 49 **Confidentiality** 1. All parties shall respect the confidentiality of the following information and data obtained in carrying out their tasks in accordance with this Regulation: (a) personal data; (b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights, unless disclosure is in the public interest. 2. Without prejudice to paragraph 1, information exchanged on a confidential basis between the competent national authorities and between competent national authorities and the Commission shall not be disclosed without the prior agreement of the competent national authority that originally provided the information.	*Article 18* **Confidentiality** 1. Without prejudice to existing national provisions and practices in the area of confidentiality, Members States shall ensure that all parties and persons concerned by the application of this Directive are required to treat as confidential information obtained in the execution of their tasks. […] […] More particularly business, professional and trade secrets shall be treated as confidential, unless the divulging of such information is necessary in order to protect the health and safety of persons.	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor shall it affect the obligations of the persons concerned to provide information under criminal law. 4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have bilateral or multilateral confidentiality agreements and arrangements when those agreements and arrangements ensure that any exchange of information is in accordance with applicable Union law.	2. The provisions of paragraph 1 shall not affect the obligations of the Member States and the notified bodies with regard to mutual exchange of information and the issuing of warnings. 3. Any decisions taken by the Member States and by the Commission in accordance with Articles 9 and 11 shall be published.	
Article 50 **Penalties** 1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive and may include criminal penalties for serious infringements. 2. Member States shall, by 20 October 2026, notify the Commission of those rules and of those measures and shall notify it without delay of any subsequent amendment affecting them.	*Article 23* **Penalties** Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 29 June 2008 and shall notify it without delay of any subsequent amendment affecting them.	

	Article 24 **Amendment of Directive 95/16/EC** Directive 95/16/EC is hereby amended as follows: 1.in Article 1, paragraphs 2 and 3 shall be replaced by the following: 2. 'For the purposes of this Directive, "lift" shall mean a lifting appliance serving specific levels, having a carrier moving along guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal, intended for the transport of: — persons, — persons and goods, — goods alone if the carrier is accessible, that is to say a person may enter it without difficulty, and fitted with controls situated inside the carrier or within reach of a person inside the carrier. Lifting appliances moving along a fixed course even where they do not move along guides which are rigid shall be considered as lifts falling within the scope of this Directive. A "carrier" means a part of the lift by which persons and/or goods are supported in order to be lifted or lowered. 3. This Directive shall not apply to: — lifting appliances whose speed is not greater than 0,15 m/s, — construction site hoists, — cableways, including funicular railways, — lifts specially designed and constructed for military or police purposes, — lifting appliances from which work can be carried out, — mine winding gear, — lifting appliances intended for lifting performers during artistic performances,	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
	— lifting appliances fitted in means of transport, — lifting appliances connected to machinery and intended exclusively for access to workstations including maintenance and inspection points on the machinery, — rack and pinion trains, — escalators and mechanical walkways.'; 2. in Annex I, point 1.2 shall be replaced by the following: 1.2. 'Carrier The carrier of each lift must be a car. This car must be designed and constructed to offer the space and strength corresponding to the maximum number of persons and the rated load of the lift set by the installer. Where the lift is intended for the transport of persons, and where its dimensions permit, the car must be designed and constructed in such a way that its structural features do not obstruct or impede access and use by disabled persons and so as to allow any appropriate adjustments intended to facilitate its use by them.'	
CHAPTER IX ***TRANSITIONAL AND FINAL PROVISIONS***		
Article 51 **Repeals** 1. Directive 73/361/EEC is repealed. References to the repealed Directive 73/361/EEC shall be construed as references to this Regulation. 2. Directive 2006/42/EC is repealed with effect from 20 January 2027. References to the repealed Directive 2006/42/EC shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex XII.	*Article 25* **Repeal** Directive 98/37/EC is hereby repealed. References made to the repealed Directive shall be construed as being made to this Directive and should be read in accordance with the correlation table in Annex XII.	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
	Article 26 **Transposition** 1. Member States shall adopt and publish the provisions necessary to comply with this Directive by 29 June 2008 at the latest. They shall forthwith inform the Commission thereof. They shall apply those provisions with effect from 29 December 2009. When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made. 2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive, together with a table showing how the provisions of this Directive correspond to the national provisions adopted.	Transposition in national law only needed for directives.
Article 52 **Transitional provisions** 1. Member States shall not impede the making available on the market of products which were placed on the market in conformity with Directive 2006/42/EC before 20 January 2027. However, Chapter VI of this Regulation shall apply, as from 19 July 2023, *mutatis mutandis* to such products instead of Article 11 of that Directive, including products for which a procedure has already been initiated under Article 11 of Directive 2006/42/EC. 2. EC type-examination certificates and approval decisions issued in accordance with Article 12 of Directive 2006/42/EC shall remain valid until they.	*Article 27* **Derogation** Until 29 June 2011 Member States may allow the placing on the market and the putting into service of portable cartridge-operated fixing and other impact machinery which are in conformity with the national provisions in force upon adoption of this Directive.	

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments
Article 53 **Evaluation and review** 1. By 20 July 2028 and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public. 2. Taking account of technical progress and practical experience gained in Member States as indicated in Article 6, the Commission shall in its report include an evaluation on the following aspects of this Regulation: (a) the essential health and safety requirements set out in Annex III; (b) the conformity assessment procedure applicable to machinery or related products listed in Annex I. Where appropriate, the report shall be accompanied by a legislative proposal for amendment of the relevant provisions of this Regulation. 3. By 20 July 2026 and every five years thereafter, the Commission shall submit a specific report on the assessment of Article 6(4) and (5) of this Regulation to the European Parliament and to the Council. The reports shall be made public. The Commission shall in its reports include the following: (a) a summary of data and information provided by Member States in accordance with Article 6(5) during the reporting period; (b) an assessment of the list of categories of machinery or related products in Annex I in view of the criteria set out in Article 6(4). In the reports, the Commission shall assess the appropriateness and availability of data and information provided by Member States, including its sufficiency and suitability for the purposes of making comparisons, identifying any shortcomings, necessary to ensure effective functioning and enforcement of Article 6.		

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Machinery Regulation 2023/1230/EU	Machinery Directive 2006/42/EC	Comments

Article 54
 	
Entry into force and application
 	
This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
 	
It shall apply from 20 January 2027.
 	
However, the following Articles shall apply from the following dates:
 	
a) Articles 26 to 42 from 20 January 2024;
 	
b) Article 50(1) from 20 October 2026;
 	
c) Article 6(7) and Articles 48 and 52 from 19 July 2023;
 	
d) Article 6(2) to (6), (8) and (11) and Articles 47 and 53(3) from 20 July 2024.
	Article 28
	
	Entry into force
	
	This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Union.	

This Regulation shall be binding in its entirety and directly applicable in all Member States.	*Article 29* **Addressees** This Directive is addressed to the Member States.	
Done at Strasbourg, 14 June 2023 For the European Parliament The President R. METSOLA For the Council The President J. ROSWALL	Done at Strasbourg, 17 May 2006. For the European Parliament The President J. BORRELL FONTELLES For the Council The President H. WINKLER	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex I Regulation	Annex IV Directive	Comments
ANNEX I **Categories of machinery or related products to which one of the procedures referred to in article 25 (2) and (3) shall be applied**	**ANNEX IV** **Categories of machinery to which one of the procedures referred to in Article 12(3) and (4) must be applied**	
Part A Categories of machinery or related products to which a procedure referred to in Article 25(2) shall be applied: 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.	14. Removable mechanical transmission devices including their guards. 15. Guards for removable mechanical transmission devices. 16. Vehicle servicing lifts. 18. Portable cartridge-operated fixing and other impact machinery.	
Part B Categories of machinery or related products to which one of the procedures referred to in Article 25(3) shall be applied: 1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types: 1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed; 1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;	1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types: 1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed; 1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;	

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Annex I Regulation	Annex IV Directive	Comments
1.3 sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;	1.3 sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;	
1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.	1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.	
2. Hand-fed surface planing machinery for woodworking.	2. Hand-fed surface planing machinery for woodworking.	
3. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.	3. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.	
4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:	4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:	
4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;	4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;	
4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.	4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.	
5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.	5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.	
6. Hand-fed tenoning machinery with several tool holders for woodworking.	6. Hand-fed tenoning machinery with several tool holders for woodworking.	
7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.	7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.	
8. Portable chainsaws for woodworking.	8. Portable chainsaws for woodworking.	
9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.	9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.	
10. Injection or compression plastics-moulding machinery with manual loading or unloading.	10. Injection or compression plastics-moulding machinery with manual loading or unloading.	
11. Injection or compression rubber-moulding machinery with manual loading or unloading.	11. Injection or compression rubber-moulding machinery with manual loading or unloading.	

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Annex I Regulation	Annex IV Directive	Comments
12. Machinery for underground working of the following types: 12.1. locomotives and brake-vans; 12.2. hydraulic-powered roof supports.	12. Machinery for underground working of the following types: 12.1. locomotives and brake-vans; 12.2. hydraulic-powered roof supports.	
13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.	13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.	
14. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than 3 m..	17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres.	
15. Protective devices designed to detect the presence of persons.	19. Protective devices designed to detect the presence of persons.	
16. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11.	20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11.	
17. Logic units to ensure safety functions.	21. Logic units to ensure safety functions.	
18. Roll-over protective structures (ROPS).	22. Roll-over protective structures (ROPS).	
19. Falling-object protective structures (FOPS).	23. Falling-object protective structures (FOPS).	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex II Regulation	Annex V Directive	Comments
ANNEX II **Indicative list of safety components**	**ANNEX V** **Indicative list of the safety components referred to in Article 2(c)**	
1. Guards for removable mechanical transmission devices.	1. Guards for removable mechanical transmission devices.	
2. Protective devices designed to detect the presence of persons.	2. Protective devices designed to detect the presence of persons.	
3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in items 9, 10 and 11 of Annex I, Part B.	3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in items 9, 10 and 11 of Annex IV.	
4. Logic units to ensure safety functions.	4. Logic units to ensure safety functions.	
5. Valves with additional means for failure detection intended for the control of dangerous movements of machinery.	5. Valves with additional means for failure detection intended for the control of dangerous movements on machinery.	
6. Extraction systems for machinery emissions.	6. Extraction systems for machinery emissions.	
7. Guards and protective devices designed to protect persons against moving parts involved in the process on the machinery.	7. Guards and protective devices designed to protect persons against moving parts involved in the process on the machinery.	
8. Monitoring devices for loading and movement control in lifting machinery.	8. Monitoring devices for loading and movement control in lifting machinery.	
9. Restraint systems to keep persons on their seats.	9. Restraint systems to keep persons on their seats.	
10. Emergency stop devices.	10. Emergency stop devices.	
11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.	11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.	
12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex III.	12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex I.	
13. Systems and devices to reduce the emission of noise and vibrations.	13. Systems and devices to reduce the emission of noise and vibrations.	
14. Roll-over protective structures (ROPS).	14. Roll-over protective structures (ROPS).	
15. Falling-object protective structures (FOPS).	15. Falling-object protective structures (FOPS).	
16. Two-hand control devices.	16. Two-hand control devices.	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex II Regulation	Annex V Directive	Comments
17. The following components for machinery designed for lifting and/or lowering persons between different landings:	17. Components for machinery designed for lifting and/or lowering persons between different landings and included in the following list:	
(a) devices for locking landing doors;	(a) devices for locking landing doors;	
(b) devices to prevent the load-carrying unit from falling or unchecked upwards movement;	(b) devices to prevent the load-carrying unit from falling or unchecked upwards movement;	
(c) overspeed limitation devices;	(c) overspeed limitation devices;	
(d) energy-accumulating shock absorbers, non-linear or with damping of the return movement;	(d) energy-accumulating shock absorbers, — non-linear, or — with damping of the return movement;	
(e) energy-dissipating shock absorbers;	(e) energy-dissipating shock absorbers;	
(f) safety devices fitted to jacks of hydraulic power circuits and used to prevent falls;	(f) safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls;	
(g) safety switches containing electronic components.	(g) electric safety devices in the form of safety switches containing electronic components.	
18. Software ensuring safety functions		
19. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions.		
20. Filtration systems intended to be integrated into machinery cabins in order to protect operators or other persons against hazardous materials and substances, includingplant protection products, and filters for such filtration systems.		

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Annex III Regulation	Annex I Directive	Comments
ANNEX III ***Essential health and safety requirements relating to the design and construction of machinery or related products***	***ANNEX I*** ***Essential health and safety requirements relating to the design and construction of machinery***	
	1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS 1.1. GENERAL REMARKS	
Part A Definitions	1.1.1. Definitions	
For the purposes of this Annex, the following definitions apply:	For the purpose of this Annex:	
(a) 'hazard' means a potential source of injury or damage to health; (b) 'danger zone' means any zone within and/or around a machinery or related product in which a person is subject to a risk to his or her health or safety; (c) 'exposed person' means any person wholly or partially in a danger zone; (d) 'operator' means the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving a machinery or related product; (e) 'risk' means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation; (f) 'guard' means a part of a machinery or related product used specifically to provide protection by means of a physical barrier; (g) 'protective device' means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard;	(a) 'hazard' means a potential source of injury or damage to health; (b) 'danger zone' means any zone within and/or around machinery in which a person is subject to a risk to his health or safety; (c) 'exposed person' means any person wholly or partially in a danger zone; (d) 'operator' means the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving machinery; (e) 'risk' means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation; (f) 'guard' means a part of the machinery used specifically to provide protection by means of a physical barrier; (g) 'protective device' means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard;	

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(h) 'intended use' means the use of a machinery or a related product in accordance with the information provided in the instructions for use; (i) 'reasonably foreseeable misuse' means the use of a machinery or a related product in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.	(h) 'intended use' means the use of machinery in accordance with the information provided in the instructions for use; (i) 'reasonably foreseeable misuse' means the use of machinery in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.	
Part B GENERAL PRINCIPLES	GENERAL PRINCIPLES	
1. The manufacturer of machinery or a related product shall ensure that a risk assessment is carried out in order to determine the essential health and safety requirements, which apply to the machinery or related product. The machinery or related product shall then be designed and constructed to eliminate hazards or, if that is not possible, to minimise all relevant risks, taking into account the results of the risk assessment.	1. The manufacturer of machinery or his authorised representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.	
By the iterative process of risk assessment and risk reduction referred to in the first subparagraph, the manufacturer shall:	By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorised representative shall:	
(a) determine the limits of the machinery or related product, which include the intended use and any reasonably foreseeable misuse thereof;	— determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof,	
(b) identify the hazards that may be generated by the machinery or related product and the associated hazardous situations;	— identify the hazards that can be generated by the machinery and the associated hazardous situations,	
(c) estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence;	— estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence,	
(d) evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Regulation;	— evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Directive,	

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(e) eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).	— eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).	
The risk assessment and risk reduction shall include hazards that might arise during the lifecycle of the machinery or related product that are foreseeable at the time of placing the machinery or related product on the market as an intended evolution of its fully or partially self-evolving behaviour or logic as a result of the machinery or related product designed to operate with varying levels of autonomy. The risk assessment and risk reduction shall include risks resulting from interactions between machinery in order to achieve the same end that are arranged and controlled so that they function as an integral whole, thus forming machinery as defined in Article 3, point 1, point (d).		
2. The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery or related product in question when it is used under the conditions foreseen by the manufacturer or in foreseeable abnormal situations. However, the principles of safety integration established in section 1.1.2 and the obligations concerning marking of machinery or related product referred to in section 1.7.3, instructions referred to in section 1.7.4 apply in all cases.	2. The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery in question when it is used under the conditions foreseen by the manufacturer or his authorised representative or in foreseeable abnormal situations. In any event, the principles of safety integration referred to in section 1.1.2 and the obligations concerning marking of machinery and instructions referred to in sections 1.7.3 and 1.7.4 apply.	
3. The essential health and safety requirements laid down in this Annex are mandatory; however, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery or related product shall, as far as possible, be designed and constructed with the purpose of approaching those objectives.	3. The essential health and safety requirements laid down in this Annex are mandatory; However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives.	

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4. This Annex is organised into six chapters. The first chapter is of general scope and applicable to all machinery or related product. The other chapters refer to certain sorts of more specific hazards. Nevertheless, it is essential to examine the whole of this Annex in order to be sure of meeting all the relevant essential health and safety requirements. When a machinery or related product is being designed, the requirements of the first chapter and the requirements of one or more of the other chapters shall be taken into account, depending on the results of the risk assessment carried out in accordance with point 1 of these General Principles. Essential health and safety requirements for the protection of the environment are applicable only to the machinery or related product referred to in section 2.4. 5. These general principles shall apply to the risk assessment carried out by the manufacturer of partly completed machinery.	4. This Annex is organised in several parts. The first one is of general scope and applicable to all kinds of machinery. The other parts refer to certain kinds of more specific hazards. Nevertheless, it is essential to examine the whole of this Annex in order to be sure of meeting all the relevant essential requirements. When machinery is being designed, the requirements of the general part and the requirements of one or more of the other parts shall be taken into account, depending on the results of the risk assessment carried out in accordance with point 1 of these General Principles. Essential health and safety requirements for the protection of the environment are applicable only to the machinery referred to in section 2.4.	
1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS 1.1. GENERAL REMARKS		
1.1.1. Applicability The obligations laid down by the essential health and safety requirements are applicable to partly completed machinery insofar as those requirements are relevant. The relevant requirements in relation to partly completed machinery do not cover the requirements that can only be fulfilled at the time of the incorporation of the partly completed machinery. However, the principles of safety integration established in section 1.1.2 are applicable in all cases.		

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1.1.2. **Principles of safety integration**	1.1.2. **Principles of safety integration**	
(a) Machinery or related product shall be designed and constructed so that they are fit for their function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.	(a) Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.	
The aim of protective measures shall be to eliminate any risk throughout the foreseeable lifetime of the machinery or related product including the phases of transport, assembly, dismantling, disabling and scrapping.	The aim of measures taken must be to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping.	
(b) In selecting the most appropriate methods, the manufacturer shall apply the following principles, in the order given:	(b) In selecting the most appropriate methods, the manufacturer or his authorised representative must apply the following principles, in the order given:	
(i) eliminate hazards or, if that is not possible, minimise risks (inherently safe machinery or related product design and construction);	— eliminate or reduce risks as far as possible (inherently safe machinery design and construction),	
(ii) take the necessary protective measures in relation to risks that cannot be eliminated;	— take the necessary protective measures in relation to risks that cannot be eliminated,	
(iii) inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.	— inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.	
(c) When designing and constructing machinery or a related product and when drafting the instructions for use, the manufacturer shall envisage not only the intended use of the machinery or related product but also any reasonably foreseeable misuse thereof.	(c) When designing and constructing machinery and when drafting the instructions, the manufacturer or his authorised representative must envisage not only the intended use of the machinery but also any reasonably foreseeable misuse thereof.	
The machinery or related product shall be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions for use shall draw the user's attention to ways — which experience has shown might occur — in which the machinery or related product should not be used.	The machinery must be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions must draw the user's attention to ways — which experience has shown might occur — in which the machinery should not be used.	

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(d) Machinery or related product shall be designed and constructed to take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment. (e) Machinery or related product shall be designed and constructed in such a way that it is possible for the user, where applicable, to test the safety functions. The machinery or related product shall be supplied with all the special equipment and accessories, and where appropriate, with the description of specific functional test procedures, essential to enable it to be tested, adjusted, maintained and used safely.	(d) Machinery must be designed and constructed to take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment. (e) Machinery must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.	
1.1.3. **Materials and products** The materials used to construct machinery or related product, or products used or created during its use, shall not endanger the health and safety of person. In particular, where fluids are used, machinery or related product shall be designed and constructed to prevent risks due to filling, use, recovery or draining.	1.1.3. **Materials and products** The materials used to construct machinery or products used or created during its use must not endanger persons' safety or health. In particular, where fluids are used, machinery must be designed and constructed to prevent risks due to filling, use, recovery or draining.	
1.1.4. **Lighting** Machinery or related product shall be supplied with integral lighting suitable for the operations concerned, where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity. Machinery or related product shall be designed and constructed so that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to the lighting. Internal parts requiring frequent inspection and adjustment, and maintenance areas shall be provided with appropriate lighting.	1.1.4. **Lighting** Machinery must be supplied with integral lighting suitable for the operations concerned where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity. Machinery must be designed and constructed so that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to the lighting. Internal parts requiring frequent inspection and adjustment, and maintenance areas must be provided with appropriate lighting.	
1.1.5. **Design of machinery or a related product to facilitate its handling** Machinery or a related product or each component part thereof, shall:	1.1.5. **Design of machinery to facilitate its handling** Machinery, or each component part thereof, must:	

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(a) be capable of being handled and transported safely; (b) be packaged or designed so that it can be stored safely and without damage.	— be capable of being handled and transported safely, — be packaged or designed so that it can be stored safely and without damage.	
During the transportation of the machinery or related product or its component parts, there shall be no possibility of sudden movements or of hazards due to instability as long as the machinery or related product or its component parts are handled in accordance with the instructions.	During the transportation of the machinery and/or its component parts, there must be no possibility of sudden movements or of hazards due to instability as long as the machinery and/or its component parts are handled in accordance with the instructions.	
Where the weight, size or shape of machinery or a related product or its various component parts prevents it or them from being moved by hand, the machinery or related product or each component part shall: (a) either be fitted with attachments for lifting gear, or (b) be designed so that it can be fitted with such attachments, or (c) be shaped in such a way that standard lifting gear can easily be attached.	Where the weight, size or shape of machinery or its various component parts prevents them from being moved by hand, the machinery or each component part must: — either be fitted with attachments for lifting gear, or — be designed so that it can be fitted with such attachments, or — be shaped in such a way that standard lifting gear can easily be attached.	
Where machinery or a related product or one of its component parts is to be moved by hand, it shall either: (a) be easily moveable, or (b) be equipped for picking up and moving safely.	Where machinery or one of its component parts is to be moved by hand, it must: — either be easily moveable, or — be equipped for picking up and moving safely.	
Special arrangements shall be made for the handling of tools and/or machinery or related product parts, which, even if lightweight, could be hazardous.	Special arrangements must be made for the handling of tools and/or machinery parts which, even if lightweight, could be hazardous.	
1.1.6. **Ergonomics** Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator shall be eliminated or reduced to the minimum possible, taking into account at least, the following ergonomic principles:	1.1.6. **Ergonomics** Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic principles such as:	

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(a) allowing for the variability of the operator's physical dimensions, strength and stamina; (b) avoiding the need for demanding work postures or movements and manual force exertions that exceed the operator's capacity; (c) providing enough space for movements of the parts of the operator's body; (d) avoiding a machine-determined work rate; (e) avoiding monitoring that requires lengthy concentration; (f) adapting the human-machine interface to the foreseeable characteristics of the operators, including with respect to machinery or a related product with intended fully or partially self-evolving behaviour or logic that is designed to operate with varying levels of autonomy; (g) where relevant, adapting machinery or a related product with intended fully or partially self-evolving behaviour or logic that is designed to operate with varying levels of autonomy to respond to people adequately and appropriately (such as verbally through words and non-verbally through gestures, facial expressions or body movement) and to communicate its planned actions (such as what it is going to do and why) to operators in a comprehensible manner.	— allowing for the variability of the operator's physical dimensions, strength and stamina, — providing enough space for movements of the parts of the operator's body, — avoiding a machine-determined work rate, — avoiding monitoring that requires lengthy concentration, — adapting the man/machinery interface to the foreseeable characteristics of the operators.	
1.1.7. **Operating positions** The operating position shall be designed and constructed in such a way as to avoid any risk due to exhaust gases or lack of oxygen. If the machinery or related product is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery or related product itself gives rise to a hazardous environment, adequate means shall be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.	1.1.7. **Operating positions** The operating position must be designed and constructed in such a way as to avoid any risk due to exhaust gases and/or lack of oxygen. If the machinery is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery itself gives rise to a hazardous environment, adequate means must be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.	

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Where appropriate, the operating position shall be fitted with an adequate cabin designed, constructed or equipped to fulfil the above requirements. The exit shall allow rapid evacuation. Moreover, when applicable, an emergency exit shall be provided in a direction which is different from the usual exit.	Where appropriate, the operating position must be fitted with an adequate cabin designed, constructed and/or equipped to fulfil the above requirements. The exit must allow rapid evacuation. Moreover, when applicable, an emergency exit must be provided in a direction which is different from the usual exit.	
1.1.8. **Seating** Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery or related product shall be designed for the installation of seats. If the operator is intended to sit during operation and the operating position is an integral part of the machinery or related product, the seat shall be provided with the machinery or related product. The operator's seat shall enable him or her to maintain a stable position. Furthermore, the seat and its distance from the control devices shall be capable of being adapted to the operator. If the machinery or related product is subject to vibrations, the seat shall be designed and constructed in such a way as to reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. The seat mountings shall withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material shall be provided.	1.1.8. Seating Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery must be designed for the installation of seats. If the operator is intended to sit during operation and the operating position is an integral part of the machinery, the seat must be provided with the machinery. The operator's seat must enable him to maintain a stable position. Furthermore, the seat and its distance from the control devices must be capable of being adapted to the operator. If the machinery is subject to vibrations, the seat must be designed and constructed in such a way as to reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. The seat mountings must withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material must be provided.	

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1.1.9. **Protection against corruption** The machinery or related product shall be designed and constructed so that the connection to it of another device, via any feature of the connected device itself or via any remote device that communicates with the machinery or related product does not lead to a hazardous situation. A hardware component transmitting signal or data, relevant for connection or access to software that is critical for the compliance of the machinery or related product with the relevant health and safety requirements shall be designed so that it is adequately protected against accidental or intentional corruption. The machinery or related product shall collect evidence of a legitimate or illegitimate intervention in that hardware component, when relevant for connection or access to software that is critical for the compliance of the machinery or related product. Software and data that are critical for the compliance of the machinery or related product with the relevant essential health and safety requirements shall be identified as such and shall be adequately protected against accidental or intentional corruption. The machinery or related product shall identify the software installed on it that is necessary for it to operate safely, and shall be able to provide that information at all times in an easily accessible form. The machinery or related product shall collect evidence of a legitimate or illegitimate intervention in the software or a modification of the software installed on the machinery or related product or its configuration.		
1.2. CONTROL SYSTEMS	**1.2. CONTROL SYSTEMS**	
1.2.1. **Safety and reliability of control systems** Control systems shall be designed and constructed in such a way as to prevent hazardous situations from arising. Control systems shall be designed and constructed in such a way that:	1.2.1. **Safety and reliability of control systems** Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:	

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(a) they can withstand, where appropriate to the circumstances and the risks, the intended operating stresses and intended and unintended external influences, including reasonably foreseeable malicious attempts from third parties leading to a hazardous situation;	— they can withstand the intended operating stresses and external influences,	
(b) a fault in the hardware or the logic of the control system shall not lead to hazardous situations;	— a fault in the hardware or the software of the control system does not lead to hazardous situations,	
(c) errors in the control system logic shall not lead to hazardous situations;	— errors in the control system logic do not lead to hazardous situations,	
(d) the limits of the safety functions are to be established as part of the risk assessment performed by the manufacturer and no modifications are allowed to the settings or rules generated by the machinery or related product or by operators, including during the machinery or related product learning phase, where such modifications could lead to hazardous situations;		
(e) reasonably foreseeable human errors during operation shall not lead to hazardous situations;	— reasonably foreseeable human error during operation does not lead to hazardous situations.	
(f) the tracing log of the data generated in relation to an intervention and of the versions of safety software uploaded after the machinery or related product has been placed on the market or put into service is enabled for five years after such upload, exclusively to demonstrate the conformity of the machinery or related product with this Annex further to a reasoned request from a competent national authority.		
Control systems of machinery or related products with fully or partially self-evolving behaviour or logic that are designed to operate with varying levels of autonomy shall be designed and constructed in such a way that:		Specific requirements for Artificial Intelligence.
(a) they shall not cause the machinery or related product to perform actions beyond its defined task and movement space;		

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(b) recording of data on the safety related decision-making process for software-based safety systems ensuring safety function including safety components, after the machinery or related product has been placed on the market or put into service, is enabled and that such data is retained for one year after its collection, exclusively to demonstrate the conformity of the machinery or related product with this Annex further to a reasoned request from a competent national authority; (c) it shall be possible at all times to correct the machinery or related product in order to maintain its inherent safety.		
Particular attention shall be given to the following points: (a) the machinery or related product shall not start unexpectedly; (b) the parameters of the machinery or related product shall not change in an uncontrolled way, where such change could lead to hazardous situations; (c) modifications to the settings or rules, generated by the machinery or related product or by operators, including during the machinery or related product learning phase, shall be prevented, where such modifications could lead to hazardous situations; (d) the machinery or related product shall not be prevented from stopping if the stop command has already been given; (e) no moving part of the machinery or related product or piece held by the machinery or related product shall fall or be ejected; (f) automatic or manual stopping of the moving parts, whatever they may be, shall be unimpeded; (g) the protective devices shall remain fully effective or give a stop command; (h) the safety-related parts of the control system shall apply in a coherent way to the whole of an assembly of a machinery or related product.	Particular attention must be given to the following points: — the machinery must not start unexpectedly, — the parameters of the machinery must not change in an uncontrolled way, where such change may lead to hazardous situations, — the machinery must not be prevented from stopping if the stop command has already been given, — no moving part of the machinery or piece held by the machinery must fall or be ejected, — automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded, — the protective devices must remain fully effective or give a stop command, — the safety-related parts of the control system must apply in a coherent way to the whole of an assembly of machinery and/or partly completed machinery.	

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For wireless control, a failure of the communication or connection or a faulty connection shall not lead to a hazardous situation.	For cable-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication.	
1.2.2. Control devices Control devices shall be: (a) clearly visible and identifiable, using pictograms where appropriate; (b) positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity; (c) designed in such a way that the movement of the control device is consistent with its effect; (d) located outside the danger zones, except where necessary for certain control devices such as an emergency stop or a teach pendant; (e) positioned in such a way that their operation cannot cause additional risk; (f) designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate action; (g) made in such a way as to withstand foreseeable forces, paying particular attention to emergency stop devices liable to be subjected to considerable forces. Where a control device is designed and constructed to perform several different actions, namely, where there is no one-to-one correspondence, the action to be performed shall be clearly displayed and subject to confirmation, where necessary. Control devices shall be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles. Machinery or related products shall be fitted with indicators as required for safe operation. The operator shall be able to read them from the control position.	1.2.2. ***Control devices*** Control devices must be: — clearly visible and identifiable, using pictograms where appropriate, — positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity, — designed in such a way that the movement of the control device is consistent with its effect, — located outside the danger zones, except where necessary for certain control devices such as an emergency stop or a teach pendant, — positioned in such a way that their operation cannot cause additional risk, — designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate action, — made in such a way as to withstand foreseeable forces; particular attention must be paid to emergency stop devices liable to be subjected to considerable forces. Where a control device is designed and constructed to perform several different actions, namely where there is no one-to-one correspondence, the action to be performed must be clearly displayed and subject to confirmation, where necessary. Control devices must be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles. Machinery must be fitted with indicators as required for safe operation. The operator must be able to read them from the control position.	

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From each control position, the operator shall be able to ensure that no one is in the danger zones, or the control system shall be designed and constructed in such a way that starting is prevented while someone is in the danger zone. If neither of these possibilities is applicable, before the machinery or related product starts, an acoustic and/or visual warning signal shall be given. The exposed persons shall have time to leave the danger zone or prevent the machinery starting up. If necessary, means shall be provided to ensure that the machinery or related product can be controlled only from control positions located in one or more predetermined zones or locations. Where there is more than one control position, the control system shall be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops. When the machinery or related product has two or more operating positions, each position shall be provided with all the required control devices without the operators hindering or putting each other into a hazardous situation.	From each control position, the operator must be able to ensure that no-one is in the danger zones, or the control system must be designed and constructed in such a way that starting is prevented while someone is in the danger zone. If neither of these possibilities is applicable, before the machinery starts, an acoustic and/or visual warning signal must be given. The exposed persons must have time to leave the danger zone or prevent the machinery starting up. If necessary, means must be provided to ensure that the machinery can be controlled only from control positions located in one or more predetermined zones or locations. Where there is more than one control position, the control system must be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops. When machinery has two or more operating positions, each position must be provided with all the required control devices without the operators hindering or putting each other into a hazardous situation.	
1.2.3. **Starting** It must be possible to start the machinery or related product only by voluntary actuation of a control device provided for the purpose. The same requirement applies: (a) when restarting the machinery or related product after a stoppage, whatever the cause; (b) when effecting a significant change in the operating conditions. However, the restarting of the machinery or related product or a change in operating conditions may be effected by voluntary actuation of a device other than the control device provided for the purpose, on condition that this does not lead to a hazardous situation.	1.2.3. **Starting** It must be possible to start machinery only by voluntary actuation of a control device provided for the purpose. The same requirement applies: — when restarting the machinery after a stoppage, whatever thecause, — when effecting a significant change in the operating conditions. However, the restarting of the machinery or a change in operating conditions may be effected by voluntary actuation of a device other than the control device provided for the purpose, on condition that this does not lead to a hazardous situation.	

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For the machinery or related product functioning in automatic mode, the starting of the machinery or related product, restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation. Where the machinery or related product has several starting control devices and the operators can therefore put each other in danger, additional devices shall be fitted to rule out such risks. If safety requires that starting and/or stopping shall be performed in a specific sequence, there shall be devices that ensure that these operations are performed in the correct order.	For machinery functioning in automatic mode, the starting of the machinery, restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation. Where machinery has several starting control devices and the operators can therefore put each other in danger, additional devices must be fitted to rule out such risks. If safety requires that starting and/or stopping must be performed in a specific sequence, there must be devices which ensure that these operations are performed in the correct order.	
1.2.4. **Stopping**	1.2.4. **Stopping**	
1.2.4.1. **Normal stop** The machinery or related product shall be fitted with a control device whereby the machinery can be brought safely to a complete stop. Each workstation shall be fitted with a control device to stop some or all of the functions of the machinery or related product, depending on the existing hazards, so that the machinery or related product is rendered safe. The machinery or related product's stop control shall have priority over the start controls. Once the machinery or related product or its hazardous functions have stopped, the energy supply to the actuators concerned shall be cut off.	1.2.4.1. **Normal stop** Machinery must be fitted with a control device whereby the machinery can be brought safely to a complete stop. Each workstation must be fitted with a control device to stop some or all of the functions of the machinery, depending on the existing hazards, so that the machinery is rendered safe. The machinery's stop control must have priority over the start controls. Once the machinery or its hazardous functions have stopped, the energy supply to the actuators concerned must be cut off.	
1.2.4.2. **Operational stop** Where, for operational reasons, a stop control that does not cut off the energy supply to the actuators is required, the stop condition shall be monitored and maintained.	1.2.4.2. **Operational stop** Where, for operational reasons, a stop control that does not cut off the energy supply to the actuators is required, the stop condition must be monitored and maintained.	

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1.2.4.3. **Emergency stop** The machinery or related product shall be fitted with one or more emergency stop devices to enable actual or impending danger to be averted. The following exceptions apply: (a) the machinery or related product in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken; (b) portable hand-held and/or hand-guided machinery or related product. The device shall: (a) have clearly identifiable, clearly visible and quickly accessible control devices; (b) stop the hazardous process as quickly as possible, without creating additional risks; (c) where necessary, trigger or permit the triggering of certain safeguard movements. Once active operation of the emergency stop device has ceased following a stop command, that command shall be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it shall not be possible to engage the device without triggering a stop command; it shall be possible to disengage the device only by an appropriate operation, and disengaging the device shall not restart the machinery or related product but only permit restarting. The emergency stop function shall be available and operational at all times, regardless of the operating mode. Emergency stop devices shall be a backup to other safeguarding measures and not a substitute for them.	1.2.4.3. **Emergency stop** Machinery must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted. The following exceptions apply: — machinery in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken, — portable hand-held and/or hand-guided machinery. The device shall: — have clearly identifiable, clearly visible and quickly accessible control devices, — stop the hazardous process as quickly as possible, without creating additional risks, — where necessary, trigger or permit the triggering of certain safeguard movements. Once active operation of the emergency stop device has ceased following a stop command, that command must be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it must not be possible to engage the device without triggering a stop command; it must be possible to disengage the device only by an appropriate operation, and disengaging the device must not restart the machinery but only permit restarting. The emergency stop function must be available and operational at all times, regardless of the operating mode. Emergency stop devices must be a back-up to other safeguarding measures and not a substitute for them.	

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1.2.4.4. **Assembly of machinery or related products** In the case of machinery or a related product or parts of machinery or a related product designed to work together, the machinery or a related product shall be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery or related products itself but also all related equipment, if its continued operation may be dangerous.	1.2.4.4. **Assembly of machinery** In the case of machinery or parts of machinery designed to work together, the machinery must be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery itself but also all related equipment, if its continued operation may be dangerous.	
1.2.5. **Selection of control or operating modes** The control or operating mode selected shall override all other control or operating modes, with the exception of the emergency stop. If the machinery or related product has been designed and constructed to allow its use in several control or operating modes requiring different protective measures and/or work procedures, it shall be fitted with a mode selector, which can be locked in each position. Each position of the selector shall be clearly identifiable and shall correspond to a single operating or control mode. The selector may be replaced by another selection method, which restricts the use of certain functions of the machinery or related product to certain categories of operator. If, for certain operations, the machinery or related product shall be able to operate with a guard displaced or removed and/or a protective device disabled, the control or operating mode selector shall simultaneously: (a) disable all other control or operating modes; (b) permit operation of hazardous functions only by control devices requiring sustained action; (c) permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked sequences;	1.2.5. **Selection of control or operating modes** The control or operating mode selected must override all other control or operating modes, with the exception of the emergency stop. If machinery has been designed and constructed to allow its use in several control or operating modes requiring different protective measures and/or work procedures, it must be fitted with a mode selector which can be locked in each position. Each position of the selector must be clearly identifiable and must correspond to a single operating or control mode. The selector may be replaced by another selection method which restricts the use of certain functions of the machinery to certain categories of operator. If, for certain operations, the machinery must be able to operate with a guard displaced or removed and/or a protective device disabled, the control or operating mode selector must simultaneously: — disable all other control or operating modes, — permit operation of hazardous functions only by control devices requiring sustained action, — permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked sequences,	

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(d) prevent any operation of hazardous functions by voluntary or involuntary action on the machinery's or related product's sensors. If these four conditions cannot be fulfilled simultaneously, the control or operating mode selector shall activate other protective measures designed and constructed to ensure a safe intervention zone. In addition, the operator shall be able to control the operation of the parts he or she is working on from the adjustment point.	— prevent any operation of hazardous functions by voluntary or involuntary action on the machine's sensors. If these four conditions cannot be fulfilled simultaneously, the control or operating mode selector must activate other protective measures designed and constructed to ensure a safe intervention zone. In addition, the operator must be able to control operation of the parts he is working on from the adjustment point.	
1.2.6. **Failure of the power supply or communication network connection** The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply or communication network connection to the machinery or related product shall not lead to hazardous situations. Particular attention shall be given to the following: (a) the machinery or related product shall not start unexpectedly; (b) the parameters of the machinery shall not change in an uncontrolled way when such change can lead to hazardous situations; (c) the machinery or related product shall not be prevented from stopping if the stop command has already been given; (d) no moving part of the machinery or related product or piece held by the machinery or related product shall fall or be ejected; (e) automatic or manual stopping of the moving parts, whatever they may be, shall be unimpeded; (f) the protective devices shall remain fully effective or give a stop command.	1.2.6. **Failure of the power supply** The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply to the machinery must not lead to dangerous situations. Particular attention must be given to the following points: — the machinery must not start unexpectedly, — the parameters of the machinery must not change in an uncontrolled way when such change can lead to hazardous situations, — the machinery must not be prevented from stopping if the command has already been given, — no moving part of the machinery or piece held by the machinery must fall or be ejected, — automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded, — the protective devices must remain fully effective or give a stop command.	

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Annex III Regulation	Annex I Directive	Comments
1.3. **PROTECTION AGAINST MECHANICAL RISKS**	1.3. **PROTECTION AGAINST MECHANICAL HAZARDS**	
1.3.1. **Risk of loss of stability** The machinery or related product and its components and fittings shall be stable enough to avoid overturning, falling or uncontrolled movements during transportation, assembly, dismantling and any other action involving the machinery or related product. If the shape of the machinery or related products itself or its intended installation does not offer sufficient stability, appropriate means of anchorage shall be incorporated and indicated in the instructions for use.	1.3.1. **Risk of loss of stability** Machinery and its components and fittings must be stable enough to avoid overturning, falling or uncontrolled movements during transportation, assembly, dismantling and any other action involving the machinery. If the shape of the machinery itself or its intended installation does not offer sufficient stability, appropriate means of anchorage must be incorporated and indicated in the instructions.	
1.3.2. **Risk of break-up during operation** The various parts of machinery or related product and their linkages shall be able to withstand the stresses to which they are subject when used. The durability of the materials used shall be adequate for the nature of the working environment foreseen by the manufacturer, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion. The instructions shall indicate the type and frequency of inspections and maintenance required for safety reasons. They shall, where appropriate, indicate the parts subject to wear and the criteria for replacement. Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned shall be mounted, positioned or guarded in such a way that any fragments will be contained, preventing hazardous situations. Both rigid and flexible pipes carrying fluids, particularly those under high pressure, shall be able to withstand the foreseen internal and external stresses and shall be firmly attached or protected to ensure that no risk is presented by a rupture.	1.3.2. **Risk of break-up during operation** The various parts of machinery and their linkages must be able to withstand the stresses to which they are subject when used. The durability of the materials used must be adequate for the nature of the working environment foreseen by the manufacturer or his authorised representative, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion. The instructions must indicate the type and frequency of inspections and maintenance required for safety reasons. They must, where appropriate, indicate the parts subject to wear and the criteria for replacement. Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned must be mounted, positioned and/or guarded in such a way that any fragments will be contained, preventing hazardous situations. Both rigid and flexible pipes carrying fluids, particularly those under high pressure, must be able to withstand the foreseen internal and external stresses and must be firmly attached and/or protected to ensure that no risk is posed by a rupture.	

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Where the material to be processed is fed to the tool automatically, the following conditions shall be fulfilled to avoid risks to persons: (a) when the work piece comes into contact with the tool, the latter shall have attained its normal working condition; (b) when the tool starts and/or stops (intentionally or accidentally), the feed movement and the tool movement shall be coordinated.	Where the material to be processed is fed to the tool automatically, the following conditions must be fulfilled to avoid risks to persons: — when the workpiece comes into contact with the tool, the latter must have attained its normal working condition, — when the tool starts and/or stops (intentionally or accidentally), the feed movement and the tool movement must be coordinated.	
1.3.3. **Risks due to falling or ejected objects** Precautions shall be taken to prevent risks from falling or ejected objects.	1.3.3. **Risks due to falling or ejected objects** Precautions must be taken to prevent risks from falling or ejected objects.	
1.3.4. **Risks due to surfaces, edges or angles** Insofar as their purpose allows, accessible parts of the machinery or a related product shall have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.	1.3.4. **Risks due to surfaces, edges or angles** Insofar as their purpose allows, accessible parts of the machinery must have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.	
1.3.5. **Risks related to a combined machinery or related product** Where the machinery or related product is intended to carry out several different operations with manual removal of the piece between each operation (combined machinery or related product), it shall be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a risk for exposed persons. For this purpose, it shall be possible to start and stop separately any elements that are not protected.	1.3.5. **Risks related to combined machinery** Where the machinery is intended to carry out several different operations with manual removal of the piece between each operation (combined machinery), it must be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a risk for exposed persons. For this purpose, it must be possible to start and stop separately any elements that are not protected.	

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1.3.6. **Risks related to variations in operating conditions** Where the machinery or related product performs operations under different conditions of use, it shall be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.	1.3.6. **Risks related to variations in operating conditions** Where the machinery performs operations under different conditions of use, it must be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.	
1.3.7. **Risks related to moving parts** The moving parts of the machinery or related product shall be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or shall, where risks persist, be fitted with guards or protective devices. All necessary steps shall be taken to prevent accidental blockage of moving parts. In cases where, despite the precautions taken, a blockage is likely to occur, the necessary specific protective devices and tools shall, when appropriate, be provided to enable the equipment to be safely unblocked. The instructions for use and, where possible, a sign on the machinery or related product shall identify these specific protective devices and how they are to be used. The prevention of risks of contact leading to hazard situations and the psychological stress that may be caused by the interaction with the machine shall be adapted to: (a) human-machine coexistence in a shared space without direct collaboration; (b) human-machine interaction.	1.3.7. **Risks related to moving parts** The moving parts of machinery must be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or must, where risks persist, be fitted with guards or protective devices. All necessary steps must be taken to prevent accidental blockage of moving parts involved in the work. In cases where, despite the precautions taken, a blockage is likely to occur, the necessary specific protective devices and tools must, when appropriate, be provided to enable the equipment to be safely unblocked. The instructions and, where possible, a sign on the machinery shall identify these specific protective devices and how they are to be used.	
1.3.8. **Choice of protection against risks arising from moving parts** Guards or protective devices designed to protect against risks arising from moving parts shall be selected on the basis of the type of risk. The following guidelines shall be used to help to make the choice.	1.3.8. **Choice of protection against risks arising from moving parts** Guards or protective devices designed to protect against risks arising from moving parts must be selected on the basis of the type of risk. The following guidelines must be used to help to make the choice.	

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Annex III Regulation	Annex I Directive	Comments
1.3.8.1. **Moving transmission parts** Guards designed to protect persons against the hazards generated by moving transmission parts shall be: (a) either fixed guards as referred to in section 1.4.2.1, or (b) interlocking movable guards as referred to in section 1.4.2.2. Interlocking movable guards shall be used where frequent access is envisaged.	1.3.8.1. **Moving transmission parts** Guards designed to protect persons against the hazards generated by moving transmission parts must be: — either fixed guards as referred to in section 1.4.2.1, or — interlocking movable guards as referred to in section 1.4.2.2. Interlocking movable guards should be used where frequent access is envisaged.	
1.3.8.2. **Moving parts involved in the process** (i) Guards or protective devices designed to protect persons against the hazards generated by moving parts involved in the process shall be: (a) either fixed guards as referred to in section 1.4.2.1, or (b) interlocking movable guards as referred to in section 1.4.2.2, or (c) protective devices as referred to in section 1.4.3, or (d) a combination of the above. (ii) However, when certain moving parts directly involved in the process cannot be made completely inaccessible during operation owing to operations requiring operator intervention, such parts shall be fitted with: (a) fixed guards or interlocking movable guards preventing access to those sections of the parts that are not used in the work, and (b) adjustable guards as referred to in section 1.4.2.3 restricting access to those sections of the moving parts where access is necessary.	1.3.8.2. **Moving parts involved in the process** Guards or protective devices designed to protect persons against the hazards generated by moving parts involved in the process must be: — either fixed guards as referred to in section 1.4.2.1, or — interlocking movable guards as referred to in section 1.4.2.2, or — protective devices as referred to in section 1.4.3, or — a combination of the above. However, when certain moving parts directly involved in the process cannot be made completely inaccessible during operation owing to operations requiring operator intervention, such parts must be fitted with: — fixed guards or interlocking movable guards preventing access to those sections of the parts that are not used in the work, and — adjustable guards as referred to in section 1.4.2.3 restricting access to those sections of the moving parts where access is necessary.	

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1.3.9. **Risks of uncontrolled movements** When a part of the machinery or related product has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, shall be prevented or shall be such that it does not present a risk.	1.3.9. **Risks of uncontrolled movements** When a part of the machinery has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, must be prevented or must be such that it does not present a hazard.	
1.4. REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES	**1.4. REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES**	
1.4.1. **General requirements** Guards and protective devices shall: (a) be of robust construction; (b) be securely held in place; (c) not give rise to any additional hazard; (d) not be easy to by-pass or render non-operational; (e) be located at an adequate distance from the danger zone; (f) cause minimum obstruction to the view of the production process, and; (g) enable essential work to be carried out on the installation and/or replacement of tools and for maintenance purposes by restricting access exclusively to the area where the work has to be done, if possible, without the guard having to be removed or the protective device having to be disabled. In addition, guards shall, where possible, protect against the ejection or falling of materials or objects and against emissions generated by the machinery or related product.	1.4.1. **General requirements** Guards and protective devices must: — be of robust construction, — be securely held in place, — not give rise to any additional hazard, — not be easy to by-pass or render non-operational, — be located at an adequate distance from the danger zone, — cause minimum obstruction to the view of the production process, and — enable essential work to be carried out on the installation and/or replacement of tools and for maintenance purposes by restricting access exclusively to the area where the work has to be done, if possible, without the guard having to be removed or the protective device having to be disabled. In addition, guards must, where possible, protect against the ejection or falling of materials or objects and against emissions generated by the machinery.	

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Annex III Regulation	Annex I Directive	Comments
1.4.2. **Special requirements for guards**	1.4.2. **Special requirements for guards**	
1.4.2.1. **Fixed guards** Fixed guards shall be fixed by systems that can be opened or removed only with tools. Their fixing systems shall remain attached to the guards or to the machinery or related product when the guards are removed. Where possible, guards shall be incapable of remaining in place without their fixings.	1.4.2.1. **Fixed guards** Fixed guards must be fixed by systems that can be opened or removed only with tools. Their fixing systems must remain attached to the guards or to the machinery when the guards are removed. Where possible, guards must be incapable of remaining in place without their fixings.	
1.4.2.2. **Interlocking movable guards** Interlocking movable guards shall: (a) as far as possible remain attached to the machinery or related product when open; (b) be designed and constructed in such a way that they can be adjusted only by means of an intentional action. Interlocking movable guards shall be associated with an interlocking device that: (a) prevents the start of hazardous machinery or related product functions until they are closed and (b) gives a stop command whenever they are no longer closed. Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery or related product functions has ceased, movable guards shall be associated with a guard locking device in addition to an interlocking device that: (a) prevents the start of hazardous machinery or related product functions until the guard is closed and locked, and (b) keeps the guard closed and locked until the risk of injury from the hazardous machinery or related product functions has ceased.	1.4.2.2. **Interlocking movable guards** Interlocking movable guards must: — as far as possible remain attached to the machinery when open, — be designed and constructed in such a way that they can be adjusted only by means of an intentional action. Interlocking movable guards must be associated with an interlocking device that: — prevents the start of hazardous machinery functions until they are closed and — gives a stop command whenever they are no longer closed. Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery functions has ceased, movable guards must be associated with a guard locking device in addition to an interlocking device that: — prevents the start of hazardous machinery functions until the guard is closed and locked, and — keeps the guard closed and locked until the risk of injury from the hazardous machinery functions has ceased.	

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Interlocking movable guards shall be designed in such a way that the absence or failure of one of their components prevents starting or stops the hazardous machinery or related product functions.	Interlocking movable guards must be designed in such a way that the absence or failure of one of their components prevents starting or stops the hazardous machinery functions.	
1.4.2.3. **Adjustable guards restricting access** Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work shall be: (a) adjustable manually or automatically, depending on the type of work involved; and (b) readily adjustable without the use of tools.	1.4.2.3. **Adjustable guards restricting access** Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work must be: — adjustable manually or automatically, depending on the type of work involved, and — readily adjustable without the use of tools.	
1.4.3. **Special requirements for protective devices** Protective devices shall be designed and incorporated into the control system in such a way that: (a) moving parts cannot start up while they are within the operator's reach; (b) persons cannot reach moving parts while the parts are moving, and (c) the absence or failure of one of their components prevents starting or stops the moving parts. Protective devices shall be adjustable only by means of an intentional action.	1.4.3. **Special requirements for protective devices** Protective devices must be designed and incorporated into the control system in such a way that: — moving parts cannot start up while they are within the operator's reach, — persons cannot reach moving parts while the parts are moving, and — the absence or failure of one of their components prevents starting or stops the moving parts. Protective devices must be adjustable only by means of an intentional action.	
1.5. RISKS DUE TO OTHER CAUSES	**1.5. RISKS DUE TO OTHER HAZARDS**	
1.5.1. **Electricity supply** Where machinery or related products have an electricity supply, they shall be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented.	1.5.1. **Electricity supply** Where machinery has an electricity supply, it must be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented.	

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The safety objectives set out in Directive 2014/35/EU shall apply to a machinery or related products. However, the obligations concerning conformity assessment and the placing on the market or putting into service of a machinery or related products with regard to electrical risks are governed solely by this Regulation.	The safety objectives set out in Directive 73/23/EEC shall apply to machinery. However, the obligations concerning conformity assessment and the placing on the market and/or putting into service of machinery with regard to electrical hazards are governed solely by this Directive.	
1.5.2. **Static electricity** Machinery or related products shall be designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.	1.5.2. **Static electricity** Machinery must be designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.	
1.5.3. **Energy supply other than electricity** Where machinery or related products are powered by source of energy other than electricity, they shall be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy.	1.5.3. **Energy supply other than electricity** Where machinery is powered by source of energy other than electricity, it must be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy.	
1.5.4. **Errors of fitting** Errors likely to be made when fitting or refitting certain parts, which could be a source of risk, shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves or their housings. The same information shall be given on moving parts or their housings where the direction of movement needs to be known in order to avoid a risk. Where necessary, the instructions for use shall give further information on these risks. Where a faulty connection can be the source of risk, incorrect connections shall be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.	1.5.4. **Errors of fitting** Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk. Where necessary, the instructions must give further information on these risks. Where a faulty connection can be the source of risk, incorrect connections must be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.	

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1.5.5. **Extreme temperatures** Steps shall be taken to eliminate any risk of injury arising from contact with or proximity to machinery or related product parts or materials at high or very low temperatures. The necessary steps shall also be taken to avoid or protect against the risk of hot or very cold material being ejected.	1.5.5. **Extreme temperatures** Steps must be taken to eliminate any risk of injury arising from contact with or proximity to machinery parts or materials at high or very low temperatures. The necessary steps must also be taken to avoid or protect against the risk of hot or very cold material being ejected.	
1.5.6. **Fire** Machinery or related products shall be designed and constructed in such a way as to avoid any risk of fire or overheating presented by the machinery or related product itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery or related product.	1.5.6. **Fire** Machinery must be designed and constructed in such a way as to avoid any risk of fire or overheating posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery.	
1.5.7. **Explosion** Machinery or related products shall be designed and constructed in such a way as to avoid any risk of explosion presented by the machinery or related product itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery or related product. Machinery or related products shall comply, as far as the risk of explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific Union harmonisation legislation.	1.5.7. **Explosion** Machinery must be designed and constructed in such a way as to avoid any risk of explosion posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery. Machinery must comply, as far as the risk of explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific Community Directives.	
1.5.8. **Noise** Machinery or related products shall be designed and constructed in such a way that risks resulting from the emission of airborne noise are reduced to the lowest level, taking account of technical progress and the availability of means of reducing noise, in particular at source. The level of noise emission may be assessed with reference to comparative emission data for similar machinery or related product.	1.5.8. **Noise** Machinery must be designed and constructed in such a way that risks resulting from the emission of airborne noise are reduced to the lowest level, taking account of technical progress and the availability of means of reducing noise, in particular at source. The level of noise emission may be assessed with reference to comparative emission data for similar machinery.	

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1.5.9. **Vibrations** Machinery or related products shall be designed and constructed in such a way that risks resulting from vibrations produced by the machinery or related product are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source. The level of vibration emission may be assessed with reference to comparative emission data for similar machinery or related products.	1.5.9. **Vibrations** Machinery must be designed and constructed in such a way that risks resulting from vibrations produced by the machinery are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source. The level of vibration emission may be assessed with reference to comparative emission data for similar machinery.	
1.5.10. **Radiation** Undesirable radiation emissions from the machinery or related products shall be eliminated or be reduced to levels that do not have adverse effects on persons. Any functional ionising radiation emissions shall be limited to the lowest level, which is sufficient for the proper functioning of the machinery or related product during setting, operation and cleaning. Where a risk exists, the necessary protective measures shall be taken. Any functional non-ionising radiation emissions during setting, operation and cleaning shall be limited to levels that do not have adverse effects on persons.	1.5.10. **Radiation** Undesirable radiation emissions from the machinery must be eliminated or be reduced to levels that do not have adverse effects on persons. Any functional ionising radiation emissions must be limited to the lowest level which is sufficient for the proper functioning of the machinery during setting, operation and cleaning. Where a risk exists, the necessary protective measures must be taken. Any functional non-ionising radiation emissions during setting, operation and cleaning must be limited to levels that do not have adverse effects on persons.	
1.5.11. **External radiation** Machinery or related products shall be designed and constructed in such a way that external radiation does not interfere with its operation.	1.5.11. **External radiation** Machinery must be designed and constructed in such a way that external radiation does not interfere with its operation.	
1.5.12. **Laser radiation** Where laser equipment is used, the following shall be taken into account: (a) laser equipment on machinery or related products shall be designed and constructed in such a way as to prevent any accidental radiation;	1.5.12. **Laser radiation** Where laser equipment is used, the following should be taken into account: — laser equipment on machinery must be designed and constructed in such a way as to prevent any accidental radiation,	

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(b) laser equipment on machinery or related products shall be protected in such a way that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health; (c) optical equipment for the observation or adjustment of laser equipment on machinery or related products shall be such that no health risk is created by laser radiation.	— laser equipment on machinery must be protected in such a way that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health, — optical equipment for the observation or adjustment of laser equipment on machinery must be such that no health risk is created by laser radiation.	
1.5.13. **Emissions of hazardous materials and substances** Machinery or related products shall be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided. Where a hazard cannot be eliminated, the machinery or related product shall be so equipped that hazardous materials and substances can be contained, captured, evacuated, precipitated by water spraying, filtered or treated by another equally effective method. Where the process is not totally enclosed during normal operation of the machinery or related product, the devices for containment or capture, filtration or separation and evacuation shall be situated in such a way as to have the maximum effect.	1.5.13. **Emissions of hazardous materials and substances** Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided. Where a hazard cannot be eliminated, the machinery must be so equipped that hazardous materials and substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another equally effective method. Where the process is not totally enclosed during normal operation of the machinery, the devices for containment and/or evacuation must be situated in such a way as to have the maximum effect.	
1.5.14. **Risk of being trapped in a machine** Machinery or related products shall be designed, constructed or fitted with a means of preventing a person from being enclosed within it or, if that is impossible, with a means of summoning help.	1.5.14. **Risk of being trapped in a machine** Machinery must be designed, constructed or fitted with a means of preventing a person from being enclosed within it or, if that is impossible, with a means of summoning help.	

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1.5.15. **Risk of slipping, tripping or falling** Parts of the machinery or related products where persons are liable to move about or stand shall be designed and constructed in such a way as to prevent persons slipping, tripping or falling on or off these parts. Where appropriate, these parts shall be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.	1.5.15. **Risk of slipping, tripping or falling** Parts of the machinery where persons are liable to move about or stand must be designed and constructed in such a way as to prevent persons slipping, tripping or falling on or off these parts. Where appropriate, these parts must be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.	
1.5.16. **Lightning** Machinery or related products in need of protection against the effects of lightning while being used shall be fitted with a system for conducting the resultant electrical charge to earth.	1.5.16. **Lightning** Machinery in need of protection against the effects of lightning while being used must be fitted with a system for conducting the resultant electrical charge to earth.	
1.6. MAINTENANCE	**1.6. MAINTENANCE**	
1.6.1. **Machinery or related product maintenance** Adjustment and maintenance points shall be located outside danger zones. It shall be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while the machinery or related product is at a standstill. If one or more of the above conditions cannot be satisfied for technical reasons, measures shall be taken to ensure that these operations can be carried out safely (see section 1.2.5). In the case of automated machinery and, where necessary, other machinery or related products, a connecting device for mounting diagnostic fault-finding equipment shall be provided.	1.6.1. **Machinery maintenance** Adjustment and maintenance points must be located outside danger zones. It must be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while machinery is at a standstill. If one or more of the above conditions cannot be satisfied for technical reasons, measures must be taken to ensure that these operations can be carried out safely (see section 1.2.5). In the case of automated machinery and, where necessary, other machinery, a connecting device for mounting diagnostic fault-finding equipment must be provided.	

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Automated machinery or related product components, which have to be changed frequently, shall be capable of being removed and replaced easily and safely. Access to the components shall enable these tasks to be carried out with the necessary technical means in accordance with a specified operating method.	Automated machinery components which have to be changed frequently must be capable of being removed and replaced easily and safely. Access to the components must enable these tasks to be carried out with the necessary technical means in accordance with a specified operating method.	
1.6.2. **Access to operating positions and servicing points** Machinery or related products shall be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment, maintenance and cleaning of the machinery or related product. In the case of machinery or related products into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses shall be dimensioned and adapted for the use of rescue equipment in such a way that an emergency rescue of the persons is possible.	1.6.2. **Access to operating positions and servicing points** Machinery must be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment and maintenance of the machinery.	
1.6.3. **Isolation of energy sources** Machinery or related products shall be fitted with means to isolate it from all energy sources. Such isolators shall be clearly identified. They shall be capable of being locked if reconnection could endanger persons. Isolators shall also be capable of being locked where an operator is unable, from any of the points to which he or she has access, to check that the energy is still cut off. In the case of machinery or related products capable of being plugged into an electricity supply, removal of the plug is sufficient, if the operator can check from any of the points to which he or she has access that the plug remains removed. After the energy is cut off, it shall be possible to dissipate normally any energy remaining or stored in the circuits of the machinery or related product without risk to persons.	1.6.3. **Isolation of energy sources** Machinery must be fitted with means to isolate it from all energy sources. Such isolators must be clearly identified. They must be capable of being locked if reconnection could endanger persons. Isolators must also be capable of being locked where an operator is unable, from any of the points to which he has access, to check that the energy is still cut off. In the case of machinery capable of being plugged into an electricity supply, removal of the plug is sufficient, provided that the operator can check from any of the points to which he has access that the plug remains removed. After the energy is cut off, it must be possible to dissipate normally any energy remaining or stored in the circuits of the machinery without risk to persons.	

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As an exception to the requirement laid down in the previous paragraphs, certain circuits may remain connected to their energy sources in order, for example, to hold parts, to protect information, to light interiors, etc. In this case, special steps shall be taken to ensure operator safety.	As an exception to the requirement laid down in the previous paragraphs, certain circuits may remain connected to their energy sources in order, for example, to hold parts, to protect information, to light interiors, etc. In this case, special steps must be taken to ensure operator safety.	
1.6.4. **Operator intervention** The machinery or related product shall be so designed, constructed and equipped that the need for operator intervention is limited. If operator intervention cannot be avoided, it shall be possible to carry it out easily and safely.	1.6.4. **Operator intervention** Machinery must be so designed, constructed and equipped that the need for operator intervention is limited. If operator intervention cannot be avoided, it must be possible to carry it out easily and safely.	
1.6.5. **Cleaning of internal parts** The machinery or related product shall be designed and constructed in such a way that it is possible to clean internal parts, which have contained dangerous substances or mixtures without entering them; any necessary unblocking shall also be possible from the outside. If it is impossible to avoid entering the machinery or related product, it shall be designed and constructed in such a way as to allow cleaning to take place safely.	1.6.5. **Cleaning of internal parts** The machinery must be designed and constructed in such a way that it is possible to clean internal parts which have contained dangerous substances or preparations without entering them; any necessary unblocking must also be possible from the outside. If it is impossible to avoid entering the machinery, it must be designed and constructed in such a way as to allow cleaning to take place safely.	
1.7. INFORMATION	**1.7. INFORMATION**	
1.7.1. **Information and warnings on the machinery or related product** Information and warnings on the machinery or related products shall preferably be provided in the form of readily understandable symbols or pictograms.	1.7.1. **Information and warnings on the machinery** Information and warnings on the machinery should preferably be provided in the form of readily understandable symbols or pictograms.	

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Any written or verbal information and warnings must be expressed in a language which can be easily understood by users, as determined by the Member State concerned.	Any written or verbal information and warnings must be expressed in an official Community language or languages, which may be determined in accordance with the Treaty by the Member State in which the machinery is placed on the market and/or put into service and may be accompanied, on request, by versions in any other official Community language or languages understood by the operators.	
1.7.1.1. **Information and information devices** The information needed to control a machinery or related product shall be provided in a form that is unambiguous and easily understood. It shall not be excessive to the extent of overloading the operator. Visual display units or any other interactive means of communication between the operator and the machinery or related product shall be easily understood and easy to use.	1.7.1.1. **Information and information devices** The information needed to control machinery must be provided in a form that is unambiguous and easily understood. It must not be excessive to the extent of overloading the operator. Visual display units or any other interactive means of communication between the operator and the machine must be easily understood and easy to use.	
1.7.1.2. **Warning devices** Where the health and safety of persons may be endangered by a fault in the operation of an unsupervised machinery or related product, the machinery or related product shall be equipped in such a way as to give an appropriate acoustic or light signal as a warning. Where machinery or related product is equipped with warning devices, these shall be unambiguous and easily perceived. The operator shall have facilities to check the operation of such warning devices at all times. The requirements of the specific Union legal acts concerning colours and safety signals shall be complied with.	1.7.1.2. **Warning devices** Where the health and safety of persons may be endangered by a fault in the operation of unsupervised machinery, the machinery must be equipped in such a way as to give an appropriate acoustic or light signal as a warning. Where machinery is equipped with warning devices these must be unambiguous and easily perceived. The operator must have facilities to check the operation of such warning devices at all times. The requirements of the specific Community Directives concerning colours and safety signals must be complied with.	

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1.7.2. **Warning of residual risks** Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, shall be provided.	1.7.2. **Warning of residual risks** Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, must be provided.	
1.7.3. **Marking of machinery or related products** In addition to the marking requirements in article 10 and 24, machinery or related products shall be marked visibly, legibly and indelibly.	1.7.3. **Marking of machinery** All machinery must be marked visibly, legibly and indelibly with the following minimum particulars: — the business name and full address of the manufacturer and, where applicable, his authorised representative, — designation of the machinery, — the CE Marking (see Annex III), — designation of series or type, — serial number, if any, — the year of construction, that is the year in which the manufacturing process is completed. It is prohibited to pre-date or post-date the machinery when affixing the CE marking.	Those requirements are now covered in Regulation on Article 10 and 20.
Machinery or related products covered by chapters 2 to 6 of this Annex shall also be marked according to the additional requirements set out in those chapters.		
Furthermore, machinery or a related product designed and constructed for use in a potentially explosive atmosphere shall be marked accordingly.	Furthermore, machinery designed and constructed for use in a potentially explosive atmosphere must be marked accordingly.	
Machinery or related products shall also bear full information relevant to its type and essential for safe use. Such information is subject to the requirements set out in section 1.7.1.	Machinery must also bear full information relevant to its type and essential for safe use. Such information is subject to the requirements set out in section 1.7.1.	
Where machinery or related product part is handled during use with lifting equipment, its mass shall be indicated legibly, indelibly and unambiguously.	Where a machine part must be handled during use with lifting equipment, its mass must be indicated legibly, indelibly and unambiguously.	

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Annex III Regulation	Annex I Directive	Comments
1.7.4. **Instructions for use**	1.7.4. **Instructions**	
	All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service.	Requirement from directive moved on Article 10 of the regulation section 7.
	The instructions accompanying the machinery must be either 'Original instructions' or a 'Translation of the original instructions', in which case the translation must be accompanied by the original instructions.	
In addition to the obligations set out in Article 10(7), instructions for use shall be drawn up as set out below.	The instructions must be drafted in accordance with the principles set out below.	
By way of exception to Article 10(7), the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or its authorised representative may be supplied in only one official language of the Union which the specialised personnel understand.	By way of exception, the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his authorised representative may be supplied in only one Community language which the specialised personnel understand.	
1.7.4.1. **General principles for the drafting of instructions for use**	1.7.4.1. **General principles for the drafting of instructions**	
	(a) The instructions must be drafted in one or more official Community languages. The words 'Original instructions' must appear on the language version(s) verified by the manufacturer or his authorised representative.	
	(b) Where no 'Original instructions' exist in the official language(s) of the country where the machinery is to be used, a translation into that/those language(s) must be provided by the manufacturer or his authorised representative or by the person bringing the machinery into the language area in question. The translations must bear the words 'Translation of the original instructions'.	
(a) The contents of the instructions for use shall cover not only the intended use of the machinery or related product but also take into account any reasonably foreseeable misuse thereof;	(c) The contents of the instructions must cover not only the intended use of the machinery but also take into account any reasonably foreseeable misuse thereof.	

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(b) In the case of a machinery or related products intended for use by non-professional operators, the wording and layout of the instructions for use shall take into account the level of general education and acumen that can reasonably be expected from such operators.	(d) In the case of machinery intended for use by non-professional operators, the wording and layout of the instructions for use must take into account the level of general education and acumen that can reasonably be expected from such operators.	
1.7.4.2. **Contents of the instructions for use** 1. Instructions for use shall contain, where applicable, at least the following information: (a) the business name and full address of the manufacturer and, where applicable, of its authorised representative; (b) the designation of the machinery or related product as marked on the machinery or related product itself, except for the serial number (see section 1.7.3); (c) the EU declaration of conformity, or the internet address or machine-readable code, where the EU declaration of conformity can be accessed, in accordance with article 10(8). (d) a general description of the machinery or related product; (e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery or related product and for checking its correct functioning; (f) a description of the workstation(s) likely to be occupied by operators; (g) a description of the intended use of the machinery or related product; (h) warnings concerning ways in which the machinery or related product must not be used that experience has shown might occur;	1.7.4.2. **Contents of the instructions** Each instruction manual must contain, where applicable, at least the following information: (a) the business name and full address of the manufacturer and of his authorised representative; (b) the designation of the machinery as marked on the machinery itself, except for the serial number (see section 1.7.3); (c) the EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature; (d) a general description of the machinery; (e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning; (f) a description of the workstation(s) likely to be occupied by operators; (g) a description of the intended use of the machinery; (h) warnings concerning ways in which the machinery must not be used that experience has shown might occur;	

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(i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery or related product is to be mounted;	(i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery is to be mounted;	
(j) instructions relating to installation and assembly for reducing noise or vibration;	(j) instructions relating to installation and assembly for reducing noise or vibration;	
(k) instructions for the putting into service and use of the machinery or related product and, if necessary, instructions for the training of operators;	(k) instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators;	
(l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;	(l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;	
(m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;	(m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;	
(n) the essential characteristics of tools, which may be fitted to the machinery or related product;	(n) the essential characteristics of tools which may be fitted to the machinery;	
(o) the conditions in which the machinery or related product meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;	(o) the conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;	
(p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery or related product and of its various parts where these are regularly to be transported separately;	(p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately;	
(q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;	(q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;	

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(r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed taking account of the design and the use of the machinery or related product;	(r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed;	
(s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;	(s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;	
(t) the specifications of the spare parts to be used, when these affect the health and safety of operators;	(t) the specifications of the spare parts to be used, when these affect the health and safety of operators;	
(u) the following information on airborne noise emissions:	(u) the following information on airborne noise emissions:	
(i) the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB (A); where this level does not exceed 70 dB (A), this fact shall be indicated;	— the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated,	
(ii) the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 μPa);	— the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 μPa),	
(iii) the A-weighted sound power level emitted by the machinery or related product, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A).	— the A-weighted sound power level emitted by the machinery, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A).	
These values shall be either those actually measured for the machinery or related product in question or those established on the basis of measurements taken for a technically comparable machinery or for a technically comparable related product, which is representative of the machinery or related product to be produced.	These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.	
In the case of a very large machinery or related product, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery or related product may be indicated.	In the case of very large machinery, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery may be indicated.	

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Where the harmonised standards or common specifications adopted by the Commission in accordance with Article 20(3) cannot be applied, sound levels shall be measured using the most appropriate method for the machinery or related product. Whenever sound emission values are indicated, the uncertainties surrounding these values shall be specified. The operating conditions of the machinery or related product during measurement and the measuring methods used shall be described.	Where the harmonised standards are not applied, sound levels must be measured using the most appropriate method for the machinery. Whenever sound emission values are indicated the uncertainties surrounding these values must be specified. The operating conditions of the machinery during measurement and the measuring methods used must be described.	
Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels shall be measured at a distance of 1 m from the surface of the machinery or related product and at a height of 1, 6 m from the floor or access platform. The position and value of the maximum sound pressure shall be indicated. With respect to noise reduction machinery or related products, the instructions for use shall specify, where appropriate, how to correctly assemble and install that equipment (see also section 1.7.4.2(1), point (j)).	Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels must be measured at a distance of 1 meter from the surface of the machinery and at a height of 1,6 meters from the floor or access platform. The position and value of the maximum sound pressure must be indicated.	
Where specific Union legal acts lay down other requirements for the measurement of sound pressure levels or sound power levels, those legal acts shall be applied and the corresponding provisions of this section shall not apply; (v) information on the necessary precautions, devices and means for the immediate and gentle rescue of persons;	Where specific Community Directives lay down other requirements for the measurement of sound pressure levels or sound power levels, those Directives must be applied and the corresponding provisions of this section shall not apply;	
(w) where machinery or related products are likely to emit non-ionising radiation, which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons;	(v) where machinery is likely to emit non-ionising radiation which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons.	

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(x) where the design of machinery or related products allows emissions of hazardous substances from the machinery or related product, the characteristics of the capturing, filtration or discharge device if such device is not provided with the machinery or related product, and any of the following: (i) the flow rate for the emission of hazardous materials and substances from the machinery or related product; (ii) the concentration of hazardous materials or substances around the machinery or related product coming from the machinery or related product or from materials or substances used with the machinery or related product; (iii) the effectiveness of the capturing or filtration device and the conditions to be observed to maintain its effectiveness over time. The values referred to in the first subparagraph shall either be actually measured for the machinery or related product in question or established based on measurements in respect of technically comparable machinery or a technically comparable related product, which is representative of the state of the art.		
1.7.5 Sales literature Sales literature describing the machinery or related product shall not contradict the instructions for use as regards health and safety aspects. Sales literature describing the performance characteristics of the machinery or related product shall contain the same information on emissions as is contained in the instructions for use.	1.7.4.3. **Sales literature** Sales literature describing the machinery must not contradict the instructions as regards health and safety aspects. Sales literature describing the performance characteristics of machinery must contain the same information on emissions as is contained in the instructions.	

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2. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY AND RELATED PRODUCTS Machinery and related products for foodstuffs, machinery and related products for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery and related products, portable fixing and other impact machinery and related products, machinery and related products for working wood and material with similar physical characteristics and machinery and related products for pesticide application shall meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).	**2. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY** Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics and machinery for pesticide application must meet all the essential health and safety requirements set out in this chapter (see General Principles, point 4).	
2.1. MACHINERY AND RELATED PRODUCTS FOR FOODSTUFFS AND MACHINERY AND RELATED PRODUCTS FOR COSMETICS OR PHARMACEUTICAL PRODUCTS	**2.1. FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS**	
2.1.1. **General** Machinery or related products intended for use with foodstuffs or with cosmetics or pharmaceutical products shall be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion. The following requirements shall be observed: (a) materials in contact with, or intended to come into contact with, foodstuffs or water intended for human consumption or cosmetics or pharmaceutical products shall satisfy the conditions laid down in the relevant Union legal acts; the machinery or related product shall be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible, disposable parts shall be used; (b) all surfaces in contact with foodstuffs or water intended for human consumption or cosmetics or pharmaceutical products, other than surfaces of disposable parts, shall:	2.1.1. **General** Machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion. The following requirements must be observed: (a) materials in contact with, or intended to come into contact with, foodstuffs or cosmetics or pharmaceutical products must satisfy the conditions set down in the relevant Directives. The machinery must be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible disposable parts must be used; (b) all surfaces in contact with foodstuffs or cosmetics or pharmaceutical products, other than surfaces of disposable parts, must:	

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(i) be smooth and have neither ridges nor crevices, which could harbour organic materials. The same applies to their joinings; (ii) be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum; (iii) be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the inside surfaces shall have curves with a radius sufficient to allow thorough cleaning; (c) it shall be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery or related product (if possible, in a 'cleaning' position); (d) machinery or related products shall be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot be cleaned; (e) machinery or related product shall be designed and constructed in such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery or related products shall be designed and constructed in such a way that continuing compliance with this requirement can be checked.	— be smooth and have neither ridges nor crevices which could harbour organic materials. The same applies to their joinings, — be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum, — be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the inside surfaces must have curves with a radius sufficient to allow thorough cleaning; (c) it must be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery (if possible, in a 'cleaning' position); (d) machinery must be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot be cleaned; (e) machinery must be designed and constructed in such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery must be designed and constructed in such a way that continuing compliance with this requirement can be checked.	
2.1.2. **Instructions for use** The instructions for use for machinery or related products for foodstuffs and machinery or related product for cosmetics or pharmaceutical products shall indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.	2.1.2. **Instructions** The instructions for foodstuffs machinery and machinery for use with cosmetics or pharmaceutical products must indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.	

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Annex III Regulation	Annex I Directive	Comments
2.2. PORTABLE HAND-HELD OR HAND-GUIDED MACHINERY OR RELATED PRODUCTS	**2.2. PORTABLE HAND-HELD AND/OR HAND-GUIDED MACHINERY**	
2.2.1. **General** Portable hand-held or hand-guided machinery or related products shall: (a) depending on the type of machinery or related product, have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size, arranged in such a way as to ensure the stability of the machinery or related product under the intended operating conditions; (b) except where technically impossible, or where there is an independent control device, in the case of handles which cannot be released in complete safety, be fitted with manual start and stop control devices arranged in such a way that the operator can operate them without releasing the handles; (c) present no risks of accidental starting or continued operation after the operator has released the handles; equivalent steps shall be taken if this requirement is not technically feasible; (d) permit, where necessary, visual observation of the danger zone and of the action of the tool with the material being processed. (e) have a device or a connected exhaust system, with an extraction connection outlet or equivalent system to capture or reduce emissions of hazardous substances; this requirement does not apply if it leads to a new hazard or where the main function of the machinery or related product is the application of hazardous substances and to emissions of internal combustion engines. (f) be designed and constructed in such a way that the handles of portable machinery or related products make starting and stopping straightforward.	2.2.1. **General** Portable hand-held and/or hand-guided machinery must: — depending on the type of machinery, have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size, arranged in such a way as to ensure the stability of the machinery under the intended operating conditions, — except where technically impossible, or where there is an independent control device, in the case of handles which cannot be released in complete safety, be fitted with manual start and stop control devices arranged in such a way that the operator can operate them without releasing the handles, — present no risks of accidental starting and/or continued operation after the operator has released the handles. Equivalent steps must be taken if this requirement is not technically feasible, — permit, where necessary, visual observation of the danger zone and of the action of the tool with the material being processed. The handles of portable machinery must be designed and constructed in such a way as to make starting and stopping straightforward.	

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Annex III Regulation	Annex I Directive	Comments
2.2.1.1. **Instructions for use** The instructions for use shall give the following information concerning vibrations, expressed as acceleration (m/s²), and transmitted by portable handheld and hand-guided machinery or related product: (a) the vibration total value from continuous vibrations to which the hand-arm system is subjected; (b) the mean value of the peak amplitude of the acceleration from repeated shock vibrations, to which the hand-arm system is subjected; (c) the uncertainty of both measurements. The values referred to in the first subparagraph shall either be those actually measured for the machinery or related product in question or those established on the basis of measurements in respect of a technically comparable machinery or related product, which is representative of the state of the art. If harmonised standards or common specifications adopted by the Commission in accordance with Article 20(3) cannot be applied, the vibration data shall be measured using the most appropriate measurement code for the machinery or related product. The operating conditions during measurement and the methods used for measurement, or the reference of the harmonised standard applied, shall be specified.	2.2.1.1. **Instructions** The instructions must give the following information concerning vibrations transmitted by portable hand-held and hand-guided machinery: — the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s2. Where this value does not exceed 2,5 m/s2, this must be mentioned, — the uncertainty of measurement. These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced. If harmonised standards are not applied, the vibration data must be measured using the most appropriate measurement code for the machinery. The operating conditions during measurement and the methods used for measurement, or the reference of the harmonised standard applied, must be specified.	
2.2.2. **Portable fixing and other impact machinery or related products**	2.2.2. **Portable fixing and other impact machinery**	
2.2.2.1. **General** Portable fixing and other impact machinery or related products shall be designed and constructed in such a way that:	2.2.2.1. **General** Portable fixing and other impact machinery must be designed and constructed in such a way that:	

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(a) energy is transmitted to the impacted element by the intermediary component that does not leave the device; (b) an enabling device prevents impact unless the machinery or related product is positioned correctly with adequate pressure on the base material; (c) involuntary triggering is prevented; where necessary, an appropriate sequence of actions on the enabling device and the control device shall be required to trigger an impact; (d) accidental triggering is prevented during handling or in case of shock; (e) loading and unloading operations can be carried out easily and safely. Where necessary, it shall be possible to fit the device with splinter guard(s) and the appropriate guard(s) shall be provided by the manufacturer of the machinery or related product.	— energy is transmitted to the impacted element by the intermediary component that does not leave the device, — an enabling device prevents impact unless the machinery is positioned correctly with adequate pressure on the base material, — involuntary triggering is prevented; where necessary, an appropriate sequence of actions on the enabling device and the control device must be required to trigger an impact, — accidental triggering is prevented during handling or in case of shock, — loading and unloading operations can be carried out easily and safely. Where necessary, it must be possible to fit the device with splinter guard(s) and the appropriate guard(s) must be provided by the manufacturer of the machinery.	
2.2.2.2. **Instructions for use** The instructions for use shall give the necessary information regarding: (a) the accessories and interchangeable equipment that can be used with the machinery or related product; (b) the suitable fixing or other impacted elements to be used with the machinery or related product; (c) where appropriate, the suitable cartridges to be used.	2.2.2.2. **Instructions** The instructions must give the necessary information regarding: — the accessories and interchangeable equipment that can be used with the machinery, — the suitable fixing or other impacted elements to be used with the machinery, — where appropriate, the suitable cartridges to be used.	
2.3. MACHINERY OR RELATED PRODUCTS FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS Machinery or related products for working wood and materials with similar physical characteristics shall comply with the following requirements:	**2.3. MACHINERY FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS** Machinery for working wood and materials with similar physical characteristics must comply with the following requirements:	

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Annex III Regulation	Annex I Directive	Comments
(a) the machinery or related product shall be designed, constructed or equipped in such a way that the piece being machined can be placed and guided in safety; where the piece is hand-held on a work-bench, the latter shall be sufficiently stable during the work and shall not impede the movement of the piece;	(a) the machinery must be designed, constructed or equipped in such a way that the piece being machined can be placed and guided in safety; where the piece is hand-held on a work-bench, the latter must be sufficiently stable during the work and must not impede the movement of the piece;	
(b) where the machinery or related product is likely to be used in conditions involving the risk of ejection of work pieces or parts of them, it shall be designed, constructed, or equipped in such a way as to prevent such ejection, or, if this is not possible, so that the ejection does not engender risks for the operator and/or exposed persons;	(b) where the machinery is likely to be used in conditions involving the risk of ejection of workpieces or parts of them, it must be designed, constructed, or equipped in such a way as to prevent such ejection, or, if this is not possible, so that the ejection does not engender risks for the operator and/or exposed persons;	
(c) the machinery or related product shall be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down;	(c) the machinery must be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down;	
(d) where the tool is incorporated into a non-fully automated machinery or related product, that machinery or related product shall be designed and constructed in such a way as to eliminate or reduce the risk of accidental injury.	(d) where the tool is incorporated into a non-fully automated machine, the latter must be designed and constructed in such a way as to eliminate or reduce the risk of accidental injury.	

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Annex III Regulation	Annex I Directive	Comments
2.4. MACHINERY OR RELATED PRODUCTS FOR PLANT PROTECTION PRODUCTS APPLICATION	**2.4. MACHINERY FOR PESTICIDE APPLICATION**	
2.4.1. For the purposes of section 2.4., the following definition applies: 'Machinery or related products for plant protection products application' means machinery or related products specifically intended for the application of plant protection products within the meaning of Article 2(1), of Regulation (EC) No 1107/2009 of the European Parliament and of the Council [1]. _____ [1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).	2.4.1. **Definition** 'Machinery for pesticide application' means machinery specifically intended for the application of plant protection products within the meaning of Article 2(1) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market [1]. _____ [1] OJ L 309, 24.11.2009, p. 1.	
2.4.2. **General** The manufacturer of machinery or related products for plant protection products application shall ensure that an assessment is carried out of the risks of unintended exposure of the environment to plant protection products, in accordance with the process of risk assessment and risk reduction referred to in the General Principles, point 1. Machinery or related products for plant protection products application shall be designed and constructed taking into account the results of the risk assessment referred to in the first subparagraph so that the machinery or related products can be operated, adjusted and maintained without unintended exposure of the environment to pesticides. Leakage shall be prevented at all times.	2.4.2. **General** The manufacturer of machinery for pesticide application or his authorised representative must ensure that an assessment is carried out of the risks of unintended exposure of the environment to pesticides, in accordance with the process of risk assessment and risk reduction referred to in the General Principles, point 1. Machinery for pesticide application must be designed and constructed taking into account the results of the risk assessment referred to in the first paragraph so that the machinery can be operated, adjusted and maintained without unintended exposure of the environment to pesticides. Leakage must be prevented at all times.	

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Annex III Regulation	Annex I Directive	Comments
2.4.3. **Controls and monitoring** It shall be possible to easily and accurately control, monitor and immediately stop the plant protection products application from the operating positions.	2.4.3. **Controls and monitoring** It must be possible to easily and accurately control, monitor and immediately stop the pesticide application from the operating positions.	
2.4.4. **Filling and emptying** The machinery or related product shall be designed and constructed to facilitate precise filling with the necessary quantity of pesticide and to ensure easy and complete emptying, while preventing spillage of plant protection products and avoiding the contamination of the water source during such operations.	2.4.4. **Filling and emptying** The machinery must be designed and constructed to facilitate precise filling with the necessary quantity of pesticide and to ensure easy and complete emptying, while preventing spillage of pesticide and avoiding the contamination of the water source during such operations.	
2.4.5. **Application of plant protection products**	2.4.5. **Application of pesticides**	
2.4.5.1. **Application rate** The machinery or related product shall be fitted with means of adjusting the application rate easily, accurately and reliably.	2.4.5.1. **Application rate** The machinery must be fitted with means of adjusting the application rate easily, accurately and reliably.	
2.4.5.2. **Distribution, deposition and drift of plant protection products** The machinery or related product shall be designed and constructed to ensure that the plant protection product is deposited on target areas, to minimise losses to other areas and to prevent drift of plant protection products to the environment. Where appropriate, an even distribution and homogeneous deposition shall be ensured.	2.4.5.2. **Distribution, deposition and drift of pesticide** The machinery must be designed and constructed to ensure that pesticide is deposited on target areas, to minimise losses to other areas and to prevent drift of pesticide to the environment. Where appropriate, an even distribution and homogeneous deposition must be ensured.	

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2.4.5.3. **Tests** In order to verify that the relevant parts of the machinery or related product comply with the requirements set out in sections 2.4.5.1 and 2.4.5.2 the manufacturer shall, for each type of machinery or related product concerned, perform appropriate tests, or have such tests performed.	2.4.5.3. **Tests** In order to verify that the relevant parts of the machinery comply with the requirements set out in sections 2.4.5.1 and 2.4.5.2 the manufacturer or his authorised representative must, for each type of machinery concerned, perform appropriate tests, or have such tests performed.	
2.4.5.4. **Losses during stoppage** The machinery or related product shall be designed and constructed to prevent losses while the plant protection products application function is stopped.	2.4.5.4. **Losses during stoppage** The machinery must be designed and constructed to prevent losses while the pesticide application function is stopped.	
2.4.6. **Maintenance**	2.4.6. **Maintenance**	
2.4.6.1. **Cleaning** The machinery or related product shall be designed and constructed to allow its easy and thorough cleaning without contamination of the environment.	2.4.6.1. **Cleaning** The machinery must be designed and constructed to allow its easy and thorough cleaning without contamination of the environment.	
2.4.6.2. **Servicing** The machinery or related product shall be designed and constructed to facilitate the changing of worn parts without contamination of the environment.	2.4.6.2. **Servicing** The machinery must be designed and constructed to facilitate the changing of worn parts without contamination of the environment.	
2.4.7. **Inspections** It shall be possible to easily connect the necessary measuring instruments to the machinery or related product to check the correct functioning of the machinery or related product.	2.4.7. **Inspections** It must be possible to easily connect the necessary measuring instruments to the machinery to check the correct functioning of the machinery.	

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2.4.8. **Marking of nozzles, strainers and filters** Nozzles, strainers and filters shall be marked so that their type and size can be clearly identified.	2.4.8. **Marking of nozzles, strainers and filters** Nozzles, strainers and filters must be marked so that their type and size can be clearly identified.	
2.4.9. **Indication of plant protection product in use** Where appropriate, the machinery or related product shall be fitted with a specific mounting on which the operator can place the name of the plant protection product in use.	2.4.9. **Indication of pesticide in use** Where appropriate, the machinery must be fitted with a specific mounting on which the operator can place the name of the pesticide in use.	
2.4.10. **Instructions for use** The instructions for use shall provide the following information: (a) precautions to be taken during mixing, loading, application, emptying, cleaning, servicing and transport operations in order to avoid contamination of the environment; (b) detailed conditions of use for the different operating environments envisaged, including the corresponding preparation and adjustments required to ensure the deposition of plant protection product on target areas while minimising losses to other areas, to prevent drift to the environment and, where appropriate, to ensure an even distribution and homogeneous deposition of pesticide; (c) the range of types and sizes of nozzles, strainers and filters that can be used with the machinery or related product; (d) the frequency of checks and the criteria and method for the replacement of parts subject to wear that affect the correct functioning of the machinery or related product, such as nozzles, strainers and filters; (e) specification of calibration, daily maintenance, winter preparation and other checks necessary to ensure the correct functioning of the machinery or related product;	2.4.10. **Instructions** The instructions must provide the following information: (a) precautions to be taken during mixing, loading, application, emptying, cleaning, servicing and transport operations in order to avoid contamination of the environment; (b) detailed conditions of use for the different operating environments envisaged, including the corresponding preparation and adjustments required to ensure the deposition of pesticide on target areas while minimising losses to other areas, to prevent drift to the environment and, where appropriate, to ensure an even distribution and homogeneous deposition of pesticide; (c) the range of types and sizes of nozzles, strainers and filters that can be used with the machinery; (d) the frequency of checks and the criteria and method for the replacement of parts subject to wear that affect the correct functioning of the machinery, such as nozzles, strainers and filters; (e) specification of calibration, daily maintenance, winter preparation and other checks necessary to ensure the correct functioning of the machinery;	

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(f) types of plant protection products that may cause incorrect functioning of the machinery or related product; (g) an indication that the operator should keep updated the name of the plant protection product in use on the specific mounting referred to in section 2.4.9; (h) the connexion and use of any special equipment or accessories, and the necessary precautions to be taken; (i) an indication that the machinery or related product may be subject to national requirements for regular inspection by designated bodies, as provided for in Directive 2009/128/EC of the European Parliament and of the Council [1]; _____ 1. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71). (j) (the features of the machinery or related product, which shall be inspected to ensure its correct functioning; (k) instructions for connecting the necessary measuring instruments.	(f) types of pesticides that may cause incorrect functioning of the machinery; (g) an indication that the operator should keep updated the name of the pesticide in use on the specific mounting referred to in section 2.4.9; (h) the connexion and use of any special equipment or accessories, and the necessary precautions to be taken; (i) an indication that the machinery may be subject to national requirements for regular inspection by designated bodies, as provided for in Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides [(1)]; _____ (1) OJ L 309, 24.11.2009, p. 71. (j) the features of the machinery which must be inspected to ensure its correct functioning; (k) instructions for connecting the necessary measuring instruments.	
3. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY OR RELATED PRODUCTS	**3. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO THE MOBILITY OF MACHINERY**	
Machinery or related products presenting risks due to its mobility shall meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).	Machinery presenting hazards due to its mobility must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).	

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Annex III Regulation	Annex I Directive	Comments
3.1. GENERAL	**3.1. GENERAL**	
3.1.1. For the purposes of this section, the following definitions apply: (a) 'Machinery or related products presenting risks due to its mobility' means (i) machinery or related products, the operation of which requires either mobility while working, or continuous or semi continuous movement between a succession of fixed working locations; or (ii) machinery or related products which are operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another. (b) 'Driver' means an operator responsible for the movement of a machinery or related product, who may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control (c) 'Autonomous mobile machinery' means mobile machinery which has an autonomous mode, in which all the essential safety functions of the mobile machinery are ensured in its travel and working operations area without permanent interaction of an operator; (d) 'Supervisor' means a person responsible for the supervision of autonomous mobile machinery. (e) 'Supervisory function' means remote non-permanent surveillance of autonomous mobile machinery by a device allowing to receive information or alerts and to give limited orders to this machinery.	3.1.1. **Definitions** (a) 'Machinery presenting hazards due to its mobility' means — machinery the operation of which requires either mobility while working, or continuous or semi-continuous movement between a succession of fixed working locations, or — machinery which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another. (b) 'Driver' means an operator responsible for the movement of a machine. The driver may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control.	

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Annex III Regulation	Annex I Directive	Comments
3.2. WORK POSITIONS	**3.2. WORK POSITIONS**	
3.2.1. **Driving position** Visibility from the driving position shall be such that the driver can, in complete safety for himself or herself and the exposed persons operate the machinery or related product and its tools in their foreseeable conditions of use. Where necessary, appropriate devices shall be provided to remedy risks due to inadequate direct vision. Machinery or related product on which the driver is transported shall be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks. The driving position of ride-on drivers shall be designed and constructed in such a way that a driver's cab may be fitted, provided this does not increase the risk and there is room for it. The cab shall incorporate a place for the instructions needed for the driver.	3.2.1. **Driving position** Visibility from the driving position must be such that the driver can, in complete safety for himself and the exposed persons, operate the machinery and its tools in their foreseeable conditions of use. Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision. Machinery on which the driver is transported must be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks. The driving position of ride-on drivers must be designed and constructed in such a way that a driver's cab may be fitted, provided this does not increase the risk and there is room for it. The cab must incorporate a place for the instructions needed for the driver.	
3.2.2. **Seating** Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the surroundings should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4: (a) the machinery shall be designed or equipped with a restraint system so as to keep the persons in their seats or in the protective structure, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Where there is a significant risk of roll or tip over and its restraint system is not used it shall not be possible for the machinery to move. Such restraint systems or provision shall take ergonomic principles into account and shall not be fitted if they increase the risk.	3.2.2. **Seating** Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the ground should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4, their seats must be designed or equipped with a restraint system so as to keep the persons in their seats, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems should not be fitted if they increase the risk.	

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(b) a visual and audible signal shall be provided at the driving position alerting the driver when the driver is in the driving position and not using the restraint system.		
3.2.3. **Positions for other persons** If the conditions of use provide that persons other than the driver may occasionally or regularly be transported by the machinery or work on it, appropriate positions shall be provided which enable them to be transported or to work on it without risk. The second and third subparagraphs of section 3.2.1 also apply to the places provided for persons other than the driver.	3.2.3. **Positions for other persons** If the conditions of use provide that persons other than the driver may occasionally or regularly be transported by the machinery or work on it, appropriate positions must be provided which enable them to be transported or to work on it without risk. The second and third paragraphs of section 3.2.1 also apply to the places provided for persons other than the driver.	
3.2.4. **Supervisory function** Where relevant, autonomous mobile machinery or related products shall have a supervisory function specific to the autonomous mode. This function shall allow the supervisor to remotely receive information from the machinery. The supervisory function shall only allow actions to stop and to start remotely the machinery or related product or move it to a safe position and a safe state to avoid causing other risks. It shall be designed and constructed to allow those actions only when the supervisor can see directly or indirectly the machine's movement and working area and the protective devices are operational. The information the supervisor receives from the machinery when the supervisory function is active shall enable the supervisor to have a complete and accurate view of the operation, movement and safe positioning of the machinery in its travel and working area. This information shall alert the supervisor of the occurrence of unforeseen or dangerous situations present or impending, which require the intervention of the supervisor. If the supervisory function is not active, the machinery shall not be able to operate.		

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Annex III Regulation	Annex I Directive	Comments
3.3. CONTROL SYSTEMS	**3.3. CONTROL SYSTEMS**	
If necessary, steps shall be taken to prevent unauthorised use of controls. In the case of remote controls, each control unit shall clearly identify the machinery or related product to be controlled from that unit. The remote-control system shall be designed and constructed in such a way as to affect only: (a) the machinery or related product in question; (b) the functions in question. Remote controlled machinery or related products shall be designed and constructed in such a way that it will respond only to signals from the intended control units. For autonomous mobile machinery or related product, the control system shall be designed to perform the safety functions by itself as set out in this section, even when actions are ordered by using a remote supervisory function.	If necessary, steps must be taken to prevent unauthorised use of controls. In the case of remote controls, each control unit must clearly identify the machinery to be controlled from that unit. The remote-control system must be designed and constructed in such a way as to affect only: — the machinery in question, — the functions in question. Remote controlled machinery must be designed and constructed in such a way that it will respond only to signals from the intended control units.	
3.3.1. **Control devices** The driver shall be able to actuate all control devices required to operate the machinery or related product from the driving position, except for functions, which can be safely actuated only by using control devices located elsewhere. These functions include, in particular, those for which operators other than the driver are responsible or for which the driver has to leave the driving position in order to control them safely. Where there are pedals, they shall be so designed, constructed and fitted as to allow safe operation by the driver with the minimum risk of incorrect operation. They shall have a slip-resistant surface and be easy to clean.	3.3.1. **Control devices** The driver must be able to actuate all control devices required to operate the machinery from the driving position, except for functions which can be safely actuated only by using control devices located elsewhere. These functions include, in particular, those for which operators other than the driver are responsible or for which the driver has to leave the driving position in order to control them safely. Where there are pedals, they must be so designed, constructed and fitted as to allow safe operation by the driver with the minimum risk of incorrect operation. They must have a slip-resistant surface and be easy to clean.	

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Where their operation can lead to hazards, notably dangerous movements, the control devices, except for those with pre-set positions, shall return to the neutral position as soon as they are released by the operator. In the case of wheeled machinery, the steering system shall be designed and constructed in such a way as to reduce the force of sudden movements of the steering wheel or the steering lever caused by shocks to the guide wheels. Any control that locks the differential shall be so designed and arranged that it allows the differential to be unlocked when the machinery is moving. The sixth paragraph of section 1.2.2, concerning acoustic and/or visual warning signals, applies only in the case of reversing.	Where their operation can lead to hazards, notably dangerous movements, the control devices, except for those with preset positions, must return to the neutral position as soon as they are released by the operator. In the case of wheeled machinery, the steering system must be designed and constructed in such a way as to reduce the force of sudden movements of the steering wheel or the steering lever caused by shocks to the guide wheels. Any control that locks the differential must be so designed and arranged that it allows the differential to be unlocked when the machinery is moving. The sixth paragraph of section 1.2.2, concerning acoustic and/or visual warning signals, applies only in the case of reversing.	
3.3.2. **Starting/moving** All travel movements of self-propelled machinery with a ride-on driver shall be possible only if the driver is at the controls. Where, for operating purposes, machinery is fitted with devices which exceed its normal clearance zone (e.g., stabilisers, jib, etc.), the driver shall be provided with the means of checking easily, before moving the machinery, that such devices are in a particular position which allows safe movement. This also applies to all other parts which; to allow safe movement, have to be in particular positions, locked if necessary. Where it does not give rise to other risks, movement of the machinery shall depend on safe positioning of the aforementioned parts. It shall not be possible for unintentional movement of the machinery to occur while the engine is being started. The movement of an autonomous mobile machinery shall take into account the risks related to the area where it is intended to move and work.	3.3.2. **Starting/moving** All travel movements of self-propelled machinery with a ride-on driver must be possible only if the driver is at the controls. Where, for operating purposes, machinery is fitted with devices which exceed its normal clearance zone (e.g., stabilisers, jib, etc.), the driver must be provided with the means of checking easily, before moving the machinery, that such devices are in a particular position which allows safe movement. This also applies to all other parts which, to allow safe movement, have to be in particular positions, locked if necessary. Where it does not give rise to other risks, movement of the machinery must depend on safe positioning of the aforementioned parts. It must not be possible for unintentional movement of the machinery to occur while the engine is being started.	

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3.3.3. **Travelling function**	3.3.3. **Travelling function**	
Without prejudice to road traffic regulations, self-propelled machinery and its trailers shall meet the requirements for slowing down, stopping, braking and immobilisation so as to ensure safety under all the operating, load, speed, ground and gradient conditions allowed for.	Without prejudice to road traffic regulations, self-propelled machinery and its trailers must meet the requirements for slowing down, stopping, braking and immobilisation so as to ensure safety under all the operating, load, speed, ground and gradient conditions allowed for.	
The driver shall be able to slow down and stop self-propelled machinery by means of a main device. Where safety so requires, in the event of a failure of the main device, or in the absence of the energy supply needed to actuate the main device, an emergency device with a fully independent and easily accessible control device shall be provided for slowing down and stopping.	The driver must be able to slow down and stop self-propelled machinery by means of a main device. Where safety so requires, in the event of a failure of the main device, or in the absence of the energy supply needed to actuate the main device, an emergency device with a fully independent and easily accessible control device must be provided for slowing down and stopping.	
Where safety so requires, a parking device shall be provided to render stationary machinery immobile. This device may be combined with one of the devices referred to in the second paragraph, if it is purely mechanical.	Where safety so requires, a parking device must be provided to render stationary machinery immobile. This device may be combined with one of the devices referred to in the second paragraph, provided that it is purely mechanical.	
Remote-controlled machinery shall be equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations: (a) if the driver loses control; (b) if it receives a stop signal; (c) if a fault is detected in a safety-related part of the system; (d) if no validation signal is detected within a specified time.	Remote-controlled machinery must be equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations: — if the driver loses control, — if it receives a stop signal, — if a fault is detected in a safety-related part of the system, — if no validation signal is detected within a specified time.	
Section 1.2.4 does not apply to the travelling function.	Section 1.2.4 does not apply to the travelling function.	
Autonomous mobile machinery or related products shall comply, with one or both where necessary according to the risk assessment, of the following conditions: (i) it shall move and operate in an enclosed zone fitted with a peripheral protection system comprising guards or protective devices;		

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(ii) it shall be equipped with devices intended to detect any human, domestic animal or any other obstacle in its vicinity, where those obstacles could give rise to a risk to health and safety of persons or of domestic animals or to safe operation of the machinery or related product. The movements of mobile machinery or related product connected with one or more trailers or towed equipment, including autonomous mobile machinery or related product, connected with one or more trailers or towed equipment, shall not give rise to risks for persons, domestic animals or any other obstacle in the danger zone of such machinery or related product and trailers or towed equipment.		
3.3.4. **Movement of pedestrian-controlled machinery** Movement of pedestrian-controlled self-propelled machinery shall be possible only through sustained action on the relevant control device by the driver. In particular, it shall not be possible for movement to occur while the engine is being started. The control systems for pedestrian-controlled machinery shall be designed in such a way as to minimise the risks arising from inadvertent movement of the machine towards the driver, in particular: (a) Crushing; (b) injury from rotating tools. The speed of travel of the machinery shall be compatible with the pace of a driver on foot. In the case of machinery on which a rotary tool may be fitted, it shall not be possible to actuate the tool when the reverse control is engaged, except where the movement of the machinery results from movement of the tool. In the latter case, the reversing speed shall be such that it does not endanger the driver.	3.3.4. **Movement of pedestrian-controlled machinery** Movement of pedestrian-controlled self-propelled machinery must be possible only through sustained action on the relevant control device by the driver. In particular, it must not be possible for movement to occur while the engine is being started. The control systems for pedestrian-controlled machinery must be designed in such a way as to minimise the risks arising from inadvertent movement of the machine towards the driver, in particular: — crushing, — injury from rotating tools. The speed of travel of the machinery must be compatible with the pace of a driver on foot. In the case of machinery on which a rotary tool may be fitted, it must not be possible to actuate the tool when the reverse control is engaged, except where the movement of the machinery results from movement of the tool. In the latter case, the reversing speed must be such that it does not endanger the driver.	

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3.3.5. **Control circuit failure** A failure in the power supply to the power-assisted steering, where fitted, shall not prevent machinery from being steered during the time required to stop it. For autonomous mobile machinery, a failure in the steering system shall not have an impact on the safety of the machinery.	3.3.5. **Control circuit failure** A failure in the power supply to the power-assisted steering, where fitted, must not prevent machinery from being steered during the time required to stop it.	
3.4. PROTECTION AGAINST MECHANICAL RISKS	**3.4. PROTECTION AGAINST MECHANICAL HAZARDS**	
3.4.1. **Uncontrolled movements** Machinery or related products shall be designed, constructed and where appropriate placed on its mobile support in such a way as to ensure that, when moved, uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.	3.4.1. **Uncontrolled movements** Machinery must be designed, constructed and where appropriate placed on its mobile support in such a way as to ensure that, when moved, uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.	
3.4.2. **Moving transmission parts** By way of exception to section 1.3.8.1, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access.	3.4.2. **Moving transmission parts** By way of exception to section 1.3.8.1, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access.	
3.4.3. **Roll-over and tip-over** Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery shall be fitted with an appropriate protective structure, unless this increases the risk. This structure shall be such that in the event of rolling or tipping over it affords the ride-on person(s) an adequate deflection-limiting volume.	3.4.3. **Roll-over and tip-over** Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery must be fitted with an appropriate protective structure, unless this increases the risk. This structure must be such that in the event of rolling or tipping over it affords the ride-on person(s) an adequate deflection-limiting volume.	

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In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer shall, for each type of structure concerned, perform appropriate tests or have such tests performed.	In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.	
3.4.4. **Falling objects** Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk due to falling objects or material, the machinery shall be designed and constructed in such a way as to take account of this risk and fitted, if its size allows, with an appropriate protective structure. This structure shall be such that, in the event of falling objects or material, it guarantees the ride-on person(s) an adequate deflection-limiting volume. In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer shall, for each type of structure concerned, perform appropriate tests or have such tests performed.	3.4.4. **Falling objects** Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk due to falling objects or material, the machinery must be designed and constructed in such a way as to take account of this risk and fitted, if its size allows, with an appropriate protective structure. This structure must be such that, in the event of falling objects or material, it guarantees the ride-on person(s) an adequate deflection-limiting volume. In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.	
3.4.5. **Means of access** Handholds and steps shall be designed, constructed and arranged in such a way that the operators use them instinctively and do not use the control devices to assist access.	3.4.5. **Means of access** Handholds and steps must be designed, constructed and arranged in such a way that the operators use them instinctively and do not use the control devices to assist access.	
3.4.6. **Towing devices** All machinery used to tow or to be towed shall be fitted with towing or coupling devices designed, constructed and arranged in such a way as to ensure easy and secure connection and disconnection and to prevent accidental disconnection during use. Insofar as the tow bar load so requires, such machinery shall be equipped with a support with a bearing surface suited to the load and the ground.	3.4.6. **Towing devices** All machinery used to tow or to be towed must be fitted with towing or coupling devices designed, constructed and arranged in such a way as to ensure easy and secure connection and disconnection and to prevent accidental disconnection during use. Insofar as the tow bar load so requires, such machinery must be equipped with a support with a bearing surface suited to the load and the ground.	

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3.4.7. **Transmission of power between self-propelled machinery (or tractor) and recipient machinery** Removable mechanical transmission devices linking self-propelled machinery (or a tractor) to the first fixed bearing of recipient machinery shall be designed and constructed in such a way that any part that moves during operation is protected over its whole length. On the side of the self-propelled machinery (or tractor), the power take-off to which the removable mechanical transmission device is attached shall be protected either by a guard fixed and linked to the self-propelled machinery (or tractor) or by any other device offering equivalent protection. It shall be possible to open this guard for access to the removable transmission device. Once it is in place, there shall be enough room to prevent the drive shaft damaging the guard when the machinery (or the tractor) is moving. On the recipient machinery side, the input shaft shall be enclosed in a protective casing fixed to the machinery. Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machinery. The removable mechanical transmission device shall be marked accordingly. All recipient machinery, the operation of which requires a removable mechanical transmission device to connect it to self-propelled machinery (or a tractor), shall have a system for attaching the removable mechanical transmission device so that, when the machinery is uncoupled, the removable mechanical transmission device and its guard are not damaged by contact with the ground or part of the machinery. The outside parts of the guard shall be so designed, constructed and arranged that they cannot turn with the removable mechanical transmission device. The guard shall cover the transmission to the ends of the inner jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in the case of wide-angle universal joints.	3.4.7. **Transmission of power between self-propelled machinery (or tractor) and recipient machinery** Removable mechanical transmission devices linking self-propelled machinery (or a tractor) to the first fixed bearing of recipient machinery must be designed and constructed in such a way that any part that moves during operation is protected over its whole length. On the side of the self-propelled machinery (or tractor), the power take-off to which the removable mechanical transmission device is attached must be protected either by a guard fixed and linked to the self-propelled machinery (or tractor) or by any other device offering equivalent protection. It must be possible to open this guard for access to the removable transmission device. Once it is in place, there must be enough room to prevent the drive shaft damaging the guard when the machinery (or the tractor) is moving. On the recipient machinery side, the input shaft must be enclosed in a protective casing fixed to the machinery. Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machinery. The removable mechanical transmission device must be marked accordingly. All recipient machinery, the operation of which requires a removable mechanical transmission device to connect it to self-propelled machinery (or a tractor), must have a system for attaching the removable mechanical transmission device so that, when the machinery is uncoupled, the removable mechanical transmission device and its guard are not damaged by contact with the ground or part of the machinery. The outside parts of the guard must be so designed, constructed and arranged that they cannot turn with the removable mechanical transmission device. The guard must cover the transmission to the ends of the inner jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in the case of wide-angle universal joints.	

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If means of access to working positions are provided near to the removable mechanical transmission device, they shall be designed and constructed in such a way that the shaft guards cannot be used as steps, unless designed and constructed for that purpose.	If means of access to working positions are provided near to the removable mechanical transmission device, they must be designed and constructed in such a way that the shaft guards cannot be used as steps, unless designed and constructed for that purpose.	
3.5. PROTECTION AGAINST OTHER RISKS	**3.5. PROTECTION AGAINST OTHER RISKS**	
3.5.1. **Batteries** The battery housing shall be designed and constructed in such a way as to prevent the electrolyte being ejected on to the operator in the event of rollover or tip over and to avoid the accumulation of vapours in places occupied by operators. Machinery or related product shall be designed and constructed in such a way that the battery can be disconnected with the aid of an easily accessible device provided for that purpose. The batteries with automatic charging for mobile machinery or related products, including autonomous mobile machinery or related products, shall be designed to prevent hazards referred to in sections 1.3.8.2. and 1.5.1., including the risks of contact or collision of the machinery or related product with a person or other machinery or related products when the machinery or related product moves autonomously to the charging station.	3.5.1. **Batteries** The battery housing must be designed and constructed in such a way as to prevent the electrolyte being ejected on to the operator in the event of rollover or tipover and to avoid the accumulation of vapours in places occupied by operators. Machinery must be designed and constructed in such a way that the battery can be disconnected with the aid of an easily accessible device provided for that purpose.	
3.5.2. **Fire** Depending on the hazards anticipated by the manufacturer, machinery shall, where its size permits: (a) either allow easily accessible fire extinguishers to be fitted, or (b) be provided with built-in extinguisher systems.	3.5.2. **Fire** Depending on the hazards anticipated by the manufacturer, machinery must, where its size permits: — either allow easily accessible fire extinguishers to be fitted, or — be provided with built-in extinguisher systems.	

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3.5.3. **Emissions of hazardous substances** The second and third paragraphs of section 1.5.13 do not apply where the main function of the machinery is the application of hazardous substances. However, the operator shall be protected against the risk of exposure to such hazardous emissions. Ride-on mobile machinery having application of hazardous substances as the main function shall be equipped with filtration cabs or equivalent safety measures.	3.5.3. **Emissions of hazardous substances** The second and third paragraphs of section 1.5.13 do not apply where the main function of the machinery is the spraying of products. However, the operator must be protected against the risk of exposure to such hazardous emissions.	
3.5.4. **Risk of contact with live overhead power lines** Depending on their height, mobile machinery or related products shall, where relevant, be designed, constructed and equipped, so as to prevent the risk of contact with an energised overhead power line or the risk of creating an electric arc between any part of the machinery or an operator driving the machinery and an energised overhead power line. When the risk to the persons operating machinery incurred by the contact with an energised overhead power line cannot be fully avoided, mobile machinery or related products shall be designed, constructed and equipped so as to prevent any electrical hazards.		
3.6. INFORMATION AND INDICATIONS	**3.6. INFORMATION AND INDICATIONS**	
3.6.1. **Signs, signals and warnings** All machinery or related products shall have signs and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, so as to ensure the health and safety of persons. They shall be chosen, designed and constructed in such a way as to be clearly visible and indelible. Without prejudice to the provisions of road traffic regulations, machinery or related products with a ride-on driver shall have the following equipment:	3.6.1. **Signs, signals and warnings** All machinery must have signs and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, so as to ensure the health and safety of persons. They must be chosen, designed and constructed in such a way as to be clearly visible and indelible. Without prejudice to the provisions of road traffic regulations, machinery with a ride-on driver must have the following equipment:	

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(a) an acoustic warning device to alert persons; (b) a system of light signals relevant to the intended conditions of use; the latter requirement does not apply to machinery or related products intended solely for underground working and having no electrical power; (c) where necessary, there shall be an appropriate connection between a trailer and the machinery or related product for the operation of signals. Remote-controlled machinery or related products which, under normal conditions of use, exposes persons to the risk of impact or crushing shall be fitted with appropriate means to signal its movements or with means to protect persons against such risks. The same applies to machinery or related products, which involves, when in use, the constant repetition of a forward and backward movement on a single axis where the area to the rear of the machine is not directly visible to the driver. Machinery or related products shall be constructed in such a way that the warning and signalling devices cannot be disabled unintentionally. Where it is essential for safety, such devices shall be provided with the means to check that they are in good working order and their failure shall be made apparent to the operator. Where the movement of machinery or its tools is particularly hazardous, signs on the machinery shall be provided to warn against approaching the machinery while it is working; the signs shall be legible at a sufficient distance to ensure the safety of persons who have to be in the vicinity.	— an acoustic warning device to alert persons, — a system of light signals relevant to the intended conditions of use; the latter requirement does not apply to machinery intended solely for underground working and having no electrical power, — where necessary, there must be an appropriate connection between a trailer and the machinery for the operation of signals. Remote-controlled machinery which, under normal conditions of use, exposes persons to the risk of impact or crushing must be fitted with appropriate means to signal its movements or with means to protect persons against such risks. The same applies to machinery which involves, when in use, the constant repetition of a forward and backward movement on a single axis where the area to the rear of the machine is not directly visible to the driver. Machinery must be constructed in such a way that the warning and signalling devices cannot be disabled unintentionally. Where it is essential for safety, such devices must be provided with the means to check that they are in good working order and their failure must be made apparent to the operator. Where the movement of machinery or its tools is particularly hazardous, signs on the machinery must be provided to warn against approaching the machinery while it is working; the signs must be legible at a sufficient distance to ensure the safety of persons who have to be in the vicinity.	
3.6.2. **Marking** (1) The following shall be shown legibly and indelibly on all machinery or related products: (a) nominal power expressed in kilowatts (kW); (b) mass of the most usual configuration, in kilograms (kg);	3.6.2. **Marking** The following must be shown legibly and indelibly on all machinery: — nominal power expressed in kilowatts (kW), — mass of the most usual configuration, in kilograms (kg);	

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(2) In addition, where appropriate, the following shall be shown legibly and indelibly on all machinery or related products: (a) maximum drawbar pull provided for at the coupling hook, in Newtons (N); (b) maximum vertical load provided for on the coupling hook, in Newtons (N).	and, where appropriate: — maximum drawbar pull provided for at the coupling hook, in Newtons (N), — maximum vertical load provided for on the coupling hook, in Newtons (N).	
3.6.3. **Instructions for use**	3.6.3. **Instructions**	
3.6.3.1. **Vibrations** The instructions for use shall give the following information concerning vibrations, expressed as acceleration (m/s2), transmitted by the machinery or related products to the hand-arm system or to the whole body: (a) the vibration total value from continuous vibrations to which the hand-arm system is subjected; (b) the mean value of the peak amplitude of the acceleration from repeated shock vibrations, to which the hand-arm system is subjected; (c) the highest root means square value of weighted acceleration to which the whole body is subjected, if it exceeds 0, 5 m/s2. Where this value does not exceed 0, 5 m/s2, this shall be mentioned; (d) the uncertainty of measurements. These values shall be either those actually measured for the machinery or related product in question or those established on the basis of measurements taken for technically comparable machinery or related products, which is representative of the machinery or related products to be produced.	3.6.3.1. **Vibrations** The instructions must give the following information concerning vibrations transmitted by the machinery to the hand-arm system or to the whole body: — the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s2. Where this value does not exceed 2,5 m/s2, this must be mentioned, — the highest root means square value of weighted acceleration to which the whole body is subjected, if it exceeds 0,5 m/s2. Where this value does not exceed 0,5 m/s2, this must be mentioned, — the uncertainty of measurement. These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.	

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Where harmonised standards or common specifications adopted by the Commission in accordance with Article 20(3) cannot be applied, the vibration shall be measured using the most appropriate measurement code for the machinery or related products concerned. The operating conditions during measurement and the measurement codes used shall be described.	Where harmonised standards are not applied, the vibration must be measured using the most appropriate measurement code for the machinery concerned. The operating conditions during measurement and the measurement codes used must be described.	
3.6.3.2. **Multiple uses** The instructions for use for machinery or related product allowing several uses depending on the equipment used and the instructions for use for the interchangeable equipment shall contain the information necessary for safe assembly and use of the basic machinery or related product and the interchangeable equipment that can be fitted.	The instructions for machinery allowing several uses depending on the equipment used and the instructions for the interchangeable equipment must contain the information necessary for safe assembly and use of the basic machinery and the interchangeable equipment that can be fitted.	
3.6.3.3. **Autonomous mobile machinery or related product** The instructions for use of autonomous mobile machinery or related products shall specify the characteristics of its intended travel, working areas and danger zones.		
4. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS	**4. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS**	
Machinery or related product presenting hazards due to lifting operations shall meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).	Machinery presenting hazards due to lifting operations must meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).	
4.1. GENERAL	**4.1. GENERAL**	

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4.1.1. **For the purposes of section 4.1., the following definitions apply:** (a) 'Lifting operation' means a movement of unit loads consisting of goods and/or persons necessitating, at a given moment, a change of level; (b) 'Guided load' means a load where the total movement is made along rigid or flexible guides whose position is determined by fixed points; (c) 'Working coefficient' means the arithmetic ratio between the load guaranteed by the manufacturer up to which a component is able to hold it and the maximum working load marked on the component; (d) 'Test coefficient' means the arithmetic ratio between the load used to carry out the static or dynamic tests on the machinery or related product or lifting accessory and the maximum working load marked on the lifting machinery or lifting accessory; (e) 'Static test' means the test during which machinery or lifting accessory is first inspected and subjected to a force corresponding to the maximum working load multiplied by the appropriate static test coefficient and then re-inspected once the said load has been released to ensure that no damage has occurred; (f) 'Dynamic test' means the test during which lifting machinery is operated in all its possible configurations at the maximum working load multiplied by the appropriate dynamic test coefficient with account being taken of the dynamic behaviour of the lifting machinery in order to check that it functions properly; (g) 'Carrier' means a part of the machinery or related product on or in which persons and/or goods are supported in order to be lifted.	4.1.1. **Definitions** (a) 'Lifting operation' means a movement of unit loads consisting of goods and/or persons necessitating, at a given moment, a change of level. (b) 'Guided load' means a load where the total movement is made along rigid or flexible guides whose position is determined by fixed points. (c) 'Working coefficient' means the arithmetic ratio between the load guaranteed by the manufacturer or his authorised representative up to which a component is able to hold it and the maximum working load marked on the component. (d) 'Test coefficient' means the arithmetic ratio between the load used to carry out the static or dynamic tests on lifting machinery or a lifting accessory and the maximum working load marked on the lifting machinery or lifting accessory. (e) 'Static test' means the test during which lifting machinery or a lifting accessory is first inspected and subjected to a force corresponding to the maximum working load multiplied by the appropriate static test coefficient and then re-inspected once the said load has been released to ensure that no damage has occurred. (f) 'Dynamic test' means the test during which lifting machinery is operated in all its possible configurations at the maximum working load multiplied by the appropriate dynamic test coefficient with account being taken of the dynamic behaviour of the lifting machinery in order to check that it functions properly. (g) 'Carrier' means a part of the machinery on or in which persons and/or goods are supported in order to be lifted.	
4.1.2. **Protection against mechanical risks**	4.1.2. **Protection against mechanical hazards**	

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4.1.2.1. **Risks due to lack of stability** Machinery or related products shall be designed and constructed in such a way that the stability required by section 1.3.1 is maintained both in service and out of service, including all stages of transportation, assembly and dismantling, during foreseeable component failures and also during the tests carried out in accordance with the instructions for use. To that end, the manufacturer shall use the appropriate verification methods.	4.1.2.1. **Risks due to lack of stability** Machinery must be designed and constructed in such a way that the stability required by section 1.3.1 is maintained both in service and out of service, including all stages of transportation, assembly and dismantling, during foreseeable component failures and also during the tests carried out in accordance with the instruction handbook. To that end, the manufacturer or his authorised representative must use the appropriate verification methods.	
4.1.2.2. **Machinery running on guide rails and rail tracks** Machinery or related products shall be provided with devices, which act on the guide rails or tracks to prevent derailment. If, despite such devices, there remains a risk of derailment or of failure of a rail or of a running component, devices shall be provided which prevent the equipment, component or load from falling or the machinery from overturning.	4.1.2.2. **Machinery running on guide rails and rail tracks** Machinery must be provided with devices which act on the guide rails or tracks to prevent derailment. If, despite such devices, there remains a risk of derailment or of failure of a rail or of a running component, devices must be provided which prevent the equipment, component or load from falling or the machinery from overturning.	
4.1.2.3. **Mechanical strength** Machinery or related products, including lifting accessories and their components shall be capable of withstanding the stresses to which they are subjected during their lifetime, both in and, where applicable, out of use, under the installation and operating conditions provided for and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons. This requirement shall also be satisfied during transport, assembly and dismantling. Machinery or related products, including lifting accessories shall be designed and constructed in such a way as to prevent failure from fatigue and wear, taking due account of their intended use and any reasonably foreseeable misuse.	4.1.2.3. **Mechanical strength** Machinery, lifting accessories and their components must be capable of withstanding the stresses to which they are subjected, both in and, where applicable, out of use, under the installation and operating conditions provided for and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons. This requirement must also be satisfied during transport, assembly and dismantling. Machinery and lifting accessories must be designed and constructed in such a way as to prevent failure from fatigue and wear, taking due account of their intended use.	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

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The materials used shall be chosen on the basis of the intended working environments, with particular regard to corrosion, abrasion, impacts, extreme temperatures, fatigue, brittleness, radiation and ageing.	The materials used must be chosen on the basis of the intended working environments, with particular regard to corrosion, abrasion, impacts, extreme temperatures, fatigue, brittleness and ageing.	
Machinery or related products, including lifting accessories shall be designed and constructed in such a way as to withstand the overload in the static tests without permanent deformation or patent defect. Strength calculations shall take account of the value of the static test coefficient chosen to guarantee an adequate level of safety. That coefficient has, as a general rule, the following values: (a) manually-operated machinery or related products, including lifting accessories: 1, 5; (b) other machinery or related products: 1,25.	Machinery and lifting accessories must be designed and constructed in such a way as to withstand the overload in the static tests without permanent deformation or patent defect. Strength calculations must take account of the value of the static test coefficient chosen to guarantee an adequate level of safety. That coefficient has, as a general rule, the following values: (a) manually-operated machinery and lifting accessories: 1,5; (b) other machinery: 1,25.	
Machinery or related products shall be designed and constructed in such a way as to undergo, without failure, the dynamic tests carried out using the maximum working load multiplied by the dynamic test coefficient. This dynamic test coefficient is chosen so as to guarantee an adequate level of safety: the coefficient is, as a general rule, equal to 1,1. As a general rule, the tests will be performed at the nominal speeds provided for. Should the control circuit of the machinery allow for a number of simultaneous movements, the tests shall be carried out under the least favourable conditions, as a general rule by combining the movements concerned.	Machinery must be designed and constructed in such a way as to undergo, without failure, the dynamic tests carried out using the maximum working load multiplied by the dynamic test coefficient. This dynamic test coefficient is chosen so as to guarantee an adequate level of safety: the coefficient is, as a general rule, equal to 1,1. As a general rule, the tests will be performed at the nominal speeds provided for. Should the control circuit of the machinery allow for a number of simultaneous movements, the tests must be carried out under the least favourable conditions, as a general rule by combining the movements concerned.	
4.1.2.4. **Pulleys, drums, wheels, ropes and chains** Pulleys, drums and wheels shall have a diameter commensurate with the size of the ropes or chains with which they can be fitted. Drums and wheels shall be designed, constructed and installed in such a way that the ropes or chains with which they are equipped can be wound without coming off.	4.1.2.4. **Pulleys, drums, wheels, ropes and chains** Pulleys, drums and wheels must have a diameter commensurate with the size of the ropes or chains with which they can be fitted. Drums and wheels must be designed, constructed and installed in such a way that the ropes or chains with which they are equipped can be wound without coming off.	

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Ropes used directly for lifting or supporting the load shall not include any splicing other than at their ends. Splicings are, however, tolerated in installations, which are intended by design to be modified regularly according to needs of use. Complete ropes and their endings shall have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 5. Lifting chains shall have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 4. In order to verify that an adequate working coefficient has been attained, the manufacturer shall, for each type of chain and rope used directly for lifting the load and for the rope ends, perform the appropriate tests or have such tests performed.	Ropes used directly for lifting or supporting the load must not include any splicing other than at their ends. Splicings are, however, tolerated in installations which are intended by design to be modified regularly according to needs of use. Complete ropes and their endings must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 5. Lifting chains must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 4. In order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of chain and rope used directly for lifting the load and for the rope ends, perform the appropriate tests or have such tests performed.	
4.1.2.5. **Lifting accessories and their components** Lifting accessories and their components shall be sized with due regard to fatigue and ageing processes for a number of operating cycles consistent with their expected life-span as specified in the operating conditions for a given application. Moreover: (a) the working coefficient of wire-rope/rope-end combinations shall be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 5. Ropes shall not comprise any splices or loops other than at their ends; (b) where chains with welded links are used, they shall be of the short-link type. The working coefficient of chains shall be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;	4.1.2.5. **Lifting accessories and their components** Lifting accessories and their components must be sized with due regard to fatigue and ageing processes for a number of operating cycles consistent with their expected life-span as specified in the operating conditions for a given application. Moreover: (a) the working coefficient of wire-rope/rope-end combinations must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 5. Ropes must not comprise any splices or loops other than at their ends; (b) where chains with welded links are used, they must be of the short-link type. The working coefficient of chains must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;	

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(c) the working coefficient for textile ropes, slings or webbing is dependent on the material, method of manufacture, dimensions and use. This coefficient shall be chosen in such a way as to guarantee an adequate level of safety; it is, as a general rule, equal to 7, provided the materials used are shown to be of very good quality and the method of manufacture is appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety. Textile ropes, slings or webbings shall not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling; (d) all metallic components making up, or used with, a sling shall have a working coefficient chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4; (e) the maximum working load of a multilegged sling is determined on the basis of the working coefficient of the weakest leg, the number of legs and a reduction factor which depends on the slinging configuration; (f) in order to verify that an adequate working coefficient has been attained, the manufacturer shall, for each type of component referred to in (a) to (d), perform the appropriate tests or have such tests performed.	(c) the working coefficient for textile ropes or slings is dependent on the material, method of manufacture, dimensions and use. This coefficient must be chosen in such a way as to guarantee an adequate level of safety; it is, as a general rule, equal to 7, provided the materials used are shown to be of very good quality and the method of manufacture is appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety. Textile ropes and slings must not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling; (d) all metallic components making up, or used with, a sling must have a working coefficient chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4; (e) the maximum working load of a multilegged sling is determined on the basis of the working coefficient of the weakest leg, the number of legs and a reduction factor which depends on the slinging configuration; (f) in order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of component referred to in (a), (b), (c) and (d), perform the appropriate tests or have such tests performed.	
4.1.2.6. **Control of movements** Devices for controlling movements shall act in such a way that the machinery or related product on which they are installed is kept safe. (a) Machinery or related products shall be designed and constructed or fitted with devices in such a way that the amplitude of movement of its components is kept within the specified limits. The operation of such devices shall, where appropriate, be preceded by a warning.	4.1.2.6. **Control of movements** Devices for controlling movements must act in such a way that the machinery on which they are installed is kept safe. (a) Machinery must be designed and constructed or fitted with devices in such a way that the amplitude of movement of its components is kept within the specified limits. The operation of such devices must, where appropriate, be preceded by a warning.	

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(b) Where several fixed or rail-mounted machinery or related products can be manoeuvred simultaneously in the same place, with risks of collision, such machinery shall be designed and constructed in such a way as to make it possible to fit systems enabling these risks to be avoided. (c) Machinery or related products shall be designed and constructed in such a way that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine. (d) It shall not be possible, under normal operating conditions, to lower the load solely by friction brake, except in the case of machinery or related products whose function requires it to operate in that way. (e) Holding devices shall be designed and constructed in such a way that inadvertent dropping of the loads is avoided.	(b) Where several fixed or rail-mounted machines can be manoeuvred simultaneously in the same place, with risks of collision, such machinery must be designed and constructed in such a way as to make it possible to fit systems enabling these risks to be avoided. (c) Machinery must be designed and constructed in such a way that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine. (d) It must not be possible, under normal operating conditions, to lower the load solely by friction brake, except in the case of machinery whose function requires it to operate in that way. (e) Holding devices must be designed and constructed in such a way that inadvertent dropping of the loads is avoided.	
4.1.2.7. **Movements of loads during handling** The operating position of machinery shall be located in such a way as to ensure the widest possible view of trajectories of the moving parts, in order to avoid possible collisions with persons, equipment or other machinery, which might be manoeuvring at the same time and liable to constitute a hazard. Machinery with guided loads shall be designed and constructed in such a way as to prevent persons from being injured by movement of the load, the carrier or the counterweights, if any.	4.1.2.7. **Movements of loads during handling** The operating position of machinery must be located in such a way as to ensure the widest possible view of trajectories of the moving parts, in order to avoid possible collisions with persons, equipment or other machinery which might be manoeuvring at the same time and liable to constitute a hazard. Machinery with guided loads must be designed and constructed in such a way as to prevent persons from being injured by movement of the load, the carrier or the counterweights, if any.	
4.1.2.8. **Machinery serving fixed landings**	4.1.2.8. **Machinery serving fixed landings**	

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4.1.2.8.1. **Movements of the carrier** The movement of the carrier of machinery serving fixed landings shall be rigidly guided to and at the landings. Scissor systems are also regarded as rigid guidance.	4.1.2.8.1. **Movements of the carrier** The movement of the carrier of machinery serving fixed landings must be rigidly guided to and at the landings. Scissor systems are also regarded as rigid guidance.	
4.1.2.8.2. **Access to the carrier** Where persons have access to the carrier, the machinery shall be designed and constructed in such a way as to ensure that the carrier remains stationary during access, in particular while it is being loaded or unloaded. The machinery shall be designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.	4.1.2.8.2. **Access to the carrier** Where persons have access to the carrier, the machinery must be designed and constructed in such a way as to ensure that the carrier remains stationary during access, in particular while it is being loaded or unloaded. The machinery must be designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.	
4.1.2.8.3. **Risks due to contact with the moving carrier** Where necessary in order to fulfil the requirement expressed in the second paragraph of section 4.1.2.7, the travel zone shall be rendered inaccessible during normal operation. When, during inspection or maintenance, there is a risk that persons situated under or above the carrier may be crushed between the carrier and any fixed parts, sufficient free space shall be provided either by means of physical refuges or by means of mechanical devices blocking the movement of the carrier.	4.1.2.8.3. **Risks due to contact with the moving carrier** Where necessary in order to fulfil the requirement expressed in the second paragraph of section 4.1.2.7, the travel zone must be rendered inaccessible during normal operation. When, during inspection or maintenance, there is a risk that persons situated under or above the carrier may be crushed between the carrier and any fixed parts, sufficient free space must be provided either by means of physical refuges or by means of mechanical devices blocking the movement of the carrier.	
4.1.2.8.4. **Risk due to the load falling off the carrier** Where there is a risk due to the load falling off the carrier, the machinery shall be designed and constructed in such a way as to prevent this risk.	4.1.2.8.4. **Risk due to the load falling off the carrier** Where there is a risk due to the load falling off the carrier, the machinery must be designed and constructed in such a way as to prevent this risk.	

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4.1.2.8.5. **Landings** Risks due to contact of persons at landings with the moving carrier or other moving parts shall be prevented. Where there is a risk due to persons falling into the travel zone when the carrier is not present at the landings, guards shall be fitted in order to prevent this risk. Such guards shall not open in the direction of the travel zone. They shall be fitted with an interlocking device with guard locking controlled by the position of the carrier that prevents: (a) hazardous movements of the carrier until the guards are closed and locked; (b) hazardous opening of a guard until the carrier has stopped at the corresponding landing.	4.1.2.8.5. **Landings** Risks due to contact of persons at landings with the moving carrier or other moving parts must be prevented. Where there is a risk due to persons falling into the travel zone when the carrier is not present at the landings, guards must be fitted in order to prevent this risk. Such guards must not open in the direction of the travel zone. They must be fitted with an interlocking device controlled by the position of the carrier that prevents: — hazardous movements of the carrier until the guards are closed and locked, — hazardous opening of a guard until the carrier has stopped at the corresponding landing.	
4.1.3. **Fitness for purpose** When lifting machinery or related products, including lifting accessories, are placed on the market or are first put into service, the manufacturer shall ensure, by taking appropriate measures or having them taken, that the machinery or related products, including lifting accessories, which are ready for use — whether manually or power-operated — can fulfil their specified functions safely. The static and dynamic tests referred to in section 4.1.2.3 shall be performed on all lifting machinery or related products ready to be put into service. Where the machinery or related products cannot be assembled in the manufacturer's premises, the appropriate measures shall be taken at the place of use by the manufacturer. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.	4.1.3. **Fitness for purpose** When lifting machinery or lifting accessories are placed on the market or are first put into service, the manufacturer or his authorised representative must ensure, by taking appropriate measures or having them taken, that the machinery or the lifting accessories which are ready for use — whether manually or power-operated — can fulfil their specified functions safely. The static and dynamic tests referred to in section 4.1.2.3 must be performed on all lifting machinery ready to be put into service. Where the machinery cannot be assembled in the manufacturer's premises or in the premises of his authorised representative, the appropriate measures must be taken at the place of use. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.	
4.2. REQUIREMENTS FOR MACHINERY OR RELATED PRODUCTS WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT	**4.2. REQUIREMENTS FOR MACHINERY WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT**	

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4.2.1. **Control of movements** Hold-to-run control devices shall be used to control the movements of the machinery or related product or their equipment. However, for partial or complete movements in which there is no risk of the load or the machinery or related product colliding, the said devices may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.	4.2.1. **Control of movements** Hold-to-run control devices must be used to control the movements of the machinery or its equipment. However, for partial or complete movements in which there is no risk of the load or the machinery colliding, the said devices may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.	
4.2.2. **Loading control** Machinery or related product with a maximum working load of not less than 1 000 kg or an overturning moment of not less than 40 000 Nm shall be fitted with devices to warn the driver and prevent dangerous movements in the event: (a) of overloading, either as a result of the maximum working load or the maximum working moment due to the load being exceeded, or (b) of the overturning moment being exceeded.	4.2.2. **Loading control** Machinery with a maximum working load of not less than 1 000 kilograms or an overturning moment of not less than 40 000 Nm must be fitted with devices to warn the driver and prevent dangerous movements in the event: — of overloading, either as a result of the maximum working load or the maximum working moment due to the load being exceeded, or — of the overturning moment being exceeded.	
4.2.3. **Installations guided by ropes** Rope carriers, tractors or tractor carriers shall be held by counterweights or by a device allowing permanent control of the tension.	4.2.3. **Installations guided by ropes** Rope carriers, tractors or tractor carriers must be held by counterweights or by a device allowing permanent control of the tension.	
4.3. INFORMATION AND MARKINGS	**4.3. INFORMATION AND MARKINGS**	
4.3.1. **Chains, ropes and webbing** Each length of lifting chain, rope or webbing not forming part of an assembly shall bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer and the identifying reference of the relevant certificate. The certificate mentioned above shall show at least the following information:	4.3.1. **Chains, ropes and webbing** Each length of lifting chain, rope or webbing not forming part of an assembly must bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer or his authorised representative and the identifying reference of the relevant certificate. The certificate mentioned above must show at least the following information:	

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(a) the name and address of the manufacturer; (b) a description of the chain or rope, which includes: (i) its nominal size, (ii) its construction, (iii) the material from which it is made, and (iv) any special metallurgical treatment applied to the material; (c) the test method used; (d) the maximum load to which the chain or rope should be subjected in service. A range of values may be given on the basis of the intended applications.	(a) the name and address of the manufacturer and, if appropriate, his authorised representative; (b) a description of the chain or rope which includes: — its nominal size, — its construction, — the material from which it is made, and — any special metallurgical treatment applied to the material; (c) the test method used; (d) the maximum load to which the chain or rope should be subjected in service. A range of values may be given on the basis of the intended applications.	
4.3.2. **Lifting accessories** Lifting accessories shall show the following particulars: (a) identification of the material where this information is needed for safe use; (b) the maximum working load. In the case of lifting accessories on which marking is physically impossible, the particulars referred to in the first paragraph shall be displayed on a plate or other equivalent means and securely affixed to the accessory. The particulars shall be legible and located in a place where they are not liable to disappear as a result of wear or jeopardise the strength of the accessory.	4.3.2. **Lifting accessories** Lifting accessories must show the following particulars: — identification of the material where this information is needed for safe use, — the maximum working load. In the case of lifting accessories on which marking is physically impossible, the particulars referred to in the first paragraph must be displayed on a plate or other equivalent means and securely affixed to the accessory. The particulars must be legible and located in a place where they are not liable to disappear as a result of wear or jeopardise the strength of the accessory.	
4.3.3. **Lifting machinery or related products** The maximum working load shall be prominently marked on the lifting machinery or related product. This marking shall be legible, indelible and in an un-coded form.	4.3.3. **Lifting machinery** The maximum working load must be prominently marked on the machinery. This marking must be legible, indelible and in an un-coded form.	

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Where the maximum working load depends on the configuration of the lifting machinery or related product, each operating position shall be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the working load permitted for each configuration. Machinery or related product intended for lifting goods only, equipped with a carrier, which allows access to persons, shall bear a clear and indelible warning prohibiting the lifting of persons. This warning shall be visible at each place where access is possible.	Where the maximum working load depends on the configuration of the machinery, each operating position must be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the working load permitted for each configuration. Machinery intended for lifting goods only, equipped with a carrier which allows access to persons, must bear a clear and indelible warning prohibiting the lifting of persons. This warning must be visible at each place where access is possible.	
4.4. INSTRUCTIONS FOR USE	**4.4. INSTRUCTIONS**	
4.4.1. **Lifting accessories** Each lifting accessory or each commercially indivisible batch of lifting accessories shall be accompanied by instructions setting out at least the following particulars: (a) the intended use; (b) the limits of use (particularly for lifting accessories such as magnetic or vacuum pads which do not fully comply with section 4.1.2.6(e)); (c) instructions for assembly, use and maintenance; (d) the static test coefficient used.	4.4.1. **Lifting accessories** Each lifting accessory or each commercially indivisible batch of lifting accessories must be accompanied by instructions setting out at least the following particulars: (a) the intended use; (b) the limits of use (particularly for lifting accessories such as magnetic or vacuum pads which do not fully comply with section 4.1.2.6(e)); (c) instructions for assembly, use and maintenance; (d) the static test coefficient used.	
4.4.2. **Lifting machinery or related products** Lifting machinery or related products shall be accompanied by instructions for use containing information on: (a) the technical characteristics of the lifting machinery or related product, and in particular: (i) the maximum working load and, where appropriate, a copy of the load plate or load table described in the second paragraph of section 4.3.3,	4.4.2. **Lifting machinery** Lifting machinery must be accompanied by instructions containing information on: (a) the technical characteristics of the machinery, and in particular: — the maximum working load and, where appropriate, a copy of the load plate or load table described in the second paragraph of section 4.3.3,	

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(ii) the reactions at the supports or anchors and, where appropriate, characteristics of the tracks, (iii) where appropriate, the definition and the means of installation of the ballast; (b) the contents of the logbook, if the latter is not supplied with the lifting machinery; (c) advice for use, particularly to offset the lack of direct vision of the load by the operator; (d) where appropriate, a test report detailing the static and dynamic tests carried out by or for the manufacturer; (e) for lifting machinery or related products, which is not assembled on the premises of the manufacturer in the form in which it is to be used, the necessary instructions for performing the measures referred to in section 4.1.3 before they are first put into service.	— the reactions at the supports or anchors and, where appropriate, characteristics of the tracks, — where appropriate, the definition and the means of installation of the ballast; (b) the contents of the logbook, if the latter is not supplied with the machinery; (c) advice for use, particularly to offset the lack of direct vision of the load by the operator; (d) where appropriate, a test report detailing the static and dynamic tests carried out by or for the manufacturer or his authorised representative; (e) for machinery which is not assembled on the premises of the manufacturer in the form in which it is to be used, the necessary instructions for performing the measures referred to in section 4.1.3 before it is first put into service.	
5. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY OR RELATED PRODUCTS INTENDED FOR UNDERGROUND WORK	**5. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY INTENDED FOR UNDERGROUND WORK**	
Machinery or related products intended for underground work shall meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).	Machinery intended for underground work must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).	
5.1. RISKS DUE TO LACK OF STABILITY Powered roof supports shall be designed and constructed in such a way as to maintain a given direction when moving and not slip before and while they come under load and after the load has been removed. They shall be equipped with anchorages for the top plates of the individual hydraulic props.	**5.1. RISKS DUE TO LACK OF STABILITY** Powered roof supports must be designed and constructed in such a way as to maintain a given direction when moving and not slip before and while they come under load and after the load has been removed. They must be equipped with anchorages for the top plates of the individual hydraulic props.	

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5.2. MOVEMENT Powered roof supports shall allow for unhindered movement of persons.	**5.2. MOVEMENT** Powered roof supports must allow for unhindered movement of persons.	
5.3. CONTROL DEVICES The accelerator and brake controls for movement of machinery running on rails shall be hand-operated. However, enabling devices may be foot-operated. The control devices of powered roof supports shall be designed and positioned in such a way that, during displacement operations, operators are sheltered by a support in place. The control devices shall be protected against any accidental release.	**5.3. CONTROL DEVICES** The accelerator and brake controls for movement of machinery running on rails must be hand-operated. However, enabling devices may be foot-operated. The control devices of powered roof supports must be designed and positioned in such a way that, during displacement operations, operators are sheltered by a support in place. The control devices must be protected against any accidental release.	
5.4. STOPPING Self-propelled machinery running on rails for use in underground work shall be equipped with an enabling device acting on the circuit controlling the movement of the machinery such that movement is stopped if the driver is no longer in control of the movement.	**5.4. STOPPING** Self-propelled machinery running on rails for use in underground work must be equipped with an enabling device acting on the circuit controlling the movement of the machinery such that movement is stopped if the driver is no longer in control of the movement.	
5.5. FIRE Section 3.5.2 (b) is mandatory in respect of machinery or related products, which comprises highly flammable parts. The braking system of machinery or related products intended for use in underground workings shall be designed and constructed in such a way that it does not produce sparks or cause fires. Machinery or related products with internal combustion engines for use in underground workings shall be fitted only with engines using fuel with a low vaporising pressure and which exclude any spark of electrical origin.	**5.5. FIRE** The second indent of section 3.5.2 is mandatory in respect of machinery which comprises highly flammable parts. The braking system of machinery intended for use in underground workings must be designed and constructed in such a way that it does not produce sparks or cause fires. Machinery with internal combustion engines for use in underground workings must be fitted only with engines using fuel with a low vaporising pressure and which exclude any spark of electrical origin.	
5.6. EXHAUST EMISSIONS Exhaust emissions from internal combustion engines shall not be discharged upwards.	**5.6. EXHAUST EMISSIONS** Exhaust emissions from internal combustion engines must not be discharged upwards.	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex III Regulation	Annex I Directive	Comments
6. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY OR RELATED PRODUCTS PRESENTING PARTICULAR RISKS DUE TO THE LIFTING OF PERSONS	**6. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PRESENTING PARTICULAR HAZARDS DUE TO THE LIFTING OF PERSONS**	
Machinery or related products presenting risks due to the lifting of persons shall meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).	Machinery presenting hazards due to the lifting of persons must meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).	
6.1. GENERAL 6.1.1. **Mechanical strength** The carrier, including any trapdoors, shall be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load. The working coefficients for components set out in sections 4.1.2.4 and 4.1.2.5 are inadequate for machinery or related product intended for the lifting of persons and shall, as a general rule, be doubled. Machinery or related products intended for lifting persons or persons and goods shall be fitted with a suspension or supporting system for the carrier designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk of the carrier falling. If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.	**6.1. GENERAL** The carrier, including any trapdoors, must be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load. The working coefficients for components set out in sections 4.1.2.4 and 4.1.2.5 are inadequate for machinery intended for the lifting of persons and must, as a general rule, be doubled. Machinery intended for lifting persons or persons and goods must be fitted with a suspension or supporting system for the carrier designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk of the carrier falling. If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.	
6.1.2. **Loading control for machinery or related products moved by power other than human strength** The requirements of section 4.2.2 apply regardless of the maximum working load and overturning moment, unless the manufacturer can demonstrate that there is no risk of overloading or overturning.	6.1.2. **Loading control for machinery moved by power other than human strength** The requirements of section 4.2.2 apply regardless of the maximum working load and overturning moment, unless the manufacturer can demonstrate that there is no risk of overloading or overturning.	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex III Regulation	Annex I Directive	Comments
6.2. CONTROL DEVICES Where safety requirements do not impose other solutions, the carrier shall, as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier. In operation, those control devices shall override any other devices controlling the same movement with the exception of emergency stop devices. The control devices for the movements referred to in the first paragraph shall be of the hold-to-run type except where the carrier is completely enclosed. If there is no risk of persons or objects on the carrier colliding or falling and no other risks due to the upward and downward movements of the carrier, control devices authorising automatic stops at preselected positions may be used instead of hold-to-run type control devices.	**6.2. CONTROL DEVICES** Where safety requirements do not impose other solutions, the carrier must, as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier. In operation, those control devices must override any other devices controlling the same movement with the exception of emergency stop devices. The control devices for these movements must be of the hold-to-run type except where the carrier itself is completely enclosed.	
6.3. RISKS TO PERSONS IN OR ON THE CARRIER	**6.3. RISKS TO PERSONS IN OR ON THE CARRIER**	
6.3.1. **Risks due to movements of the carrier** Machinery or related products for lifting persons shall be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for persons.	6.3.1. **Risks due to movements of the carrier** Machinery for lifting persons must be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for persons.	
6.3.2. **Risk of persons falling from the carrier** The carrier shall not tilt to an extent, which creates a risk of the occupants falling, including when the machinery or related product and carrier are moving. Where the carrier is designed as a workstation, provision shall be made to ensure stability and to prevent hazardous movements.	6.3.2. **Risk of persons falling from the carrier** The carrier must not tilt to an extent which creates a risk of the occupants falling, including when the machinery and carrier are moving. Where the carrier is designed as a work station, provision must be made to ensure stability and to prevent hazardous movements.	

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Annex III Regulation	Annex I Directive	Comments
If the measures referred to in section 1.5.15 are not adequate, carriers shall be fitted with a sufficient number of suitable anchorage points for the number of persons permitted on the carrier. The anchorage points shall be strong enough for the use of personal protective equipment against falls from a height. Any trapdoor in floors or ceilings or side doors shall be designed and constructed in such a way as to prevent inadvertent opening and shall open in a direction that obviates any risk of falling, should they open unexpectedly.	If the measures referred to in section 1.5.15 are not adequate, carriers must be fitted with a sufficient number of suitable anchorage points for the number of persons permitted on the carrier. The anchorage points must be strong enough for the use of personal protective equipment against falls from a height. Any trapdoor in floors or ceilings or side doors must be designed and constructed in such a way as to prevent inadvertent opening and must open in a direction that obviates any risk of falling, should they open unexpectedly.	
6.3.3. **Risk due to objects falling on the carrier** Where there is a risk of objects falling on the carrier and endangering persons, the carrier shall be equipped with a protective roof.	6.3.3. **Risk due to objects falling on the carrier** Where there is a risk of objects falling on the carrier and endangering persons, the carrier must be equipped with a protective roof.	
6.4. MACHINERY OR RELATED PRODUCTS SERVING FIXED LANDINGS	**6.4. MACHINERY SERVING FIXED LANDINGS**	
6.4.1. **Risks to persons in or on the carrier** The carrier shall be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfil this requirement, the carrier itself shall be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless the doors are closed. The doors shall remain closed if the carrier stops between landings where there is a risk of falling from the carrier. Machinery or related products shall be designed, constructed and, where necessary, equipped with devices in such a way as to prevent uncontrolled upward or downward movement of the carrier. These devices shall be able to stop the carrier at its maximum working load and at the foreseeable maximum speed.	6.4.1. **Risks to persons in or on the carrier** The carrier must be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfil this requirement, the carrier itself must be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless the doors are closed. The doors must remain closed if the carrier stops between landings where there is a risk of falling from the carrier. The machinery must be designed, constructed and, where necessary, equipped with devices in such a way as to prevent uncontrolled upward or downward movement of the carrier. These devices must be able to stop the carrier at its maximum working load and at the foreseeable maximum speed.	

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Annex III Regulation	Annex I Directive	Comments
The stopping action shall not cause deceleration harmful to the occupants, whatever the load conditions.	The stopping action must not cause deceleration harmful to the occupants, whatever the load conditions.	
6.4.2. **Controls at landings** Controls, other than those for emergency use, at landings shall not initiate movements of the carrier when: (a) the control devices in the carrier are being operated, (b) the carrier is not at a landing.	6.4.2. **Controls at landings** Controls, other than those for emergency use, at landings must not initiate movements of the carrier when: — the control devices in the carrier are being operated, — the carrier is not at a landing.	
6.4.3. **Access to the carrier** The guards at the landings and on the carrier shall be designed and constructed in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons to be lifted.	6.4.3. **Access to the carrier** The guards at the landings and on the carrier must be designed and constructed in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons to be lifted.	
6.5. MARKINGS The carrier shall bear the information necessary to ensure safety including: (a) the number of persons permitted on the carrier, (b) the maximum working load.	**6.5. MARKINGS** The carrier must bear the information necessary to ensure safety including: — the number of persons permitted on the carrier, — the maximum working load.	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex IV Regulation	Annex VII Directive	Comments
Annex IV **Technical documentation**	**ANNEX VII**	
Part A **Technical documentation for machinery and related products** The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the machinery or related product with the applicable essential health and safety requirements set out in Annex III.	**A. Technical file for machinery** This part describes the procedure for compiling a technical file. The technical file must demonstrate that the machinery complies with the requirements of this Directive. It must cover the design, manufacture and operation of the machinery to the extent necessary for this assessment. The technical file must be compiled in one or more official Community languages, except for the instructions for the machinery, for which the special provisions of Annex I, section 1.7.4.1 apply.	
The technical documentation shall include at least the following elements:	1. The technical file shall comprise the following:	
	(a) a construction file including:	
(a) a complete description of the machinery or related product and of its intended use;	— a general description of the machinery,	
(b) the documentation on risk assessment demonstrating the procedure carried out, including:	— the documentation on risk assessment demonstrating the procedure followed, including:	
(i) a list of the essential health and safety requirements that are applicable to the machinery or related product,	(i) a list of the essential health and safety requirements which apply to the machinery,	
(ii) the description of the protective measures implemented to meet each applicable essential health and safety requirement and, when appropriate, the indication of the residual risks associated with the machinery or related product,	(ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,	
(c) design and manufacturing drawings and schemes of the machinery or related product and of its components, sub-assemblies and circuits;	— the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,	Requirement from the Directive has been split into 2 requirements in Regulation (see below).

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex IV Regulation	Annex VII Directive	Comments
(d) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (c) and of the operation of the machinery or related product;	— the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,	Requirement from the Directive has been split into 2 requirements in Regulation (see above).
(e) the references of the harmonised standards referred to in Article 20(1) or common specifications adopted by the Commission in accordance with Article 20(3) that have been applied for the design and manufacture of the machinery or related product. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts, which have been applied;	— the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,	
(f) where harmonised standards or common specifications have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to meet each applicable essential health and safety requirements;		
(g) reports and/or results of the design calculations, tests, inspections and examinations carried out to verify the conformity of the machinery or related product with the applicable essential health and safety requirements;	— full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements,	
	— any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,	
	— a copy of the EC declaration of conformity;	Already included in requirement (k). See below
(h) a description of the means used by the manufacturer during the production of the machinery or related product to ensure the conformity of the machinery or related product produced with the design specifications;		
(i) a copy of the manufacturer's instructions for use and the information set out in section 1.7.4 of Annex III;	— a copy of the instructions for the machinery,	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex IV Regulation	Annex VII Directive	Comments
(j) where appropriate, the EU declaration of incorporation for partly completed machinery set out in Annex V, Part B, and the assembly instructions set out in Annex XI;	— where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery,	
(k) where appropriate, copies of the EU declaration of conformity of machinery or related products as well as any product covered by other EU harmonisation legislations incorporated into the machinery or related product;	— where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery,	
(l) for machinery or related products produced in series, the internal measures that will be implemented to ensure that the machinery or related product remains in conformity with this Regulation;	(b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of this Directive.	
(m) the source code or programming logic of the safety related software to demonstrate the conformity of the machinery or related product with this Regulation further to a reasoned request from a competent national authority provided that is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III;		
(n) for sensor-fed, remotely-driven, or autonomous machinery or related products, if the safety related operations are controlled by sensor data, a description, where appropriate, of the general characteristics, capabilities and limitations of the system, data, development, testing and validation processes used;		
(o) the results of research and tests on components, fittings or the machinery or related product carried out by the manufacturer to determine whether by its design or construction it is capable of being assembled and put into service safely.	The manufacturer must carry out necessary research and tests on components, fittings or the completed machinery to determine whether by its design or construction it is capable of being assembled and put into service safely. The relevant reports and results shall be included in the technical file.	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex IV Regulation	Annex VII Directive	Comments
Part B **Technical documentation for partly completed machinery**	**B. Relevant technical documentation for partly completed machinery**	
The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the partly completed machinery with the applicable essential health and safety requirements set out in Annex III.	This part describes the procedure for compiling relevant technical documentation. The documentation must show which requirements of this Directive are applied and fulfilled. It must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the essential health and safety requirements applied. The documentation must be compiled in one or more official Community languages.	
The technical documentation shall include at least the following elements:	It shall comprise the following:	
	(a) a construction file including:	
(a) a complete description of the partly completed machinery and of its intended function when incorporated into or assembled with machinery or other partly completed machinery or equipment;		
(b) the risk assessment documentation showing the procedure carried out, including:	— the risk assessment documentation showing the procedure followed, including:	
(i) a list of the essential health and safety requirements which apply to the partly completed machinery,	(i) a list of the essential health and safety requirements applied and fulfilled,	
(ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks,	(ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks,	
(c) design and manufacturing drawings and schemes of the partly completed machinery and of its components, sub-assemblies and circuits;	— the overall drawing of the partly completed machinery and drawings of the control circuits,	

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Annex IV Regulation	Annex VII Directive	Comments
(d) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (c) and of the operation of the partly completed machinery;		
(e) the references of the harmonised standards referred to in Article 20(1) or common specifications adopted by the Commission in accordance with Article 20(3) that have been applied for the design and manufacture of the partly completed machinery. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts, which have been applied;	(iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,	
(f) where harmonised standards or common specifications have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to meet each applicable essential health and safety requirement;		
(g) reports and/or results of the design calculations, tests, inspections and examinations carried out to verify the conformity of the partly completed machinery with the applicable essential health and safety requirements;	— full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the partly completed machinery with the applied essential health and safety requirements,	
	(iv) any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,	
(h) a description of the means used by the manufacturer during the production of the partly completed machinery to ensure the conformity of the partly completed machinery produced with the design specifications;		
(i) a copy of the assembly instructions for the partly completed machinery set out in Annex XI;	(v) a copy of the assembly instructions for the partly completed machinery;	
(j) for partly completed machinery products produced in series, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied;	(b) for series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied.	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex IV Regulation	Annex VII Directive	Comments
(k) the source code or programming logic of the safety related software upon a reasoned request from a competent national authority provided that is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III: (l) for sensor-fed, remotely-driven, or autonomous partly completed machinery, if the safety related operations are controlled by sensor data, a description, where appropriate, of the general characteristics, capabilities and limitations of the system, data, development, testing and validation processes used. (m) the results of research and tests on components, fittings or the partly completed machinery carried out by the manufacturer to determine whether by its design or construction it is capable of being assembled and incorporated safely.	The manufacturer must carry out necessary research and tests on components, fittings or the partly completed machinery to determine whether by its design or construction it is capable of being assembled and used safely. The relevant reports and results shall be included in the technical file.	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex V Regulation	Annex II Directive	Comments
ANNEX V **EU declaration of conformity and EU declaration of incorporation**	**ANNEX II** **Declarations**	
	1. CONTENT	
Part A. **EU declaration of conformity of machinery and related products No …**[1] _____ 1. It is optional for the manufacturer to assign a number to the declaration of conformity.	**A. EC DECLARATION OF CONFORMITY OF THE MACHINERY**	
	This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex I, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters. This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.	Directive requirement covered in Article 21 section 2 of the regulation.
The EU declaration of conformity shall contain the following particulars:	The EC declaration of conformity must contain the following particulars:	
1. The Machinery or related product (product, type, model, batch or serial number) or substantially modified machinery or related product;	3. description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name;	Requirement from the Directive has been split into 2 requirements in Regulation (see below).
2. Name and address of the manufacturer and, where applicable, its authorised representative: For lifting machinery which is intended to be permanently installed in a building or a structure: and which cannot be assembled in the manufacturer's premises but can only be assembled at the place of use, the address of that place.	1. business name and full address of the manufacturer and, where appropriate, his authorised representative;	
4. This declaration of conformity is issued under the sole responsibility of the manufacturer:	2. name and address of the person authorised to compile the technical file, who must be established in the Community;	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex V Regulation	Annex II Directive	Comments
5. Object of the declaration (identification of the machinery or related product allowing traceability; where necessary for the identification of the machinery or related product, a colour image of sufficient clarity may be included).	3. description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name;	Requirement from the Directive has been split into 2 requirements in Regulation (see above).
6. The object of the declaration described in point 5 is in conformity with the relevant Union harmonisation legislation.	4. a sentence expressly declaring that the machinery fulfils all the relevant provisions of this Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies. These references must be those of the texts published in the Official Journal of the European Union;	
7. References to the harmonised standards referred to in Article 20(1) or common specifications adopted by the Commission in accordance with Article 20(3) that were applied, including the date of the publication of the reference to harmonised standards in the *Official Journal of the European Union* or of the common specification, or references to the other technical specifications, including their date, in relation to which conformity is declared. In the event of partial application of harmonised standards or common specifications, the EU declaration of conformity shall specify the parts which were applied.	7. where appropriate, a reference to the harmonised standards used, as referred to in Article 7(2); 8. where appropriate, the reference to other technical standards and specifications used;	
8. Where applicable, the notified body … (name, number) … performed the EU type-examination (Module B) and issued the EU type-examination certificate … (reference to that certificate), followed by conformity to type based on internal production control (module C) or the conformity based on unit verification (module G) or full quality assurance (module H).	5. where appropriate, the name, address and identification number of the notified body which carried out the EC type-examination referred to in Annex IX and the number of the EC type-examination certificate; 6. where appropriate, the name, address and identification number of the notified body which approved the full quality assurance system referred to in Annex X;	
9. Where applicable, the machinery or related product is subject to the conformity assessment procedure based on internal production control (Module A).		
10. Additional information:		

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex V Regulation	Annex II Directive	Comments
Signed for and on behalf of: … (place and date of issue): (name, function) (signature):	9. the place and date of the declaration; 10. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.	
Part B. **EU declaration of incorporation of partly completed machinery No… [1]** _____ 1. It is optional to assign a number to the declaration of conformity.	**B. DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY**	
	This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex 1, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.	
The declaration of incorporation shall contain the following particulars:	The declaration of incorporation must contain the following particulars:	
	2. name and address of the person authorised to compile the relevant technical documentation, who must be established in the Community;	
1. The partly completed machinery (product, type, model batch or serial number).	3. description and identification of the partly completed machinery including generic denomination, function, model, type, serial number and commercial name;	Requirement from the Directive has been split into 2 requirements in Regulation (see below).
2. Name and address of the manufacturer and, where applicable, its authorised representative:	1. business name and full address of the manufacturer of the partly completed machinery and, where appropriate, his authorised representative;	
3. This declaration of incorporation is issued under the sole responsibility of the manufacturer.		
4. Object of the declaration (identification of partly completed machinery allowing traceability; where necessary for the identification of the partly completed machinery, a colour image of sufficient clarity may be included).	3. description and identification of the partly completed machinery including generic denomination, function, model, type, serial number and commercial name;	Requirement from the Directive has been split into 2 requirements in Regulation (see above).

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex V Regulation	Annex II Directive	Comments
5. A sentence declaring which essential requirements set out in Annex III of Regulation (EU) 2023/1230 of the European Parliament and of the Council are applied and fulfilled and that the relevant technical documentation was drawn-up in accordance with Annex IV, part B, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Union harmonisation legislation.	4. a sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives. These references must be those of the texts published in the Official Journal of the European Union;	
6. References to the harmonised standards referred to in Article 20(1) or common specifications adopted by the Commission in accordance with Article 20(3) that were applied, including the date of the standard or of the common specification, or references to the other technical specifications, including their date, in relation to which conformity is declared. In the event of partial application of harmonised standards or common specifications, the EU declaration of incorporation shall specify the parts which were applied.		
7. An undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery.	5. an undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery;	
8. A statement that the partly completed machinery shall not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with this Regulation.	6. a statement that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of this Directive, where appropriate;	
9. Additional information: Signed for and on behalf of: … (place and date of issue): (name, function) (signature):	7. the place and date of the declaration; 8. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.	

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Annex V Regulation	Annex II Directive	Comments
	2. CUSTODY The manufacturer of machinery or his authorised representative shall keep the original EC declaration of conformity for a period of at least 10 years from the last date of manufacture of the machinery. The manufacturer of partly completed machinery or his authorised representative shall keep the original declaration of incorporation for a period of at least 10 years from the last date of manufacture of the partly completed machinery.	Requirement from Directive moved to Regulation Article 10. Requirement from Directive moved to Regulation Article 11 section 3.

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex VI Regulation	Annex VIII Directive	Comments
ANNEX VI **Internal production control** **(Module A)**	**ANNEX VIII** **Assessment of conformity with internal checks on the manufacture of machinery**	
1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his or her sole responsibility that the machinery or related product concerned satisfies the applicable requirements of this Regulation.	1. This Annex describes the procedure by which the manufacturer or his authorised representative, who carries out the obligations laid down in points 2 and 3, ensures and declares that the machinery concerned satisfies the relevant requirements of this Directive.	
2. Technical documentation The manufacturer shall draw up the technical documentation described in Annex IV, Part A.	2. For each representative type of the series in question, the manufacturer or his authorised representative shall draw up the technical file referred to in Annex VII, part A.	
3. Manufacturing The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured machinery or related product with the technical documentation referred to in point 2 and with the applicable requirements of this Regulation.	3. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured machinery with the technical file referred to in Annex VII, part A, and with the requirements of this Directive.	
4. CE marking and EU declaration of conformity 4.1. The manufacturer shall affix the CE marking to machinery or related products, individually, that satisfies the applicable requirements of this Regulation. 4.2. The manufacturer shall draw up an EU declaration of conformity for each machinery or related product model in accordance with Article 21 and keep it, together with the technical documentation, at the disposal of the national authorities for at least 10 years after the machinery or related product has been placed on the market or put into service. The EU declaration of conformity shall identify the machinery or related product model for which it has been drawn up.		

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex VI Regulation	Annex VIII Directive	Comments
A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. 5. Authorised representative The manufacturer's obligations set out in point 4 may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.		

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex VII Regulation	Annex IX Directive	Comments
ANNEX VII **EU type-examination** **(Module B)**	**ANNEX IX** **EC type-examination**	
1. EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a machinery or related product and verifies and attests that the technical design of the machinery or related product meets the applicable requirements of this Regulation.	EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative model of machinery referred to in Annex IV (hereafter named the type) satisfies the provisions of this Directive.	
	1. The manufacturer or his authorised representative must, for each type, draw up the technical file referred to in Annex VII, part A.	
2. EU type-examination shall be carried out by assessment of the adequacy of the technical design of the machinery or related product through examination of the technical documentation, plus examination of a specimen of the machinery or related product that is representative of the production envisaged (production type).		
3. Application for EU type-examination		
The manufacturer shall lodge an application for EU type-examination with a single notified body of its choice.	2. For each type, the application for an EC type-examination shall be submitted by the manufacturer or his authorised representative to a notified body of his choice.	
The application shall include:	The application shall include:	
(a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;	— the name and address of the manufacturer and, where appropriate, his authorised representative,	
(b) a written declaration that the same application has not been lodged with any other notified body;	— a written declaration that the application has not been submitted to another notified body,	
(c) the technical documentation described in Annex IV, Part A;	— the technical file.	
(d) the access to the specimen(s) of the machinery or related product representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme.	Moreover, the applicant shall place at the disposal of the notified body a sample of the type. The notified body may ask for further samples if the test programme so requires.	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex VII Regulation	Annex IX Directive	Comments
For machinery products produced in series where each item is adapted to fit an individual user, specimens shall be provided that are representative of the range of different users, while for machinery products produced as a single unit to accommodate the special needs of an individual user, a basic model shall be provided.		
4. EU type-examination		
The notified body shall:	3. The notified body shall:	
(a) examine the technical documentation to assess the adequacy of the technical design of the machinery or related product. In conducting such an examination, Annex IV, Part A, second subparagraph, point (h) and (l), need not be taken into account;		
(b) for machinery or related products produced in series where each item is adapted to fit an individual user, examine the description of the measures to assess their adequacy;		
(c) verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements that have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications adopted by the Commission in accordance with Article 20(3), as well as the elements that have been designed in accordance with other technical specifications;	3.1. examine the technical file, check that the type was manufactured in accordance with it and establish which elements have been designed in accordance with the relevant provisions of the standards referred to in Article 7(2), and those elements whose design is not based on the relevant provisions of those standards;	
(d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, or common specifications adopted by the Commission in accordance with Article 20(3), those have been applied correctly;	3.3. where harmonised standards referred to in Article 7(2) were used, carry out or have carried out appropriate inspections, measurements and tests to verify that those standards were actually applied;	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex VII Regulation	Annex IX Directive	Comments
(e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications adopted by the Commission in accordance with Article 20(3) have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly.	3.2. carry out or have carried out appropriate inspections, measurements and tests to ascertain whether the solutions adopted satisfy the essential health and safety requirements of this Directive, where the standards referred to in Article 7(2) were not applied;	
	3.4. agree with the applicant as to the place where the check that the type was manufactured in accordance with the examined technical file and the necessary inspections, measurements and tests will be carried out.	
5. Evaluation report The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.		
6. EU type-examination certificate		
6.1. Where the type meets the applicable essential health and safety requirements, the notified body shall issue an EU type-examination certificate to the manufacturer.	4. If the type satisfies the provisions of this Directive, the notified body shall issue the applicant with an EC type-examination certificate. The certificate shall include the name and address of the manufacturer and his authorised representative, the data necessary for identifying the approved type, the conclusions of the examination and the conditions to which its issue may be subject.	Requirement from the Directive has been split into multiple requirements in Regulation (see below section 6.2 part b and c).
The period of validity of a newly issued certificate and, where appropriate, of a renewed certificate shall not exceed five years.		
6.2. The EU type-examination certificate shall contain at least the following information:		
(a) the name and identification number of the notified body;		

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex VII Regulation	Annex IX Directive	Comments
(b) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;	4. If the type satisfies the provisions of this Directive, the notified body shall issue the applicant with an EC type-examination certificate. The certificate shall include the name and address of the manufacturer and his authorised representative, […]	Requirement from the Directive has been split into multiple requirements in Regulation (see above section 6.1 and below section 6.2 part c).
(c) an identification of the machinery or related product covered by the certificate (type number);	4. […], the data necessary for identifying the approved type, the conclusions of the examination and the conditions to which its issue may be subject.	Requirement from the Directive has been split into multiple requirements in Regulation (see above section 6.1 and section 6.2 part b).
(d) a statement that the machinery or related product type complies with the applicable essential health and safety requirements;		
(e) where harmonised standards or common specifications adopted by the Commission in accordance with Article 20(3) have been fully or partially applied, the references of those standards or common specifications or parts thereof;		
(f) where other technical specifications have been applied, the references of those technical specifications;		
(g) the date of issue, the date of expiry and, where appropriate, the date(s) of renewal;		
(h) any conditions attached to the issuing of the certificate.		
	The manufacturer and the notified body shall retain a copy of this certificate, the technical file and all relevant documents for a period of 15 years from the date of issue of the certificate.	
6.3. The EU type-examination certificate may have one or more annexes attached.		
6.4. Where the type does not satisfy the applicable essential health and safety requirements, the notified body shall refuse to issue an EU type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.	5. If the type does not satisfy the provisions of this Directive, the notified body shall refuse to issue the applicant with an EC type-examination certificate, giving detailed reasons for its refusal. It shall inform the applicant, the other notified bodies and the Member State which notified it. An appeal procedure must be available.	Requirement related to the communication to other Notified Bodies is moved to Article 40. The appeal procedure requirement is moved to Article 39.

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex VII Regulation	Annex IX Directive	Comments
7. Review of the EU type-examination certificate		
7.1. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art, which indicate that the approved type may no longer comply with the applicable essential health and safety requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.	9.1. The notified body has the ongoing responsibility of ensuring that the EC type-examination certificate remains valid. It shall inform the manufacturer of any major changes which would have an implication on the validity of the certificate. The notified body shall withdraw certificates which are no longer valid.	
7.2. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type-examination certificate of all modifications to the approved type and of all modifications to the technical documentation that may affect the conformity of the machinery or related product with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate.	6. The applicant shall inform the notified body which retains the technical file relating to the EC type-examination certificate of all modifications to the approved type.	
7.3. The manufacturer shall ensure that the machinery or related product continues to fulfil the applicable essential health and safety requirements in light of the state of the art.	9.2. The manufacturer of the machinery concerned has the ongoing responsibility of ensuring that the said machinery meets the corresponding state of the art.	
7.4. The manufacturer shall ask the notified body to review the EU type-examination certificate either:		
(a) in the case of a modification to the approved type referred to in point 7.2;		
(b) in the case of a change in the state of the art referred to in point 7.3;		
(c) at the latest, before the date of expiry of the certificate.	9.3. The manufacturer shall request from the notified body the review of the validity of the EC type-examination certificate every five years.	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex VII Regulation	Annex IX Directive	Comments
In the case referred to in point (c), the review may lead to a renewal of the EU type-examination certificate only when the application is submitted by the manufacturer at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU type-examination certificate. Where the manufacturer fails to comply with the deadlines mentioned above, the review may lead only to an approval in the form of an addition to the original EU type-examination certificate and the expiry date of the certificate shall be that of the original certificate.		
7.5. The notified body shall examine the machinery or related product type and, where necessary in the light of the changes made, carry out the relevant tests to ensure that the approved type continues to fulfil the applicable essential health and safety requirements.	The notified body shall examine these modifications and shall then either confirm the validity of the existing EC type-examination certificate or issue a new one if the modifications are liable to compromise conformity with the essential health and safety requirements or the intended working conditions of the type.	
If the notified body is satisfied that the approved type continues to fulfil the applicable essential health and safety requirements, it shall renew the EU type-examination certificate or issue an addition to the original EU type-examination certificate. The notified body shall ensure that the review procedure is finalised before the expiry date of the EU type-examination certificate.	From Annex VII section 9.3, second paragraph: If the notified body finds that the certificate remains valid, taking into account the state of the art, it shall renew the certificate for a further five years.	Duration of the validity of certificate is expressed in Annex VII section 6.1 of the regulation.
7.6. Where the conditions referred to in points (a) and (b) of point 7.4 are not met, a simplified review procedure shall apply. The manufacturer shall supply the notified body with the following: (a) its name and address and data identifying the EU type-examination certificate concerned; (b) confirmation that there has been no modification to the approved type as referred to in point 7.2, including materials, sub-components or sub-assemblies, nor to the relevant harmonised standards or common specifications adopted by the Commission in accordance with Article 20(3) or other technical specifications applied;		

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex VII Regulation	Annex IX Directive	Comments
(c) confirmation that there has been no change in the state of the art as referred to in point 7.3; and (d) where not already supplied, copies of current product drawings and photographs, product marking and information; Where the notified body has confirmed that no modification to the approved type referred to in point 7.2 and no change in the state of the art referred to in point 7.3 has occurred, the simplified review procedure shall be applied and the examinations and tests referred to in point 7.5 shall not be carried out. In that case, the notified body shall renew the EU type-examination certificate. The costs associated with that renewal shall be proportionate to the administrative burden of the simplified procedure. If the notified body finds that a change in the state of the art referred to in point 7.3 has occurred, the procedure set out in point 7.5 shall apply. 7.7. If, following the review, the notified body concludes that the EU type-examination certificate is no longer valid, the body shall withdraw it and the manufacturer shall cease the placing on the market of the machinery or related product concerned. 8. Each notified body shall inform its notifying authority concerning the EU type-examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted. Each notified body shall inform the other notified bodies concerning the EU type-examination certificates and/or any additions thereto, which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the EU type-examination certificates and/or additions thereto which it has issued.		

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Annex VII Regulation	Annex IX Directive	Comments
The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU type-examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.	7. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC type-examination certificates. On reasoned request, the Commission and the Member States may obtain a copy of the technical file and the results of the examinations carried out by the notified body.	
The notified body shall keep a copy of the EU type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, for a period of five years after the expiry of the validity of that certificate. 9. The manufacturer shall keep a copy of the EU type-examination certificate, its annexes and additions, together with the technical documentation at the disposal of the national authorities, for at least 10 years after the machinery or related product has been placed on the market or put into service. 10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7.2, 7.4 and 9, provided that they are specified in the mandate.	From Annex VII section 9.3, last paragraph: The manufacturer and the notified body shall retain a copy of this certificate, of the technical file and of all the relevant documents for a period of 15 years from the date of issue of the certificate.	Manufacturer's obligation linked to the duration of keeping document is detailed in Article 10 of the regulation.
	8. Files and correspondence referring to the EC type-examination procedures shall be written in the official Community language(s) of the Member State where the notified body is established or in any other official Community language acceptable to the notified body.	For manufacturer's obligations, refer to Article 10 of the regulation.
	9. Validity of the EC type-examination certificate	
	9.4. In the event that the validity of the EC-type examination certificate is not renewed, the manufacturer shall cease the placing on the market of the machinery concerned.	For manufacturer's obligations linked to the placing on the market or putting into service of a machinery or related product, refer to Article 10 of the regulation.

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex VIII Regulation	Annex VIII Directive	Comments
ANNEX VIII **Conformity to type based on internal production control** **(Module C)** 1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares under his or her sole responsibility that the machinery or related product concerned is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation. 2. Manufacturing The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured machinery or related product with the type described in the EU type-examination certificate and with the applicable requirements of this Regulation. 3. CE marking and EU declaration of conformity 3.1. The manufacturer shall affix the CE marking to each individual machinery or related product that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation. 3.2. The manufacturer shall draw up an EU declaration of conformity for a machinery or related product model and keep it at the disposal of the national authorities for 10 years after the machinery or related product has been placed on the market or put into service. The EU declaration of conformity shall identify the machinery or related product for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.	**ANNEX VIII** **Assessment of conformity with internal checks on the manufacture of machinery** From Annex VIII 3. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured machinery with the technical file referred to in Annex VII, part A, and with the requirements of this Directive.	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex VIII Regulation	Annex VIII Directive	Comments
4. Authorised representative The manufacturer's obligations set out in point 3 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.		

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex IX Regulation	Annex X Directive	Comments
ANNEX IX **Conformity based on full quality assurance** **(Module H)**	**ANNEX X** **Full quality assurance**	
1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his or her sole responsibility that the machinery or related product concerned satisfies the requirements of this Regulation that apply to it.	This Annex describes the conformity assessment of machinery referred to in Annex IV, manufactured using a full quality assurance system, and the procedure whereby a notified body assesses and approves the quality system and monitors its application.	
2. Manufacturing The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the machinery or related product concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.	1. The manufacturer must operate an approved quality system for design, manufacture, final inspection and testing, as specified in point 2, and shall be subject to the surveillance referred to in point 3.	
3. Quality system	2. Quality system	
3.1. The manufacturer shall lodge an application for assessment of its quality system with the notified body of its choice, for the machinery or related product concerned.	2.1. The manufacturer or his authorised representative shall lodge an application for assessment of his quality system to a notified body of his choice.	Authorised representative activities are specified in section 8 of this annex.
The application shall include:	The application shall contain:	
(a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;	— the name and address of the manufacturer and, where appropriate, his authorised representative,	
	— the places of design, manufacture, inspection, testing and storage of the machinery,	
(b) the technical documentation escribed in Annex IV, Part A, points (a) to (g), (i) to (k) and (m) to (o) for one model of each category of machinery or related products intended to be manufactured.	— the technical file described in Annex VII, Part A, for one model of each category of machinery referred to in Annex IV which he intends to manufacture,	
(c) the documentation concerning the quality system; and	— the documentation on the quality system,	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex IX Regulation	Annex X Directive	Comments
(d) a written declaration that the same application has not been lodged with any other notified body.	— a written declaration that the application has not been submitted to another notified body.	
3.2. The quality system shall ensure compliance of the machinery or related products with the requirements of this Regulation that apply to them.	2.2. The quality system must ensure conformity of the machinery with the provisions of this Directive.	
All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.	All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner, in the form of measures, procedures and written instructions. The documentation on the quality system must permit a uniform interpretation of the procedural and quality measures, such as quality programmes, plans, manuals and records.	
It shall, in particular, contain an adequate description of:	It must contain, in particular, an adequate description of:	
(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;	— the quality objectives, the organisational structure, and the responsibilities and powers of the management with regard to the design and quality of the machinery,	
(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or common specification adopted by the Commission in accordance with Article 20(3) will not be applied in full, the means, including other technical specifications, that will be used to ensure that the essential health and safety requirements of this Regulation that apply to the machinery or related product will be met;	— the technical design specifications, including standards that will be applied and, where the standards referred to in Article 7(2) are not applied in full, the means that will be used to ensure that the essential health and safety requirements of this Directive are fulfilled,	
(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the machinery or related product;	— the design inspection and design verification techniques, processes and systematic actions that will be used when designing machinery covered by this Directive,	
(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex IX Regulation	Annex X Directive	Comments
(e) the examinations and tests that will be carried out before, during and after manufacture and the frequency with which they will be carried out;	— the inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,	
(f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;	— the quality records, such as inspection reports and test data, calibration data, and reports on the qualifications of the personnel concerned,	
(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.	— the means of monitoring the achievement of the required design and quality of the machinery, as well as the effective operation of the quality system.	
3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.	2.3. The notified body shall assess the quality system to determine whether it satisfies the requirements of point 2.2.	
It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.	The elements of the quality system which conform to the relevant harmonised standard shall be presumed to conform to the corresponding requirements referred to in point 2.2.	
In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant machinery or related product field and technology concerned, and with knowledge of the applicable essential health and safety requirements set out in Annex III. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(b), to verify the manufacturer's ability to identify the applicable essential health and safety requirements set out in Annex III of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the machinery or related product with those requirements.	The team of auditors must have at least one member who is experienced in the assessment of the technology of the machinery. The assessment procedure shall include an inspection to be carried out at the manufacturer's premises. During the assessment, the team of auditors shall carry out a review of the technical files referred to in point 2.1, second paragraph, third indent to ensure their compliance with the relevant health and safety requirements.	
The manufacturer or its authorised representative shall be notified of the decision.	The manufacturer or his authorised representative shall be notified of the decision.	
The notification shall contain the conclusions of the audit and the reasoned assessment decision.	The notification shall contain the conclusions of the examination and the reasoned assessment decision. An appeal procedure must be available.	Appeal procedure requirement among Notified body decision is detailed in Article 37 of regulation.

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex IX Regulation	Annex X Directive	Comments
3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.	2.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to ensure that it remains appropriate and effective.	
3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.	The manufacturer or his authorised representative shall inform the notified body which approved the quality system of any planned change to it.	Authorised representative activities are specified in section 8 of this annex.
The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.	The notified body shall evaluate the proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in point 2.2, or whether a re-assessment is necessary.	
It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the assessment and the reasoned assessment decision.	It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.	
4. Surveillance under the responsibility of the notified body	3. Surveillance under the responsibility of the notified body	
4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.	3.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.	
4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide that body with all necessary information, in particular:	3.2. The manufacturer shall, for inspection purposes, allow the notified body access to the places of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, such as:	
(a) the quality system documentation;	— the documentation concerning the quality system,	
(b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;	— the quality records provided for in that part of the quality system concerned with design, such as the results of analyses, calculations, tests, etc.,	
(c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.	— the quality records provided for in that part of the quality system concerned with manufacture, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.	

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex IX Regulation	Annex X Directive	Comments
4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.	3.3. The notified body shall conduct periodic audits to make sure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report. The frequency of the periodic audits shall be such that a full reassessment is carried out every three years.	
4.4. In addition, the notified body may pay unexpected visits to the manufacturer.	3.4. Moreover, the notified body may pay the manufacturer unannounced visits. The need for these additional visits and their frequency will be determined on the basis of a visit monitoring system managed by the notified body. In particular, the following factors will be taken into account in the visits monitoring system: — the results of previous surveillance visits, — the need to monitor remedial measures, — where appropriate, special conditions attaching to approval of the system, — significant modifications in the organisation of the manufacturing process, measures or techniques.	
During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.	On the occasion of such visits, the notified body may, if necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if a test was carried out, with a test report.	
5. CE marking and EU declaration of conformity		
5.1. The manufacturer shall affix the required CE marking set out in this Regulation, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that satisfies the applicable requirements of this Regulation.		

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex IX Regulation	Annex X Directive	Comments
5.2. The manufacturer shall draw up a written EU declaration of conformity for each machinery or related product model and keep it at the disposal of the national authorities for at least 10 years after the machinery or related product has been placed on the market or put into service. The EU declaration of conformity shall identify the machinery or related product model for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.		
6. The manufacturer shall, for at least 10 years after the machinery or related product has been placed on the market or put into service, keep at the disposal of the national authorities:	4. The manufacturer or his authorised representative shall keep available for the national authorities, for a period of ten years from the last date of manufacture:	Authorised representative activities are specified in section 8 of this annex.
(a) the technical documentation referred to in point 3.1(b);	— the documentation referred to in point 2.1,	
(b) the documentation concerning the quality system referred to in point 3.1(c);		This requirement was introduced in point 2.1 in the Directive
(c) the information relating to the change referred to in point 3.5, as approved;		This requirement was introduced in point 2.4 in the Directive
(d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.	— the decisions and reports of the notified body referred to in point 2.4, third and fourth subparagraphs, and in points 3.3 and 3.4.	
7. Each notified body shall inform its notifying authority of quality system approval decisions issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approval decisions refused, suspended or otherwise restricted. Each notified body shall inform the other notified bodies of quality system approval decisions, which it has refused, suspended or withdrawn, and, upon request, of quality system approval decisions, which it has issued.		

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex IX Regulation	Annex X Directive	Comments
8. Authorised representative The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.		

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex X Regulation	No equivalency in Directive	Comments
ANNEX X **CONFORMITY BASED ON UNIT VERIFICATION** **(Module G)** 1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on its sole responsibility that the machinery or related product, which is subject to point 4, is in conformity with the essential health and safety requirements set out in Annex III. 2. Technical documentation The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the machinery or related product's conformity with the relevant essential health and safety requirements set out in Annex III, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable essential health and safety requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the machinery or related product. The technical documentation shall, wherever applicable, contain at least the following elements: (a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative; (b) the technical documentation for the unit of machinery or related products intended to be manufactured. In addition, the technical documentation shall, wherever applicable, contain at least: (i) the elements set out in points (a) to (g) of Annex IV, Part A; (ii) the documentation concerning the quality system; and		New evaluation procedure possibility.

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex X Regulation	No equivalency in Directive	Comments
(iii) a written declaration that the same application has not been lodged with any other notified body. 2.1. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for at least 10 years after the machinery or related product has been placed on the market. 3. Manufacturing The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured machinery or related product with the applicable essential health and safety requirements set out in Annex III. 4. Verification A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or common specifications, or equivalent tests, to check the conformity of the machinery or related product with the applicable essential health and safety requirements set out in Annex III, or have them carried out. In the absence of such a harmonised standard and/or common specification the notified body concerned shall decide on the appropriate tests to be carried out. The notified body shall issue a certificate in respect of the examinations and tests carried out and shall affix its identification number to the approved machinery or related product, or have it affixed under its responsibility. The manufacturer shall keep the certificates at the disposal of the national authorities for at least 10 years after the machinery or related product has been placed on the market. 5. CE marking and EU declaration of conformity 5.1. The manufacturer shall affix the required CE marking set out in Article 10(2) and, under the responsibility of the notified body referred to in point 4, that body's identification number, to the machinery or related product that satisfies the applicable essential health and safety requirements set out in Annex III.		

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex X Regulation	No equivalency in Directive	Comments
5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for at least 10 years after the machinery or related product has been placed on the market or put into service. The EU declaration of conformity shall identify the machinery or related product for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. 6. Authorised representative The manufacturer's obligations set out in points 2.1 and 5 may be fulfilled by its authorised representative, acting on its behalf and under its responsibility, provided that those obligations are specified in the mandate.		

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex XI Regulation	Annex VI Directive	Comments
ANNEX XI **Assembly instructions for partly completed machinery**	**ANNEX VI** **Assembly instructions for partly completed machinery**	
1. The assembly instructions for partly completed machinery shall contain a description of the conditions, which are to be met to ensure that the partly completed machinery is correctly incorporated in machinery or other partly completed machinery or equipment, and that the machinery or other partly completed machinery or equipment with the incorporated partly completed machinery does not compromise health and safety of persons and, where appropriate, domestic animals and property and, where applicable, of the environment.	The assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the final machinery, so as not to compromise safety and health.	
2. The assembly instructions shall contain relevant information to be used in the instructions of the machinery or other partly completed machinery or equipment, in which the partly completed machinery is to be assembled. Each assembly instruction shall contain, where applicable, at least the following information: (a) a general description of the partly completed machinery; (b) the drawings, diagrams, descriptions and explanations necessary for the incorporation into the final machinery, maintenance and repair of the partly completed machinery and for checking its correct functioning; (c) warnings concerning the ways in which the partly completed machinery must not be used that experience has shown might occur; (d) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the partly completed machinery is to be mounted; (e) information regarding noise or vibration which is likely to be reduced by the incorporation;	The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative.	Requirements related to the language to be used for instructions are detailed in Article 10 section 7 of the regulation.

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex XI Regulation	Annex VI Directive	Comments
(f) information about the essential health and safety requirements set out in Annex III which are applicable to the partly completed machinery; (g) the essential characteristics of tools, which may be fitted to the partly completed machinery; (h) the conditions in which the partly completed machinery meets the requirement of stability, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns; (i) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the partly completed machinery and of its various parts where these are regularly to be transported separately; (j) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked; (k) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed taking account of the design; (l) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations; (m) the specifications of the spare parts to be used, when these affect the health and safety of operators; (n) a clear description of which version of the assembly instructions corresponds to the partly completed machinery model; If the partly completed machinery is intended to be used in machinery covered by Annex III, chapters 2 to 6, the assembly instructions must also contain relevant information to be used in the instructions for use for this machinery.		

New text	Text deleted	Text whose form has been changed	Old directive text moved from/to another part of the same directive for easier comparison with the corresponding part of the new regulation

Annex XI Regulation	Annex VI Directive	Comments
3. The assembly instructions for partly completed machinery shall contain the EU declaration of incorporation, or the internet address or machine readable code where the EU declaration of incorporation can be accessed.		

Additional content: Scope of application of regulation and specific Union harmonisation legislation (Article 2 & 9)

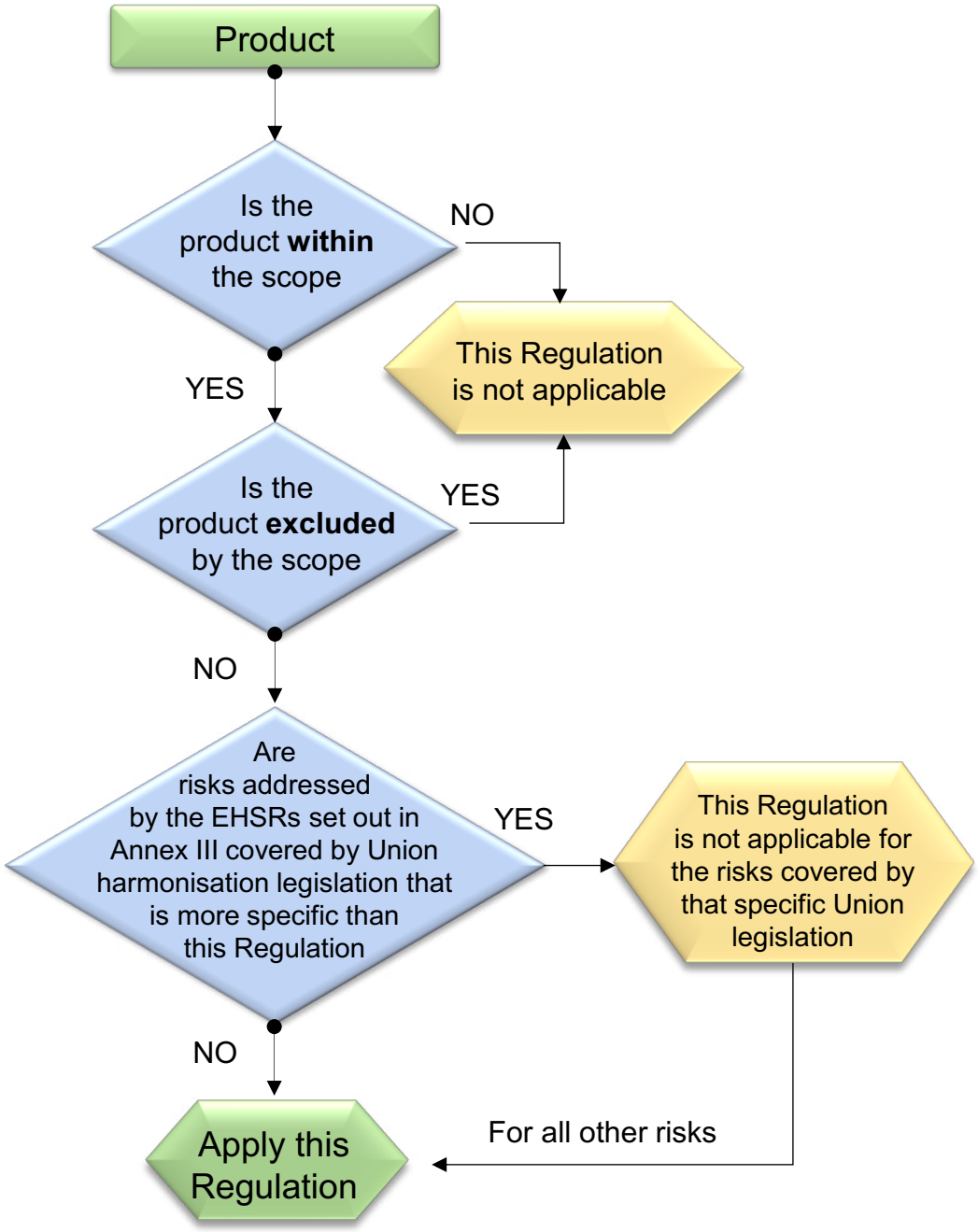


Figure 1: Article 2 and Article 9 schematic representation

Additional content:
Schematic representation of Article 6

Figure 2: Article 6 general overview

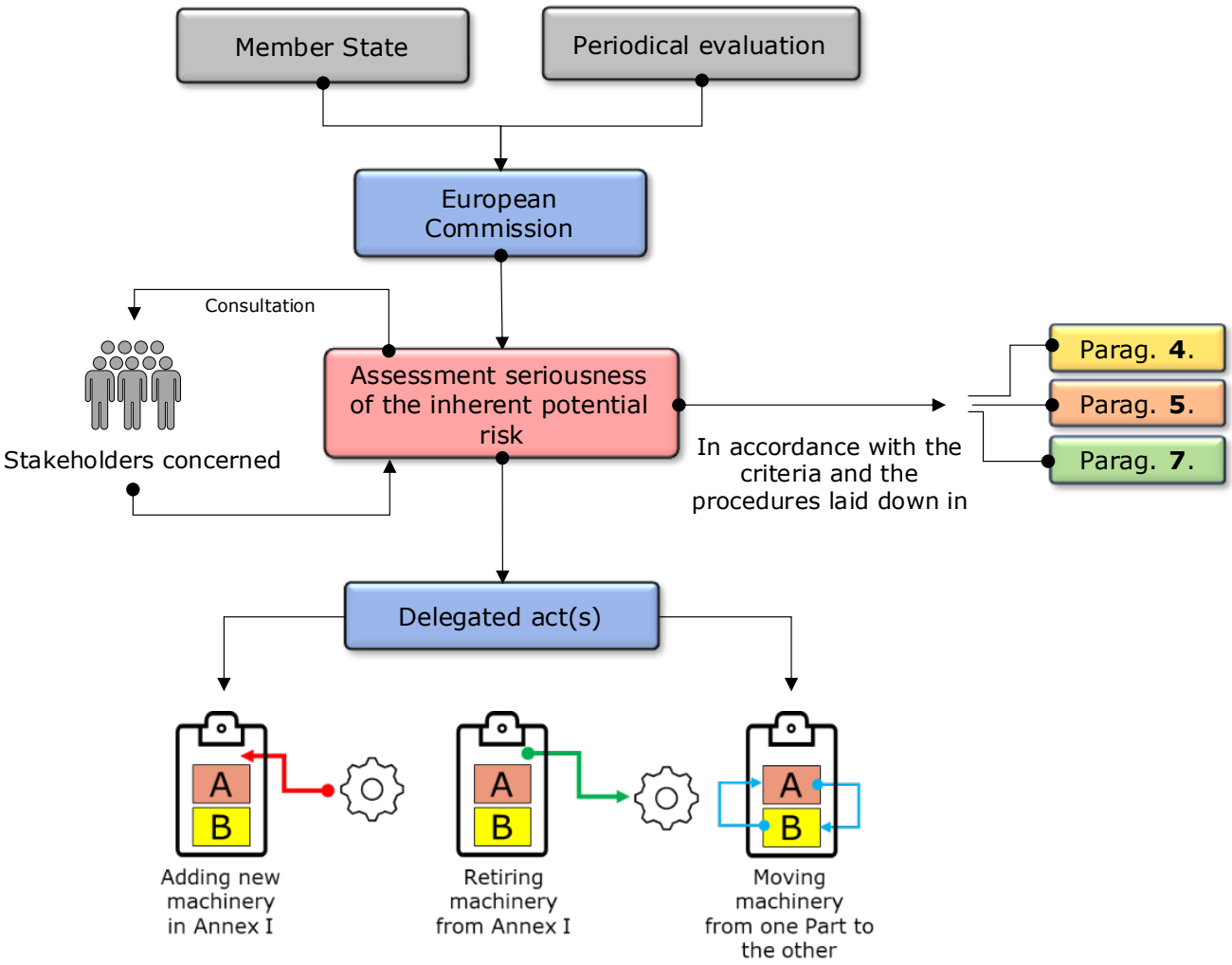
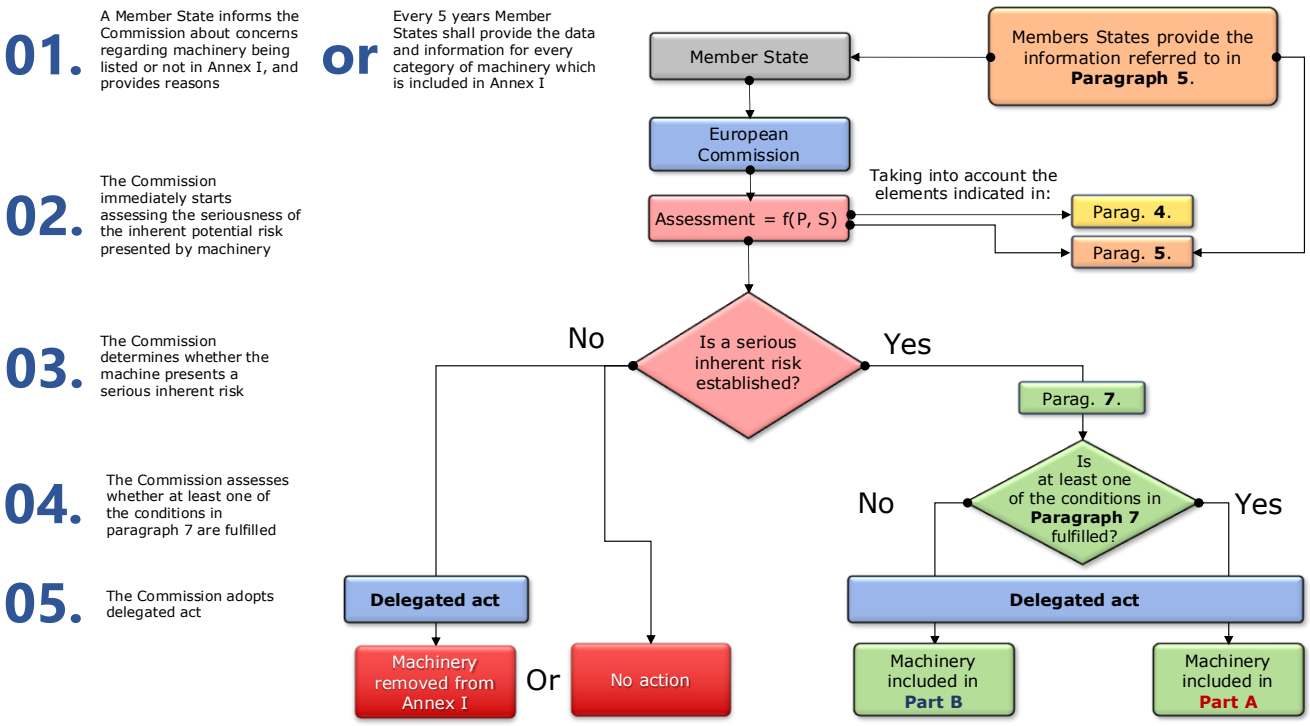
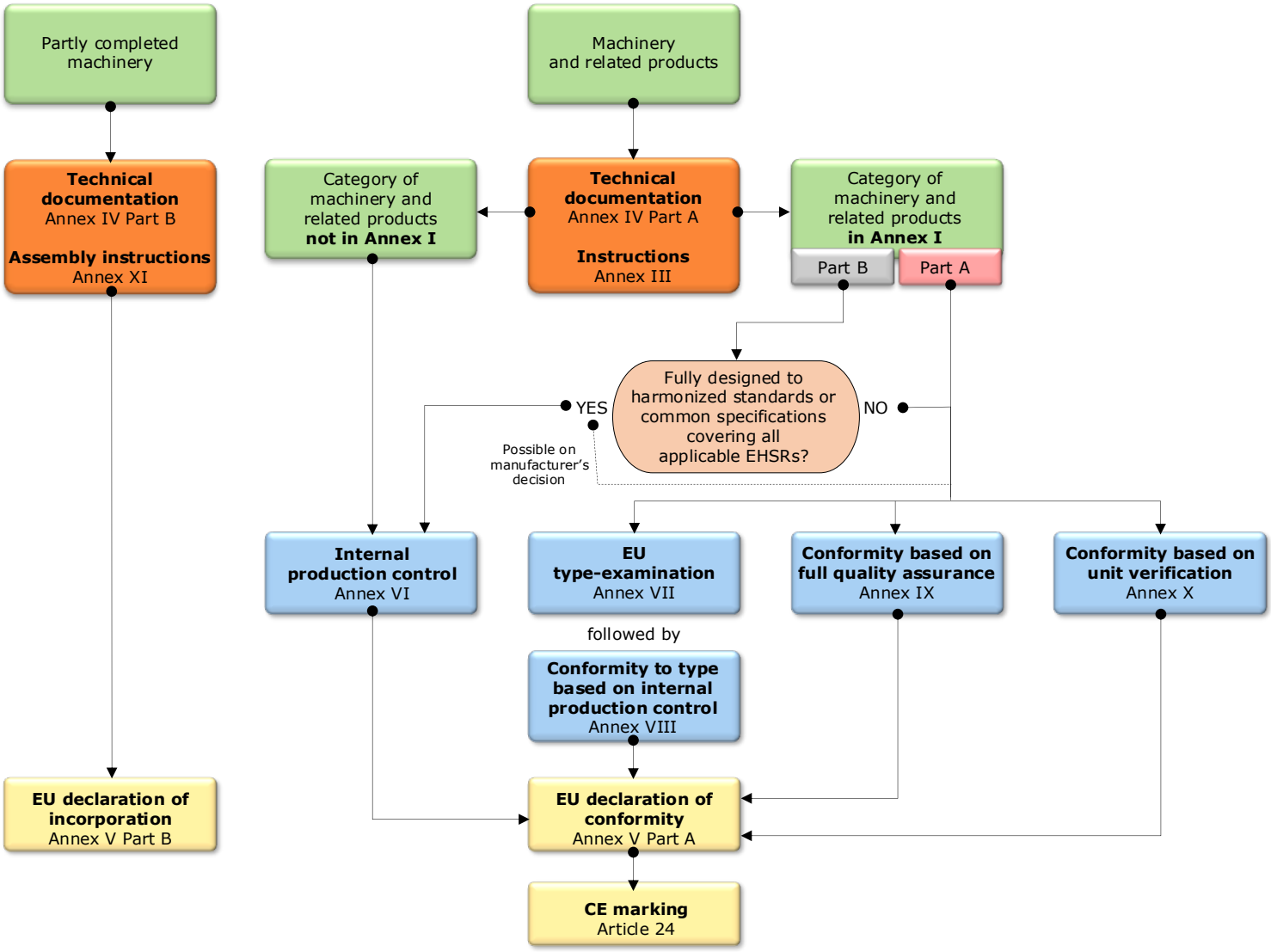


Figure 3: Article 6 detailed process



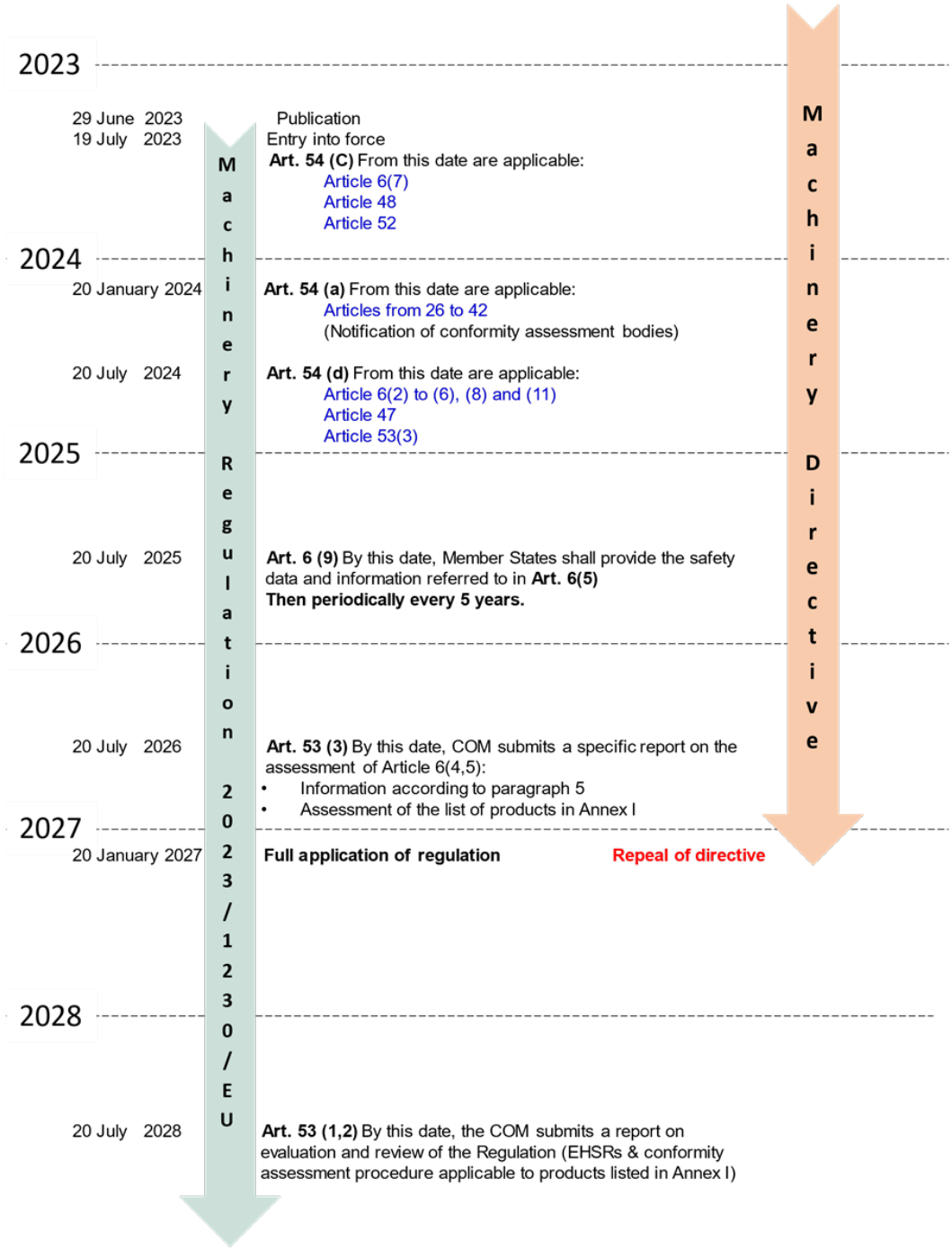
Additional content:
Schematic representation of assessment procedures (Article 10 & 11)

Figure 4: Assessment procedure diagram



Additional content: Milestones

Figure 5 : Milestones for Machinery regulation 2023/1230/EU and Machinery Directive 2006/42/EC



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