

Taylor Wessing Redline Version

Proposal for a regulation on machinery products of the European Parliament and of the Council

– August 2022 –

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Amendments made in Redline are intended to show the opinion of the Committee on the Internal Market and Consumer Protection of the European Parliament.

Amendments made in Redline and marked **gray** are intended to show the opinion of the Committee on Employment and Social Affairs of the European Parliament. If grey amendments are in brackets [EXAMPLE], they contradict or are redundant to amendments made by the Committee on the Internal Market and Consumer Protection. Amendments highlighted marked **gray** are intended to illustrate the legislative procedure; the Committee on the Internal Market and Consumer Protection has reached its opinion also on the basis of these changes.

The opinion of the cited Committee's can be found here:
https://www.europarl.europa.eu/doceo/document/A-9-2022-0141_EN.html#_section2

The official EU document building the base of this document can be found here:
https://eur-lex.europa.eu/resource.html?uri=cellar:1f0f10ee-a364-11eb-9585-01aa75ed71a1.0001.01/DOC_2&format=DOC



Brussels, 21.4.2021
COM(2021) 202 final

ANNEXES 1 to 11

ANNEXES

to the

**Proposal for a Regulation of the European Parliament and of the Council
on machinery products**

{SEC(2021) 165 final} - {SWD(2021) 82 final} - {SWD(2021) 83 final}

ANNEX I

Categories of machinery products subject to a specific conformity assessment procedure

Part A **HIGH-RISK MACHINERY PRODUCTS**

- ~~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;~~
 - ~~1.3. 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.~~
- ~~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.~~
- ~~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;~~
 - ~~4.2. 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.~~
- ~~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.~~
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.
- ~~10. Injection or compression plastics moulding machinery with manual loading or unloading.~~
- ~~11. Injection or compression rubber moulding machinery with manual loading or unloading.~~
- ~~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.
14. Removable mechanical transmission devices including their guards.
15. Guards for removable mechanical transmission devices.
16. Vehicle servicing lifts.
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.
18. Portable cartridge-operated fixing and other impact machinery.
- ~~19. Protective devices designed to detect the presence of persons.~~
- ~~20. Power operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11.~~
- ~~21. Logic units to ensure safety functions.~~
- ~~22. Roll-over protective structures (ROPS).~~
- ~~23. Falling object protective structures (FOPS).~~
24. AI systems with self-determining and evolving behaviour that are a safety component and are developed through any machine-learning techniques and approaches. ~~Software ensuring safety functions, including AI systems.~~
- 24a. Safety component with fully or partially evolving behaviour or logic.
25. Machinery embedding AI systems with self-determining and evolving behaviour as a safety component that has not been placed independently on the market and are developed through any machine-learning techniques and approaches. ~~ensuring safety functions.~~ [Machinery embedding a component ensuring safety functions with fully or partially evolving behaviour or logic.]

Part B

- 25a. 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:
 - 25a.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;
 - 25a.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;
 - 25a.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;

- 25a.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.
- 25b. Hand-fed surface planing machinery for woodworking.
- 25c. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.
- 25d. 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:
- 25d.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;
- 25d.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.
- 25e. Combined machinery of the types referred to in points 25a to 25d and in point 25g for working with wood and material with similar physical characteristics.
- 25f. Hand-fed tenoning machinery with several tool holders for woodworking.
- 25g. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.
- 25h. Injection or compression plastics-moulding machinery with manual loading or unloading.
- 25i. Injection or compression rubber-moulding machinery with manual loading or unloading.
- 25j. Machinery for underground working of the following types:
- 25j.1. locomotives and brake-vans;
- 25j.2. hydraulic-powered roof supports.
- 25k. Protective devices designed to detect the presence of persons.
- 25l. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 25h and 25i.
- 25m. Logic units to ensure safety functions.
- 25n. Roll-over protective structures (ROPS).
- 25o. Falling-object protective structures (FOPS).

ANNEX II

INDICATIVE LIST OF SAFETY COMPONENTS

1. Guards for removable mechanical transmission devices.
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 points 9, 10 and 11 of Annex I.
4. Logic units to ensure safety functions.
5. Valves with additional means for failure detection intended for the control of dangerous movements of machinery.
6. Extraction systems for machinery emissions.
7. Guards and protective devices designed to protect persons against moving parts involved in the process of the machinery.
8. Monitoring devices for loading and movement control in lifting machinery.
9. Restraint systems to keep persons in their seats.
10. Emergency stop devices.
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.
13. Systems and devices to reduce the emission of noise and vibrations.
14. Roll-over protective structures (ROPS).
15. Falling-object protective structures (FOPS).
16. Two-hand control devices.
17. The following components for machinery designed for lifting and/or lowering persons between different landings:
 - (a) devices for locking landing doors;
 - (b) devices to prevent the load-carrying unit from falling or unchecked upwards movement;
 - (c) overspeed limitation devices;
 - (d) energy-accumulating shock absorbers, non-linear or with damping of the return movement;
 - (e) energy-dissipating shock absorbers;
 - (f) safety devices fitted to jacks of hydraulic power circuits and used to prevent falls;
 - (g) safety switches containing electronic components.

18. ~~AI systems with self-determining and evolving behaviour that are a safety component and are developed through any machine-learning techniques and approaches.~~ Software ensuring safety functions, including AI systems.
19. Filtration systems intended to be integrated into machinery cabins in order to protect operators or other persons against hazardous materials and substances, including pesticides, and filters for such filtration systems.

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ANNEX III

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF MACHINERY PRODUCTS

GENERAL PRINCIPLES

1. The manufacturer of a machinery product ~~or his or her authorised representative~~ shall ensure that a risk assessment is carried out in order to determine the health and safety requirements, which apply to the machinery product. The machinery product shall then be designed and constructed to prevent and minimise all relevant risks, 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 ~~or his or her authorised representative~~ shall:

- (a) determine the limits of the machinery product, which include the intended use and any reasonably foreseeable misuse thereof;
- (b) determine the 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 a machinery product as defined in Article 3, point (1), point (d);
- (c) identify the hazards that may be generated by the machinery product and the associated hazardous situations, including hazards that may be generated during the lifecycle of the machinery product that are foreseeable at the time of placing of the machinery product on the market as an intended evolution of its fully or partially evolving behaviour or logic as a result of the machinery product designed to operate based on machine learning technologies, potentially with varying levels of autonomy; ~~In this respect, where the machinery product integrates an artificial intelligence system, the machinery risk assessment shall consider the risk assessment for that artificial intelligence system that has been carried out pursuant to the Regulation ... of the European Parliament and of the Council⁺ on a European approach for Artificial Intelligence⁺;~~
- (d) estimate the risks, taking into account the severity of the possible injury or damage to health, including mental health, and the probability of its occurrence;
- (e) evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Regulation;
- (f) eliminate the hazards or sufficiently reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).

2. The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery product in question when it is used under the conditions foreseen by the manufacturer ~~or his or her authorised representative~~ or in foreseeable abnormal situations. However, the principles of safety integration established in

⁺ ~~— OJ: Please insert in the text the number of the Regulation contained in document ... and insert the number, date, title and OJ reference of that Regulation in the footnote~~

section 1.1.2 and the obligations concerning marking of machinery products and instructions referred to in sections 1.7.3 and 1.7.4 apply in all cases.

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 product shall, as far as possible, be designed and constructed with the purpose of approaching those objectives.

4. This Annex is organised into six chapters. The first chapter is of general scope and applicable to all machinery products. 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 requirements. When a machinery 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 product referred to in section 2.4.

1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

1.1. GENERAL REMARKS

1.1.1. Definitions

For the purpose of this Annex:

- (a) 'hazard' means a potential source of injury or damage to health, including mental health;
- (b) 'danger zone' means any zone within and/or around a machinery 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 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 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;
- (h) 'intended use' means the use of a machinery product in accordance with the information provided in the instructions for use;
- (i) 'reasonably foreseeable misuse' means the use of a machinery product in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.

1.1.2. Principles of safety integration

- (a) A machinery product shall be designed and constructed so that it is fit for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the reasonably foreseeable conditions of use ~~foreseen~~ but also taking into account any reasonably foreseeable

use or misuse thereof. The aim of protective measures shall be to eliminate any risk throughout the foreseeable ~~lifetime~~lifecycle of the machinery product including the phases of transport, assembly, dismantling, disabling and scrapping.

- (b) In selecting the most appropriate methods, the manufacturer ~~or his or her authorised representative~~ shall apply the following principles, in the order given:
- i. eliminate or reduce risks as far as possible (inherently safe machinery product design and construction);
 - ii. 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.
- (c) When designing and constructing a machinery product and when drafting the instructions, the manufacturer ~~or his or her authorised representative~~ shall envisage not only the intended use of the machinery product but also any reasonably foreseeable misuse thereof. The machinery 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 shall draw the user's attention to ways — which experience has shown might occur — in which the machinery product should not be used.
- (d) A machinery 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) A machinery product shall be designed and constructed in such a way that it is possible ~~for the user~~ to test the safety functions, ~~and t~~ The machinery 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.

(ea) The provisions set out in this Annex must be implemented and interpreted with the concurrence of the European Agency for Safety and Health at work (EU-OSHA) in a way that fully secures the health and safety of workers or machinery products operators. Manufacturers and suppliers of the machinery products must always aim to provide the highest possible OHS standards in order to ensure accident prevention and safe use of machinery products. Machinery product operators must be provided with adequate protective equipment to ensure safe use and maintenance.

1.1.3. Materials and products

The materials used to construct a machinery product, or products used or created during its use, shall not endanger persons' safety or health. In particular, where fluids are used, machinery products shall be designed and constructed to prevent risks due to filling, use, recovery or draining.

1.1.4. Lighting

A machinery 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.

A machinery 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.

1.1.5. Design of a machinery product to facilitate its handling

A machinery product or each component part thereof, shall:

- (a) be capable of being handled and transported safely;
- (b) be packaged or designed so that it can be stored safely and without damage.

During the transportation of the machinery product ~~and~~/or its component parts, there shall be no possibility of sudden movements or of hazards due to instability as long as the machinery product ~~and~~/or its component parts are handled in accordance with the instructions.

Where the weight, size or shape of a machinery product or its various component parts prevents it or them from being moved by hand, the machinery 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 a machinery 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.

Special arrangements shall be made for the handling of tools and/or machinery product parts, which, even if lightweight, could be hazardous.

1.1.6. Ergonomics

Under the intended conditions of use, the discomfort, fatigue and physical and cognitive workload~~psychological stress~~[cognitive workload] faced by the operator shall be eliminated or reduced to the minimum possible, taking into account ergonomic principles such as:

- (a) allowing for the variability of the operator's physical dimensions, strength and stamina;
- (b) providing enough space for movements of the parts of the operator's body;
- (c) ~~avoiding-preventing~~ a machine-determined work rate by allowing adaptations [by allowing adaptations];
- (d) ~~avoiding-preventing~~ monitoring that requires lengthy concentration;
- (e) adapting the human-machinery product interface including the security systems and the emergency stop systems, to the foreseeable characteristics of the operators, including with respect to a machinery product with intended fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy;
- (f) adapting a machinery product with intended fully or partially evolving behaviour or logic that is designed to operate based on machine learning technologies, potentially

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 ["and to communicate its planned actions (such as what it is going to do and why) to operators in a comprehensible manner" to be deleted].

(fa) communicating a machinery product's planned actions (what it is going to do and why) to operators in a comprehensible manner.

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 ~~and~~/or lack of oxygen.

If the machinery product is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery 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.

Where appropriate, the operating position shall be fitted with an adequate cabin designed, constructed ~~and~~/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.

1.1.8. Seating

Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery 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 product, the seat shall be provided with the machinery product.

The operator's seat shall enable him 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 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.

1.1.9. Protection against corruption

The machinery 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 product does not lead to ~~a~~-potentially hazardous situations.

A hardware component relevant for connection to, or access to, software [or access to software] that is critical for the compliance of the machinery product with the relevant health and safety requirements shall be designed so that it is adequately protected against accidental or intentional corruption. The machinery product shall collect evidence of a legitimate or illegitimate intervention in ~~the~~-that [aforementioned] hardware component.

Software and data that are critical for the compliance of the machinery product with the relevant health and safety requirements shall be identified as such and shall be adequately protected against accidental or intentional corruption.

The machinery 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 product shall collect evidence of a legitimate or illegitimate intervention in the software or a modification of the software installed on the machinery product or its configuration.

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:

- (a) they can withstand, where appropriate to the circumstances and the risks, the intended operating stresses and intended and unintended external influences, including predictable misuse ~~[predictable misuse] malicious attempts~~ from third parties creating a potentially ~~to create a~~ [potentially] hazardous situation or function ~~[or function]~~;
- (b) a fault in the hardware or the logic of the control system shall not lead to hazardous situations;
- (c) errors in the control system logic shall not lead to hazardous situations;
- (d) the safety functions cannot be changed or upgraded beyond the limits defined by the manufacturer in the machinery product risk assessment. The establishment of the limits of the safety functions shall be part of the risk assessment performed by the manufacturer, including any modifications to the settings or rules generated by the machinery product or by operators, covering also its development based on machine ~~[its development based on machine] the-learning-phase~~, which cannot go beyond the limits addressed in the risk assessment;
- (e) reasonably foreseeable human errors during operation shall 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 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 product with this Annex further to a reasoned request from a competent national authority;
- (g) recording of data on the safety related machine-learning ~~decision-making~~ process after the machinery 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 product with this Annex further to a reasoned request from a competent national authority.

Control systems of machinery products with fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy shall be designed and constructed in such a way that:

- (a) they shall not cause the machinery product to perform actions beyond its defined task and movement space;

- (b) it shall be possible at all times to correct the machinery product in order to maintain its inherent safety.

Particular attention shall be given to the following points:

- (a) the machinery product shall not start unexpectedly;
- (b) the parameters of the machinery product shall not change in an uncontrolled way, where such change may lead to hazardous situations;
- (c) modifications to the settings or rules, generated by the machinery product or by operators covering also the ~~learning~~ process of machine learning [process of machine learning] phase, shall be prevented, where such modifications may lead to hazardous situations;
- (d) the machinery product shall not be prevented from stopping if the stop command has already been given;
- (e) no moving part of the machinery product or piece held by the machinery 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 product.

For wireless control, a failure of the communication or connection or a faulty connection shall not lead to a hazardous situation.

For autonomous mobile machinery products, 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.

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 products shall be fitted with indicators as required for safe operation. The operator shall be able to read them from the control position.

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 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 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 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.

1.2.3. Starting

It shall be possible to start the machinery product only by voluntary actuation of a control device provided for the purpose.

The same requirement applies:

- (a) when restarting the machinery product after a stoppage, whatever the cause;
- (b) when effecting a significant change in the operating conditions.

However, the restarting of the machinery 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.

For the machinery product functioning in automatic mode, the starting of the machinery 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 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.

1.2.4. Stopping

1.2.4.1. Normal stop

The machinery 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 product, depending on the existing hazards, so that the machinery product is rendered safe.

The machinery product's stop control shall have priority over the start controls.

Once the machinery product or its hazardous functions have stopped, the energy supply to the actuators concerned shall 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.

1.2.4.3. Emergency stop

The machinery 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 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 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 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.

1.2.4.4. Assembly of machinery products

In the case of a machinery product or parts of a machinery product designed to work together, the machinery shall be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery product 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 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 product to certain categories of operator.

If, for certain operations, the machinery 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;
- (d) prevent any operation of hazardous functions by voluntary or involuntary action on the machine 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.

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 product shall not lead to hazardous situations.

Particular attention shall be given to the following:

- (a) the machinery 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 product shall not be prevented from stopping if the stop command has already been given;
- (d) no moving part of the machinery product or piece held by the machinery 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.

1.3. PROTECTION AGAINST MECHANICAL RISKS

1.3.1. Risk of loss of stability

The machinery 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 product.

If the shape of the machinery product itself or its intended installation does not offer sufficient stability, appropriate means of anchorage shall be incorporated and indicated in the instructions.

1.3.2. Risk of break-up during operation

The various parts of machinery 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 or his or her authorised representative, 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 ~~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, shall be able to withstand the foreseen internal and external stresses and shall be firmly attached and/or protected to ensure that no risk is posed by a rupture.

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.

1.3.3. Risks due to falling or ejected objects

Precautions shall 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 shall have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.

1.3.5. Risks related to a combined machinery product

Where the machinery product is intended to carry out several different operations with manual removal of the piece between each operation (combined machinery 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.

1.3.6. Risks related to variations in operating conditions

Where the machinery 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.

1.3.7. Risks related to moving parts and cognitive workload~~psychological stress~~ [psychological stress and cognitive workload]

The moving parts of the machinery 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 and, where possible, a sign on the machinery 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 cognitive workload ~~psychological stress~~ [as well as the psychological stress and the cognitive workload] 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) [direct] human-machine collaboration in a shared space ~~interaction~~.

~~The machinery product with fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy shall be adapted to respond to people adequately and appropriately (verbally through words or nonverbally through gestures, facial expressions or body movement) and to communicate its planned actions (what it is going to do and why) to operators in a comprehensible manner.~~

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.

1.3.8.1. 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.

1.3.8.2. 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 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.

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.

1.3.9. Risks of uncontrolled movements

When a part of the machinery 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.

1.4. 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 product.

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 product when the guards are removed.

Where possible, guards shall 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 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 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 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 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 product functions has ceased.

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 product 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.

1.4.3. 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.

1.5. RISKS DUE TO OTHER CAUSES

1.5.1. Electricity supply

Where a machinery product has an electricity supply, it shall be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented.

The safety objectives set out in Directive 2014/35/EU shall apply to a machinery product. However, the obligations concerning conformity assessment and the placing on the market ~~and/or~~ putting into service of a machinery product with regard to electrical risks are governed solely by this Regulation.

1.5.2. Static electricity

A machinery product 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.

1.5.3. Energy supply other than electricity

Where a machinery product is powered by source of energy other than electricity, it shall 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 ~~and/or~~ their housings. The same information shall 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 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.

1.5.5. Extreme temperatures

Steps shall be taken to eliminate any risk of injury arising from contact with or proximity to machinery 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.

1.5.6. Fire

A machinery product shall be designed and constructed in such a way as to avoid any risk of fire or overheating posed by the machinery product itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery product.

1.5.7. Explosion

A machinery product shall be designed and constructed in such a way as to avoid any risk of explosion posed by the machinery product itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery product.

A machinery product 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.

1.5.8. Noise

A machinery product 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 product.

1.5.9. Vibrations

A machinery product shall be designed and constructed in such a way that risks resulting from vibrations produced by the machinery 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 products.

1.5.10. Radiation

Undesirable radiation emissions from the machinery product 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 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.

1.5.11. External radiation

A machinery product shall 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 a machinery product shall be designed and constructed in such a way as to prevent any accidental radiation;
- (b) laser equipment on a machinery product 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 a machinery product shall be such that no health risk is created by laser radiation.

1.5.13. Emissions of hazardous materials and substances

A machinery product 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 risk cannot be eliminated, the machinery 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. In cases where the use of external devices is not feasible, information on the use of appropriate personal protective equipment (PPE) shall be provided in the operating instructions.

Where the process is not totally enclosed during normal operation of the machinery 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.

1.5.14. Risk of being trapped in a machine

A machinery product 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.

1.5.15. Risk of slipping, tripping or falling

Parts of the machinery product 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.

1.5.16. Lightning

A machinery product 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.

1.6. MAINTENANCE

1.6.1. Machinery 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 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 product, a connecting device for mounting diagnostic fault-finding equipment shall be provided.

Automated machinery 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.

1.6.2. Access to operating positions and servicing points

Machinery 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.

In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses shall be designed in dimensioned and adapted for the use of rescue equipment in such a way that guarantees a timely emergency rescue of the persons ~~is guaranteed~~.

1.6.3. Isolation of energy sources

A machinery product 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 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 product without risk to persons.

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.

1.6.4. Operator intervention

The machinery 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.

1.6.5. Cleaning of internal parts

The machinery shall 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 shall also be possible from the outside. If it is impossible to avoid entering the machinery, it shall be designed and constructed in such a way as to allow cleaning to take place safely.

1.7. INFORMATION

1.7.1. Information and warnings on the machinery product

Information and warnings on the machinery product shall preferably be provided in the form of readily understandable symbols or pictograms.

1.7.1.1. Information and information devices

The information needed to control a machinery 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 product shall 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 product, the machinery product shall be equipped in such a way as to give an appropriate acoustic or light signal as a warning.

Where a machinery 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 legislation concerning colours and safety signals shall be complied with.

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.

1.7.3. Marking of a machinery product

All machinery products shall be marked visibly, legibly and indelibly with the following minimum particulars:

- (a) the business name and full address of the manufacturer and, where applicable, his or her authorised representative;
- (b) designation of the machinery product;
- (c) the CE marking;
- (d) designation of series or type;
- (e) serial number, if any;
- (f) 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 product when affixing the CE marking.

Furthermore, a machinery product designed and constructed for use in a potentially explosive atmosphere shall be marked accordingly.

A machinery product 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.

Where a machine product part shall be handled during use with lifting equipment, its mass shall be indicated legibly, indelibly and unambiguously.

1.7.4. Instructions

The instructions accompanying the machinery product shall be either 'Original instructions' or a 'Translation of the original instructions', in which case the translation shall be accompanied by the original instructions.

By way of exception, the maintenance instructions intended for use by specialised personnel mandated by the manufacturer ~~or his or her authorised representative~~ may be supplied in only one official language of the Union which the specialised personnel understand.

The instructions ~~may~~ shall be provided in a digital format over the entire lifecycle. ~~However, upon purchaser's request at the time of the purchase~~ of the machinery product. However, under the purchaser's request, the instructions shall be provided in paper format free of charge up to two years after the purchase of the machinery product.

When the instructions are provided in digital format, the manufacturer shall:

- (a) mark on the machinery product and in an accompanying paper how to access the digital instructions;
- (b) clearly describe which version of the instructions corresponds to the machinery product model;
- (c) be presented in a format that makes it possible for the end user to download the instructions over the lifetime of the machinery product [over the entire lifecycle of the machinery product] 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 machine. This requirement also applies to a machinery product where the instruction manual is embedded in the software of the machinery product. ~~General principles for the drafting of instructions~~

1.7.4.1. General principles for the drafting of instructions

- (a) The instructions shall be drafted in one or more official languages of the Union. The words 'Original instructions' shall appear on the language version(s) verified by the manufacturer or his or her authorised representative;
- (b) Where no 'Original instructions' exist in the official language or languages of the Member State where the machinery product is to be used, a translation into that/those language(s) shall be provided by the manufacturer or his or her authorised representative or by the person bringing the machinery product into the language area in question. The translations shall bear the words 'Translation of the original instructions';
- (c) The contents of the instructions shall cover not only the intended use of the machinery product but also take into account any reasonably foreseeable misuse thereof;
- (d) In the case of a machinery product 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.

1.7.4.2. Contents of the instructions

1. Each instruction manual shall contain, where applicable, at least the following information:

- (a) the business name and full address of the manufacturer and, where applicable, of his or her authorised representative;
- (b) the designation of the machinery product as marked on the machinery product itself, except for the serial number (see section 1.7.3);
- (c) the EU declaration of conformity, or a document setting out the contents of the EU declaration of conformity, showing the particulars of the machinery product, not necessarily including the serial number and the signature, or the internet address

where the EU declaration of conformity can be accessed over the lifetime of the machinery product; [over the entire lifecycle of the machinery product];

- (d) a general description of the machinery product;
- (e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery 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 product;
- (h) warnings concerning ways in which the machinery product shall not be used that experience has shown might occur;
- (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 product is to be mounted;
- (j) instructions relating to installation and assembly for reducing noise or vibration;
- (k) instructions for the putting into service and use of the machinery product 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;
- (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 product;
- (o) the conditions in which the machinery product 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 product 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;
- (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 product;
- (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;
- (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;

- ii. the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 μ Pa);
- iii. the A-weighted sound power level emitted by the machinery product, 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 product in question or those established on the basis of measurements taken for a technically comparable machinery product, which is representative of the machinery product to be produced.

In the case of a very large machinery product, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery product may be indicated.

Where the harmonised standards or technical specifications adopted by the Commission in accordance with Article 17(3) cannot be applied, sound levels shall be measured using the most appropriate method for the machinery product. Whenever sound emission values are indicated, the uncertainties surrounding these values shall be specified. The operating conditions of the machinery product during measurement and the measuring methods used shall 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 metre from the surface of the machinery product and at a height of 1,6 metres from the floor or access platform. The position and value of the maximum sound pressure shall be indicated.

With respect to noise reduction machinery products, the instructions shall specify, where appropriate, how to correctly assemble and install that equipment (see also section 1.7.4.2(1), point (j)).

Where specific Union legislation lays 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) where a machinery product 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;
- (w) where the machinery product design allows emissions of hazardous substances from the machinery product, the characteristics of the capturing, filtration or discharge device if such device is not provided with the machinery product, and any of the following:
 - i. the flow rate for the emission of hazardous materials and substances from the machinery product,
 - ii. the concentration of hazardous materials or substances around the machinery product coming from the machinery product or from materials or substances used with the machinery 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 product in question or established based on measurements in respect

of a technically comparable machinery product, which is representative of the state of the art.

1.7.4.3. Sales literature

Sales literature describing the machinery product shall not contradict the instructions as regards health and safety aspects. Sales literature describing the performance characteristics of machinery products shall contain the same information on emissions as is contained in the instructions.

2. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY PRODUCTS

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 shall meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).

2.1. FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS

2.1.1. General

Machinery 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 cosmetics or pharmaceutical products shall satisfy the conditions set down in the relevant Union legal acts. The machinery 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 cosmetics or pharmaceutical products, other than surfaces of disposable parts, shall:
 - 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 (if possible, in a 'cleaning' position);
- (d) machinery 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 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 shall be designed and constructed in such a way that continuing compliance with this requirement can be checked.

2.1.2. Instructions

The instructions for foodstuffs machinery and machinery for use with 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.

2.2. PORTABLE HAND-HELD ~~AND/OR~~ HAND-GUIDED MACHINERY

2.2.1. General

Portable hand-held ~~and/or~~ hand-guided machinery shall:

- (a) 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;
- (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 ~~and/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 where its application would result in the creation of a new risk, where the main function of the machinery is the spraying of hazardous substances and to emissions of internal combustion engines. Where the use of external devices is not feasible, information on the use of appropriate personal protective equipment (PPE) ~~The handles of portable machinery shall be designed and constructed in such a way as to make starting and stopping straightforward~~ designed and constructed in such a way as to make starting and stopping straightforward.

The handles of portable machinery shall be designed and constructed in such a way as to make starting and stopping that machinery straightforward. [Machinery may only be equipped with a connection for an exhaust system if it is intended for this kind of operation. In situations where the use of external devices is not feasible, information on the use of appropriate personal protective equipment (PPE) shall be provided in the operating instructions.]

2.2.1.1. Instructions

The instructions shall give the following information concerning vibrations, expressed as acceleration (m/s^2), and transmitted by portable handheld and hand-guided machinery:

- (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 in question or those established on the basis of measurements in respect of a technically comparable machinery product, which is representative of the state of the art.

If harmonised standards or technical specifications adopted by the Commission in accordance with Article 17(3) cannot be applied, the vibration data shall 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, shall be specified.

2.2.2. Portable fixing and other impact machinery

2.2.2.1. General

Portable fixing and other impact machinery shall be designed and constructed in such a way that:

- (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 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.

2.2.2.2. Instructions

The instructions shall give the necessary information regarding:

- (a) the accessories and interchangeable equipment that can be used with the machinery;
- (b) the suitable fixing or other impacted elements to be used with the machinery;
- (c) where appropriate, the suitable cartridges to be used.

2.3. MACHINERY FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS

Machinery for working wood and materials with similar physical characteristics shall comply with the following requirements:

- (a) the machinery 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;

- (b) where the machinery 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;
- (c) the machinery 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;
- (d) where the tool is incorporated into a non-fully automated machine, the latter shall be designed and constructed in such a way as to eliminate or reduce the risk of accidental injury.

2.4. MACHINERY FOR PLANT PROTECTION PRODUCTS APPLICATION

2.4.1. Definition

‘Machinery for plant protection products application’ means machinery specifically intended for the application of plant protection products within the meaning of Article 2, point (1), of Regulation (EC) No 1107/2009 of the European Parliament and of the Council².

2.4.2. General

The manufacturer of machinery for pesticide application or his or her authorised representative shall 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 shall be designed and constructed taking into account the results of the risk assessment referred to in the first subparagraph so that the machinery can be operated, adjusted and maintained without unintended exposure of the environment to pesticides.

Leakage shall be prevented at all times.

2.4.3. Controls and monitoring

It shall 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 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 pesticide and avoiding the contamination of the water source during such operations.

2.4.5. Application of pesticides

2.4.5.1. Application rate

The machinery shall be fitted with means of adjusting the application rate easily, accurately and reliably.

2.4.5.2. Distribution, deposition and drift of pesticide

² 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).

The machinery shall 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 shall be ensured.

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 or her authorised representative shall, for each type of machinery concerned, perform appropriate tests, or have such tests performed.

2.4.5.4. Losses during stoppage

The machinery shall be designed and constructed to prevent losses while the pesticide application function is stopped.

2.4.6. Maintenance

2.4.6.1. Cleaning

The machinery shall be designed and constructed to allow its easy and thorough cleaning without contamination of the environment.

2.4.6.2. Servicing

The machinery shall 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 to check the correct functioning of the machinery.

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.

2.4.9. Indication of pesticide in use

Where appropriate, the machinery shall be fitted with a specific mounting on which the operator can place the name of the pesticide in use.

2.4.10. Instructions

The instructions 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 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;
 - (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 ³;
 - (j) the features of the machinery, which shall 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

~~Machinery presenting risks due to its mobility shall meet all the~~ The essential health and safety requirements ~~laid down~~ described in this chapter Annex are mandatory (see General Principles, point 4). Machinery product shall be designed and constructed with the purpose of approaching those objectives.

3.1. GENERAL

3.1.1. Definitions

- (a) ‘Machinery presenting risks due to its mobility’ means
 - i. machinery 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 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 a person responsible for the movement of a machine, who may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control or may remotely supervise the autonomous mobile machinery product regardless of the distance and the means of control communication.
- (c) ‘Autonomous mobile machinery’ means a mobile machinery that has an autonomous mode, in which all the essential safety functions of the mobile machinery are ensured

³ 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).

in its travel and working operations area without permanent interaction of an operator.

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 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 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.

3.2.2. 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, 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. Such restraint systems or provision shall take ergonomic principles into account and shall [have an ergonomic design and shall] not be fitted if they increase the risk.

The machinery shall not be able to move when the restraint system is not active in case there is a significant risk of tipping or rolling over. A visual ~~or~~ and audible signal shall be provided at the driving position alerting the driver when driver is in the driving position and not using the restraint system ~~is not active~~.

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.

3.2.4. Supervisory control function

Autonomous mobile machinery products shall have a supervisory control function specific to the autonomous mode. This function shall allow the operator to remotely receive information from the machine. The supervisory control function shall only allow actions to stop and to start ~~remotely~~ the machine remotely and. ~~It shall be designed and constructed to include a function which would allow~~ he operator to bring the machinery into a secure state. ~~those actions only when the driver can see directly or indirectly the machine's movement and working area and the protective devices are operational.~~

The information the driver receives from the machine when the supervisory control function is active shall enable the driver to have a complete and accurate view of the operation, movement and safe positioning of the machine in its travel and working area.

This information shall alert the driver of the occurrence of unforeseen or dangerous situations present or impending, which require driver's intervention.

If the supervisory control function is not active, the machinery shall not be able to operate.

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 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 in question;
- (b) the functions in question.

Remote controlled machinery shall 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 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.

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.

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 product shall take into account the risks related to the area where it is intended to move and work.

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.

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.

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.

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.

Section 1.2.4 does not apply to the travelling function.

Autonomous mobile machinery products shall comply with at least one [at least one] any of the following two [two] conditions:

- (a) it shall move and operate in an enclosed zone fitted with a peripheral protection system comprising guards or protective devices;
- (b) 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 product.

The movements of mobile machinery products connected with one or more trailers or towed equipment, including autonomous mobile machinery products, 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 products 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.

3.3.5. 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.

3.4. PROTECTION AGAINST MECHANICAL RISKS

3.4.1. Uncontrolled movements

A machinery product 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.

3.4.2. 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.

In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his or her authorised representative 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 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 or his or her authorised representative shall, 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.

3.4.6. 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.

3.4.7. 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.

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.

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.

A machinery 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, including autonomous mobile machinery 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 collusion of the machine with a person or another machine when the machine moves autonomously to the charging station.

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.

3.5.3. 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 shall be protected against the risk of exposure to such hazardous emissions.

Ride-on mobile machinery having spraying of products as the main function shall be equipped with filtration cabs or equivalent safety measures.

3.5.4. Risk of contact with live overhead power lines

Depending on the height of the machinery products, mobile machinery product 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 of contact or electric arc with an energised overhead power line cannot be fully avoided, mobile machinery products shall be designed, constructed and equipped in such a way that all hazards of an electrical nature are prevented or can be prevented in the event of contact or electrical arc with an energized power line.

3.6. INFORMATION AND INDICATIONS

3.6.1. Signs, signals and warnings

All machinery 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 product with a ride-on driver shall have the following equipment:

- (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 product 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 product for the operation of signals.

Remote-controlled machinery 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 product, 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 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.

3.6.2. Marking

The following shall be shown legibly and indelibly on all machinery products:

- (a) nominal power expressed in kilowatts (kW);
- (b) mass of the most usual configuration, in kilograms (kg);

and, where appropriate:

- (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).

3.6.3. Instructions

3.6.3.1. Vibrations

The instructions shall give the following information concerning vibrations, expressed as acceleration (m/s^2), transmitted by the machinery 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 mean square value of weighted acceleration to which the whole body is subjected, if it exceeds 0,5 m/s^2 . Where this value does not exceed 0,5 m/s^2 , this shall be mentioned;
- (d) the uncertainty of measurements.

These values shall 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.

Where harmonised standards or technical specifications adopted by the Commission in accordance with Article 17(3) cannot be applied, the vibration shall be measured using the most appropriate measurement code for the machinery concerned.

The operating conditions during measurement and the measurement codes used shall be described.

3.6.3.2. Multiple uses

The instructions for a machinery product allowing several uses depending on the equipment used and the instructions for the interchangeable equipment shall contain the information necessary for safe assembly and use of the basic machinery product and the interchangeable equipment that can be fitted.

3.6.3.3. Autonomous mobile machinery products

The instructions for use of autonomous mobile machinery 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

Machinery 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).

4.1. GENERAL

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 or her 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

4.1.2.1. Risks due to lack of stability

Machinery 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 instruction handbook. To that end, the manufacturer or his or her authorised representative shall use the appropriate verification methods.

4.1.2.2. Machinery running on guide rails and rail tracks

Machinery 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.

4.1.2.3. Mechanical strength

Machinery, 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 and 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.

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.

Machinery and 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 and lifting accessories: 1, 5;
- (b) other machinery: 1,25.

Machinery 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.

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.

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 or his or her authorised representative 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.

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;
- (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 or his or her authorised representative shall, 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 on which they are installed is kept safe.

- (a) Machinery 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.
- (b) Where several fixed or rail-mounted machine 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 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 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.

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.

4.1.2.8. Machinery serving fixed landings

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.

4.1.2.8.2. *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.

4.1.2.8.3. *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.

4.1.2.8.4. *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.

4.1.2.8.5. *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 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.

4.1.3. Fitness for purpose

When lifting machinery or lifting accessories are placed on the market or are first put into service, the manufacturer ~~or his or her authorised representative~~ shall 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 shall 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 or her authorised representative, the appropriate measures shall be taken at the place of use by the manufacturer, or by his or her authorised representative or by another subject on the manufacturers' behalf. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.

4.2. REQUIREMENTS FOR MACHINERY PRODUCTS WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT

4.2.1. Control of movements

Hold-to-run control devices shall 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 with a maximum working load of not less than 1 000 kilograms 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.

4.2.3. 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.

4.3. 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 or his or her authorised representative and the identifying reference of the relevant [declaration of conformity certificate](#).

The certificate mentioned above shall show at least the following information:

- (a) the name and address of the manufacturer and, if appropriate, his or her authorised representative;
- (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.

4.3.2. Lifting accessories

Lifting accessories shall show the following particulars:

- i. identification of the material where this information is needed for safe use;
- ii. 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.

4.3.3. Lifting machinery

The maximum working load shall be prominently marked on the machinery. This marking shall be legible, indelible and in an un-coded form.

Where the maximum working load depends on the configuration of the machinery, 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 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.

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.

4.4.2. Lifting machinery

Lifting machinery shall be accompanied by instructions containing information on:

- (a) the technical characteristics of the machinery, 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,
 - 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 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 or her 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 PRODUCTS INTENDED FOR UNDERGROUND WORK

Machinery products intended for underground work shall 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.

5.2. MOVEMENT

Powered roof supports shall 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.

5.4. 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.

5.5. FIRE

Section 3.5.2 (b) is mandatory in respect of machinery, which comprises highly flammable parts.

The braking system of machinery 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 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.

5.6. EXHAUST EMISSIONS

Exhaust emissions from internal combustion engines shall not be discharged upwards.

6. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PRODUCTS PRESENTING PARTICULAR RISKS DUE TO THE LIFTING OF PERSONS

Machinery 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).

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 intended for the lifting of persons and shall, as a general rule, be doubled. Machinery 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.

6.1.2. 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.

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

6.3. RISKS TO PERSONS IN OR ON THE CARRIER

6.3.1. Risks due to movements of the carrier

Machinery 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.

6.3.2. 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 and carrier are moving.

Where the carrier is designed as a workstation, provision shall be made to ensure stability and to prevent hazardous movements.

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.

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.

6.4. 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.

The machinery 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.

The stopping action shall 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.

6.4.3. 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.

6.5. 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.

ANNEX IV

A. TECHNICAL DOCUMENTATION FOR MACHINERY PRODUCTS

The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the machinery product with the applicable essential health and safety requirements set out in Annex III.

The technical documentation shall include at least the following elements:

- (a) a complete description of the machinery product and of its intended use;
- (b) an assessment of the risks against which the machinery product is designed and constructed;
- (c) a list of the essential health and safety requirements that are applicable to the machinery product;
- (d) design and manufacturing drawings and schemes of the machinery product and of its components, sub-assemblies and circuits;
- (e) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the machinery product;
- (f) the references of the harmonised standards or technical specifications adopted by the Commission in accordance with Article 17(3) that have been applied for the design and manufacture of the machinery. In the event of partial application of harmonised standards, the documentation shall specify the parts, which have been applied;
- (g) where harmonised standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;
- (h) the results of the design calculations, inspections and examinations carried out to verify the conformity of the machinery with the applicable essential health and safety requirements;
- (i) reports on the tests carried out to verify the conformity of the machinery with the applicable essential health and safety requirements;
- (j) a description of the means used by the manufacturer during the production of the machinery to ensure the conformity of the machinery produced with the design specifications;
- (k) a copy of the manufacturer's instructions and the information set out in section 1.7.4 of Annex III;
- (l) where appropriate, the declaration of incorporation for partly completed machinery set out in Annex V and the relevant assembly instructions for such machinery;
- (m) for machinery products produced in series, the internal measures that will be implemented to ensure that the machinery product remains in conformity with this Regulation;
- (n) the source code or programmed logic of the safety related software to demonstrate the conformity of the machinery 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;

- (o) for sensor-fed, remotely-driven, or autonomous machinery product, 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, ~~without prejudice to the requirements for artificial intelligence (AI) systems set out in the Regulation (EU) .../... of the European Parliament and of the Council⁺ on a European approach for Artificial Intelligence if the safety related software includes an AI system;~~
- (p) the results of research and tests on components, fittings or the completed machinery carried out by the manufacturer to determine whether by its design or construction it is capable of being assembled and put into service safely.

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.

The technical documentation shall include at least the following elements:

- (a) a complete description of the partly completed machinery and of its function when incorporated into or assembled with machinery or other partly completed machinery or equipment~~intended use;~~
- (b) an assessment of the risks against the partly completed machinery is designed and constructed; a list of the essential health and safety requirements that are applicable to the partly completed machinery;
- (c) design and manufacturing drawings and schemes of the partly completed machinery and of its components, sub-assemblies and circuits;
- (d) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the partly completed machinery;
- (e) the references of the harmonised standards referred to in Article 18 that have been applied for the design and manufacture of the partly completed machinery. In the event of partial application of harmonised standards, the documentation shall specify the parts, which have been applied;
- (f) where harmonised standards have not been applied or have been only partially applied, description of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;
- (g) the results of the design calculations, inspections and examinations carried out to verify the conformity of the partly completed machinery with the applicable essential health and safety requirements;
- (h) reports on the tests carried out to verify the conformity of the partly completed machinery with the applicable essential health and safety requirements;

~~⁺ OJ: Please insert in the text the number of the Regulation contained in document ... and insert the number, date, title and OJ reference of that Regulation in the footnote.~~

- (i) 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;
- (j) [the EU declaration of incorporation for](#) ~~a copy of the assembly instructions for the~~ partly completed machinery set out in [Annex V and the relevant assembly instructions for such machinery set out in](#) ~~section 1.7.4 of Annex XIII~~;
- (k) for partly completed machinery ~~products~~ produced in series, the internal measures that will be implemented to ensure that the partly completed machinery product remains in conformity with the essential health and safety requirements applied;
- (l) the source code or programmed 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;
- (m) 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, ~~without prejudice to the requirements for artificial intelligence (AI) systems set out in the Regulation (EU) .../... of the European Parliament and of the Council⁺ on a European approach for Artificial Intelligence if the safety related software includes a AI system~~;
- (n) the results of research and tests on components, fittings or the completed machinery carried out by the manufacturer to determine whether by its design or construction it is capable of being assembled and put into service safely.

⁺ ~~OJ: Please insert in the text the number of the Regulation contained in document ... and insert the number, date, title and OJ reference of that Regulation in the footnote.~~

ANNEX V

EU DECLARATION OF CONFORMITY OF MACHINERY PRODUCTS EXCEPT FOR PARTLY COMPLETED MACHINERY No...⁴

This declaration relates exclusively to machinery products, except for partly completed 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 unless there is a substantial modification of the machinery product.

1. The EU declaration of conformity shall contain the following particulars: Machinery product (product, type, batch or serial number):
2. Name and address of the manufacturer and, where applicable, his or her authorised representative:
3. The address where the ~~machine~~ machinery product is permanently installed only for lifting machinery product installed in a building or a structure:
4. This declaration of conformity is issued under the sole responsibility of the manufacturer:
5. Object of the declaration (identification of machinery product allowing traceability; where necessary for the identification of the machinery product, a colour image of sufficient clarity may be included):
6. The object of the declaration described in point 4⁶ is in conformity with the relevant Union harmonisation legislation:
7. References to the relevant harmonised standards used or technical specifications adopted by the Commission in accordance with Article 17(3), including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:
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):
9. Where applicable, the machinery product is subject to the conformity assessment procedure ... (either internal production control (Module A) or full quality assurance (module H) ... under surveillance of the notified body ... (name, number):
10. Additional information:

Signed for and on behalf of: ...

(place and date of issue):

(name, function) (signature):

⁴ It is optional for the manufacturer to assign a number to the declaration of conformity.

EU DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY No...⁵

The declaration of incorporation shall contain the following particulars:

1. Partly Completed Machinery (product, type, batch or serial number):
2. Name and address of the manufacturer and, where applicable, his or her 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):
5. A sentence declaring which essential requirements of Regulation (EU) .../..... of the European Parliament and of the Council⁶ are applied and fulfilled and that the relevant technical documentation was drawn-up in accordance with part B of Annex IV, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Union harmonisation legislation:
6. References to the relevant harmonised standards used or technical specification adopted by the Commission in accordance with Article 17(3), including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:
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:
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 where appropriate:
9. Additional information:

Signed for and on behalf of: ...

(place and date of issue):

(name,

function)

(signature):

⁵ It is optional to assign a number to the declaration of conformity.

⁶ OJ: Please insert in the text the number of the Regulation contained in document ...and insert the number, date, title and OJ reference of that Regulation in the footnote

ANNEX VI

INTERNAL PRODUCTION CONTROL

(Module A)

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 product satisfies the applicable requirements of this Regulation.

2. Technical documentation

The manufacturer shall draw up the technical documentation described in Annex IV.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured machinery product with the technical documentation referred to in point 2 and with the applicable requirements of this Regulation.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking to each individual machinery product that satisfies the applicable requirements of this Regulation.

4.2. The manufacturer shall draw up an EU declaration of conformity for each machinery product model in accordance with Article 20 and keep it, together with the technical documentation, at the disposal of the national authorities for ten years after the machinery product has been placed on the market or put into service. The EU declaration of conformity shall identify the machinery 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.

5. Authorised representative

The manufacturer's obligations set out in point 4 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.

ANNEX VII

EU TYPE-EXAMINATION

(Module B)

1. EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a machinery product and verifies and attests that the technical design of the machinery product meets the applicable requirements of this Regulation.
2. EU type-examination shall be carried out by assessment of the adequacy of the technical design of the machinery product through examination of the technical documentation, plus examination of a specimen of the machinery 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 his or her choice.

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;
 - (b) a written declaration that the same application has not been lodged with any other notified body;
 - (c) the technical documentation described in Annex IV;
 - (d) the specimen(s) of the machinery product representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme. 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:

- (a) examine the technical documentation to assess the adequacy of the technical design of the machinery product. In conducting such an examination, Annex IV, second subparagraph, point (j), need not be taken into account;
- (b) for machinery 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 technical specifications adopted by the Commission in accordance with

Article 17(3), as well as the elements that have been designed in accordance with other technical specifications;

- (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, those have been applied correctly;
- (e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or technical specifications adopted by the Commission in accordance with Article 17(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.

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, as mentioned in Article 32, 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.

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;
- (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;
- (c) an identification of the machinery product covered by the certificate (type number);
- (d) a statement that the machinery product type complies with the applicable essential health and safety requirements;
- (e) where harmonised standards or technical specifications adopted by the Commission in accordance with Article 17(3) have been fully or partially applied, the references of those standards or parts thereof;
- (f) where other technical specifications have been applied, the references of those technical specifications;
- (g) where applicable, the performance level(s) or protection class of the machinery product;
- (h) the date of issue, the date of expiry and, where appropriate, the date(s) of renewal;
- (i) any conditions attached to the issuing 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.

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.

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 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.

7.3. The manufacturer shall ensure that the machinery product continues to fulfil the applicable essential health and safety requirements in light of the 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.

In order to allow the notified body to fulfil its tasks, the manufacturer shall submit his or her application at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU type-examination certificate.

7.5. The notified body shall examine the machinery 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. 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. The notified body shall ensure that the review procedure is finalised before the expiry date of the EU type-examination certificate.

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) His or her 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 technical specifications adopted by the Commission in accordance with Article 17(3) or other technical specifications applied;

- (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 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.

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.

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 10 years after the machinery product has been placed on the market.
- 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.

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 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 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 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 a written EU declaration of conformity for a machinery product model and keep it at the disposal of the national authorities for 10 years after the machinery product has been placed on the market. The EU declaration of conformity shall identify the machinery 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.

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.

ANNEX IX

CONFORMITY BASED ON FULL QUALITY ASSURANCE

(Module H)

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 product concerned satisfy the requirements of this Regulation that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the machinery product concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his or her quality system with the notified body of his or her choice, for the machinery product concerned.

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;
- (b) the technical documentation for one model of each category of products intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:
 - (i) a general description of the machinery product;
 - (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
 - (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the machinery product;
 - (iv) a list of the harmonised standards or technical specifications adopted by the Commission in accordance with Article 17(3) and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Regulation where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
 - (v) results of design calculations made, examinations carried out, etc.;
 - (vi) test reports;
 - (vii) the documentation concerning the quality system; and

- (viii) a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the products with the requirements of this Regulation that apply to them.

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.

It shall, in particular, contain 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;
- (b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or technical specification adopted by the Commission in accordance with Article 17(3) and/or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Regulation that apply to the machinery product will be met;
- (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the machinery product pertaining to the product category covered;
- (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (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;
- (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- (g) the means of monitoring the achievement of the required design and product quality and 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.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and with knowledge of the applicable requirements of this Regulation. 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), point (ii), to verify the manufacturer's ability to identify the applicable requirements of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the machinery product with those requirements.

The manufacturer ~~or his or her authorised representative~~ shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 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.
- 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 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.

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

- 4.1. 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 it with all necessary information, in particular:
 - (a) the quality system documentation;
 - (b) the quality records as provided for by the design part of the quality system, such as 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.
- 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.
- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. 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.

5. ~~C~~EU conformity marking and EU declaration of conformity

- 5.1. The manufacturer shall affix the ~~required-CEconformity~~ 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 machinery product that satisfies the applicable requirements of this Regulation.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each machinery product model and keep it at the disposal of the national authorities for ten years after the machinery product has been placed on the market. The EU declaration of conformity shall identify the 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 a period ending at least ten years after the machinery product has been placed on the market, keep at the disposal of the national authorities:
 - (a) the technical documentation referred to in point 3.1;
 - (b) the documentation concerning the quality system referred to in point 3.1;
 - (c) the change referred to in point 3.5, as approved;
 - (d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.
7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals, which it has refused, suspended or withdrawn, and, upon request, of quality system approvals, which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 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.

ANNEX X

ASSEMBLY INSTRUCTIONS FOR PARTLY COMPLETED MACHINERY

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 the final machinery product, and that the final machinery product does not compromise health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment.

The assembly instructions shall be written in an official language of the Union understandable to the manufacturer of the machinery product in which the partly completed machinery is to be assembled, or to that manufacturer's authorised representative.

[The assembly instructions may be provided by the manufacturer in electronic form.](#)

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ANNEX XI

CORRELATION TABLE

Directive 2006/42/EC	This Regulation
Article 1	Article 2
Article 2	Article 3
Article 3	Article 8 and Article 9
Article 4	-
Article 5	Article 7
Article 6	Article 4
Article 7	Article 17 (1)
Article 8 (1)	Article 45
Article 8 (2)	-
Article 9	-
Article 10	Article 42 (3)
Article 11	Article 41 to Article 44
Article 12	Article 21
Article 13	Article 22
Article 14	Article 24 to Article 40
Article 15	Article 23
Article 16	Article 19
Article 17	Article 20
Article 18	Article 47
Article 19	-

Directive 2006/42/EC	This Regulation
Article 20	-
Article 21	Article 51
Article 21 a	Article 45
Article 22	Article 46
Article 23	Article 48
Article 24	-
Article 25	Article 49
Article 26	-
Article 27	-
Article 28	Article 52
Article 29	Article 52
Annex I - General principles	Annex III - General principles
Annex I, Section 1	Anne III, Section 1
Annex I, Section 2	Annex III, Section 2
Annex I, Section 3	Annex III, Section 3
Annex I, Section 4	Annex III, Section 4
Annex I, Section 5	Annex III, Section 5
Annex I, Section 6	Annex III, Section 6
Annex II, Parts A and B	Annex V
Annex III	-
Annex IV	Annex I
Annex V	Annex II
Annex VI	Annex X
Annex VII, Parts A and B	Annex IV, Parts A and B

Directive 2006/42/EC	This Regulation
Annex VIII	Annex VI
Annex IX	Annex VII
Annex X	Annex VIII
Annex XI	Article 28

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