

L.N. 250 of 2001

**PRODUCT SAFETY ACT
(ACT NO. V OF 2001)**

Machinery Regulations, 2001

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, 2001, the Minister for Economic Services, acting on the advice of the Malta Standards Authority, has made the following regulations:-

1.1. The title of these regulations is the Machinery Regulations, 2001. Citation and commencement.

1.2. These regulations shall become operative on the 1st July, 2002, which date shall be notified by the Authority in the Government Gazette.

1.2.1. Provided that the requirement of regulation 5 of these regulations and the CE marking shall not be obligatory prior to the 1st January 2003 in respect of:

1.2.1.1. stocks of machinery already placed on the market prior to the 1st July, 2002;

1.2.1.2. machinery ordered before the 1st July, 2002 and imported into Malta up to the 30th June, 2002.

1.2.2. Provided that the requirement of regulation 5 of these regulations and the CE marking shall not be obligatory prior to the 1st January, 2003 in respect of machinery manufactured in Malta up to 31st December, 2002 and which is in compliance with other Orders and/or regulations currently in force in Malta.

1.2.3. Provided that the requirement to provide information to the Commission referred to in regulation 7.4 shall come into force on such date as the Minister responsible for consumer affairs, after consultation with the Malta Standards Authority, may prescribe.

2.1. These regulations shall apply to machinery and lay down the essential health and safety requirements therefor, as defined in Schedule I to these regulations.

2.1.1. It shall also apply to safety components placed on the market separately.

2.1.2. "relevant machinery" is all machinery other than machinery which is excluded from the scope of these regulations pursuant to regulation 2.2 below.

2.2. The following are excluded from the scope of these regulations:

- machinery whose only power source is directly applied manual effort, unless it is a machine used for lifting or lowering loads,
- medical devices,
- special equipment for use in fairgrounds and/or amusement parks,
- steam boilers, tanks and pressure vessels,
- machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity,
- radioactive sources forming part of a machine,
- firearms,
- storage tanks and pipelines for petrol, diesel fuel, inflammable liquids and dangerous substances,
- means of transport, i.e. vehicles and their trailers intended solely for transporting passengers by air or on road, rail or water networks, as well as means of transport in so far as such means are designed for transporting goods by air, on public road or rail networks or on water. Vehicles used in the mineral extraction industry shall not be excluded,
- seagoing vessels and mobile offshore units together with equipment on board such vessels or units,
- cableways, including funicular railways, for the public or private transportation of persons,
- agricultural and forestry tractors, as defined in Article 1(1) of Directive 74/150/EEC¹,
- machines specially designed and constructed for military or police purposes,
- lifts which permanently serve specific levels of buildings and constructions, having a car moving between guides which are

¹ Council Directive 74/150/EEC of 4 March 1974 on the approximation of the laws of the Member States relating to the type-approval of wheeled agricultural or forestry tractors (OJ L 84, 28.3.1974, p. 10). Directive as last amended by Decision 95/1/EC, Euratom, ECSC (OJ L 1.1.1995, p. 1).

rigid and inclined at an angle of more than 15 degrees to the horizontal and designed for the transport of:

- (i) persons;
- (ii) persons and goods;
- (iii) goods alone if the car is accessible, that is to say, a person may enter it without difficulty, and fitted with controls situated inside the car or within reach of a person inside,
 - means of transport of persons using rack and pinion rail mounted vehicles,
 - mine winding gear,
 - theatre elevators,
 - construction site hoists intended for lifting persons or persons and goods.

3.1. For the purposes of these regulations, the following Definitions. definitions shall apply:

3.1.1. “machinery” means:

3.1.1.1. an assembly of linked parts or components, at least one of which moves, with the appropriate actuators, control and power circuits, etc., joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material;

3.1.1.2. an assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;

3.1.1.3. interchangeable equipment modifying the function of a machine, which is placed on the market for the purpose of being assembled with a machine or a series of different machines or with a tractor by the operator himself in so far as this equipment is not a spare part or a tool.

3.1.2. “safety component” means a component, provided that it is not interchangeable equipment, which the manufacturer or his local authorized representative places on the market to fulfil a safety function when in use and the failure or malfunctioning of which endangers the safety or health of exposed persons.

3.1.3. “The Directive” means Council Directive 98/37/EC² on the approximation of the laws of the member States relating to machinery, as amended by Directive 98/79/EC³ of the European Parliament and of the Council.

² OJ No. L207, 23-07-98, P.1

³ OJ No. L331, 07-12-98, P.1

3.1.4. "Harmonised Standard" means a technical specification adopted by the European Committee for Standardisation (CEN) or the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), upon a remit from the European Commission in accordance with Directive 98/34/EC⁴ of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations as amended by Directive 98/48/EC⁵ of the European Parliament and of the Council.

3.1.5. "National Standard transposing the Harmonised Standard" means a Standard issued by one of the members of CEN/CENELEC/ETSI which is declared and noted to be technically equivalent to the Harmonised Standard originally issued by CEN/CENELEC/ETSI.

3.1.6. "OJ" means the Official Journal of the European Communities.

3.1.7. "Community" means the European Community.

3.1.8. "business" includes a profession and an undertaking, and a supply in the course of a business includes any supply by a business.

3.1.9. "essential health and safety requirements" means the requirements in Annex I of the Machinery Directive which is set out in Schedule I hereto;

3.1.9.1. "relevant essential health and safety requirements" in relation to relevant machinery means those provisions of the essential health and safety requirements which are applicable to that particular relevant machinery for the purposes of establishing that it satisfies the essential health and safety requirements of the Machinery Directive;

Provided that, subject to regulation 4.2 (a) below, in so far as such provisions relate to risks which are covered by other Community Directives and to the extent that any enactment implementing any such Directive applies to that machinery those provisions shall not be relevant essential health and safety requirements for the purposes of these regulations.

⁴OJ No. L204, 21-07-98, P.37

⁵OJ No. L217, 05-08-98, P.18

3.1.10. “safe” in relation to relevant machinery means that, when the machinery is properly installed and maintained and used for the purposes for which it is intended, there is no risk (apart from one reduced to a minimum) of its being the cause or occasion of death or injury to persons or, where appropriate, to domestic animals or damage to property, and cognate expressions shall be construed accordingly;

3.1.10.1. For the purposes of this definition, when considering whether or not a risk has been reduced to a minimum, regard shall be had to the practicability of so reducing that risk at the time of the construction of the relevant machinery.

3.1.11. “approved body” means a body responsible for carrying out functions relating to the conformity assessment procedures set out in Article 8 of the Machinery Directive and described in regulation 6 below which has been notified by the member State concerned to the Commission and the other member States pursuant to Article 9(1) of the Machinery Directive.

3.1.12. “EC type-examination certificate” means a certificate issued by an approved body certifying that an example of relevant machinery satisfies those provisions of the Machinery Directive which apply to it.

3.1.13. “CE marking” means the CE conformity marking consisting of the symbol ‘CE’ as set out in Schedule III to these regulations.

3.1.14. “Manufacturer” means the person, who is primarily responsible for designing and manufacturing the relevant machinery so that it complies with the requirements of these regulations.

3.1.15. “Local authorised representative” means any person (or organisation) established in Malta who has been appointed by the manufacturer to act on his behalf in carrying out certain tasks required by these regulations.

3.1.16. “Importer” means any person who places relevant machinery from a foreign country on to the Maltese market so that he supplies such product on the first occasion that it is supplied in Malta.

3.1.17. “Person who supplies relevant machinery” means wholesalers, distributors, retailers etc;

3.1.17.1. "supply" includes offering to supply, agreeing to supply, exposing for supply and possessing for supply, and cognate expressions shall be construed accordingly.

Provided that "supply" does not include exhibition at trade fairs and exhibitions of relevant machinery in respect of which the provisions of these regulations are not satisfied if a notice is displayed in relation to the machinery in question to the effect:-

(a) that it does not satisfy those provisions; and

(b) that it may not lawfully be supplied until the responsible person has ensured that those provisions are satisfied;

3.1.18. "Responsible person" in relation to relevant machinery means:

(a) the manufacturer thereof;

(b) the manufacturer's local authorised representative;
or

(c) where the manufacturer is not established in Malta and he has not appointed a local authorised representative, the person who places the products on the local market.

3.1.19. "Placing on the market" means importation, wholesale, retail sale and distribution free of charge.

3.1.20. "Schedule 4 machinery" means machinery posing special hazards which is specified in Annex IV of the Machinery Directive and listed in Schedule IV hereto.

3.1.21. "series manufacture" means the manufacture of more than one item of relevant machinery of the same type in accordance with a common design.

Applicability.

4.1. The provisions of these regulations are applicable to all imported relevant machinery as well as to that manufactured for the local market.

4.1.1. No person may manufacture, import, place on the market or put into service any relevant machinery which does not comply with the provisions of these regulations.

4.2. The provisions of these regulations do not apply to:

- (a) machinery where all the essential health and safety requirements which would have applied to it, but for the provisions of this sub-paragraph, relate to risks wholly covered by Community Directives other than the Machinery Directive to the extent that any enactment implementing any such Directive is applicable to that machinery; or

- (b) machinery which is electrical equipment in so far as the risks as to the safety of such equipment are mainly of electrical origin. Such machinery shall be covered exclusively by the Low Voltage Electrical Equipment Order⁶, M37 of 1999.

5.1. No person shall supply relevant machinery unless the requirements of regulation 5.2 below are complied with in relation thereto. General requirements

5.1.1. Where a person:-

- (a) being the manufacturer of relevant machinery, himself puts that relevant machinery into service in the course of a business; or

- (b) having imported relevant machinery himself puts that relevant machinery into service in the course of a business,

for the purposes of these regulations that person shall be deemed to have supplied that relevant machinery to himself.

5.2. The requirements of this regulation are that:-

- (a) the relevant machinery satisfies the relevant essential health and safety requirements;

- (b) the appropriate conformity assessment procedure in respect of the relevant machinery has been carried out by the responsible person in accordance with one of the procedures described in regulation 6 below;

- (c) the responsible person, at his election, has issued either:-

- (i) an EC declaration of conformity in accordance with Schedule II, points A and C, to these regulations; or

⁶L.N. 23 of 1999 published in the Government Gazette No: 16,742 of 5th February, 1999.

(ii) in the case of relevant machinery which

- is intended for incorporation into other machinery or assembly with other machinery to constitute relevant machinery;
- cannot function independently;
- is not interchangeable equipment;

a declaration of incorporation in accordance with Schedule II point B to these regulations;

(d) except in the case of relevant machinery to which paragraph (c) above applies, the CE marking has been properly affixed by the responsible person to the relevant machinery in accordance with regulation 8.5 below; and

(e) the relevant machinery is in fact safe.

5.2.1. It is the responsibility of the manufacturer of relevant machinery to carry out the necessary research or tests on components, fittings or the completed machine to determine whether by its design or construction the machine is capable of being erected and put into service safely.

5.3. The free movement, placing on the market or putting into service in the Maltese territory of relevant machinery which satisfies the provisions of these regulations shall not be impeded.

5.3.1. The placing on the market of machinery, which the manufacturer or his authorised representative declares in accordance with point B of Schedule II to these regulations that it is intended to be incorporated into machinery or assembled with other machinery to constitute machinery covered by these regulations, shall not be prohibited, restricted or impeded, except where it can function independently.

5.4. 'Interchangeable equipment', as referred to in regulation 3.1.1.3, must in all cases bear the CE marking and be accompanied by the EC declaration of conformity referred to in Schedule II, point A to these regulations.

5.4.1. The placing on the market of safety components, as defined in regulation 3.1.2, where they are accompanied by an EC declaration of conformity by the manufacturer or his authorised representative as referred to in Schedule III, point C to these regulations, shall not be prohibited, restricted or impeded.

5.5. The following shall be regarded as conforming to all the provisions of these regulations, including the procedures for checking the conformity provided for in regulation 6:

- machinery bearing the CE marking and accompanied by the EC declaration of conformity referred to in Schedule II, point A to these regulations,
- safety components accompanied by the EC declaration of conformity referred to in Annex II, point C to these regulations.

5.5.1. In the absence of harmonised standards, the Director for Consumer Affairs shall take any steps he deems necessary to bring to the attention of the parties concerned the existing national technical standards and specifications which are regarded as important or relevant to the proper implementation of the essential safety and health requirements in Schedule I to these regulations.

5.6. Where a national standard transposing a harmonised standard, the reference for which has been published in the Official Journal of the European Communities, covers one or more of the essential safety requirements, machinery or safety components constructed in accordance with this standard shall be presumed to comply with the relevant essential requirements.

6.1. The manufacturer or his authorised representative must, in order to certify that machinery and safety components are in conformity with these regulations, draw up for all machinery or safety components manufactured, an EC declaration of conformity based on the model given in Schedule II, point A or C to these regulations, as appropriate.

Conformity
assessment
procedures.

6.1.1. In addition, for machinery alone, the manufacturer or his authorised representative must affix to the machine the CE marking.

6.2. Before placing on the market, the manufacturer, or his authorised representative shall:

- (a) if the machinery is not referred to in Schedule IV to these regulations, draw up the file provided for in Schedule V to these regulations;
- (b) if the machinery is referred to in Schedule IV and its manufacturer does not comply, or only partly complies, with the standards referred to in regulation 5.6 or if there are no such standards, submit an example of the machinery for the EC type-examination referred to in Schedule VI to these regulations;

(c) if the machinery is referred to in Schedule IV to these regulations and is manufactured in accordance with the standards referred to in regulation 5.6:

- either draw up the file referred to in Schedule VI to these regulations and forward it to a notified body, which will acknowledge receipt of the file as soon as possible and keep it,

- submit the file referred to in Schedule VI to these regulations to the notified body, which will simply verify that the standards referred to in regulation 5.6 have been correctly applied and will draw up a certificate of adequacy for the file,

- or submit the example of the machinery for the EC type-examination referred to in Schedule VI to these regulations.

6.3. Where the first indent of regulation 6.2(c) of these regulations applies, the provisions of the first sentence of paragraphs 5 and 7 of Schedule VI to these regulations shall also apply.

6.3.1. Where the second indent of regulation 6.2(c) of these regulations applies, the provisions of paragraphs 5, 6 and 7 of Schedule VI to these regulations shall also apply.

6.4. Where regulation 6.2(a) and the first and second indents of regulation 6.2(c) to these regulations apply, the EC declaration of conformity shall solely state conformity with the essential requirements of these regulations.

6.4.1. Where regulation 6.2(b) and the third indent of regulation 6.2(c) of these regulations apply, the EC declaration of conformity shall state conformity with the example that underwent EC type-examination.

6.5. Safety components shall be subject to the certification procedures applicable to machinery pursuant to regulations 6.2, 6.3 and 6.4. Furthermore, during EC type-examination, the notified body shall verify the suitability of the safety component for fulfilling the safety functions declared by the manufacturer.

6.6. (a) Where the machinery is subject to other regulations, transposing Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the machinery is also presumed to conform to the provisions of those other regulations.

(b) However, where one or more of those regulations allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only to the regulations applied by the manufacturer. In this case, particulars of the directives applied, as published in the Official Journal of the European Communities, must be given in the documents, notices or instructions required by the directives and accompanying such machinery.

6.7. Where neither the manufacturer nor his authorised representative fulfils the obligations of regulations 6.1 to 6.6, these obligations shall fall to any person placing the machinery or safety component on the market.

6.7.1. The same obligations shall apply to any person assembling machinery or parts thereof or safety components of various origins or constructing machinery or safety components for his own use.

6.8. The obligations referred to in regulation 7 shall not apply to persons who assemble with a machine or tractor interchangeable equipment as provided for in regulation 3, provided that the parts are compatible and each of the constituent parts of the assembled machine bears the CE marking and is accompanied by the EC declaration of conformity.

7.1. Where it is ascertained that:

- machinery bearing the CE marking, or
- safety components accompanied by the EC declaration of conformity,

Withdrawal and
prohibition from
market.

used in accordance with their intended purpose are liable to endanger the safety of persons, and, where appropriate, domestic animals or property, the Director of Consumer Affairs shall take all appropriate measures to withdraw such machinery or safety components from the market, to prohibit the placing on the market, putting into service or use thereof, or to restrict free movement thereof.

7.1.1. The Director of Consumer Affairs shall immediately inform the Head of the Consumer and Industrial Goods Directorate⁷ of the Malta Standards Authority of any such measure, indicating the reason for its decision and, in particular, whether non-conformity is due to:-

⁷L.N. 213 of 2000 - Malta Standards Authority (Establishment of Directorates) Order, 2000, published in the Government Gazette No. 17,002 of 20th October, 2000.

(a) failure to satisfy the essential requirements referred to in regulation 5.2;

(b) incorrect application of the standards referred to in regulation 5.6;

(c) shortcomings in the standards themselves referred to in regulation 5.6.

7.2. Where:

- machinery which does not comply bears the CE marking,

- a safety component which does not comply is accompanied by an EC declaration of conformity,

the Director of Consumer Affairs shall take appropriate action against whom so ever has affixed the marking or drawn up the declaration and shall so inform the Head of the Consumer and Industrial Goods Directorate of the Malta Standards Authority.

7.3. Any decision taken pursuant to these regulations which restricts the placing on the market and putting into service of machinery or a safety component shall state the exact grounds on which it is based.

7.3.1. Such a decision shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in Malta and of the time limits to which such remedies are subject.

7.4. The Head of the Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission of any measures taken in pursuance of regulations 7.1, 7.1.1, 7.2, 7.3 and 7.3.1.

CE Marking.

8.1. The CE conformity marking shall consist of the initials 'CE'.

8.1.1. The form of the marking to be used is shown in Schedule III.

8.2. The CE marking shall be affixed to machinery distinctly and visibly in accordance with point 1.7.3 of Schedule I.

8.3. The affixing of markings on the machinery which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited.

8.3.1. Any other marking may be affixed to the machinery provided that the visibility and legibility of the CE marking is not thereby reduced.

8.4. Without prejudice to regulation 7:

(a) where it is established that the CE marking has been affixed unduly, the manufacturer or his authorised representative shall be obliged to make the product conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Director of Consumer Affairs;

(b) where non-conformity continues, the Director of Consumer Affairs must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedure laid down in regulation 7.

8.5. For the purposes of these regulations, the CE marking shall be regarded as properly affixed to relevant machinery if:-

(a) the responsible person who affixes the CE marking to the relevant machinery has issued an EC declaration of conformity in respect thereof;

(b) the CE marking is affixed to the relevant machinery in a distinct, visible, legible and indelible manner; and

(c) in the case of relevant machinery which is the subject of Community Directives other than the Machinery Directive, the requirements of those other Directives have also been complied with in respect of the relevant machinery.

8.5.1. No person shall affix the CE marking to any relevant machinery unless that machinery:-

(a) satisfies the relevant essential health and safety requirements; and

(b) is safe.

8.6. A person who supplies relevant machinery which does not bear the CE marking shall, at the request of the Director of Consumer Affairs, or of an officer authorised by such Director, give any information which he has, or which is available to him, concerning the date when the relevant machinery was first supplied in the Community and explain (so far as he is able) why the machinery does not bear that mark.

Schedule I

Based on Annex I of the Directive

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

For the purposes of this Schedule 'machinery' means either 'machinery' or 'safety component' as defined in regulations 3.1.1 and 3.1.2 of these regulations.

PRELIMINARY OBSERVATIONS

1. The obligations laid down by the essential health and safety requirements apply only when the corresponding hazard exists for the machinery in question when it is used under the conditions foreseen by the manufacturer. In any event, requirements 1.1.2, 1.7.3 and 1.7.4 apply to all machinery covered by these regulations.

2. The essential health and safety requirements laid down in these regulations are mandatory. However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In this case, the machinery must as far as possible be designed and constructed with the purpose of approaching those objectives.

3. The essential health and safety requirements have been grouped according to the hazards which they cover.

Machinery presents a series of hazards which may be indicated under more than one heading in this Schedule.

The manufacturer is under an obligation to assess the hazards in order to identify all of those which apply to his machine; he must then design and construct it taking account of his assessment.

1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

1.1. General remarks

1.1.1. Definitions

For the purpose of these regulations:

1. 'danger zone' means any zone within and/or around machinery in which an exposed person is subject to a risk to his health or safety;

2. 'exposed person' means any person wholly or partially in a danger zone;

3. 'operator' means the person or persons given the task of installing, operating, adjusting, maintaining, cleaning, repairing or transporting machinery.

1.1.2. *Principles of safety integration*

(a) Machinery must be so constructed that it is fitted for its function, and can be adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen by the manufacturer.

The aim of measures taken must be to eliminate any risk of accident throughout the foreseeable lifetime of the machinery, including the phases of assembly and dismantling, even where risks of accident arise from foreseeable abnormal situations.

(b) In selecting the most appropriate methods, the manufacturer must apply the following principles, in the order given:

- eliminate or reduce risks as far as possible (inherently safe machinery design and construction),
- take the necessary protection measures in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted indicate whether any particular training is required and specify any need to provide personal protection equipment.

(c) When designing and constructing machinery, and when drafting the instructions, the manufacturer must envisage not only the normal use of the machinery but also uses which could reasonably be expected.

The machinery must be designed to prevent abnormal use if such use would engender a risk. In other cases the instructions must draw the user's attention to ways - which experience has shown might occur - in which the machinery should not be used.

(d) Under the intended conditions of use, the discomfort, fatigue and psychological stress faced by the operator must be reduced to the minimum possible taking ergonomic principles into account.

(e) When designing and constructing machinery, the manufacturer must take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protection equipment (such as footwear, gloves, etc.).

(f) Machinery must be supplied with all the essential special equipment and accessories to enable it to be adjusted maintained and used without risk.

1.1.3. *Materials and products*

• The materials used to construct machinery or products used and created during its use must not endanger exposed persons' safety or health.

In particular, where fluids are used, machinery must be designed and constructed for use without risks due to filling, use, recovery or draining.

1.1.4. *Lighting*

The manufacturer must supply integral lighting suitable for the operations concerned where its lack is likely to cause a risk despite ambient lighting of normal intensity.

The manufacturer must ensure 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 due to the lighting provided by the manufacturer.

Internal parts requiring frequent inspection, and adjustment and maintenance areas, must be provided with appropriate lighting.

1.1.5. *Design of machinery to facilitate its handling*

Machinery or each component part thereof must:

- be capable of being handled safely,
- be packaged or designed so that it can be stored safely and without damage (e.g. adequate stability, special supports, etc.).

Where the weight, size or shape of machinery or its various component parts prevents them from being moved by hand, the machinery or each component part must:

- either be fitted with attachments for lifting gear, or
- be designed so that it can be fitted with such attachments (e.g. threaded holes), or
- be shaped in such a way that standard lifting gear can easily be attached.

Where machinery or one of its component parts is to be moved by hand, it must:

- either be easily movable, or
- be equipped for picking up (e.g. hand-grips, etc.) and moving in complete safety.

Special arrangements must be made for the handling of tools and/or machinery parts, even if lightweight, which could be dangerous (shape, material, etc.).

1.2. Controls

1.2.1. *Safety and reliability of control systems*

Control systems must be designed and constructed so that they are safe and reliable, in a way that will prevent a dangerous situation arising. Above all they must be designed and constructed in such a way that:

- they can withstand the rigorous of normal use and external factors,
- errors in logic do not lead to dangerous situations.

1.2.2. *Control devices*

Control devices must be:

- clearly visible and identifiable and appropriately marked where necessary,
- positioned for safe operation without hesitation or loss of time, and without ambiguity,
- designed so that the movement of the control is consistent with its effect,
- located outside the danger zones, except for certain controls where necessary, such as emergency stop, console for training of robots,
- positioned so that their operation cannot cause additional risk,
- designed or protected so that the desired effect, where a risk is involved, cannot occur without an intentional operation,
- made so as to withstand foreseeable strain; particular attention must be paid to emergency stop devices liable to be subjected to considerable strain.

Where a control is designed and constructed to perform several different actions, namely where there is no one-to-one correspondence (e.g. keyboards, etc.), the action to be performed must be clearly displayed and subject to confirmation where necessary.

- Controls must be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles.
- Constraints due to the necessary or foreseeable use of personal protection equipment (such as footwear, gloves, etc.) must be taken into account.

Machinery must be fitted with indicators (dials, signals, etc.) as required for safe operation. The operator must be able to read them from the control position.

From the main control position the operator must be able to ensure that there are no exposed persons in the danger zones.

If this is impossible, the control system must be designed and constructed so that an acoustic and/or visual warning signal is given whenever the machinery is about to start. The exposed person must have the time and the means to take rapid action to prevent the machinery starting up.

1.2.3. *Starting*

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

The same requirement applies:

- when restarting the machinery after a stoppage, whatever the cause,
- when effecting a significant change in the operating conditions (e.g. speed, pressure, etc.), unless such restarting or change in operating conditions is without risk to exposed persons.

This essential requirement does not apply to the restarting of the machinery or to the change in operating conditions resulting from the normal sequence of an automatic cycle.

Where machinery has several starting controls and the operators can therefore put each other in danger, additional devices (e.g. enabling devices or selectors allowing only one part of the starting mechanism to be actuated at any one time) must be fitted to rule out such risks.

It must be possible for automated plant functioning in automatic mode to be restarted easily after a stoppage once the safety conditions have been fulfilled.

1.2.4. *Stopping device*

Normal stopping

Each machine must be fitted with a control whereby the machine can be brought safely to a complete stop.

Each workstation must be fitted with a control to stop some or all of the moving parts of the machinery, depending on the type of hazard, so that the machinery is rendered safe. The machinery's stop control must have priority over the start controls.

Once the machinery or its dangerous parts have stopped, the energy supply to the actuators concerned must be cut off.

Emergency stop

Each machine must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted. The following exceptions apply:

- machines 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,
- hand-held portable machines and hand-guided machines.

This device must:

- have clearly identifiable, clearly visible and quickly accessible controls,
- stop the dangerous process as quickly as possible, without creating additional hazards,
- where necessary, trigger or permit the triggering of certain safeguard movements.

Once active operation of the emergency stop control has ceased following a stop command, that command must be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it must not be possible to engage the device without triggering a stop command; it must be possible to disengage the device only by an appropriate operation, and disengaging the device must not restart the machinery but only permit restarting.

Complex installations

In the case of machinery or parts of machinery designed to work together, the manufacturer must so design and construct the machinery that the stop controls, including the emergency stop, can stop not only the machinery itself but also all equipment upstream and/or downstream if its continued operation can be dangerous.

1.2.5. Mode selection

The control mode selected must override all other control systems with the exception of the emergency stop.

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If machinery has been designed and built to allow for its use in several control or operating modes presenting different safety levels (e.g. to allow for adjustment, maintenance, inspection, etc.), it must be fitted with a mode selector which can be locked in each position. Each position of the selector must correspond to a single operating or control mode.

The selector may be replaced by another selection method which restricts the use of certain functions of the machinery to certain categories of operator (e.g. access codes for certain numerically controlled functions, etc.).

If, for certain operations, the machinery must be able to operate with its protection devices neutralized, the mode selector must simultaneously:

- disable the automatic control mode,
- permit movements only by controls requiring sustained action,
- permit the operation of dangerous moving parts only in enhanced safety conditions (e.g. reduced speed, reduced power, step-by-step, or other adequate provision) while preventing hazards from linked sequences,
- prevent any movement liable to pose a danger by acting voluntarily or involuntarily on the machine's internal sensors.

In addition, the operator must be able to control operation of the parts he is working on at the adjustment point.

1.2.6. *Failure of the power supply*

The interruption, re-establishment after an interruption or fluctuation in whatever manner of the power supply to the machinery must not lead to a dangerous situation.

In particular:

- the machinery must not start unexpectedly,
- the machinery must not be prevented from stopping if the command has already been given,
- no moving part of the machinery or piece held by the machinery must fall or be ejected,
- automatic or manual stopping of the moving parts whatever they may be must be unimpeded,
- the protection devices must remain fully effective.

1.2.7. *Failure of the control circuit*

A fault in the control circuit logic, or failure of or damage to the control circuit must not lead to dangerous situations.

In particular:

- the machinery must not start unexpectedly,
- the machinery must not be prevented ~~from stopping~~ if the command has already been given,
- no moving part of the machinery or piece held by the machinery must fall or be ejected,
- automatic or manual stopping of the moving parts whatever they may be must be unimpeded,
- the protection devices must remain fully effective.

1.2.8. *Software*

Interactive software between the operator and the command or control system of a machine must be user-friendly.

1.3. **Protection against mechanical hazards**

1.3.1. *Stability*

Machinery, components and fittings thereof must be so designed and constructed that they are stable enough, under the foreseen operating conditions (if necessary taking climatic conditions into account) for use without risk of overturning, falling or unexpected movement.

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

1.3.2. *Risk of break-up during operation*

The various parts of machinery and their linkages must be able to withstand the stresses to which they are subject when used as foreseen by the manufacturer.

The durability of the materials used must be adequate for the nature of the work place foreseen by the manufacturer, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion.

The manufacturer must indicate in the instructions the type and frequency of inspection and maintenance required for safety reasons. He must, where appropriate, indicate the parts subject to wear and the criteria for replacement.

Where a risk of rupture or disintegration remains despite the measures taken (e.g. as with grinding wheels) the moving parts must be mounted and positioned in such a way that in case of rupture their fragments will be contained.

Both rigid and flexible pipes carrying fluids, particularly those under high pressure, must be able to withstand the foreseen internal and external stresses and must be firmly attached and/or protected against all manner of external stresses and strains; precautions must be taken to ensure that no risk is posed by a rupture (sudden movement, high-pressure jets, etc.).

Where the material to be processed is fed to the tool automatically, the following conditions must be fulfilled to avoid risks to the persons exposed (e.g. tool breakage):

- when the workpiece comes into contact with the tool the latter must have attained its normal working conditions,
- when the tool starts and/or stops (intentionally or accidentally) the feed movement and the tool movement must be coordinated.

1.3.3. *Risks due to falling or ejected objects*

Precautions must be taken to prevent risks from falling or ejected objects (e.g. workpieces, tools, cuttings, fragments, waste, etc.).

1.3.4. *Risks due to surfaces, edges or angles*

In so far as their purpose allows, accessible parts of the machinery must have no sharp edges, no sharp angles, and no rough surfaces likely to cause injury.

1.3.5. *Risks related to combined machinery*

Where the machinery is intended to carry out several different operations with the manual removal of the piece between each operation (combined machinery), it must be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a danger or risk for the exposed person.

For this purpose, it must be possible to start and stop separately any elements that are not protected.

1.3.6. *Risks relating to variations in the rotational speed of tools*

When the machine is designed to perform operations under different conditions of use (e.g. different speeds or energy supply), it must be designed and constructed in

such a way that selection and adjustment of these conditions can be carried out safely and reliably.

1.3.7. *Prevention of risks related to moving parts*

The moving parts of machinery must be designed, built and laid out to avoid hazards or, where hazards persist, fixed with guards or protective devices in such a way as to prevent all risk of contact which could lead to accidents.

All necessary steps must be taken to prevent accidental blockage of moving parts involved in the work. In cases where, despite the precautions taken, a blockage is likely to occur, specific protection devices or tools, the instruction handbook and possibly a sign on the machinery should be provided by the manufacturer to enable the equipment to be safely unblocked.

1.3.8. *Choice of protection against risks related to moving parts*

Guards or protection devices used to protect against the risks related to moving parts must be selected on the basis of the type of risk. The following guidelines must be used to help make the choice.

A. Moving transmission parts

Guards designed to protect exposed persons against the risks associated with moving transmission parts (such as pulleys, belts, gears, rack and pinions, shafts, etc.) must be:

- either fixed, complying with requirements 1.4.1 and 1.4.2.1, or
- movable, complying with requirements 1.4.1 and 1.4.2.2.A,

Movable guards should be used where frequent access is foreseen.

B. Moving parts directly involved in the process

Guards or protection devices designed to protect exposed persons against the risks associated with moving parts contributing to the work (such as cutting tools, moving parts of presses, cylinders, parts in the process of being machined, etc.) must be:

- wherever possible fixed guards complying with requirements 1.4.1 and 1.4.2.1,
- otherwise, movable guards complying with requirements 1.4.1 and 1.4.2.2.B or protection devices such as sensing devices (e.g. non-material barriers, sensor mats), remote-hold protection devices (e.g. two-hand controls), or

protection devices intended automatically to prevent all or part of the operator's body from encroaching on the danger zone in accordance with requirements 1.4.1 and 1.4.3.

However, when certain moving parts directly involved in the process cannot be made completely or partially inaccessible during operation owing to operations requiring nearby operator intervention, where technically possible such parts must be fitted with:

- fixed guards, complying with requirements 1.4.1 and 1.4.2.1 preventing access to those sections of the parts that are not used in the work,
- adjustable guards, complying with requirements 1.4.1 and 1.4.2.3 restricting access to those sections of the moving parts that are strictly for the work.

1.4. Required characteristics of guards and protection devices

1.4.1. General requirements

Guards and protection devices must:

- be of robust construction,
- not give rise to any additional risk,
- not be easy to by-pass or render non-operational,
- be located at an adequate distance from the danger zone,
- cause minimum obstruction to the view of the production process,
- enable essential work to be carried out on installation and/or replacement of tools and also for maintenance by restricting access only to the area where the work has to be done, if possible without the guard or protection device having to be dismantled.

1.4.2. Special requirements for guards

1.4.2.1. Fixed guards

Fixed guards must be securely held in place.
They must be fixed by systems that can be opened only with tools.
Where possible, guards must be unable to remain in place without their fixings.

1.4.2.2. Movable guards

Type A movable guards must:

- as far as possible remain fixed to the machinery when open,

- be associated with a locking device to prevent moving parts starting up as long as these parts can be accessed and to give a stop command whenever they are no longer closed.

B. Type B movable guards must be designed and incorporated into the control system so that:

- moving parts cannot start up while they are within the operator's reach,
- the exposed person cannot reach moving parts once they have started up,
- they can be adjusted only by means of an intentional action, such as the use of a tool, key, etc.,
- the absence or failure of one of their components prevents starting or stops the moving parts,
- protection against any risk of ejection is proved by means of an appropriate barrier.

1.4.2.3. *Adjustable guards restricting access*

Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work must:

- be adjustable manually or automatically according to the type of work involved,
- be readily adjustable without the use of tools,
- reduce as far as possible the risk of ejection.

1.4.3. *Special requirements for protection devices*

Protection devices must be designed and incorporated into the control system so that:

- moving parts cannot start up while they are within the operator's reach,
- the exposed person cannot reach moving parts once they have started up,
- they can be adjusted only by means of an intentional action, such as the use of a tool, key, etc.,
- the absence or failure of one of their components prevents starting or stops the moving parts.

1.5. Protection against other hazards

• 1.5.1. *Electricity supply*

Where machinery has an electricity supply it must be designed, constructed and equipped so that all hazards of an electrical nature are or can be prevented.

The specific rules in force relating to electrical equipment designed for use within certain voltage limits must apply to machinery which is subject to those limits.

1.5.2. *Static electricity*

Machinery must be so designed and constructed as to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.

1.5.3. *Energy supply other than electricity*

Where machinery is powered by an energy other than electricity (e.g. hydraulic, pneumatic or thermal energy, etc.), it must be so designed, constructed and equipped as to avoid all potential hazards associated with these types 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 must be made impossible by the design of such parts or, failing this, by information given on the parts themselves and/or the housings. The same information must be given on moving parts and/or their housings where the direction of movement must be known to avoid a risk. Any further information that may be necessary must be given in the instructions.

Where a faulty connection can be the source of risk, incorrect fluid connections, including electrical conductors, must be made impossible by the design or, failing this, by information given on the pipes, cables, etc. and/or connector blocks.

1.5.5. *Extreme temperatures*

Steps must be taken to eliminate any risk of injury caused by contact with or proximity to machinery parts or materials at high or very low temperatures.

The risk of hot or very cold material being ejected should be assessed. Where this risk exists, the necessary steps must be taken to prevent it or, if this is not technically possible, to render it non-dangerous.

1.5.6. *Fire*

Machinery must be designed and constructed to avoid all risk of fire or overheating posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery.

1.5.7. *Explosion*

Machinery must be so designed and constructed to avoid any risk of explosion posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery.

To that end the manufacturer must take steps to:

- avoid a dangerous concentration of products,
- prevent combustion of the potentially explosive atmosphere,
- minimize any explosion which may occur so that it does not endanger the surroundings.

The same precautions must be taken if the manufacturer foresees the use of the machinery in a potentially explosive atmosphere.

Electrical equipment forming part of the machinery must conform, as far as the risk from explosion is concerned, to the provision of the specific Directives in force.

1.5.8. *Noise*

Machinery must be so designed and constructed 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.

1.5.9. *Vibration*

Machinery must be so designed and constructed that risks resulting from vibrations produced by the machinery are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source.

1.5.10. *Radiation*

Machinery must be so designed and constructed that any emission of radiation is limited to the extent necessary for its operation and that the effects on exposed persons are non-existent or reduced to non-dangerous proportions.

1.5.11. *External radiation*

• Machinery must be so designed and constructed that external radiation does not interfere with its operation.

1.5.12. *Laser equipment*

Where laser equipment is used, the following provisions should be taken into account:

- laser equipment on machinery must be designed and constructed so as to prevent any accidental radiation,
- laser equipment on machinery must be protected so that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health,
- optical equipment for the observation or adjustment of laser equipment on machinery must be such that no health risk is created by the laser rays.

1.5.13. *Emissions of dust, gases, etc.*

Machinery must be so designed, constructed and/or equipped that risks due to gases, liquids, dust, vapours and other waste materials which it produces can be avoided.

Where a hazard exists, the machinery must be so equipped that the said substances can be contained and/or evacuated.

Where machinery is not enclosed during normal operation, the devices for containment and/or evacuation must be situated as close as possible to the source emission.

1.5.14. *Risk of being trapped in a machine*

Machinery must be designed, constructed or fitted with a means of preventing an exposed 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 where persons are liable to move about or stand must be designed and constructed to prevent persons slipping, tripping or falling on or off these parts.

1.6. Maintenance

1.6.1. *Machinery maintenance*

Adjustment, lubrication and maintenance points must be located outside danger zones. It must be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while machinery is at a standstill.

If one or more of the above conditions cannot be satisfied for technical reasons, these operations must be possible without risk (see 1.2.5).

In the case of automated machinery and, where necessary, other machinery, the manufacturer must make provision for a connecting device for mounting diagnostic fault-finding equipment.

Automated machine components which have to be changed frequently, in particular for a change in manufacture or where they are liable to wear or likely to deteriorate following an accident, must be capable of being removed and replaced easily and in safety. Access to the components must enable these tasks to be carried out with the necessary technical means (tools, measuring instruments, etc.) in accordance with an operating method specified by the manufacturer.

1.6.2. *Access to operating position and servicing points*

The manufacturer must provide means of access (stairs, ladders, catwalks, etc.) to allow access in safety to all areas used for production, adjustment and maintenance operations.

1.6.3. *Isolation of energy sources*

All machinery must be fitted with means to isolate it from all energy sources. Such isolators must be clearly identified. They must be capable of being locked if reconnection could endanger exposed persons. In the case of machinery supplied with electricity through a plug capable of being plugged into a circuit, separation of the plug is sufficient.

The isolator must be capable of being locked also where an operator is unable, from any of the points to which he has access, to check that the energy is still cut off.

After the energy is cut off, it must be possible to dissipate normally any energy remaining or stored in the circuits of the machinery without risk to exposed persons.

As an exception to the above requirements, certain circuits may remain connected to their energy sources in order, for example, to hold parts, protect information, light interiors, etc. In this case, special steps must be taken to ensure operator safety.

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1.6.4. Operator intervention

· Machinery must be so designed, constructed and equipped that the need for operator intervention is limited.

If operator intervention cannot be avoided, it must be possible to carry it out easily and in safety.

1.6.5. Cleaning of internal parts

The machinery must be designed and constructed in such a way that it is possible to clean internal parts which have contained dangerous substances or preparations without entering them; any necessary unblocking must also be possible from the outside. If it is absolutely impossible to avoid entering the machinery, the manufacturer must take steps during its construction to allow cleaning to take place with the minimum of danger.

1.7. Indicators

1.7.0. Information devices

The information needed to control machinery must be unambiguous and easily understood.

It must not be excessive to the extent of overloading the operator.

Where the health and safety of exposed persons may be endangered by a fault in the operation of unsupervised machinery, the machinery must be equipped to give an appropriate acoustic or light signal as a warning.

1.7.1. Warning devices

Where machinery is equipped with warning devices (such as signals, etc.), these must be unambiguous and easily perceived.

The operator must have facilities to check the operation of such warning devices at all times.

The requirements of the specific Directives concerning colours and safety signals must be complied with.

1.7.2. Warning of residual risks

Where risks remain despite all the measures adopted or in the case of potential risks which are not evident (e.g. electrical cabinets, radioactive sources, bleeding of a

hydraulic circuit, hazard in an unseen area, etc.), the manufacturer must provide warnings.

Such warnings should preferably use readily understandable pictograms and/or be drawn up in one of the languages of the country in which the machinery is to be used, accompanied, on request, by the languages understood by the operators.

1.7.3. *Marking*

All machinery must be marked legibly and indelibly with the following minimum particulars:

- name and address of the manufacturer,
- the CE marking (see Schedule III to these regulations),
- designation of series or type,
- serial number, if any,
- the year of construction.

Furthermore, where the manufacturer constructs machinery intended for use in a potentially explosive atmosphere, this must be indicated on the machinery.

Machinery must also bear full information relevant to its type and essential to its safe use (e.g. maximum speed of certain rotating parts, maximum diameter of tools to be fitted, mass, etc.).

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

The interchangeable equipment referred to in the third indent of Article 1(2)(a), must bear the same information.

1.7.4. *Instructions*

(a) All machinery must be accompanied by instructions including at least the following:

- a repeat of the information with which the machinery is marked, except the serial number (see 1.7.3) together with any appropriate additional information to facilitate maintenance (e.g. addresses of the importer, repairers, etc.),
- foreseen use of the machinery within the meaning of 1.1.2(c),

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- workstation(s) likely to be occupied by operators,
- instructions for safe:
 - putting into service,
 - use,
 - handling, giving the mass of the machinery and its various parts where they are regularly to be transported separately,
 - assembly, dismantling,
 - adjustment,
 - maintenance (servicing and repair),
- where necessary, training instructions,
- where necessary, the essential characteristics of tools which may be fitted to the machinery.

Where necessary, the instructions should draw attention to ways in which the machinery should not be used.

(b) The instructions must be drawn up in one of the Community languages by the manufacturer or his authorized representative established in the Community. On being put into service, all machinery must be accompanied by a translation of the instructions in the language or languages of the country⁸ in which the machinery is to be used any by the instructions in the original language. This translation must be done either by the manufacturer or his authorized representative established in the Community or by the person introducing the machinery into the language area in question. By way of derogation from this requirement, the maintenance instructions for use by specialized personnel employed by the manufacturer or his authorized representative established in the Community may be drawn up in only one of the Community languages understood by that personnel.

(c) The instructions must contain the drawings and diagrams necessary for putting into service, maintenance, inspection, checking of correct operation and, where appropriate, repair of the machinery, and all useful instructions in particular with regard to safety.

(d) Any literature describing the machinery must not contradict the instructions as regards safety aspects. The technical documentation describing

⁸For machinery placed on the Maltese market or put into service locally, the translation is required to be made in either Maltese and/or English.

the machinery must give information regarding the airborne noise emissions referred to in (f) and, in the case of hand-held and/or hand-guided machinery, information regarding vibration as referred to in 2.2.

(e) Where necessary, the instructions must give the requirements relating to installation and assembly for reducing noise or vibration (e.g. use of dampers, type and mass of foundation block, etc.).

(f) The instructions must give the following information concerning airborne noise emissions by the machinery, either the actual value or a value established on the basis of measurements made on identical machinery:

- equivalent continuous A-weighted sound pressure level at workstations, where this exceeds 70 dB (A); where this level does not exceed 70 dB(A), this fact must be indicated,
- peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 µPa),
- sound power level emitted by the machinery where the equivalent continuous A-weighted sound pressure level at workstations exceeds 85 dB (A).

In the case of very large machinery, instead of the sound power level, the equivalent continuous sound pressure levels at specified positions around the machinery may be indicated.

Where the harmonized standards are not applied, sound levels must be measured using the most appropriate method for the machinery.

The manufacturer must indicate the operating conditions of the machinery during measurement and what methods have been used for the measurement.

Where the workstation(s) are undefined or cannot be defined, sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at a height of 1.60 metres from the floor or access platform. The position and value of the maximum sound pressure must be indicated.

(g) If the manufacturer foresees that the machinery will be used in a potentially explosive atmosphere, the instructions must give all the necessary information.

(h) In the case of machinery which may also be intended for use by non-professional operators, the wording and layout of the instructions for use, whilst respecting the other essential requirements mentioned above, must take into account the level of general education and acumen that can reasonably be expected from such operators.

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

2.1. Agri-foodstuffs machinery

Where machinery is intended to prepare and process foodstuffs (e.g. cooking, refrigeration, thawing, washing, handling, packaging, storage, transport or distribution), it must be so designed and constructed as to avoid any risk of infection, sickness or contagion and the following hygiene rules must be observed:

(a) materials in contact, or intended to come into contact, with the foodstuffs must satisfy the conditions set down in the relevant Directives. The machinery must be so designed and constructed that these materials can be clean before each use;

(b) all surfaces including their joinings must be smooth, and must have neither ridges nor crevices which could harbour organic materials;

(c) assemblies must be designed in such a way as to reduce projections, edges and recesses to a minimum. They should preferably be made by welding or continuous bonding. Screws, screwheads and rivets may not be used except where technically unavoidable;

(d) all surfaces in contact with the foodstuffs must be easily cleaned and disinfected, where possible after removing easily dismantled parts. The inside surfaces must have curves of a radius sufficient to allow thorough cleaning;

(e) liquid deriving from foodstuffs as well as cleaning, disinfecting and rinsing fluids should be able to be discharged from the machine without impediment (possible in a 'clean' position);

(f) machinery must be so designed and constructed as to prevent any liquids or living creatures, in particular insects, entering, or any organic matter accumulating in areas that cannot be cleaned (e.g. for machinery not mounted on feet or casters, by placing a seal between the machinery and its base, by the use of sealed units, etc.);

(g) machinery must be so designed and constructed that no ancillary substances (e.g. lubricants, etc.) can come into contact with foodstuffs. Where necessary, machinery must be designed and constructed so that continuing compliance with this requirement can be checked.

Instructions

In addition to the information required in section 1, the instructions must indicate recommended products and methods for cleaning, disinfecting and rinsing (not only for easily accessible areas but also where areas to which access is impossible or inadvisable, such as piping, have to be cleaned *in situ*).

2.2. Portable hand-held and/or hand-guided machinery

Portable hand-held and/or hand-guided machinery must conform to the following essential health and safety requirements:

- according to the type of machinery, it must have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size and arranged to ensure the stability of the machinery under the operating conditions foreseen by the manufacturer,
- except where technically impossible or where there is an independent control, in the case of handles which cannot be released in complete safety, it must be fitted with start and stop controls arranged in such a way that the operator can operate them without releasing the handles,
- it must be designed, constructed or equipped to eliminate the risks of accidental starting and/or continued operation after the operator has released the handles. Equivalent steps must be taken if this requirement is not technically feasible,
- portable hand-held machinery must be designed and constructed to allow, where necessary, a visual check of the contact of the tool with the material being processed.

Instructions

The instructions must give the following information concerning vibrations transmitted by hand-held and hand-guided machinery:

- the weighted root mean square acceleration value to which the arms are subjected, if it exceeds 2.5 m/s^2 as determined by the appropriate test code. Where the acceleration does not exceed 2.5 m/s^2 , this must be mentioned.

If there is no applicable test code, the manufacturer must indicate the measurement methods and conditions under which measurements were made.

2.3. Machinery for working wood and analogous materials

Machinery for working wood and machinery for working materials with physical and technological characteristics similar to those of wood, such as cork, bone, hardened rubber, hardened plastic material and other similar stiff material must conform to the following essential health and safety requirements:

- (a) the machinery must be designed, constructed or equipped so that the piece being machined can be placed and guided in safety; where the piece is hand-held on a work-bench the latter must be sufficiently stable during the work and must not impede the movement of the piece;

(b) where the machinery is likely to be used in conditions involving the risk of ejection of pieces of wood, it must be designed, constructed, or equipped to eliminate this ejection, or, if this is not the case, so that the ejection does not engender risks for the operator and/or exposed persons;

(c) the machinery must be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down;

(d) where the tool is incorporated into a non-fully automated machine, the latter must be so designed and constructed as to eliminate or reduce the risk of serious accidental injury, for example by using cylindrical cutter blocks, restricting depth of cut, etc.

3. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET THE PARTICULAR HAZARDS DUE TO THE MOBILITY OF MACHINERY

Machinery presenting hazards due to mobility must be designed and constructed to meet the requirements set out below.

Risks due to mobility always exist in the case of machinery which is self-propelled, towed or pushed or carried by other machinery or tractors, is operated in working areas and whose operation requires either mobility while working, be it continuous or semi-continuous movement, between a succession of fixed working positions.

Risks due to mobility may also exist in the case of machinery operated without being moved, but equipped in such a way as to enable it to be moved more easily from one place to another (machinery fitted with wheels, rollers, runners, etc. or placed on gantries, trolleys, etc.).

In order to verify that rotary cultivators and power harrows do not present unacceptable risks to the exposed persons, the manufacturer or his authorized representative must, for each type of machinery concerned, perform the appropriate tests or have such tests performed.

3.1. General

3.1.1. *Definition*

'Driver' means an operator responsible for the movement of machinery. The driver may be transported by the machinery or may be on foot, accompanying the machinery, or may be guiding the machinery by remote control (cables, radio, etc.).

3.1.2. *Lighting*

If intended by the manufacturer to be used in dark places, self-propelled machinery must be fitted with a lighting device appropriate to the work to be carried out, without prejudice to any other regulations applicable (road traffic regulations, navigation rules, etc.).

3.1.3. Design of machinery to facilitate its handling

During the handling of the machine and/or its parts, there must be no possibility of sudden movements or of hazards due to instability as long as the machine and/or its parts are handled in accordance with the manufacturer's instructions.

3.2. Work stations

3.2.1. Driving position

The driving position must be designed with due regard to ergonomic principles. There may be two or more driving positions and, in such cases, each driving position must be provided with all the requisite controls. Where there is more than one driving position, the machinery must be designed so that the use of one of them precludes the use of the others, except in emergency stops. Visibility from the driving position must be such that the driver can in complete safety for himself and the exposed persons, operate the machinery and its tools in their intended conditions of use. Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision.

Machinery must be so designed and constructed that, from the driving position, there can be no risk to the driver and operators on board from inadvertent contact with the wheels or tracks.

The driving position must be designed and constructed so as to avoid any health risk due to exhaust gases and/or lack of oxygen.

The driving position of ride-on drivers must be so designed and constructed that a driver's cab may be fitted as long as there is room. In that case, the cab must incorporate a place for the instructions needed for the driver and/or operators. The driving position must be fitted with an adequate cab where there is a hazard due to a dangerous environment.

Where the machinery is fitted with a cab, this must be designed, constructed and/or equipped to ensure that the driver has good operating conditions and is protected against any hazards that might exist (for instance: inadequate heating and ventilation, inadequate visibility, excessive noise and vibration, falling objects, penetration by objects, rolling over, etc.). The exit must allow rapid evacuation. Moreover, an emergency exit must be provided in a direction which is different from the usual exit.

The materials used for the cab and its fittings must be fire-resistant.

3.2.2. Seating

The driving seat of any machinery must enable the driver to maintain a stable position and be designed with due regard to ergonomic principles.

The seat must be designed to reduce vibrations transmitted to the driver to the lowest level that can be reasonably achieved. The seat mountings must withstand all stresses to which they can be subjected, notably in the event of rollover. Where there is no floor beneath the driver's feet, the driver must have footrests covered with a slip-resistant material.

Where machinery is fitted with provision for a rollover protection structure, the seat must be equipped with a safety belt or equivalent device which keeps the driver in his seat without restricting any movements necessary for driving or any movements caused by the suspension.

3.2.3. Other places

If the conditions of use provide that operators other than the driver are occasionally or regularly transported by the machinery, or work on it, appropriate places must be provided which enable them to be transported or to work on it without risk, particularly the risk of falling.

Where the working conditions so permit, these work places must be equipped with seats. Should the driving position have to be fitted with a cab, the other places must also be protected against the hazards which justified the protection of the driving position.

3.3. Controls

3.3.1. Control devices

The driver must be able to actuate all control devices required to operate the machinery from the driving position, except for functions which can be safely activated only by using control devices located away from the driving position. This refers in particular to working positions other than the driving position, for which operators other than the driver are responsible or for which the driver has to leave his driving position in order to carry out the manoeuvre in safety.

Where there are pedals they must be so designed, constructed and fitted to allow operation by the driver in safety with the minimum risk of confusion; they must have a slip-resistant surface and be easy to clean.

Where their operation can lead to hazards, notably dangerous movements, the machinery's controls, except for those with preset positions, must return to the neutral position as soon as they are released by the operator.

In the case of wheeled machinery, the steering system must be designed and constructed to reduce the force of sudden movements of the steering wheel or steering lever caused by shocks to the guide wheels.

Any control that locks the differential must be so designed and arranged that it allows the differential to be unlocked when the machinery is moving.

The last sentence of section 1.2.2 does not apply to the mobility function.

3.3.2. *Starting/moving*

Self-propelled machinery with a ride-on driver must be so equipped as to deter unauthorized persons from starting the engine.

Travel movements of self-propelled machinery with a ride-on driver must be possible only if the driver is at the controls.

Where, for operating purposes, machinery must be fitted with devices which exceed its normal clearance zone (e.g. stabilizers, jib, etc.), the driver must be provided with the means of checking easily, before moving the machinery, that such devices are in a particular position which allows safe movement.

This also applies to all other parts which, to allow safe movement, have to be in particular positions, locked if necessary.

Where it is technically and economically feasible, movement of the machinery must depend on safe positioning of the aforementioned parts.

It must not be possible for movement of the machinery to occur while the engine is being started.

3.3.3. *Travelling function*

Without prejudice to the provisions of road traffic regulations, self-propelled machinery and its trailers must meet the requirements for slowing down, stopping, braking and immobilization so as to ensure safety under all the operating, loading, speed, ground and gradient conditions allowed for by the manufacturer and corresponding to conditions encountered in normal use.

The driver must be able to slow down and stop self-propelled machinery by means of a main device. Where safety so requires in the event of a failure of the main device, or in the absence of the energy supply to actuate the main device, an emergency device with fully independent and easily accessible controls must be provided for slowing down and stopping.

Where safety so requires, a parking device must be provided to render stationary machinery immobile. This device may be combined with one of the devices referred to in the second paragraph, provided that it is purely mechanical.

Remote-controlled machinery must be designed and constructed to stop automatically if the driver loses control.

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Section 1.2.4 does not apply to the travelling function.

3.3.4. *Movement of pedestrian-controlled machinery*

Movement of pedestrian-controlled self-propelled machinery must be possible only through sustained action on the relevant control by the driver. In particular, it must not be possible for movement to occur while the engine is being started.

The control systems for pedestrian-controlled machinery must be designed to minimize the hazards arising from inadvertent movement of the machine towards the driver. In particular:

- (a) crushing;
- (b) injury from rotating tools.

Also, the speed of normal travel of the machine must be compatible with the pace of a driver on foot.

In the case of machinery on which a rotary tool may be fitted, it must not be possible to actuate that tool when the reversing control is engaged, except where movement of the machinery results from movement of the tool. In the latter case, the reversing speed must be such that it does not endanger the driver.

3.3.5. *Control circuit failure*

A failure in the power supply to the power-assisted steering, where fitted, must not prevent machinery from being steered during the time required to stop it.

3.4. Protection against mechanical hazards

3.4.1. *Uncontrolled movements*

When a part of a machine has been stopped, any drift away from the stopping position, for whatever reason other than action at the controls, must be such that it is not a hazard to exposed persons.

Machinery must be so designed, constructed and where appropriate placed on its mobile support so as to ensure that when moved the uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.

3.4.2. *Risk of break-up during operation*

Parts of machinery rotating at high speed which, despite the measures taken, may break up or disintegrate, must be mounted and guarded in such a way that, in case of

breakage, their fragments will be contained or, if that is not possible, cannot be projected towards the driving and/or operation positions.

3.4.3. *Rollover*

Where, in the case of self-propelled machinery with a ride-on driver and possibly ride-on operators, there is a risk of rolling over, the machinery must be designed for and be fitted with anchorage points allowing it to be equipped with a rollover protective structure (ROPS).

This structure must be such that in case of rolling over it affords the ride-on driver and where appropriate the ride-on operators an adequate deflection-limiting volume (DLV).

In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorized representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.

In addition, the earth-moving machinery listed below with a capacity exceeding 15 kW must be fitted with a rollover protective structure:

- crawler loaders or wheel loaders,
- backhoe loaders,
- crawler tractors or wheel tractors,
- scrapers, self-loading or not,
- graders,
- articulated steer dumpers.

3.4.4. *Falling objects*

Where, in the case of machinery with a ride-on driver and possibly ride-on operators, there is a risk due to falling objects or material, the machinery should be designed for, and fitted with, if its size allows, anchorage points allowing it to be equipped with a falling-object protective structure (FOPS).

This structure must be such that in the case of falling objects or material, it guarantees the ride-on operators an adequate deflection-limiting volume (DLV).

In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorized representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.

3.4.5. Means of access

Handholds and steps must be designed, constructed and arranged in such a way that the operators use them instinctively and do not use the controls for that purpose.

3.4.6. Towing devices

All machinery used to tow or to be towed must be fitted with towing or coupling devices designed, constructed and arranged to ensure easy and safe connection and disconnection, and to prevent accidental disconnection during use.

In so far as the towbar load requires, such machinery must 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

Transmission shafts with universal joints linking self-propelled machinery (or tractor) to the first fixed bearing of recipient machinery must be guarded on the self-propelled machinery side and the recipient machinery side over the whole length of the shaft and associated universal joints.

On the side of the self-propelled machinery (or tractor), the power take-off to which the transmission shaft is attached must be guarded either by a screen fixed to the self-propelled machinery (or tractor) or by any other device offering equivalent protection.

On the towed machinery side, the input shaft must be enclosed in a protective casing fixed to the machinery.

Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machine. The universal-joint transmission shaft must be marked accordingly.

All towed machinery whose operation requires a transmission shaft to connect it to self-propelled machinery or a tractor must have a system for attaching the transmission shaft so that when the machinery is uncoupled the transmission shaft and its guard are not damaged by contact with the ground or part of the machinery.

The outside parts of the guard must be so designed, constructed and arranged that they cannot turn with the transmission shaft. The guard must cover the transmission shaft 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.

Manufacturers providing means of access to working positions near to the universal joint transmission shaft must ensure that shaft guards as described in the sixth paragraph cannot be used as steps unless designed and constructed for that purpose.

3.4.8. *Moving transmission parts*

By way of derogation from section 1.3.8.A, in the case of internal combustion engines, removable guards preventing access to the moving parts in the engine compartment need not have locking 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 if the latter is in a fully enclosed cab with a lock to prevent unauthorized access.

3.5. **Protection against other hazards**

3.5.1. *Batteries*

The battery housing must be constructed and located and the battery installed so as to avoid as far as possible the chance of electrolyte being ejected on to the operator in the event of rollover and/or to avoid the accumulation of vapours in places occupied by operators.

Machinery must be so designed and constructed that the battery can be disconnected with the aid of an easily accessible device provided for that purpose.

3.5.2. *Fire*

Depending on the hazards anticipated by the manufacturer when in use, machinery must, where its size permits:

- either allow easily accessible fire extinguishers to be fitted,
- or be provided with built-in extinguisher systems.

3.5.3. *Emissions of dust, gases, etc.*

Where such hazards exist, the containment equipment provided for in section 1.5.13 may be replaced by other means, for example precipitation by water spraying.

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.

3.6. **Indications**

3.6.1. *Signs and warning*

Machinery must have means of signalling and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, to ensure the health and safety of exposed persons. They must be chosen, designed and constructed in such a way as to be clearly visible and indelible.

Without prejudice to the requirements to be observed for travelling on the public highway, machinery with a ride-on driver must have the following equipment:

- an acoustic warning device to alert exposed persons,
- a system of light signals relevant to the intended conditions of use such as stop lamps, reversing lamps and rotating beacons. The latter requirement does not apply to machinery intended solely for underground working and having no electrical power.

Remote-controlled machinery which under normal conditions of use exposes persons to the hazards of impact or crushing must be fitted with appropriate means to signal its movements or with means to protect exposed persons against such hazards. The same applies to machinery which involves, when in use, the constant repetition of a forward and backward movement on a single axis where the back of the machine is not directly visible to the driver.

Machinery must be so constructed that the warning and signalling devices cannot all be disabled unintentionally. Where this is essential for safety, such devices must be provided with the means to check that they are in good working order and their failure must be made apparent to the operator.

Where the movement of machinery or its tools is particularly hazardous, signs on the machinery must be provided to warn against approaching the machinery while it is working; the signs must be legible at a sufficient distance to ensure the safety of persons who have to be in the vicinity.

3.6.2. *Marking*

The minimum requirements set out in 1.7.3 must be supplemented by the following:

- nominal power expressed in kW,
- mass in kg of the most usual configuration and, where appropriate:
 - maximum drawbar pull provided for by the manufacturer at the coupling hook, in N,
 - maximum vertical load provided for by the manufacturer on the coupling hook, in N.

3.6.3. *Instruction handbook*

Apart from the minimum requirements set out in 1.7.4, the instruction handbook must contain the following information:

(a) regarding the vibrations emitted by the machinery, either the actual value or a figure calculated from measurements performed on identical machinery:

- the weighted root mean square acceleration value to which the arms are subjected, if it exceeds 2.5 m/s^2 , should it not exceed 2.5 m/s^2 , this must be mentioned,
- the weighted root mean square acceleration value to which the body (feet or posterior) is subjected, if it exceeds 0.5 m/s^2 , should it not exceed 0.5 m/s^2 , this must be mentioned.

Where the harmonized standards are not applied, the vibration must be measured using the most appropriate method for the machinery concerned.

The manufacturer must indicate the operating conditions of the machinery during measurement and which methods were used for taking the measurements;

(b) in the case of machinery allowing several uses depending on the equipment used, manufacturers of basic machinery to which interchangeable equipment may be attached and manufacturers of the interchangeable equipment must provide the necessary information to enable the equipment to be fitted and used safely.

4. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET THE PARTICULAR HAZARDS DUE TO A LIFTING OPERATION

Machinery presenting hazards due to lifting operations - mainly hazards of load falls and collisions or hazards of tipping caused by a lifting operation - must be designed and constructed to meet the requirements set out below.

Risks due to a lifting operation exist particularly in the case of machinery designed to move a unit load involving a change in level during the movement. The load may consist of objects, materials or goods.

4.1. General remarks

4.1.1. Definitions

(a) 'lifting accessories' means components or equipment not attached to the machine and placed between the machinery and the load or on the load in order to attach it;

(b) 'separate lifting accessories' means accessories which help to make up or use a slinging device, such as eyehooks, shackles, rings, eyebolts, etc.;

(c) 'guided load' means the load where the total movement is made along rigid or flexible guides, whose position is determined by fixed points;

(d) 'working coefficient' means the arithmetic ratio between the load guaranteed by the manufacturer up to which a piece of equipment, an accessory or machinery is able to hold it and the maximum working load marked on the equipment, accessory or machinery respectively;

(e) 'test coefficient' means the arithmetic ratio between the load used to carry out the static or dynamic tests on a piece of equipment, an accessory or machinery and the maximum working load marked on the piece of equipment, accessory or machinery;

(f) 'static test' means the test during which the machinery or the 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 no damage has occurred;

(g) 'dynamic test' means the test during which the machinery is operated in all its possible configurations at maximum working load with account being taken of the dynamic behaviour of the machinery in order to check that the machinery and safety features are functioning properly.

4.1.2. *Protection against mechanical hazards*

4.1.2.1. *Risks due to lack of stability*

Machinery must be so designed and constructed that the stability required in 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 authorized representative must use the appropriate verification methods; in particular, for self-propelled industrial trucks with lift exceeding 1.80 m, the manufacturer or his authorized representative must, for each type of industrial truck concerned, perform a platform stability test or similar test, or have such tests performed.

4.1.2.2. *Guide rails and rail tracks*

Machinery must be provided with devices which act on the guide rails or tracks to prevent derailment.

However, if derailment occurs despite such devices, or if there is a failure of a rail or of a running component, devices must be provided which prevent the equipment, component or load from falling or the machine overturning.

4.1.2.3. *Mechanical strength*

Machinery, lifting accessories and removable components must be capable of withstanding the stresses to which they are subjected, both in and, where applicable, out of use, under the installation and operating conditions provided for by the manufacturer, and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons. This requirement must also be satisfied during transport, assembly and dismantling.

Machinery and lifting accessories must be designed and constructed so as to prevent failure from fatigue or wear, taking due account of their intended use.

The materials used must be chosen on the basis of the working environments provided for by the manufacturer, with special reference to corrosion, abrasion, impacts, cold brittleness and ageing.

The machinery and the lifting accessories must be designed and constructed to withstand the overload in the static tests without permanent deformation or patent defect. The calculation must take account of the values 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 must be designed and constructed 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.

The dynamic tests must be performed on machinery ready to be put into service under normal conditions of use. As a general rule, the tests will be performed at the nominal speeds laid down by the manufacturer. Should the control circuit of the machinery allow for a number of simultaneous movements (for example, rotation and displacement of the load), the tests must be carried out under the least favourable conditions, i.e. as a general rule, by combining the movements concerned.

4.1.2.4. *Pulleys, drums, chains or ropes*

Pulleys, drums and wheels must have a diameter commensurate with the size of rope or chains with which they can be fitted.

Drums and wheels must be so designed, constructed and installed that the ropes or chains with which they are equipped can wind round without falling off.

Ropes used directly for lifting or supporting the load must not include any splicing other than at their ends (splicings are tolerated in installations which are intended from their design to be modified regularly according to needs of use). Complete ropes and their endings have a working coefficient chosen so as to guarantee an adequate level of safety; as a general rule, this coefficient is equal to five.

Lifting chains have a working coefficient chosen so as to guarantee an adequate level of safety; as a general rule, this coefficient is equal to four.

In order to verify that an adequate working coefficient has been attained, the manufacturer or his authorized representative must, for each type of chain and rope used directly for lifting the load, and for the rope ends, perform the appropriate tests or have such tests performed.

4.1.2.5. *Separate lifting accessories*

Lifting accessories must be sized with due regard to fatigue and ageing processes for a number of operating cycles consistent with their expected life-span as specified in the operating conditions for a given application.

Moreover:

(a) the working coefficient of the metallic rope/rope-end combination is chosen so as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to five. Ropes must not comprise any splices or loops other than at their ends;

(b) where chains with welded links are used, they must be of the short-link type. The working coefficient of chains of any type is chosen so as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to four;

(c) the working coefficient for textile ropes or slings is dependent on the material method of manufacture, dimensions and use. This coefficient is chosen so as to guarantee an adequate level of safety; it is, as a general rule, equal to seven, provided the materials used are shown to be of very good quality and the method of manufacture is appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety.

Textile ropes and slings must not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling;

(d) all metallic components making up, or used with, a sling must have a working coefficient chosen so as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to four;

(e) the maximum working capacity of a multilegged sling is determined on the basis of the safety 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 authorized representative must, for each type of component referred to in (a), (b), (c) and (d) perform the appropriate tests or have such tests performed.

4.1.2.6. *Control of movements*

Devices for controlling movements must act in such a way that the machinery on which they are installed is kept safe:

(a) machinery must be so designed or fitted with devices that the amplitude of movement of its components is kept within the specified limits. The operation of such devices must, where appropriate, be preceded by a warning;

(b) where several fixed or rail-mounted machines can be manoeuvred simultaneously in the same place, with risks of collision, such machines must be so designed and constructed as to make it possible to fit systems enabling these risks to be avoided;

(c) the mechanisms of machinery must be so designed and constructed that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine;

(d) it must not be possible, under normal operating conditions, to lower the load solely by friction brake, except in the case of machinery whose function requires it to operate in that way;

(e) holding devices must be so designed and constructed that inadvertent dropping of the loads is avoided.

4.1.2.7. *Handling of loads*

The driving position of machinery must be located in such a way as to ensure the widest possible view of trajectories of the moving parts, in order to avoid possible collisions with persons or equipment or other machinery which might be manoeuvring at the same time and liable to constitute a hazard.

Machinery with guided loads fixed in one place must be designed and constructed so as to prevent exposed persons from being hit by the load or the counter-weights.

4.1.2.8. *Lightning*

- Machinery in need of protection against the effects of lightning while being used must be fitted with a system for conducting the resultant electrical charges to earth.

4.2. Special requirements for machinery whose power source is other than manual effort

4.2.1. *Controls*

4.2.1.1. *Driving position*

The requirements laid down in section 3.2.1 also apply to non-mobile machinery.

4.2.1.2. *Seating*

The requirements laid down in section 3.2.2, first and second paragraphs, and those laid down in section 3.2.3 also apply to non-mobile machinery.

4.2.1.3. *Control devices*

The devices controlling movements of the machinery or its equipment must return to their neutral position as soon as they are released by the operator. 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 controls authorizing automatic stops at pre-selected levels without holding a hold-to-run control device.

4.2.1.4. *Loading control*

Machinery with a maximum working load of not less than 1,000 kilograms or an overturning moment of not less than 40,000 Nm must be fitted with devices to warn the driver and prevent dangerous movements of the load in the event of:

- overloading the machinery:
 - either as a result of maximum working loads being exceeded, or
 - as a result of the moments due to the loads being exceeded,
 - the moments conducive to overturning being exceeded as a result of the load being lifted.

4.2.2. *Installation guided by cables*

Cable carriers, tractors or tractor carriers must be held by counter-weights or by a device allowing permanent control of the tension.

4.2.3. Risks to exposed persons. Means of access to driving position and intervention points

Machinery with guided loads and machinery whose load supports follow a clearly defined path must be equipped with devices to prevent any risks to exposed persons.

Machinery serving specific levels at which operators can gain access to the load platform in order to stack or secure the load must be designed and constructed to prevent uncontrolled movement of the load platform, in particular while being loaded or unloaded.

4.2.4. Fitness for purpose

When machinery is placed on the market or is first put into service, the manufacturer or his authorized representative must ensure, by taking appropriate measures or having them taken, that lifting accessories and machinery which are ready for use - whether manually or power-operated - can fulfil their specified functions safely. The said measures must take into account the static and dynamic aspects of the machinery.

Where the machinery cannot be assembled in the manufacturer's premises, or in the premises of his authorized representative, appropriate measures must be taken at the place of use. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.

4.3. Marking

4.3.1. Chains and ropes

Each length of lifting chain, rope or webbing not forming part of an assembly must bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer or his authorized representative and the identifying reference of the relevant certificate.

The certificate should show the information required by the harmonized standards or, should those not exist, at least the following information:

- the name of the manufacturer or his authorized representative,
- the address within the Community of the manufacturer or his authorized representative, as appropriate,
- a description of the chain or rope which includes:
- its nominal size,

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- its construction,
 - the material from which it is made, and
 - any special metallurgical treatment applied to the material,
 - if tested, the standard used,
 - a maximum load to which the chain or rope should be subjected in service.
- A range of values may be given for specified applications.

4.3.2. *Lifting accessories*

All lifting accessories must show the following particulars:

- identification of the manufacturer,
- identification of the material (e.g. international classification) where this information is needed for dimensional compatibility,
- identification of the maximum working load,
- CE marking.

In the case of accessories including components such as cables or ropes, on which marking is physically impossible, the particulars referred to in the first paragraph must be displayed on a plate or by some other means and securely affixed to the accessory.

The particulars must be legible and located in a place where they are not liable to disappear as a result of machining, wear, etc., or jeopardize the strength of the accessory.

4.3.3. *Machinery*

In addition to the minimum information provided for in 1.7.3, each machine must bear, legibly and indelibly, information concerning the nominal load:

- (i) displayed in uncoded form and prominently on the equipment in the case of machinery which has only one possible value;
- (ii) where the nominal load depends on the configuration of the machine, each driving position must be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the nominal loads for each configuration.

Machinery equipped with a load support which allows access to persons and involves a risk of falling must bear a clear and indelible warning prohibiting the lifting of persons. This warning must be visible at each place where access is possible.

4.4. Instruction handbook

4.4.1. *Lifting accessories*

Each lifting accessory or each commercially indivisible batch of lifting accessories must be accompanied with an instruction handbook setting out at least the following particulars:

- normal conditions of use,
- instructions for use, assembly and maintenance,
- the limits of use (particularly for the accessories which cannot comply with 4.1.2.6(e)).

4.4.2. *Machinery*

In addition to section 1.7.4, the instruction handbook must include the following information:

- (a) the technical characteristics of the machinery, and in particular:
 - where appropriate, a copy of the load table described in section 4.3.3(ii),
 - the reactions at the supports or anchors and characteristics of the tracks,
 - where appropriate, the definition and the means of installation of the ballast;
- (b) the contents of the logbook, if the latter is not supplied with the machinery;
- (c) advice for use, particularly to offset the lack of direct sight of the load by the operator;
- (d) the necessary instructions for performing the tests before first putting into service machinery which is not assembled on the manufacturer's premises in the form in which it is to be used.

5. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY INTENDED FOR UNDERGROUND WORK

Machinery intended for underground work must be designed and constructed to meet the requirements set out below.

5.1. Risks due to lack of stability

Powered roof supports must be so designed and constructed as to maintain a given direction when moving and not slip before and while they come under load and after the load has been removed. They must be equipped with anchorages for the top plates of the individual hydraulic props.

5.2. Movement

Powered roof supports must allow for unhindered movement of exposed persons.

5.3. Lighting

The requirements laid down in the third paragraph of section 1.1.4 do not apply.

5.4. Control devices

The accelerator and brake controls for the movement of machinery running on rails must be manual. The deadman's control may be foot-operated, however.

The control devices of powered roof supports must be designed and laid out so that, during displacement operations, operators are sheltered by a support in place. The control devices must be protected against any accidental release.

5.5. Stopping

Self-propelled machinery running on rails for use in underground work must be equipped with a deadman's control acting on the circuit controlling the movement of the machinery.

5.6. Fire

The second indent of 3.5.2 is mandatory in respect of machinery which comprises highly flammable parts.

The braking system of machinery meant for use in underground working must be designed and constructed so as not to produce sparks or cause fires.

Machinery with heat engines for use in underground working must be fitted only with internal combustion engines using fuel with a low vaporising pressure and which exclude any spark of electrical origin.

5.7. Emissions of dust, gases, etc.

- * Exhaust gases from internal combustion engines must not be discharged upwards.

6. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET THE PARTICULAR HAZARDS DUE TO THE LIFTING OR MOVING OF PERSONS

Machinery presenting hazards due to the lifting or moving of persons must be designed and constructed to meet the requirements set out below.

6.1. General

6.1.1. *Definition*

For the purposes of this Chapter, 'carrier' means the device by which persons are supported in order to be lifted, lowered or moved.

6.1.2. *Mechanical strength*

The working coefficients defined in heading 4 are inadequate for machinery intended for the lifting or moving of persons and must, as a general rule, be doubled. The floor of the carrier must be designed and constructed to offer the space and strength corresponding to the maximum number of persons and the maximum working load set by the manufacturer.

6.1.3. *Loading control for types of device moved by power other than human strength*

The requirements of 4.2.1.4 apply regardless of the maximum working load figure. This requirement does not apply to machinery in respect of which the manufacturer can demonstrate that there is no risk of overloading and/or overturning.

6.2. Controls

6.2.1. Where safety requirements do not impose other solutions:

The carrier must, as a general rule, be designed and constructed so that persons inside have means of controlling movements upwards and downwards and, if appropriate, of moving the carrier horizontally in relation to the machinery.

In operation, those controls must override the other devices controlling the same movement, with the exception of the emergency stop devices.

The controls for these movements must be of the maintained command type, except in the case of machinery serving specific levels.

6.2.2. If machinery for the lifting or moving of persons can be moved with the carrier in a position other than the rest position, it must be designed and constructed so that the person or persons in the carrier have the means of preventing hazards produced by the movement of the machinery.

6.2.3. Machinery for the lifting or moving of persons must be designed, constructed or equipped so that excess speeds of the carrier do not cause hazards.

6.3. Risks of persons falling from the carrier

6.3.1. If the measures referred to in 1.1.15 are not adequate, carriers must be fitted with a sufficient number of anchorage points for the number of persons possibly using the carrier, strong enough for the attachment of personal protective equipment against the danger of falling.

6.3.2. Any trapdoors in floors or ceilings or side doors must open in a direction which obviates any risk of falling should they open unexpectedly.

6.3.3. Machinery for lifting or moving must be designed and constructed to ensure that the floor of the carrier does not tilt to an extent which creates a risk of the occupants falling, including when moving.

The floor of the carrier must be slip-resistant.

6.4. Risks of the carrier falling or overturning

6.4.1. Machinery for the lifting or moving of persons must be designed and constructed to prevent the carrier falling or overturning.

6.4.2. Acceleration and braking of the carrier or carrying vehicle, under the control of the operator or triggered by a safety device and under the maximum load and speed conditions laid down by the manufacturer, must not cause any danger to exposed persons.

6.5. Markings

Where necessary to ensure safety, the carrier must bear the relevant essential information.

Schedule II

Based on Annex II of the Directive

A. Contents of the EC declaration of conformity for machinery⁹

The EC declaration of conformity must contain the following particulars:

- name and address of the manufacturer or his authorized representative¹⁰
- description of the machinery¹¹
- all relevant provisions complied with by the machinery,
- where appropriate, name and address of the notified body and number of the EC type-examination certificate,
- where appropriate, the name and address of the notified body to which the file has been forwarded in accordance with the first indent of regulation 6.2 (c),
- where appropriate, the name and address of the notified body which has carried out the verification referred to in the second indent of regulation 6.2 (c),
- where appropriate, a reference to the harmonized standards,
- where appropriate, the national technical standards and specifications used,
- identification of the person empowered to sign on behalf of the manufacturer or his authorized representatives.

B. Contents of the declaration by the manufacturer or his authorized representatives (regulation 5.3.1)

The manufacturer's declaration referred to in regulation 5.3.1 must contain the following particulars:

- name and address of the manufacturer or the authorized representative,
- description of the machinery or machinery parts,

⁹This declaration must be drawn up in the same language as the original instructions (see Schedule I, section 1.7.4(b)) and must be either typewritten or handwritten in block capitals. It must be accompanied by a translation in one of the official languages of the country in which the machinery is to be used. This translation must be done in accordance with the same conditions as for the translation of the instructions.

¹⁰Business name and full address; authorized representatives must also give the business name and address of the manufacturer.

¹¹Description of the machinery (make, type, serial number, etc.).

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- where appropriate, the name and address of the notified body and the number of the EC type-examination certificate,
- where appropriate, the name and address of the notified body to which the file has been forwarded in accordance with the first indent of regulation 6.2 (c),
- where appropriate, the name and address of the notified body which has carried out the verification referred to in the second indent of regulation 6.2 (c),
- where appropriate, a reference to the harmonized standards,
- a statement that the machinery must not be put into service until the machinery into which it is to be incorporated has been declared in conformity with the provisions of these regulations,
- identification of the person signing.

C. Contents of the EC declaration of conformity for safety components placed on the market separately⁹

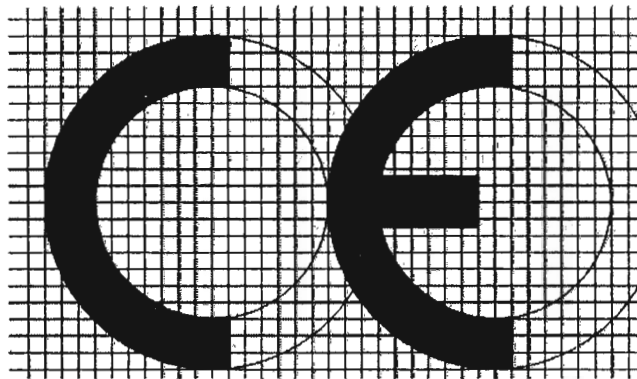
The EC declaration of conformity must contain the following particulars:

- name and address of the manufacturer or his authorized representative¹⁰,
- description of the safety component¹²,
- safety function fulfilled by the safety component, if not obvious from the description,
- where appropriate, the name and address of the notified body and the number of the EC type-examination certificate,
- where appropriate, the name and address of the notified body to which the file was forwarded in accordance with the first indent of regulation 6.2 (c),
- where appropriate, the name and address of the notified body which carried out the verification referred to in the second indent of regulation 6.2 (c),
- where appropriate, a reference to the harmonized standards,
- where appropriate, the national technical standards and specifications used,
- identification of the person empowered to sign on behalf of the manufacturer or his authorized representative.

¹² Description of the safety component (make, type, serial number, if any, etc.).

Schedule III**Based on Annex III of the Directive****CE CONFORMITY MARKING**

The CE conformity marking shall consist of the initials 'CE' taking the following form:



For the avoidance of doubt, it is hereby declared that the grid providing the background in the above graduated drawing is not part of the CE marking.

- if the CE marking is reduced or enlarged the proportions given in the above drawing must be respected,
- the various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale machinery.

Schedule IV

Based on Annex IV of the Directive

TYPES OF MACHINERY AND SAFETY COMPONENTS FOR WHICH THE PROCEDURE REFERRED TO IN REGULATION 6.2 (b) AND (c) MUST BE APPLIED

A. Machinery

1. Circular saws (single or multi-blade) for working with wood and analogous materials or for working with meat and analogous materials.
 - 1.1. Sawing machines with fixed tool during operation, having a fixed bed with manual feed of the workpiece or with a demountable power feed.
 - 1.2. Sawing machines with fixed tool during operation, having a manually operated reciprocating saw-bench or carriage.
 - 1.3. Sawing machines with fixed tool during operation, having a built-in mechanical feed device for the work-pieces, with manual loading and/or unloading.
 - 1.4. Sawing machines with movable tool during operation, with a mechanical feed device and manual loading and/or unloading.
2. Hand-fed surface planing machines for woodworking.
3. Thicknessers for one-side dressing with manual loading and/or unloading for woodworking.
4. Band-saws with a fixed or mobile bed and band-saws with a mobile carriage, with manual loading and/or unloading, for working with wood and analogous materials or for working with meat and analogous materials.
5. Combined machines of the types referred to in 1 to 4 and 7 for working with wood and analogous materials.
6. Hand-fed tenoning machines with several tool holders for woodworking.
7. Hand-fed vertical spindle moulding machines for working with wood and analogous materials.
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 machines with manual loading or unloading.

11. Injection or compression rubber-moulding machines with manual loading or unloading.

12. Machinery for underground working of the following types:

- machinery on rails: locomotives and brake-vans,
- hydraulic-powered roof supports,
- internal combustion engines to be fitted to machinery for underground working.

13. Manually-loaded trucks for the collection of household refuse incorporating a compression mechanism.

14. Guards and detachable transmission shafts with universal joints as described in section 3.4.7.

15. Vehicles servicing lifts.

16. Devices for the lifting of persons involving a risk of falling from a vertical height of more than three metres.

17. Machines for the manufacture of pyrotechnics.

B. Safety components

1. Electro-sensitive devices designed specifically to detect persons in order to ensure their safety (non-material barriers, sensor mats, electromagnetic detectors, etc.).

2. Logic units which ensure the safety functions of bimanual controls.

3. Automatic movable screens to protect the presses referred to in 9, 10 and 11.

4. Roll-over protection structures (ROPS).

5. Falling-object protective structures (FOPS).

Schedule V

Based on Annex V of the Directive

EC DECLARATION OF CONFORMITY

For the purposes of this Schedule, 'machinery' means either 'machinery' or 'safety component' as defined in regulations 3.1.1 and 3.1.2.

1. The EC declaration of conformity is the procedure by which the manufacturer, or his authorized representative declares that the machinery being placed on the market complies with all the essential health and safety requirements applying to it.

2. Signature of the EC declaration of conformity authorises the manufacturer, or his authorized representative, to affix the CE marking to the machinery.

3. Before drawing up the EC declaration of conformity, the manufacturer, or his authorized representative, shall have ensured and be able to guarantee that the documentation listed below is and will remain available on his premises for any inspection purposes:

(a) a technical construction file comprising:

- an overall drawing of the machinery together with drawings of the control circuits,

- full detailed drawings, accompanied by any calculation notes, test results, etc., required to check the conformity of the machinery with the essential health and safety requirements,

- a list of:

- the essential requirements of these regulations,

- standards, and

- other technical specifications, which were used when the machinery was designed,

- a description of methods adopted to eliminate hazards presented by the machinery,

- if he so desires, any technical report or certificate obtained from a competent body or laboratory¹³

¹³ A body or laboratory is presumed competent if it meets the assessment criteria laid down in the relevant harmonized standards.

- if he declares conformity with a harmonized standard which provides therefor, any technical report giving the results of tests carried out at his choice either by himself or by a competent body or laboratory¹³,

- a copy of the instructions for the machinery;

(b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of these regulations.

The manufacturer must carry out necessary research or tests on components, fittings or the completed machine to determine whether by its design or construction, the machine is capable of being erected and put into service safely.

Failure to present the documentation in response to a duly substantiated request by the competent national authorities may constitute sufficient grounds for doubting the presumption of conformity with the requirements of these regulations.

4. (a) The documentation referred to in 3 above need not permanently exist in a material manner but it must be possible to assemble it and make it available within a period of time commensurate with its importance.

It does not have to include detailed plans or any other specific information as regards the sub-assemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the basic safety requirements.

(b) The documentation referred to in 3 above shall be retained and kept available for the competent national authorities for at least 10 years following the date of manufacture of the machinery or of the last unit produced, in the case of series manufacture.

(c) The documentation referred to in 3 above shall be drawn up in one of the official languages of the Communities, with the exception of the instructions for the machinery.

Schedule VI

Based on Annex VI of the Directive

EC TYPE-EXAMINATION

For the purposes of this Schedule, 'machinery' means either 'machinery' or 'safety component' as defined in regulations 3.1.1 and 3.1.2.

1. EC type-examination is the procedure by which a notified body ascertains and certifies that an example of machinery satisfies the provisions of these regulations which apply to it.

2. The application for EC type-examination shall be lodged by the manufacturer or by his authorized representative, with a single notified body in respect of an example of the machinery.

The application shall include:

- the name and address of the manufacturer or his authorized representative and the place of manufacture of the machinery,
- a technical file comprising at least:
 - an overall drawing of the machinery together with drawings of the control circuits,
 - full detailed drawings, accompanied by any calculation notes, test results, etc., required to check the conformity of the machinery with the essential health and safety requirements,
 - a description of methods adopted to eliminate hazards presented by the machinery and a list of standards used,
 - a copy of the instructions for the machinery,
 - for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of these regulations.

It shall be accompanied by a machine representative of the production planned or, where appropriate, a statement of where the machine may be examined.

The documentation referred to above does not have to include detailed plans or any other specific information as regards the sub-assemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the basic safety requirements.

3. The notified body shall carry out the EC type-examination in the manner described below:

- it shall examine the technical construction file to verify its appropriateness and the machine supplied or made available to it,

- during the examination of the machine, the body shall:

- (a) ensure that it has been manufactured in conformity with the technical construction file and may safely be used under its intended working conditions;

- (b) check that standards, if used, have been properly applied;

- (c) perform appropriate examinations and tests to check that the machine complies with the essential health and safety requirements applicable to it.

4. If the example complies with the provisions applicable to it the body shall draw up an EC type-examination certificate which shall be forwarded to the applicant. That certificate shall state the conclusions of the examination, indicate any conditions to which its issue may be subject and be accompanied by the descriptions and drawings necessary for identification of the approved example.

The Commission, the Member States and the other approved bodies may obtain a copy of the certificate and, on a reasoned request, a copy of the technical construction file and of the reports on the examinations and tests carried out.

5. The manufacturer or his authorized representative shall inform the notified body of any modifications, even of a minor nature, which he has made or plans to make to the machine to which the example relates. The notified body shall examine those modifications and inform the manufacturer or his authorized representative whether the EC type-examination certificate remains valid.

6. A body which refuses to issue an EC type-examination certificate shall so inform the other notified bodies. A body which withdraws an EC type-examination certificate shall so inform the Member State which notified it. The latter shall inform the other Member States and the Commission thereof, giving the reasons for the decision.

7. The files and correspondence referring to the EC type-examination procedures shall be drawn up in an official language of the Member State where the notified body is established or in a language acceptable to it.