



The new Machinery Directive

A tool to uncover the changes
introduced by the revised directive

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KAN Kommission
Arbeitsschutz
und Normung

IMPRESSUM

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Contents

Preface and acknowledgements	3
Notes on Contributors	4
Directive 2006/42/EC	
Recitals	5
<i>Article 1</i> Scope	8
<i>Article 2</i> Definitions	10
<i>Article 3</i> Specific Directives	12
<i>Article 4</i> Market surveillance	12
<i>Article 5</i> Placing on the market and putting into service	12
<i>Article 6</i> Freedom of movement	13
<i>Article 7</i> Presumption of conformity and harmonised standards	13
<i>Article 8</i> Specific measures	14
<i>Article 9</i> Specific measures to deal with potentially hazardous machinery	14
<i>Article 10</i> Procedure for disputing a harmonised standard	14
<i>Article 11</i> Safeguard clause	15
<i>Article 12</i> Procedures for assessing the conformity of machinery	15
<i>Article 13</i> Procedure for partly completed machinery	16
<i>Article 14</i> Notified bodies	16
<i>Article 15</i> Installation and use of machinery	17
<i>Article 16</i> CE marking	17
<i>Article 17</i> Non-conformity of marking	18
<i>Article 18</i> Confidentiality	18
<i>Article 19</i> Cooperation between Member States	18
<i>Article 20</i> Legal remedies	18
<i>Article 21</i> Dissemination of information	18

<i>Article 22</i>	Committee	19
<i>Article 23</i>	Penalties	19
<i>Article 24</i>	Amendment of Directive 95/16/EC	19
<i>Article 25</i>	Repeal	20
<i>Article 26</i>	Transposition	20
<i>Article 27</i>	Derogation	20
<i>Article 28</i>	Entry into force	20
<i>Article 29</i>	Addressees	20

ANNEX I

Essential health and safety requirements relating to the design and construction of machinery

Detailed index of Annex I	21
Comparison of Annex I of Directive 2006/42/EC with Annex I of Directive 98/37/EEC	
Introduction	25
Meaning of text colours and highlighting	26

ANNEX II

Declarations	99
---------------------------	----

ANNEX III

CE marking	100
-------------------------	-----

ANNEX IV

Categories of machinery to which one of the procedures referred to in Article 12(3) and (4) must be applied	101
--	-----

ANNEX V

Indicative list of the safety components referred to in Article 2(c)	102
---	-----

ANNEX VI

Assembly instructions for partly completed machinery	103
---	-----

ANNEX VII

A. Technical file for machinery	103
B. Relevant technical documentation for partly completed machinery	105

ANNEX VIII

Assessment of conformity with internal checks on the manufacture of machinery	106
--	-----

ANNEX IX

EC type-examination	106
----------------------------------	-----

ANNEX X

Full quality assurance	108
-------------------------------------	-----

ANNEX XI

Minimum criteria to be taken into account by Member States for the notification of bodies	111
--	-----

Preface and acknowledgements

The Machinery Directive was adopted in 1989 and consolidated in 1998. Since the early nineties, a number of tools have been developed at national and European level by authorities, the European Commission and different actors to support implementation of the directive's provisions. Among these tools, European documents have been produced: firstly, the European standards for which the directive recognizes an essential role; secondly the Commission's Guidance documents, which include comments and facts in relation to the directive.

Following the latest revision of the Machinery Directive in 2006, which is to be applied from 29th December 2009, all interested parties will need to develop a deep understanding of their new and/or revised duties. This book is an attempt to help inform this process: it is based on an original reading of the essential health and safety requirements, and it includes a selection of reflections on the Articles and Annexes of the new legislative text.

This book was written by a number of experts who all have a long-standing interest in safety at work, but who also share the privilege of being – or having

been – involved in the European legislative and technical work in the field of machinery.

The book aims to pave the way for the development of new practical tools for the implementation of the directive: it especially intends to enrich the current studies and analyses on the new Machinery Directive, including the challenging task of revising the existing European Guidance document prepared by the European Commission.

A number of individuals have played a crucial role in ensuring that the book came out. These include, most importantly, our contributors, whose backgrounds cover standardisation, occupational health and safety (OHS), safety research, market surveillance; we are grateful for their insight, imagination, patience, and commitment. We are also grateful to our institutions, KAN and ETUI-REHS, without whose support we would not have been able to realize this project. Our special thanks go to Dr. Joachim Lambert and to Marc Sapir, for their encouragement throughout the work.

Ulrich Bamberg and Stefano Boy

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Jean-Paul Lacore – mechanical engineer – former *chargé de mission* for standardisation at INRS (*Institut National de Recherche et de Sécurité*), has been deeply involved in the activity of CEN/TC 114 Safety of machinery since 1985. He chaired the Working Groups drafting basic “horizontal” machinery standards such as EN 418, EN 1037, EN 1088. He also chaired the CEN/TC 114 Working Group 3, which produced the basic document EN 1070 “Safety of machinery – Terminology”.

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**DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL**

of 17 May 2006

on machinery, and amending Directive 95/16/EC (recast)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (3),

(1) OJ C 154 E, 29.5.2001, p. 164.

(2) OJ C 311, 7.11.2001, p. 1.

(3) Opinion of the European Parliament of 4 July 2002 (OJ C 271 E, 12.11.2003, p. 491), Council Common Position of 18 July 2005 (OJ C 251 E, 11.10.2005, p. 1) and Position of the European Parliament of 15 December 2005 (not yet published in the Official Journal). Council Decision of 25 April 2006.

Whereas:

- (1) Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (4) codified Directive 89/392/EEC (5). Now that new substantial amendments are being made to Directive 98/37/EC, it is desirable, in order to clarify matters, that that Directive should be recast.
 - (4) OJ L 207, 23.7.1998, p. 1. Directive as amended by Directive 98/79/EC (OJ L 331, 7.12.1998, p. 1).
 - (5) Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery (OJ L 183, 29. 6.1989, p. 9).
- (2) The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Community economy. The social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance.
- (3) Member States are responsible for ensuring the health and safety on their territory of persons, in particular of workers and consumers and, where appropriate, of domestic animals and goods, notably in relation to the risks arising out of the use of machinery.
- (4) In order to ensure legal certainty for users, the scope of this Directive and the concepts relating to its application should be defined as precisely as possible.
- (5) The Member States' mandatory provisions governing construction site hoists intended for lifting persons or persons and goods, which are often supplemented by de facto compulsory technical specifications and/or by voluntary standards, do not necessarily lead to different levels of health and safety but, because of their disparities, do nevertheless constitute barriers to trade within the Community. Moreover, the national systems for the conformity assessment and certification of these machines diverge considerably. It is therefore desirable not to exclude from the scope of this Directive construction site hoists intended for lifting persons or persons and goods.
- (6) It is appropriate to exclude from the scope of this Directive weapons, including firearms, that are subject to Council Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons (6); the exclusion of firearms should not apply to portable cartridge-operated fixing and other impact machinery designed for industrial or technical purposes only. It is necessary to provide for transitional arrangements enabling Member States to authorise the placing on the market and putting into service of such machinery manufactured in accordance with national provisions in force upon adoption of this Directive, including those implementing the Convention of 1 July 1969 on the Reciprocal Recognition of Proofmarks on Small Arms. Such transitional arrangements will also enable the European standardisation organisations to draft standards ensuring the safety level based on the state of the art.
 - (6) OJ L 256, 13.9.1991, p. 51.
- (7) This Directive does not apply to the lifting of persons by means of machines not designed for the lifting of persons. However, this does not affect the right of Member States to take national measures, in accordance with the Treaty, with respect to such machines, with a view to implementing Council Directive 89/655/EEC of 30 November 1989 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (7).
 - (7) OJ L 393, 30.12.1989, p. 13. Directive as last amended by Directive 2001/45/EC of the European Parliament and of the Council (OJ L 195, 19.7.2001, p. 46).

- (8) In relation to agricultural and forestry tractors, the provisions of this Directive concerning the risks currently not covered by Directive 2003/37/EC of the European Parliament and of the Council of 26 May 2003 on type-approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units (1) should no longer apply when such risks are covered by Directive 2003/37/EC.
- (1) OJ L 171, 9.7.2003, p. 1. Directive as last amended by Commission Directive 2005/67/EC (OJ L 273, 19.10.2005, p. 17).
- (9) Market surveillance is an essential instrument inasmuch as it ensures the proper and uniform application of Directives. It is therefore appropriate to put in place the legal framework within which market surveillance can proceed harmoniously.
- (10) Member States are responsible for ensuring that this Directive is effectively enforced on their territory and that the safety of the machinery concerned is, as far as possible, improved in accordance with its provisions. Member States should ensure their capacity to carry out effective market surveillance, taking account of guidelines developed by the Commission, in order to achieve the proper and uniform application of this Directive.
- (11) In the context of market surveillance, a clear distinction should be established between the disputing of a harmonised standard conferring a presumption of conformity on machinery and the safeguard clause relating to machinery.
- (12) The putting into service of machinery within the meaning of this Directive can relate only to the use of the machinery itself for its intended purpose or for a purpose which can reasonably be foreseen. This does not preclude the laying down of conditions of use external to the machinery, provided that it is not thereby modified in a way not specified in this Directive.
- (13) It is also necessary to provide for an adequate mechanism allowing for the adoption of specific measures at Community level requiring Member States to prohibit or restrict the placing on the market of certain types of machinery presenting the same risks to the health and safety of persons either due to shortcomings in the relevant harmonised standard(s) or by virtue of their technical characteristics, or to make such machinery subject to special conditions. In order to ensure the appropriate assessment of the need for such measures, they should be taken by the Commission, assisted by a committee, in the light of consultations with the Member States and other interested parties. Since such measures are not directly applicable to economic operators, Member States should take all necessary measures for their implementation.
- (14) The essential health and safety requirements should be satisfied in order to ensure that machinery is safe; these requirements should be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements.
- (15) Where the machinery may be used by a consumer, that is to say, a non-professional operator, the manufacturer should take account of this in the design and construction. The same applies where a machine is normally used to provide a service to a consumer.
- (16) Although the requirements of this Directive do not apply to partly completed machinery in their entirety, it is nevertheless important that the free movement of such machinery be guaranteed by means of a specific procedure.
- (17) For trade fairs, exhibitions and such like, it should be possible to exhibit machinery which does not satisfy the requirements of this Directive. However, interested parties should be properly informed that the machinery does not conform and cannot be purchased in that condition.
- (18) This Directive defines only the essential health and safety requirements of general application, supplemented by a number of more specific requirements for certain categories of machinery. In order to help manufacturers to prove conformity to these essential requirements, and to allow inspection of conformity to the essential requirements, it is desirable to have standards that are harmonised at Community level for the prevention of risks arising out of the design and construction of machinery. These standards are drawn up by private-law bodies and should retain their non-binding status.
- (19) In view of the nature of the risks involved in the use of machinery covered by this Directive, procedures for assessing conformity to the essential health and safety requirements should be established. These procedures should be devised in the light of the extent of the danger inherent in such machinery. Consequently, each category of machinery should have its appropriate procedure in conformity with Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives (2), taking account of the nature of the verification required for such machinery.
- (2) OJ L 220, 30.8.1993, p. 23.
- (20) Manufacturers should retain full responsibility for certifying the conformity of their machinery to the provisions of this Directive. Nevertheless, for certain types of machinery having a higher risk factor, a stricter certification procedure is desirable.
- (21) The CE marking should be fully recognised as being the only marking which guarantees that machinery conforms to the requirements of this Directive. All other markings which are likely to mislead third parties as to the meaning or the form of the CE marking, or both, should be prohibited.

- (22) In order to ensure the same quality for the CE marking and the manufacturer's mark, it is important that they be affixed according to the same techniques. In order to avoid confusion between any CE markings which might appear on certain components and the CE marking corresponding to the machinery, it is important that the latter marking be affixed alongside the name of the person who has taken responsibility for it, namely the manufacturer or his authorised representative.
- (23) The manufacturer or his authorised representative should also ensure that a risk assessment is carried out for the machinery which he wishes to place on the market. For this purpose, he should determine which are the essential health and safety requirements applicable to his machinery and in respect of which he must take measures.
- (24) It is essential that, before drawing up the EC declaration of conformity, the manufacturer or his authorised representative established in the Community should prepare a technical construction file. However, it is not essential that all documentation should be permanently available in material form, but it must be possible to make it available on request. It need not include detailed plans of subassemblies used for the manufacture of machinery, unless knowledge of such plans is essential in order to ascertain conformity with the essential health and safety requirements.
- (25) The addressees of any decision taken under this Directive should be informed of the reasons for such a decision and of the legal remedies open to them.
- (26) Member States should provide for penalties applicable to infringements of the provisions of this Directive. Those penalties should be effective, proportionate and dissuasive.
- (27) The application of this Directive to a number of machines intended for lifting persons requires a better delimitation of the products covered by this Directive with respect to those covered by Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts (1). A redefinition of the scope of the latter Directive is thus deemed necessary. Directive 95/16/EC should therefore be amended accordingly.
- (1) OJ L 213, 7.9.1995, p. 1. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).
- (28) Since the objective of this Directive, namely, to lay down the essential health and safety requirements in relation to design and manufacture in order to improve the safety of machinery placed on the market, cannot be sufficiently achieved by the Member States and can be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (29) In accordance with point 34 of the Interinstitutional Agreement on better law-making (2), Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.
- (2) OJ C 321, 31.12.2003, p. 1.
- (30) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (3),
- (3) OJ L 184, 17.7.1999, p. 23.

HAS ADOPTED THIS DIRECTIVE:

Machinery Directive 2006/42/EC	Comments
<p style="text-align: center;">Article 1 Scope</p> <p>1. This Directive applies to the following products:</p> <ul style="list-style-type: none"> (a) machinery; (b) interchangeable equipment; (c) safety components; (d) lifting accessories; (e) chains, ropes and webbing; (f) removable mechanical transmission devices; (g) partly completed machinery. <p>2. The following are excluded from the scope of this Directive:</p> <ul style="list-style-type: none"> (a) safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery; (b) specific equipment for use in fairgrounds and/or amusement parks; (c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity; (d) weapons, including firearms; (e) the following means of transport: <ul style="list-style-type: none"> — agricultural and forestry tractors for the risks covered by Directive 2003/37/EC, with the exclusion of machinery mounted on these vehicles, 	<p>It is necessary to read Art. 1 together with Art. 2 (definitions), Art. 3 (specific directives) and Art. 24 (amendment of Lift Directive), to understand the whole field of application of the new directive. The new directive now applies also to construction site hoists and to lifts with a speed $\leq 0,15$ m/s (see Art. 24 and recital 5).</p> <p>All products covered by the directive are now clearly mentioned in the scope (in directive 98/37/EC lifting accessories and partly completed machinery were not explicitly mentioned in the scope, but according to Annex I and IV they were de facto included). Chains, ropes, webbing and partly completed machinery are new products in the scope (see red wording).</p> <p>2. All products covered by specific directives (e.g. lifts, pressure equipment, medical devices, cable ways) are no longer mentioned in this clause because already excluded by Article 3.</p> <p>(a) This new exclusion does not apply to spare parts sold to be used also in other machinery.</p> <p>(d) All weapons are now excluded. The exclusion of firearms does not apply to portable cartridge-operated fixing machinery and other cartridge-operated impact machinery, which are now in the scope (see recital 6, Art. 27 and Annex IV).</p> <p>(e) The exclusion of means of transport has been rearranged and updated according with the new directives. Machines mounted on these means of transport are not excluded (see red wording), and that consolidates the practice followed in the application of the old directive.</p> <p>(e1) Until the Tractor Directive covers all relevant risks, both directives are to be applied in parallel (see recital 8).</p>

- motor vehicles and their trailers covered by Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers (1), **with the exclusion of machinery mounted on these vehicles,**
 - vehicles covered by Directive 2002/24/EC of the European Parliament and of the Council of 18 March 2002 relating to the type-approval of two or three-wheel motor vehicles (2), **with the exclusion of machinery mounted on these vehicles,**
 - motor vehicles exclusively intended for competition, and
 - means of transport by air, on water and on rail networks **with the exclusion of machinery mounted on these means of transport;**
- (f) seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;
- (g) machinery specially designed and constructed for military or police purposes;
- (h) **machinery specially designed and constructed for research purposes for temporary use in laboratories;**
- (i) mine winding gear;
- (j) machinery intended to move performers during artistic performances;
- (k) **electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (3):**
- **household appliances intended for domestic use,**
 - **audio and video equipment,**
 - **information technology equipment,**
 - **ordinary office machinery,**
 - **low-voltage switchgear and control gear,**
 - **electric motors;**
- (l) **the following types of high-voltage electrical equipment:**
- **switch gear and control gear,**
 - **transformers.**
- (e2) The new directive applies to all vehicle-mounted machines and to vehicles capable of reaching a maximum speed of up to 25 km/h (i.e. vehicles outside the scope of 70/156/EEC). Other vehicles outside 70/156/EEC and in the scope of the machinery directive are off-road vehicles not intended for public roads nor competition (e.g. go-carts, quads, snow-mobiles).
- (e3) The new directive applies to 2- and 3-wheeled vehicles outside the scope of 2002/24/EC e.g. vehicles for the disabled, to vehicles capable of reaching a maximum of up to 6 km/h and to mini-motorbikes with combustion engine.
- h) This is a new exclusion. It should be underlined that if the use is not “temporary”, the exclusion is not applicable.
- k) This new sub clause defines the borderline between the new machinery directive and the Low Voltage Directive (now known as 2006/95/EC). In directive 98/37 only the machinery where “the risks are mainly of electrical origin” shall be covered exclusively by Low Voltage Directive, thus depending on the risk assessment made by the manufacturer. The new directive lists the areas within which the products covered by Low Voltage Directive shall not be considered under the scope of Machinery Directive. Nevertheless the listed areas of products include numerous different electrical equipments whose identification may require some further interpretation (e.g. the concept of “domestic use”).

(1) OJ L 42, 23.2.1970, p. 1. Directive as last amended by Commission Directive 2006/28/EC (OJ L 65, 7.3.2006, p. 27).

(2) OJ L 124, 9.5.2002, p. 1. Directive as last amended by Commission Directive 2005/30/EC (OJ L 106, 27.4.2005, p. 17).

(3) OJ L 77, 26.3.1973, p. 29. Directive as amended by Directive 93/ 68/EEC (OJ L 220, 30.8.1993, p. 1).

Machinery Directive 2006/42/EC	Comments
<p style="text-align: center;">Article 2 Definitions</p> <p>For the purposes of this Directive, 'machinery' designates the products listed in Article 1(1)(a) to (f).</p> <p>The following definitions shall apply:</p> <p>(a) 'machinery' means:</p> <ul style="list-style-type: none"> — an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application, — an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion, — an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure, — assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point (g) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole, — an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort; <p>(b) 'interchangeable equipment' means a device which, after the putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool;</p> <p>(c) 'safety component' means a component:</p> <ul style="list-style-type: none"> — which serves to fulfil a safety function, — which is independently placed on the market, — the failure and/or malfunction of which endangers the safety of persons, and — which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function. 	<p>This first sentence is very important to the interpretation of the whole directive: the term "machinery" is used to indicate all the products in the scope, with the exclusion of the "partly completed machinery" to which only few specific requirements apply. (See recital 16)</p> <p>(a) It is the definition of "machinery stricto sensu".</p> <p>(a1) Also machinery without a drive system (e.g. without motor(s) and associated devices/fittings) is now in the scope (see red wording). This solves the problem of machinery driven through transmission systems connected to external energy sources, but introduces other problems and questions. Examples of questions are the followings: - What is the real meaning of "drive system"? - How can the manufacturer guarantee the noise and vibration levels, the efficacy of the control system, the stopping and/or braking times in machinery sold without motor?</p> <p>(a2 and a3) Even prior to fitting or installation, these assemblies are already machinery according to the new directive. Products referred to in "a2" are not partly completed machinery (see definition (g)); machines delivered as a construction kit, ready to be installed as in "a3", shall be considered as "machinery".</p> <p>(a4) It has been clarified that also partly completed machinery may be a part of these assemblies.</p> <p>(a5) Lifting machinery operated solely by human exertion also qualifies as "machinery".</p> <p>(b) The new definition is more specific, but does not give answers to all the questions. (E.g. a support for hand held machinery, to permit its use in a stationary mode, is interchangeable equipment?)</p> <p>(c) Safety components are now well defined in a way that does not leave room for doubt as in directive 98/37, where the definition was too general. (The most significant changes in the definition are written in red.)</p>

An indicative list of safety components is set out in Annex V, which may be updated in accordance with Article 8(1)(a);

- (d) 'lifting accessory' means a component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, **or which is intended to constitute an integral part of the load and which is independently placed on the market; slings and their components are also regarded as lifting accessories;**
- (e) 'chains, ropes and webbing' means chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;
- (f) 'removable mechanical transmission device' means a removable component for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one product;
- (g) 'partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies;
- (h) 'placing on the market' means making available for the first time in the Community machinery or partly completed machinery with a view to distribution or use, whether for reward or free of charge;
- (i) 'manufacturer' means any natural or legal person who designs and/or manufactures machinery or partly completed machinery covered by this Directive and is responsible for the conformity of the machinery or the partly completed machinery with this Directive with a view to its being placed on the market, under his own name or trademark or for his own use. In the absence of a manufacturer as defined above, any natural or legal person who places on the market or puts into service machinery or partly completed machinery covered by this Directive shall be considered a manufacturer;
- (j) 'authorised representative' means any natural or legal person established in the Community who has received a written mandate from the manufacturer to perform on his behalf all or part of the obligations and formalities connected with this Directive;
- (k) 'putting into service' means the first use, for its intended purpose, in the Community, of machinery covered by this Directive;
- (l) 'harmonised standard' means a non-binding technical specification adopted by a standardisation body, namely the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), on the basis of a remit issued by the Commission in accordance with the procedures laid down in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (1).
(1) OJ L 204, 21.7.1998, p. 37. Directive as last amended by the 2003 Act of Accession.

Annex V provides an indicative and updateable list of safety components. (In 98/37 the only examples are in Annex IV for safety components subject to EC type examination.)

(d) The definition has been clarified and extended to slings and their components.

(e) The directive does not cover all chains, ropes and webbing, but just those used for lifting purposes in lifting machinery or lifting accessories.

(g) This new definition raises a number of concerns, mainly centred around the meaning of a 'drive system'. The forthcoming Commission Guide should help clarify the distinction between machinery and partly completed machinery by providing concrete examples.

(h) to (k) The definitions clarify and harmonize important concepts common to all products.

(j) The status of "authorised representative" has been clarified: a written mandate is needed.

Machinery Directive 2006/42/EC	Comments
<p style="text-align: center;">Article 3 Specific Directives</p> <p>Where, for machinery, the hazards referred to in Annex I are wholly or partly covered more specifically by other Community Directives, this Directive shall not apply, or shall cease to apply, to that machinery in respect of such hazards from the date of implementation of those other Directives.</p>	<p>The important requirement concerning specific directives to apply for specific hazards is now dealt with in a separated article. Accordingly, all products covered by specific directives (like lifts, pressure equipment, medical devices, cable ways) are no longer mentioned in Art. 1(2) (exclusions from the scope) because already excluded by this article.</p>
<p style="text-align: center;">Article 4 Market surveillance</p> <ol style="list-style-type: none"> 1. Member States shall take all appropriate measures to ensure that machinery may be placed on the market and/or put into service only if it satisfies the relevant provisions of this Directive and does not endanger the health and safety of persons and, where appropriate, domestic animals or property, when properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen. 2. Member States shall take all appropriate measures to ensure that partly completed machinery can be placed on the market only if it satisfies the relevant provisions of this Directive. 3. Member States shall institute or appoint the competent authorities to monitor the conformity of machinery and partly completed machinery with the provisions set out in paragraphs 1 and 2. 4. Member States shall define the tasks, organisation and powers of the competent authorities referred to in paragraph 3 and shall notify the Commission and other Member States thereof and also of any subsequent amendment. 	<p>The framework for market surveillance is now clearly stated: member states must take measures against non-complying products (1 and 2), there must be a known national competent authority (3) and tasks and powers of such authority must be clearly defined and transparent (4). Directive 98/37 does not use the term "market surveillance". Usage "under conditions which can reasonably be foreseen" has now been added to usage in accordance with the "intended purpose".</p> <p>2. Partly completed machinery is now subject to market surveillance. On the other hand the safeguard clause (Art. 11) or the specific measures for potentially hazardous machinery (Art. 9) do not apply to partly completed machinery.</p>
<p style="text-align: center;">Article 5 Placing on the market and putting into service</p> <ol style="list-style-type: none"> 1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall: <ol style="list-style-type: none"> (a) ensure that it satisfies the relevant essential health and safety requirements set out in Annex I; (b) ensure that the technical file referred to in Annex VII, part A is available; (c) provide, in particular, the necessary information, such as instructions; (d) carry out the appropriate procedures for assessing conformity in accordance with Article 12; (e) draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery; (f) affix the CE marking in accordance with Article 16. 2. Before placing partly completed machinery on the market, the manufacturer or his authorised representative shall ensure that the procedure referred to in Article 13 has been completed. 3. For the purposes of the procedures referred to in Article 12, the manufacturer or his authorised representative shall have, or shall have access to, the necessary means of ensuring that the machinery satisfies the essential health and safety requirements set out in Annex I. 	<p>This article put the fundamental procedures together, and improves the wording, thus making it easier for manufacturers to understand their duties.</p> <p>(f) Now all machinery (see first comment in Art. 2 – Definitions) must bear the CE marking, thus including safety components, removable mechanical transmission devices, chains, ropes and webbing.</p> <p>2. Only this clause of Art. 5 applies to partly completed machinery. Partly completed machinery shall not bear the CE marking (the referred Art. 13 does not ask for CE marking).</p>

4. Where **machinery** is also the subject of other Directives relating to other aspects and providing for the affixing of the CE marking, the marking shall indicate that the machinery also conforms to the provisions of those other Directives.

However, where one or more of those Directives allow the manufacturer or his authorised representative to choose, during a transitional period, the system to be applied, the CE marking shall indicate conformity only to the provisions of those Directives applied by the manufacturer or his authorised representative. Particulars of the Directives applied, as published in the Official Journal of the European Union, shall be given on the EC declaration of conformity.

Article 6 Freedom of movement

1. Member States shall not prohibit, restrict or impede the placing on the market and/or putting into service in their territory of machinery which complies with this Directive.
2. Member States shall not prohibit, restrict or impede the placing on the market of partly completed machinery where the manufacturer or his authorised representative makes a declaration of incorporation, referred to in Annex II, part 1, Section B, stating that it is to be incorporated into machinery or assembled with other partly completed machinery to form machinery.
3. At trade fairs, exhibitions, demonstrations, and such like, Member States shall not prevent the showing of machinery or partly completed machinery which does not conform to this Directive, provided that a visible sign clearly indicates that it does not conform and that it will not be made available until it has been brought into conformity. Furthermore, during demonstrations of such non-conforming machinery or partly completed machinery, adequate safety measures shall be taken to ensure the protection of persons.

2. Partly completed machinery enjoys freedom of movement concerning placing on the market only. By the definition partly completed machinery “cannot in itself perform a specific application” and thus may not be put into service as such.

3. In the new directive this requirement has been extended also to partly completed machinery.

Article 7 Presumption of conformity and harmonised standards

1. Member States shall regard machinery bearing the CE marking and accompanied by the EC declaration of conformity, the content of which is set out in Annex II, part 1, Section A, as complying with the provisions of this Directive.
2. Machinery manufactured in conformity with a harmonised standard, the references to which have been published in the Official Journal of the European Union, shall be presumed to comply with the essential health and safety requirements covered by such a harmonised standard.
3. The Commission shall publish in the Official Journal of the European Union the references of the harmonised standards.
4. Member States shall take the appropriate measures to enable the social partners to have an influence at national level on the process of preparing and monitoring the harmonised standards.

2. Publication of the reference of the national standard is no longer a prerequisite.

3. Existing harmonized standards under 98/37/EC will not “automatically” give presumption of conformity to the new directive. All existing standards shall be reviewed. The first publication of harmonised standards under 2006/42/EC is expected in 2009.

4. As in 98/37 [formerly Art. 5 (3)], the member States are required to support the social partners. It will be a big challenge to verify if or how this important requirement will be implemented in practice.

Machinery Directive 2006/42/EC	Comments
<p style="text-align: center;">Article 8 Specific measures</p> <p>1. The Commission, acting in accordance with the procedure referred to in Article 22(3), may take any appropriate measure to implement the provisions relating to the following points:</p> <p>(a) updating of the indicative list of safety components in Annex V referred to in point (c) in Article 2;</p> <p>(b) restriction of the placing on the market of machinery referred to in Article 9.</p> <p>2. The Commission, acting in accordance with the procedure referred to in Article 22(2), may take any appropriate measure connected with the implementation and practical application of this Directive, including measures necessary to ensure cooperation of Member States with each other and with the Commission, as provided for in Article 19(1).</p>	<p>(a) This point gives the Commission power to modify Annex V outside normal legislative procedures – this gives the possibility to adapt the directive to the technical development of safety components, although the list is purely indicative.</p> <p>(b) The possible measures taken by the Commission are effective in all Member States. This clause and Art. 9 do not apply to partly completed machinery.</p>
<p style="text-align: center;">Article 9 Specific measures to deal with potentially hazardous machinery</p> <p>1. When, in accordance with the procedure referred to in Article 10, the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery with technical characteristics presenting risks due to the shortcomings in the standard or to make such machinery subject to special conditions. When, in accordance with the procedure referred to in Article 11, the Commission considers that a measure taken by a Member State is justified, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery presenting the same risk by virtue of its technical characteristics or to make such machinery subject to special conditions.</p> <p>2. Any Member State may request the Commission to examine the need for the adoption of the measures referred to in paragraph 1.</p> <p>3. In the cases referred to in paragraph 1, the Commission shall consult the Member States and other interested parties indicating the measures it intends to take, in order to ensure, at Community level, a high level of protection of the health and safety of persons. Taking due account of the results of this consultation, it shall adopt the necessary measures in accordance with the procedure referred to in Article 22(3).</p>	<p>This article does not apply to partly completed machinery. It describes two new procedures against hazardous machinery.</p> <p>The first procedure may be used whenever a product can be deemed hazardous on the basis of a defective standard.</p> <p>The second procedure can be invoked against a machine or an entire group of machines whenever they present the same risk of a machine whose free movement has been restricted according with the procedures of the safeguard clause. (See recital 13)</p>
<p style="text-align: center;">Article 10 Procedure for disputing a harmonised standard</p> <p>Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission or the Member State shall bring the matter before the committee set up by Directive 98/34/EC, setting out the reasons therefore. The committee shall deliver an opinion without delay. In the light of the committee’s opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union.</p>	<p>A clear distinction has been established between disputing a harmonized standard and the safeguard clause (see recital 11).</p> <p>It is clarified that the references to a harmonised standard may be published with restrictions. This confirms that normative clauses of a standard may have only partly the status of a harmonised standard: one insufficient requirement does not always “spoil” the whole standard.</p>

Article 11

Safeguard clause

1. Where a Member State ascertains that machinery covered by this Directive, bearing the CE marking, accompanied by the EC declaration of conformity and used in accordance with its intended purpose or under conditions which can reasonably be foreseen, is liable to compromise the health and safety of persons and, where appropriate, domestic animals or property, it shall take all appropriate measures to withdraw such machinery from the market, to prohibit the placing on the market and/or putting into service of such machinery or to restrict free movement thereof.
2. The Member State shall immediately inform the Commission **and the other Member States** of any such measure, indicating the reasons for its decision and, in particular, whether the non-conformity is due to:
 - (a) failure to satisfy the essential requirements referred to in Article 5(1)(a);
 - (b) incorrect application of the harmonised standards referred to in Article 7(2);
 - (c) shortcomings in the harmonised standards themselves referred to in Article 7(2).
3. The Commission shall enter into consultation with the parties concerned without delay.
The Commission shall consider, after this consultation, whether or not the measures taken by the Member State are justified, and it shall communicate its decision to the Member State which took the initiative, the other Member States, and the manufacturer or his authorised representative.
4. Where the measures referred to in paragraph 1 are based on a shortcoming in the harmonised standards and if the Member State which instigated the measures maintains its position, the Commission or the Member State shall initiate the procedure referred to in Article 10.
5. Where machinery does not conform and bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the marking and shall so inform the Commission. The Commission shall inform the other Member States.
6. The Commission shall ensure that Member States are kept informed of the progress and outcome of the procedure.

It is important to notice that the safeguard clause does not apply to partly completed machinery.

2. Now the Member States shall inform also the other Member States, not only the Commission.

Article 12

Procedures for assessing the conformity of machinery

1. The manufacturer or his authorised representative shall, in order to certify the conformity of machinery with the provisions of this Directive, apply one of the procedures for assessment of conformity described in paragraphs 2, 3 and 4.
2. Where the machinery is not referred to in Annex IV, the manufacturer or his authorised representative shall apply the procedure for assessment of conformity with internal checks on the manufacture of machinery provided for in Annex VIII.

Machinery Directive 2006/42/EC	Comments
<p>3. Where the machinery is referred to in Annex IV and manufactured in accordance with the harmonised standards referred to in Article 7(2), and provided that those standards cover all of the relevant essential health and safety requirements, the manufacturer or his authorised representative shall apply one of the following procedures:</p> <ul style="list-style-type: none"> (a) the procedure for assessment of conformity with internal checks on the manufacture of machinery, provided for in Annex VIII; (b) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3; (c) the full quality assurance procedure provided for in Annex X. <p>4. Where the machinery is referred to in Annex IV and has not been manufactured in accordance with the harmonised standards referred to in Article 7(2), or only partly in accordance with such standards, or if the harmonised standards do not cover all the relevant essential health and safety requirements or if no harmonised standards exist for the machinery in question, the manufacturer or his authorised representative shall apply one of the following procedures:</p> <ul style="list-style-type: none"> (a) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3; (b) the full quality assurance procedure provided for in Annex X. 	<p>3. For machinery in Annex IV manufactured in accordance with harmonized standards the directive no longer provides for procedures whereby the manufacturer submits the technical file to a notified body for safekeeping or verification. Self-assessment of conformity, as set out in Annex VIII, is sufficient.</p> <p>Note: As long as no harmonised standard is published under the new directive the procedure in clause 3(a) is not possible (see comments on Art. 7(3)). Late availability of harmonised standards related to the new directive may affect those manufacturers who have used harmonised standards under 98/37/EC without EC type-examination – they may need to change the type of certification as consequence of lacking harmonised standards.</p> <p>3(c) and 4(b): Full quality assurance procedure is now a new possibility for all products mentioned in Annex IV.</p>
<p style="text-align: center;">Article 13</p> <p style="text-align: center;">Procedure for partly completed machinery</p> <p>1. The manufacturer of partly completed machinery or his authorised representative shall, before placing it on the market, ensure that:</p> <ul style="list-style-type: none"> (a) the relevant technical documentation described in Annex VII, part B is prepared; (b) assembly instructions described in Annex VI are prepared; (c) a declaration of incorporation described in Annex II, part 1, Section B has been drawn up. <p>2. The assembly instructions and the declaration of incorporation shall accompany the partly completed machinery until it is incorporated into the final machinery and shall then form part of the technical file for that machinery.</p>	<p>This new article clarifies all the procedures needed before placing on the market partly completed machinery: “the relevant technical documentation” corresponds to the “technical file” of the machinery where one or more essential safety requirements are fulfilled, and the “assembly instruction” is a new document to prepare.</p> <p>2. This clause clarifies which documentation related to partly completed machinery has to be included into the technical file of the final machinery.</p>
<p style="text-align: center;">Article 14</p> <p style="text-align: center;">Notified bodies</p> <p>1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the assessment of conformity for placing on the market referred to in Article 12(3) and (4), together with the specific conformity assessment procedures and categories of machinery for which these bodies have been appointed and the identification numbers assigned to them beforehand by the Commission. Member States shall notify the Commission and other Member States of any subsequent amendment.</p> <p>2. The Member States shall ensure that the notified bodies are monitored regularly to check that they comply at all times with the criteria set out in Annex XI. The notified body shall provide all relevant information on request, including budgetary documents, to enable the Member States to ensure that the requirements of Annex XI are met.</p> <p>3. Member States shall apply the criteria set out in Annex XI in assessing the bodies to be notified and the bodies already notified.</p> <p>4. The Commission shall publish in the Official Journal of the European Union, for information, a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.</p>	<p>In this article the wording of the requirements has been improved compared to 98/37, and new points 2., 6. and 7. have been added to specify the tasks and the responsibilities of Member States, notified bodies and Commission.</p> <p>Note: Member States shall activate the procedures to notify the bodies according with the provisions of the new directive.</p>

5. Bodies meeting the assessment criteria laid down in the relevant harmonised standards, the references of which shall be published in the Official Journal of the European Union, shall be presumed to fulfil the relevant criteria.
6. If a notified body finds that relevant requirements of this Directive have not been met or are no longer met by the manufacturer or that an EC type-examination certificate or the approval of a quality assurance system should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate or the approval issued or place restrictions on it, giving detailed reasons, unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. In the event of suspension or withdrawal of the certificate or the approval or of any restriction placed on it, or in cases where intervention by the competent authority may prove necessary, the notified body shall inform the competent authority pursuant to Article 4. The Member State shall inform the other Member States and the Commission without delay. An appeal procedure shall be available.
7. The Commission shall provide for the organisation of an exchange of experience between the authorities responsible for appointment, notification and monitoring of notified bodies in the Member States, and the notified bodies, in order to coordinate the uniform application of this Directive.
8. A Member State which has notified a body shall immediately withdraw its notification if it finds:
 - (a) that the body no longer meets the criteria set out in Annex XI; or
 - (b) that the body seriously fails to fulfil its responsibilities.

The Member State shall immediately inform the Commission and the other Member States accordingly.

Article 15

Installation and use of machinery

This Directive shall not affect Member States' entitlement to lay down, in due observance of Community law, such requirements as they may deem necessary to ensure that persons, and in particular workers, are protected when using machinery, provided that this does not mean that such machinery is modified in a way not specified in this Directive.

Article 16

CE marking

1. The CE conformity marking shall consist of the initials 'CE' as shown in Annex III.
2. The CE marking shall be affixed to the machinery visibly, legibly and indelibly in accordance with Annex III.
3. The affixing on machinery of markings, signs and inscriptions which are likely to mislead third parties as to the meaning or form of the CE marking, or both, shall be prohibited. Any other marking may be affixed to the machinery provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

2. This clause further confirms that only "machinery" shall bear the CE-marking (not partly completed machinery).

3. Other types of marking shall not be likely to mislead third parties by being confused with the CE marking, either in terms of their meaning **or** their form (previously meaning **and** form). This is a further constraint on national or safety certification marks (See recital 21)

Machinery Directive 2006/42/EC	Comments
<p style="text-align: center;">Article 17 Non-conformity of marking</p> <ol style="list-style-type: none"> 1. Member States shall consider the following marking not to conform: <ol style="list-style-type: none"> (a) the affixing of the CE marking pursuant to this Directive on products not covered by this Directive; (b) the absence of the CE marking and/or the absence of the EC declaration of conformity for machinery; (c) the affixing on machinery of a marking, other than the CE marking, which is prohibited under Article 16(3). 2. Where a Member State ascertains that marking does not conform to the relevant provisions of this Directive, the manufacturer or his authorised representative shall be obliged to make the product conform and to put an end to the infringement under conditions fixed by that Member State. 3. Where non-conformity persists, the Member State shall take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedure laid down in Article 11. 	<p>This list now unambiguously describes the possible infringements.</p>
<p style="text-align: center;">Article 18 Confidentiality</p> <ol style="list-style-type: none"> 1. Without prejudice to existing national provisions and practices in the area of confidentiality, Member States shall ensure that all parties and persons concerned by the application of this Directive are required to treat as confidential information obtained in the execution of their tasks. More particularly business, professional and trade secrets shall be treated as confidential, unless the divulging of such information is necessary in order to protect the health and safety of persons. 2. The provisions of paragraph 1 shall not affect the obligations of the Member States and the notified bodies with regard to mutual exchange of information and the issuing of warnings. 3. Any decisions taken by the Member States and by the Commission in accordance with Articles 9 and 11 shall be published. 	<p>The non-disclosure requirement does not free the authorities from the requirement to publish warnings and exchange information with other Member States.</p>
<p style="text-align: center;">Article 19 Cooperation between Member States</p> <ol style="list-style-type: none"> 1. Member States shall take the appropriate measures to ensure that the competent authorities referred to in Article 4(3) cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly. 2. The Commission shall provide for the organisation of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive. 	<p>This new article stresses the objective of improving the European cooperation of the respective national market surveillance authorities. It also sets out the Commission's duties.</p>
<p style="text-align: center;">Article 20 Legal remedies</p> <p>Any measure taken pursuant to this Directive which restricts the placing on the market and/or putting into service of any machinery covered by this Directive shall state the exact grounds on which it is based. Such a measure shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time limits to which such remedies are subject.</p>	<p>See recital 25.</p>
<p style="text-align: center;">Article 21 Dissemination of information</p> <p>The Commission shall take the necessary measures for appropriate information concerning the implementation of this Directive to be made available.</p>	<p>It remains to be seen how "appropriate information" will be interpreted and concretized.</p>

<p style="text-align: center;">Article 22 Committee</p> <ol style="list-style-type: none"> 1. The Commission shall be assisted by a committee, hereinafter referred to as the 'Committee'. 2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. 3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months. 4. The Committee shall adopt its rules of procedure. 	<p>Art. 3 of the Comitology Decision provides for an advisory committee, whereby the Commission is not bound by its decisions. Art. 5 provides for a regulatory procedure that has to be in line with a Commission proposal.</p>
<p style="text-align: center;">Article 23 Penalties</p> <p>Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 29 June 2008 and shall notify it without delay of any subsequent amendment affecting them.</p>	<p>See recital 26.</p>
<p style="text-align: center;">Article 24 Amendment of Directive 95/16/EC</p> <p>Directive 95/16/EC is hereby amended as follows:</p> <ol style="list-style-type: none"> 1. In Article 1, paragraphs 2 and 3 shall be replaced by the following: <ol style="list-style-type: none"> (2) 'For the purposes of this Directive, "lift" shall mean a lifting appliance serving specific levels, having a carrier moving along guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal, intended for the transport of: <ul style="list-style-type: none"> — persons, — persons and goods, — goods alone if the carrier is accessible, that is to say a person may enter it without difficulty, and fitted with controls situated inside the carrier or within reach of a person inside the carrier. <p>Lifting appliances moving along a fixed course even where they do not move along guides which are rigid shall be considered as lifts falling within the scope of this Directive. A "carrier" means a part of the lift by which persons and/or goods are supported in order to be lifted or lowered.</p> (3) This Directive shall not apply to: <ul style="list-style-type: none"> — lifting appliances whose speed is not greater than 0,15 m/s, — construction site hoists, — cableways, including funicular railways, — lifts specially designed and constructed for military or police purposes, — lifting appliances from which work can be carried out, — mine winding gear, — lifting appliances intended for lifting performers during artistic performances, — lifting appliances fitted in means of transport, — lifting appliances connected to machinery and intended exclusively for access to workstations including maintenance and inspection points on the machinery, — rack and pinion trains, — escalators and mechanical walkways."; 	<p>This article modifies the Lift Directive giving a new definition for "lift". The scope of the amendment is to clarify the border between the fields of application of the Lift Directive and the Machinery Directive. (See recital 27.)</p> <p>The Lift Directive does not apply to lifts with a speed $\leq 0,15$ m/s and to construction site hoists. The result is that these products, which correspond to the definition of machinery, are now within the scope of the new Machinery Directive. (New requirements have been added in parts 4 and 6 of Annex I.)</p>

Machinery Directive 2006/42/EC	Comments
<p>2. in Annex I, point 1.2 shall be replaced by the following:</p> <p>1.2. 'Carrier The carrier of each lift must be a car. This car must be designed and constructed to offer the space and strength corresponding to the maximum number of persons and the rated load of the lift set by the installer. Where the lift is intended for the transport of persons, and where its dimensions permit, the car must be designed and constructed in such a way that its structural features do not obstruct or impede access and use by disabled persons and so as to allow any appropriate adjustments intended to facilitate its use by them.'</p>	
<p style="text-align: center;">Article 25 Repeal</p> <p>Directive 98/37/EC is hereby repealed <u>as from 29 December 2009</u>. References made to the repealed Directive shall be construed as being made to this Directive and should be read in accordance with the correlation table in Annex XII.</p>	<p><u>Corrigendum</u>, see Official Journal of the European Union L 76/35 of 16 March 2007.</p> <p>N.B. There are no common rules for the validity of the type examination certificates issued under 98/37/EC for Annex IV machinery – some notified bodies have already restricted the validity of certificates until 28.12.2009.</p>
<p style="text-align: center;">Article 26 Transposition</p> <p>1. Member States shall adopt and publish the provisions necessary to comply with this Directive by 29 June 2008 at the latest. They shall forthwith inform the Commission thereof. They shall apply those provisions with effect from 29 December 2009. When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.</p> <p>2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive, together with a table showing how the provisions of this Directive correspond to the national provisions adopted.</p>	<p>No transition period exists. This means that the adaptation to the new directive has to be done by the manufacturers before 29 December 2009.</p> <p>According with recital 29, Member States should be encouraged to make the table public.</p>
<p style="text-align: center;">Article 27 Derogation</p> <p>Until 29 June 2011 Member States may allow the placing on the market and the putting into service of portable cartridge operated fixing and other impact machinery which are in conformity with the national provisions in force upon adoption of this Directive.</p>	<p>As this article uses "may" (not "shall") it is up to the Member States to decide the length of transition period for these products. Transition is required as some Members States are under international CIP convention which has to be modified. (See recital 6)</p>
<p style="text-align: center;">Article 28 Entry into force</p> <p>This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Union.</p>	
<p style="text-align: center;">Article 29 Addressees</p> <p>This Directive is addressed to the Member States.</p>	

Done at Strasbourg, 17 May 2006.

For the European Parliament
The President
J. BORRELL FONTELLES

For the Council
The President
H. WINKLER

ANNEX I
Essential health and safety requirements
relating to the design and construction of machinery

Detailed Index

GENERAL PRINCIPLES	27
1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS	28
1.1. GENERAL REMARKS	28
1.1.1. Definitions	28
1.1.2. Principles of safety integration	29
1.1.3. Materials and products	30
1.1.4. Lighting	31
1.1.5. Design of machinery to facilitate its handling	31
1.1.6. Ergonomics	32
1.1.7. Operating positions	32
1.1.8. Seating	33
1.2. CONTROL SYSTEMS	33
1.2.1. Safety and reliability of control systems	33
1.2.2. Control devices	34
1.2.3. Starting	36
1.2.4. Stopping	37
1.2.4.1. Normal stop	37
1.2.4.2. Operational stop	37
1.2.4.3. Emergency stop	37
1.2.4.4. Assembly of machinery	38
1.2.5. Selection of control or operating modes	38
1.2.6. Failure of the power supply	40
1.3. PROTECTION AGAINST MECHANICAL HAZARDS	41
1.3.1. Risk of loss of stability	41
1.3.2. Risk of break-up during operation	41
1.3.3. Risks due to falling or ejected objects	42
1.3.4. Risks due to surfaces, edges or angles	42
1.3.5. Risks related to combined machinery	42
1.3.6. Risks related to variations in operating conditions	43
1.3.7. Risks related to moving parts	43
1.3.8. Choice of protection against risks arising from moving parts	43
1.3.8.1. Moving transmission parts	43
1.3.8.2. Moving parts involved in the process	44
1.3.9. Risks of uncontrolled movements	45
1.4. REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES	45
1.4.1. General requirements	45
1.4.2. Special requirements for guards	45
1.4.2.1. Fixed guards	45
1.4.2.2. Interlocking movable guards	46
1.4.2.3. Adjustable guards restricting access	47
1.4.3. Special requirements for protective devices	47

1.5. RISKS DUE TO OTHER HAZARDS	47
1.5.1. Electricity supply	47
1.5.2. Static electricity	48
1.5.3. Energy supply other than electricity	48
1.5.4. Errors of fitting	48
1.5.5. Extreme temperatures	48
1.5.6. Fire	49
1.5.7. Explosion	49
1.5.8. Noise	49
1.5.9. Vibrations	50
1.5.10. Radiation	50
1.5.11. External radiation	50
1.5.12. Laser radiation	51
1.5.13. Emissions of hazardous materials and substances	51
1.5.14. Risk of being trapped in a machine	51
1.5.15. Risk of slipping, tripping or falling	51
1.5.16. Lightning	52
1.6. MAINTENANCE	52
1.6.1. Machinery maintenance	52
1.6.2. Access to operating positions and servicing points	52
1.6.3. Isolation of energy sources	53
1.6.4. Operator intervention	53
1.6.5. Cleaning of internal parts	53
1.7. INFORMATION	54
1.7.1. Information and warnings on the machinery	54
1.7.1.1. Information and information devices	54
1.7.1.2. Warning devices	54
1.7.2. Warning of residual risks	55
1.7.3. Marking of machinery	55
1.7.4. Instructions	56
1.7.4.1. General principles for the drafting of instructions	56
1.7.4.2. Contents of the instructions	57
1.7.4.3. Sales literature	61
2. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY	61
2.1. FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS	62
2.1.1. General	62
2.1.2. Instructions	63
2.2. PORTABLE HAND-HELD AND/OR HAND-GUIDED MACHINERY	63
2.2.1. General	63
2.2.1.1. Instructions	64
2.2.2. Portable fixing and other impact machinery	64
2.2.2.1. General	64
2.2.2.2. Instructions	65
2.3. MACHINERY FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS	65

3. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO THE MOBILITY OF MACHINERY	66
3.1. GENERAL	67
3.1.1. Definitions	67
3.2. WORK POSITIONS	67
3.2.1. Driving position	67
3.2.2. Seating	69
3.2.3. Positions for other persons	69
3.3. CONTROL SYSTEMS	70
3.3.1. Control devices	70
3.3.2. Starting/moving	71
3.3.3. Travelling function	71
3.3.4. Movement of pedestrian-controlled machinery	72
3.3.5. Control circuit failure	73
3.4. PROTECTION AGAINST MECHANICAL HAZARDS	73
3.4.1. Uncontrolled movements	73
3.4.2. Moving transmission parts	73
3.4.3. Roll-over and tip-over	74
3.4.4. Falling objects	75
3.4.5. Means of access	75
3.4.6. Towing devices	75
3.4.7. Transmission of power between self-propelled machinery (or tractor) and recipient machinery	75
3.5. PROTECTION AGAINST OTHER HAZARDS	77
3.5.1. Batteries	77
3.5.2. Fire	77
3.5.3. Emissions of hazardous substances	77
3.6. INFORMATION AND INDICATIONS	78
3.6.1. Signs, signals and warnings	78
3.6.2. Marking	79
3.6.3. Instructions	79
3.6.3.1. Vibrations	79
3.6.3.2. Multiple uses	80
4. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS	80
4.1. GENERAL	80
4.1.1. Definitions	80
4.1.2. Protection against mechanical hazards	82
4.1.2.1. Risks due to lack of stability	82
4.1.2.2. Machinery running on guide rails and rail tracks	82
4.1.2.3. Mechanical strength	82
4.1.2.4. Pulleys, drums, wheels, ropes and chains	83
4.1.2.5. Lifting accessories and their components	84
4.1.2.6. Control of movements	85
4.1.2.7. Movements of loads during handling	86
4.1.2.8. Machinery serving fixed landings	86
4.1.2.8.1. Movements of the carrier	86
4.1.2.8.2. Access to the carrier	87
4.1.2.8.3. Risks due to contact with the moving carrier	87
4.1.2.8.4. Risk due to the load falling off the carrier	87
4.1.2.8.5. Landings	87
4.1.3. Fitness for purpose	88

4.2. REQUIREMENTS FOR MACHINERY WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT	88
4.2.1. Control of movements	88
4.2.2. Loading control	89
4.2.3. Installations guided by ropes	89
4.3. INFORMATION AND MARKINGS	90
4.3.1. Chains, ropes and webbing	90
4.3.2. Lifting accessories	90
4.3.3. Lifting machinery	91
4.4. INSTRUCTIONS	91
4.4.1. Lifting accessories	91
4.4.2. Lifting machinery	92
5. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY INTENDED FOR UNDERGROUND WORK	93
5.1. RISKS DUE TO LACK OF STABILITY	93
5.2. MOVEMENT	93
5.3. CONTROL DEVICES	93
5.4. STOPPING	93
5.5. FIRE	93
5.6. EXHAUST EMISSIONS	94
6. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PRESENTING PARTICULAR HAZARDS DUE TO THE LIFTING OF PERSONS	94
6.1. GENERAL	94
6.1.1. Mechanical strength	94
6.1.2. Loading control for machinery moved by power other than human strength	95
6.2. CONTROL DEVICES	95
6.3. RISKS TO PERSONS IN OR ON THE CARRIER	96
6.3.1. Risks due to movements of the carrier	96
6.3.2. Risk of persons falling from the carrier	96
6.3.3. Risk due to objects falling on the carrier	96
6.4. MACHINERY SERVING FIXED LANDINGS	97
6.4.1. Risks to persons in or on the carrier	97
6.4.2. Controls at landings	97
6.4.3. Access to the carrier	98
6.5. MARKINGS	98

Comparison of Annex I of Directive 2006/42/EC with Annex I of Directive 98/37/EEC

Introduction

The present document is intended to highlight and explain the differences between Annex I of the “old” directive (98/37/EEC) and Annex I of the “new” directive (2006/42/EC), both of which express the *essential health and safety requirements (EHSRs) relating to the design and construction of machinery*.

To facilitate the comparison, the presentation of the text of the old and new Annex I has been modified in two phases.

Firstly, the disposition of the texts of the EHSRs has been modified so that the corresponding parts appear, as far as possible, on the same level. Take the case of EHSR 1.2.1:

Directive 2006/42/EC	Directive 98/37/EC
<p>1.2. CONTROL SYSTEMS</p> <p>1.2.1. Safety and reliability of control systems</p> <p>Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:</p> <ul style="list-style-type: none"> — they can withstand the intended operating stresses and external influences, — a fault in the hardware or the software of the control system does not lead to hazardous situations, — errors in the control system logic do not lead to hazardous situations, — reasonably foreseeable human error during operation does not lead to hazardous situations. 	<p>1.2. Controls</p> <p>1.2.1. <i>Safety and reliability of control systems</i></p> <p>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:</p> <ul style="list-style-type: none"> — they can withstand the rigours of normal use and external factors, — errors in logic do not lead to dangerous situations.

Secondly, conventional colours have been introduced:

Directive 2006/42/EC	Directive 98/37/EC
<p>1.2. CONTROL SYSTEMS</p> <p>1.2.1. Safety and reliability of control systems</p> <p>Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:</p> <ul style="list-style-type: none"> — they can withstand the intended operating stresses and external influences, — a fault in the hardware or the software of the control system does not lead to hazardous situations, — errors in the control system logic do not lead to hazardous situations, — reasonably foreseeable human error during operation does not lead to hazardous situations. 	<p>1.2. Controls</p> <p>1.2.1. <i>Safety and reliability of control systems</i></p> <p>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:</p> <ul style="list-style-type: none"> — they can withstand the rigours of normal use and external factors, <p>Text from 1.2.7: <i>A fault in the control circuit logic, or failure of or damage to the control circuit must not lead to dangerous situations.</i></p> <ul style="list-style-type: none"> — errors in logic do not lead to dangerous situations.

Meaning of the text colours and highlighting

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

Take the following two examples:

1.7.4.2. Contents of the instructions:

Directive 2006/42/EC	Directive 98/37/EC
(e) the drawings, diagrams, descriptions and explanations necessary for the use , maintenance and repair of the machinery and for checking its correct functioning; [Compare with old 1.7.4 (c)]	Text from 1.7.4 (c) <i>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</i>

3.2.2 Seating

Directive 2006/42/EC	Directive 98/37/EC
3.2.2. Seating	3.2.2. <i>Seating</i> <i>The driving seat of any machinery must enable the driver to maintain a stable position and be designed with due regard to ergonomic principles. [Moved to new 1.1.8, 2nd para, and new 1.1.6 applies to ergonomic principles in general]</i> <i>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. [Moved to new 1.1.8, 3rd para]</i>

Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>ANNEX I</p> <p>Essential health and safety requirements relating to the the design and construction of machinery</p> <p>GENERAL PRINCIPLES</p> <p>1. The manufacturer of machinery or his authorised representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.</p> <p>By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorised representative shall:</p> <ul style="list-style-type: none"> – determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof, – identify the hazards that can be generated by the machinery and the associated hazardous situations, – estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence, – evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Directive, – eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b). 	<p>ANNEX I</p> <p>ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF MACHINERY AND SAFETY COMPONENTS</p> <p>For the purposes of this Annex 'machinery' means either 'machinery' or 'safety component' as defined in Article 1(2).</p> <p>PRELIMINARY OBSERVATIONS</p> <p>Text from the last paragraph of the Preliminary Observations 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</p>	<p>ANNEX I applies only to "machinery". It does not apply to "partly completed machinery" (it applies only to finished products). Nevertheless one or more of the essential requirements in this Annex may be applied and fulfilled in partly completed machinery: in this case these essential requirements shall be indicated in the "declaration of incorporation" (see Annex II B (4)).</p> <p>According to Article 2 the term "machinery" designates the following products:</p> <ul style="list-style-type: none"> – machinery, – interchangeable equipment, – safety components; – lifting accessories; – chains, ropes and webbing; – removable mechanical transmission devices. <p>Risk assessment (previously „hazard analysis“) has been made a priority in accordance with its importance.</p> <p>The design of machinery is based on the iterative process of risk assessment and risk reduction, according to the procedure indicated in the 5 indents of the general principle 1., which closely correspond to the provisions set out in sub-clause 5.1.3 of EN ISO 12100-1:2003.</p>	
new text	deleted text	text having undergone formal changes	text copied from another part of the „old“ directive

Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>2. The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery in question when it is used under the conditions foreseen by the manufacturer or his authorised representative or in foreseeable abnormal situations. In any event, the principles of safety integration referred to in section 1.1.2 and the obligations concerning marking of machinery and instructions referred to in sections 1.7.3 and 1.7.4 apply.</p> <p>3. The essential health and safety requirements laid down in this Annex are mandatory; However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives.</p> <p>4. This Annex is organised in several parts. The first one has a general scope and is applicable to all kinds of machinery. The other parts refer to certain kinds of more specific hazards. Nevertheless, it is essential to examine the whole of this Annex in order to be sure of meeting all the relevant essential requirements. When machinery is being designed, the requirements of the general part and the requirements of one or more of the other parts shall be taken into account, depending on the results of the risk assessment carried out in accordance with point 1 of these General Principles.</p>	<p>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.</p> <p>In any event, requirements 1.1.2, 1.7.3 and 1.7.4 apply to all machinery covered by this Directive.</p> <p>2. The essential health and safety requirements laid down in this Directive 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.</p> <p>3. The essential health and safety requirements have been grouped according to the hazards which they cover.</p> <p>Machinery presents a series of hazards which may be indicated under more than one heading in this Annex.</p> <p>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. [The last paragraph has been used to inspire the beginning of "General principles" No 1 of the new directive]</p>	<p>The reader will note that the requirement to take into account, when designing machinery, the foreseeable abnormal situations in its use, expressed only in 1.1.2 Principles of safety integration of the old directive, has been integrated in the General Principles of the new directive. (See also 1.1.2 of the new directive).</p> <p>This new, reformulated paragraph explains the structure of Annex I and how it should be used.</p>	
<p>1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS</p> <p>1.1. GENERAL REMARKS</p> <p>1.1.1. Definitions</p> <p>For the purpose of this Annex:</p> <p>(a) 'hazard' means a potential source of injury or damage to health;</p> <p>(b) 'danger zone' means any zone within and/or around machinery in which a person is subject to a risk to his health or safety;</p> <p>(c) 'exposed person' means any person wholly or partially in a danger zone;</p>	<p>1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS</p> <p>1.1. General remarks</p> <p>1.1.1. Definitions</p> <p>For the purpose of this Directive:</p> <p>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;</p> <p>2. 'exposed person' means any person wholly or partially in a danger zone;</p>	<p>Section 1 applies to all machinery. Additional requirements for specific types of machinery and certain kinds of more specific hazards are contained in sections 2 to 6.</p> <p>Six definitions have been added and – to be consistent with the terminology used in the European harmonized standards of the machinery safety programme – all these definitions have been aligned with clause 3 of EN ISO 12100-1:2003.</p>	
new text	deleted text	text having undergone formal changes	text copied from another part of the „old“ directive

<p>(d) 'operator' means the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving machinery;</p> <p>(e) 'risk' means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation;</p> <p>(f) 'guard' means a part of the machinery used specifically to provide protection by means of a physical barrier;</p> <p>(g) 'protective device' means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard;</p> <p>(h) 'intended use' means the use of machinery in accordance with the information provided in the instructions for use;</p> <p>(i) 'reasonably foreseeable misuse' means the use of machinery in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.</p>	<p>3. 'operator' means the person or persons given the task of installing, operating, adjusting, maintaining, cleaning, repairing or transporting machinery.</p>	<p>(e) Corresponds to EN ISO 12100-1:2003, sub-clause 3.11 (see also sub-clause 3.9)</p> <p>(f) Corresponds to EN ISO 12100-1:2003, sub-clause 3.25.</p> <p>(g) Corresponds to EN ISO 12100-1:2003, sub-clause 3.26.</p> <p>(h) Corresponds to EN ISO 12100-1:2003, sub-clause 3.22.</p> <p>(i) Corresponds to EN ISO 12100-1:2003, sub-clause 3.23.</p>
<p>1.1.2. Principles of safety integration</p>	<p>1.1.2. <i>Principles of safety integration</i></p>	
<p>(a) Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.</p> <p>The aim of measures taken must be to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping.</p>	<p>(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.</p> <p>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. [The concept "foreseeable abnormal situations" appears in General Principles, 2, of the new directive]</p>	<p>Reasonably foreseeable misuse, as defined in 1.1.1 (i) of the new directive, should be considered as generating a particular form of foreseeable abnormal situation (see above General Principles, 2). EN ISO 12100-1:2003, sub-clause 5.3, addresses the whole lifecycle of the machine ; in particular, it mentions transport, de-commissioning and disposal (the term "disposal" may include "disabling and scrapping"); it should be noted that the list in the directive is not exhaustive (it does not contain all the stages that need to be considered).</p>
<p>(b) In selecting the most appropriate methods, the manufacturer or his authorised representative must apply the following principles, in the order given:</p> <ul style="list-style-type: none"> – eliminate or reduce risks as far as possible (inherently safe machinery design and construction), – take the necessary protective measures in relation to risks that cannot be eliminated, 	<p>(b) In selecting the most appropriate methods, the manufacturer must apply the following principles, in the order given:</p> <ul style="list-style-type: none"> – 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, 	

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>– inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.</p> <p>(c) When designing and constructing machinery and when drafting the instructions, the manufacturer or his authorised representative must envisage not only the intended use of the machinery but also any reasonably foreseeable misuse thereof.</p> <p>The machinery must be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions must draw the user's attention to ways – which experience has shown might occur – in which the machinery should not be used.</p> <p>(d) Machinery must be designed and constructed to take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment.</p> <p>(e) Machinery must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.</p> <p>1.1.3. Materials and products</p> <p>The materials used to construct machinery or products used or created during its use must not endanger persons' safety or health. In particular, where fluids are used, machinery must be designed and constructed to prevent risks due to filling, use, recovery or draining.</p>	<p>– 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.</p> <p>(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.</p> <p>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.</p> <p>(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. [Moved to 1.1.6 of the new directive]</p> <p>(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.).</p> <p>(f) Machinery must be supplied with all the essential special equipment and accessories to enable it to be adjusted, maintained and used without risk.</p> <p><i>1.1.3. Materials and products</i></p> <p>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.</p>	

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1.1.4. **Lighting**

Machinery must be supplied with integral lighting suitable for the operations concerned where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity.

Machinery must be designed and constructed so that

there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to the lighting.

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

1.1.5. **Design of machinery to facilitate its handling**

Machinery, or each component part thereof, must:

- be capable of being handled and transported safely,
- be packaged or designed so that it can be stored safely and without damage.

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

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

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

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.).

Text from 3.1.3, that concerns mobility only:

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.

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.

As regards the zones of shadow, irritating dazzle and stroboscopic effects caused by lighting, the reference is no longer to the lighting "provided by the manufacturer", but to the lighting in general. Therefore, the manufacturer should provide sufficient information so that the artificial lighting in the working environment cannot cause dangerous shadows, dazzles and stroboscopic effects.

The words "and transported" has been added because there is evidence of past accidents having occurred during transportation, due to lack of information provided by the machinery manufacturer.

All examples given between brackets in the old directive, and intended to illustrate the various requirements, have been removed throughout the text. This makes sense in a directive that has to be as general as possible, without running the risk of getting bogged down in details. Nevertheless, as a result, important information originally intended to clarify the text is lost.

The content of this additional paragraph comes from the old 3.1.3 that only covered mobile machinery; it now applies to all machinery. The aspect covered by the requirement is partly covered by sub-clauses 4.6 and 5.2.6 of EN ISO 12100-2:2003, both dealing with stability. Some C-type standards for mobile machinery express specific requirements (e.g. EN 474-1:2006, Earth moving machinery, clause 5.15 'Retrieval, transportation, lifting and towing').

Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>Where machinery or one of its component parts is to be moved by hand, it must:</p> <ul style="list-style-type: none"> – either be easily moveable, or – be equipped for picking up and moving safely. 	<p>Where machinery or one of its component parts is to be moved by hand, it must:</p> <ul style="list-style-type: none"> – either be easily movable, or – be equipped for picking up (e.g. hand-grips, etc.) and moving in complete safety. 		
<p>Special arrangements must be made for the handling of tools and/or machinery parts which, even if lightweight, could be hazardous.</p>	<p>Special arrangements must be made for the handling of tools and/or machinery parts, even if lightweight, which could be dangerous (shape, material, etc.).</p>		
<p>1.1.6. Ergonomics</p>	<p>Text from 1.1.2 d:</p>		
<p>Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic principles such as:</p>	<p><i>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.</i></p>	<p>Instead of being an all-inclusive requirement in a sub-section (section 1.1.2.d of Directive 98/37/EC), "ergonomics" is now formulated as an objective in itself and referred to in concrete terms.</p>	
<ul style="list-style-type: none"> – allowing for the variability of the operator's physical dimensions, strength and stamina, – providing enough space for movements of the parts of the operator's body, – avoiding a machine-determined work rate, – avoiding monitoring that requires lengthy concentration, – adapting the man/machinery interface to the foreseeable characteristics of the operators. 		<p>At first sight the new 1.1.6 appears like a mixture of what is displayed in EN ISO 12100-2:2003 (from 4.8.2 to 4.8.8) and EN 614-1:2006 (from 4.2 to 4.4). In fact, the list in 1.1.6 includes "principles" which, in fact, are only specific requirements and not main "ergonomic principles" as identified by EN 614-1. Standardisation achievements have not been exploited, because important elements indicated by EN 614-1 are left aside: posture, suitability for the task, learning and individualisation, controllability, error tolerance, among others. As regards the reference to <i>stamina</i> - whose meaning lies at the boundary between physical and cognitive ergonomics - it remains to be seen how designers will consider this aspect in machinery design.</p>	
<p>1.1.7. Operating positions</p>	<p>Text from 3.2.1, that concerns mobility only:</p>		
<p>The operating position must be designed and constructed in such a way as to avoid any risk due to exhaust gases and/or lack of oxygen.</p>	<p><i>The driving position must be designed and constructed so as to avoid any health risk due to exhaust gases and/or lack of oxygen.</i></p>		
<p>If the machinery is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery itself gives rise to a hazardous environment, adequate means must be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.</p>	<p><i>The driving position must be fitted with an adequate cab where there is a hazard due to a dangerous environment.</i></p>		
<p>Where appropriate, the operating position must be fitted with an adequate cabin designed, constructed and/or equipped to fulfil the above requirements.</p>	<p><i>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.).</i></p>	<p>The requirements in the old 3.2.1 only applied to hazards due to the mobility of machinery; the requirements of 1.1.7 of the new directive apply to all hazards associated to machinery. EN ISO 12100-2:2003 sub-clause 5.2.1 requires to provide protection against all possible hazards, including hazards due to the environment, emission hazards, etc.</p>	
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The exit must allow rapid evacuation. Moreover, when applicable, an emergency exit must be provided in a direction which is different from the usual exit.

1.1.8. Seating

Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery must be designed for the installation of seats.

If the operator is intended to sit during operation and the operating position is an integral part of the machinery, the seat must be provided with the machinery.

The operator's seat must enable him to maintain a stable position. Furthermore, the seat and its distance from the control devices must be capable of being adapted to the operator.

If the machinery is subject to vibrations, the seat must be designed and constructed in such a way as to reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. The seat mountings must withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material must be provided.

1.2. CONTROL SYSTEMS

1.2.1. Safety and reliability of control systems

Control systems must be designed and constructed

in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:

- they can withstand the intended operating stresses and external influences,
- a fault in the hardware or the software of the control system does not lead to hazardous situations,
- errors in the control system logic do not lead to hazardous situations,
- reasonably foreseeable human error during operation does not lead to hazardous situations.

The exit must allow rapid evacuation. Moreover, an emergency exit must be provided in a direction which is different from the usual exit.

Text from 3.2.2, that deals with mobility only:

Where the working conditions so permit, these work places must be equipped with seats.

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.

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 rigours of normal use and external factors,

Text from 1.2.7:

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

- errors in logic do not lead to dangerous situations.

EN ISO 12100-2:2003 does not cover "exit". All C-type standards relating to mobile machinery should cover "exit"; today, only few C-standards for mobile machinery do so (e.g. EN 474-1:1994, sub-clause 4.2.2.4).

The new 1.1.8 extends to all machinery the requirements given in the old 3.2.2, only addressed to minimize the hazards due to mobility. The explicit recommendation in the old 3.2.2 to design the seat "with due regard to ergonomic principles" has not been maintained in the new 1.1.8, most likely because basic ergonomic principle dealt with in the new 1.1.6 are intended to be applied to all machinery.

The requirements concerning vibrations complement EHSR 1.5.9, that recommends – in particular – to reduce machinery vibrations at the source. Sub-clause 5.4.3 of EN ISO 12100-2:2003 indicate additional protective measures intended to reduce vibrations.

The requirements of the Electromagnetic Compatibility Equipment Directive also need to be met (old 89/336, new 2004/108/EC; transition period until 20 July 2009).

The new wording reflects the state of the art in control system technology, where there is a distinction between software and hardware. Software and hardware aspects are covered in EN ISO 12100-2:2003, sub-clauses 4.11.7.2 and 4.11.7.3.

EN 954-1:1996 clause 4.4 and EN ISO 13849-1:2006 clause 4.8 require to use ergonomic principles in order to increase the usability of the machine and its control system, thus minimizing the possibility of hazardous unwanted human action.

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>Particular attention must be given to the following points:</p> <ul style="list-style-type: none"> – the machinery must not start unexpectedly, – the parameters of the machinery must not change in an uncontrolled way, where such change may lead to hazardous situations, – the machinery must not be prevented from stopping if the stop command has already been given, – no moving part of the machinery or piece held by the machinery must fall or be ejected, – automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded, – the protective devices must remain fully effective or give a stop command, – the safety-related parts of the control system must apply in a coherent way to the whole of an assembly of machinery and/or partly completed machinery. <p>For cable-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication.</p>	<p>Text from 1.2.7: <i>In particular:</i></p> <ul style="list-style-type: none"> – 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. 	<p>Prevention of unexpected start-up is dealt with in EN 1037:1996.</p> <p>EN ISO 12100-2:2003 clause 4.11.1 mentions the uncontrolled speed change as one typical example of hazardous machine behaviour.</p> <p>In 98/37/EC the requirement concerning unexpected start-up was placed in EHSR 1.2.7 <i>Failure of the control circuit</i>; therefore unexpected start-up was considered <u>only</u> as a consequence of such a <i>failure</i>. Now, with the migration of the requirement from old 1.2.7 to new 1.2.1, the new directive aims at preventing unexpected start-up resulting from any cause associated with the design of the control system (including, of course, the behaviour in case of failures).</p> <p>The directive text could be misunderstood here. This requirement does not apply to "partly completed machinery" alone, but to "assemblies of machinery and/or partly completed machinery".</p> <p>This new requirement is equivalent to the provisions of EN ISO 12100-2, 4.11.8 <i>Principles relating to manual control</i>, hyphen h). It should be compared with the requirements concerning <i>remote-controlled machinery</i>, inserted among the requirements concerning the travelling function, in 3.3.3 of the new directive.</p>	
<p>1.2.2. Control devices</p> <p>Control devices must be:</p> <ul style="list-style-type: none"> – clearly visible and identifiable, using pictograms where appropriate, – positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity, – designed in such a way that the movement of the control device is consistent with its effect, 	<p>1.2.2. <i>Control devices</i></p> <p>Control devices must be:</p> <ul style="list-style-type: none"> – 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, 	<p>In all Annex I, the generic term "control" has been changed with "control device" or "control system" according to its intended meaning.</p> <p>In 1.2.2, "Control device" and "control" are to be considered synonyms.</p>	
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| <ul style="list-style-type: none"> – located outside the danger zones, except where necessary for certain control devices such as an emergency stop or a teach pendant, – positioned in such a way that their operation cannot cause additional risk, – designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate action, – made in such a way as to withstand foreseeable forces; particular attention must be paid to emergency stop devices liable to be subjected to considerable forces. | <ul style="list-style-type: none"> – 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. |
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Where a control device is designed and constructed to perform several different actions, namely where there is no one-to-one correspondence, the action to be performed must be clearly displayed and subject to confirmation, where necessary.

Control devices must be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles.

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

From each control position, the operator must be able to ensure that no-one is in the danger zones, or the control system must be designed and constructed in such a way that starting is prevented while someone is in the danger zone.

If neither of these possibilities is applicable, before the machinery starts, an acoustic and/or visual warning signal must be given. The exposed persons must have time to leave the danger zone or prevent the machinery starting up.

If necessary, means must be provided to ensure that the machinery can be controlled only from control positions located in one or more predetermined zones or locations.

Where 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.

Text from 3.2.1, that deals with mobility only:

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.

This requirement has migrated to the new 1.1.2 (d), thus covering all design aspects – not only the design of control devices.

The old directive only relied on the possibility for the operator to check, before starting the machine, that nobody stays in the danger zone(s). In addition, the new directive introduces the possible resort to a protective device intended to automatically prevent start-up if it detects somebody in the danger zone(s).

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>Where there is more than one control position, the control system must be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops.</p> <p>When machinery has two or more operating positions, each position must be provided with all the required control devices without the operators hindering or putting each other into a hazardous situation.</p> <p>1.2.3. Starting</p> <p>It must be possible to start machinery only by voluntary actuation of a control device provided for the purpose.</p> <p>The same requirement applies:</p> <ul style="list-style-type: none"> – when restarting the machinery after a stoppage, whatever the cause, – when effecting a significant change in the operating conditions. <p>However, the restarting of the machinery or a change in operating conditions may be effected by voluntary actuation of a device other than the control device provided for the purpose, on condition that this does not lead to a hazardous situation.</p> <p>For machinery functioning in automatic mode, the starting of the machinery, restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation.</p>	<p><i>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.</i></p> <p>1.2.3. Starting</p> <p>It must be possible to start machinery only by voluntary actuation of a control device provided for the purpose.</p> <p>The same requirement applies:</p> <ul style="list-style-type: none"> – when restarting the machinery after a stoppage, whatever the cause, – when effecting a significant change in the operating conditions (e.g. speed, pressure, etc.), <p>unless such restarting or change in operating conditions is without risk to exposed persons.</p> <p>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.</p>	<p>The new requirements for coordination of several control positions are addressed in EN ISO 12100-2:2003, sub-clause 4.11.8.</p> <p>The last two paragraphs were taken over from the old 3.2.1 which only covers hazards connected with the mobility of machinery; they now apply to all machinery.</p> <p><u>Where risk assessment proves that this would not generate a hazardous situation:</u></p> <ul style="list-style-type: none"> – the old directive allows restarting a machine (or changing operating conditions) without a voluntary action; – the new directive allows restarting a machine (or changing operating conditions) exclusively by "voluntary actuation of a device other than the control device provided for the purpose", thus excluding restarting (or changing operating conditions) by any unintentional action, in line with the requirement expressed in the 4th indent of the 4th paragraph of 1.2.5). <p>The exclusion, in the new directive, of involuntary restart (or involuntary change in operating conditions) is in line with the modifications in 1.2.1 <i>Safety and reliability of control systems</i>, where it is stated that "the machinery must not start unexpectedly". See the comment to 1.2.1.</p> <p>Examples of "devices other than the control devices provided for the purpose" are <i>control guards and sensitive protective equipment used for cycle initiation</i> (see respectively 5.3.2.5 and 5.2.5.3 of EN ISO 12100-2:2003).</p> <p>The new directive clearly expresses the condition allowing to depart from the basic requirement, if automatic restarting (or change in operating conditions) "does not lead to a hazardous situation".</p>

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Where machinery has several starting control devices and the operators can therefore put each other in danger, additional devices

must be fitted to rule out such risks. If safety requires that starting and/or stopping must be performed in a specific sequence, there must be devices which ensure that these operations are performed in the correct order.

1.2.4. Stopping

1.2.4.1. Normal stop

Machinery must be fitted with a control device whereby the machinery can be brought safely to a complete stop.

Each workstation must be fitted with a control device to stop some or all of the functions of the machinery, depending on the existing hazards, so that the machinery is rendered safe.

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

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

1.2.4.2. Operational stop

Where, for operational reasons, a stop control that does not cut off the energy supply to the actuators is required, the stop condition must be monitored and maintained.

1.2.4.3. Emergency stop

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

- machinery in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken,

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,

The new requirement shall also be applied to the coordination between the feed movement and the tool movement, as indicated in the last hyphen of sub-clause 1.3.2 of new and old Annex I.

In spite of its title, the old 1.2.4 implicitly dealt with the *stopping function*. The new 1.2.4 unambiguously deals with this function.

The old 1.2.4 considered only the stopping of *moving parts* (mechanical hazard only), whereas the new 1.2.4 pertinently deals with all *hazard-generating functions* the stopping of which suppresses the hazard they generate.

The controlled stop with power left available to the machine actuators is defined in EN 60204-1:1997, clause 9.2.2. (category 2 stop) and in EN 1037:1995, clause 6.4. The new requirement reflects the reliability of state-of-the-art control technology, that ensures safe stop conditions even if the energy supply to the actuators is not cut off.

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<ul style="list-style-type: none"> – portable hand-held and/or hand-guided machinery. <p>The device must:</p> <ul style="list-style-type: none"> – have clearly identifiable, clearly visible and quickly accessible control devices, – stop the hazardous process as quickly as possible, without creating additional risks, – where necessary, trigger or permit the triggering of certain safeguard movements. <p>Once active operation of the emergency stop device has ceased following a stop command, that command must be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it must not be possible to engage the device without triggering a stop command; it must be possible to disengage the device only by an appropriate operation, and disengaging the device must not restart the machinery but only permit restarting.</p> <p style="color: red;">The emergency stop function must be available and operational at all times, regardless of the operating mode.</p> <p style="color: red;">Emergency stop devices must be a back-up to other safeguarding measures and not a substitute for them.</p> <p>1.2.4.4. Assembly of machinery</p> <p>In the case of machinery or parts of machinery designed to work together, the machinery must be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery itself but also all related equipment,</p> <p>if its continued operation may be dangerous.</p> <p>1.2.5. Selection of control or operating modes</p> <p>The control or operating mode selected must override all other control or operating modes, with the exception of the emergency stop.</p>	<ul style="list-style-type: none"> – hand-held portable machines and hand-guided machines. <p>This device must:</p> <ul style="list-style-type: none"> – 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. <p>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.</p> <p>Complex installations</p> <p>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.</p> <p>1.2.5. Mode selection</p> <p>The control mode selected must override all other control systems with the exception of the emergency stop.</p>	<p>These two requirements have their origin in EN 418:1992, clauses 4.1.1 and 4.1.3 and in EN ISO 13850:2006 - which supersedes EN 418 - clause 4.1.1 and 4.1.2.</p> <p>EN ISO 12100-2:2003 defines the emergency stop as "a complementary safeguarding measure" (5.1), and gives some provisions on how to achieve the emergency stop function (5.5.2).</p> <p>"assembly of machinery" is more appropriate than "complex installation" because the latter was not defined in 98/37/EC. 'Complex installation' is not used in the new directive.</p>	
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<p>If machinery has been designed and constructed to allow its use in several control or operating modes requiring different protective measures and/or work procedures, it must be fitted with a mode selector which can be locked in each position. Each position of the selector must be clearly identifiable and must correspond to a single operating or control mode.</p>	<p>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.</p>	<p>This requirement corresponds to EN ISO 12100-2:2003, clause 4.11.10, first paragraph.</p>
<p>The selector may be replaced by another selection method which restricts the use of certain functions of the machinery to certain categories of operator.</p>	<p>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.).</p>	<p>This requirement corresponds to EN ISO 12100-2:2003, clause 4.11.10, second paragraph.</p>
<p>If, for certain operations, the machinery must be able to operate with a guard displaced or removed and/or a protective device disabled, the control or operating mode selector must simultaneously:</p> <ul style="list-style-type: none"> – disable all other control or operating modes, – permit operation of hazardous functions only by control devices requiring sustained action, – permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked sequences, – prevent any operation of hazardous functions by voluntary or involuntary action on the machine's sensors. 	<p>If, for certain operations, the machinery must be able to operate with its protection devices neutralised, the mode selector must simultaneously:</p> <ul style="list-style-type: none"> – 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. 	<p>Both directives use the terms 'control (device) requiring sustained action' which means 'hold-to-run control device' as defined in EN ISO 12100-1 clause 3.26.3. 'Hold-to-run' is used in clause 4.2.1 of the new Annex I.</p> <p>The 3 first indents correspond to clause 4.11.9 of EN ISO 12100-2:2003. The fourth indent is not addressed in EN ISO 12100.</p>
<p>If these four conditions cannot be fulfilled simultaneously, the control or operating mode selector must activate other protective measures designed and constructed to ensure a safe intervention zone.</p> <p>In addition, the operator must be able to control operation of the parts he is working on from the adjustment point.</p>	<p>In addition, the operator must be able to control operation of the parts he is working on at the adjustment point.</p>	<p>This is a new opening clause for additional operating types, for example to facilitate process monitoring on machine tools in line with the objectives of the directive.</p>

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>1.2.6. <i>Failure of the power supply</i></p> <p>The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply to the machinery must not lead to dangerous situations.</p> <p>Particular attention must be given to the following points:</p> <ul style="list-style-type: none"> – the machinery must not start unexpectedly, – the parameters of the machinery must not change in an uncontrolled way when such change can lead to hazardous situations, – the machinery must not be prevented from stopping if the command has already been given, – no moving part of the machinery or piece held by the machinery must fall or be ejected, – automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded, – the protective devices must remain fully effective or give a stop command. 	<p>1.2.6. <i>Failure of the power supply</i></p> <p>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.</p> <p>In particular:</p> <ul style="list-style-type: none"> – 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. <p>1.2.7. <i>Failure of the control circuit</i></p> <p>A fault in the control circuit logic, or failure of or damage to the control circuit must not lead to dangerous situations.</p> <p>In particular:</p> <ul style="list-style-type: none"> – 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. <p>[Moved to 1.2.1 of the new directive]</p>	<p>These "points" are the same ones as in 1.2.1. Whilst 1.2.1 only covers the <i>reliability of control systems</i>, this section covers the different <i>failure modes of the power supply</i>, which can also lead to hazardous situations, even in the absence of any fault in (or failure of) the control system.</p>

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	<p>1.2.8. Software Interactive software between the operator and the command or control system of a machine must be user-friendly. [See 1.7.1.1 of the new directive]</p>	<p>See new clause 1.7.1.1 related to user interface, which is the main issue. Software can be considered a tool to create user interface.</p>
<p>1.3. PROTECTION AGAINST MECHANICAL HAZARDS</p>	<p>1.3. Protection against mechanical hazards</p>	
<p>1.3.1. Risk of loss of stability</p>	<p>1.3.1. <i>Stability</i></p>	
<p>Machinery and its components and fittings must be</p>	<p>Machinery, components and fittings thereof must be so designed and constructed that they are</p>	<p>The modifications introduced in 1.3.1 reflect the provisions for stability given in EN ISO 12100-2:2003 clause 4.6, that require to consider stability in “all phases of the life of the machine”.</p>
<p>stable enough to avoid overturning, falling or uncontrolled movements during transportation, assembly, dismantling, and any other action involving the machinery.</p>	<p>stable enough, under the foreseen operating conditions (if necessary taking climatic conditions into account) for use without risk of overturning, falling or unexpected movement.</p>	
<p>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.</p>	<p>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.</p>	
<p>1.3.2. Risk of break-up during operation</p>	<p>1.3.2. <i>Risk of break-up during operation</i></p>	
<p>The various parts of machinery and their linkages must be able to withstand the stresses to which they are subject when used.</p>	<p>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.</p>	
<p>The durability of the materials used must be adequate for the nature of the working environment foreseen by the manufacturer or his authorised representative, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion.</p>	<p>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.</p>	<p>The term “work environment” – broader in scope than “workplace” – is defined in EN ISO 6385:2004 clause 2.6 and EN 614-1:2006 clause 3.7.</p>
<p>The instructions must indicate</p>	<p>The manufacturer must indicate in the instructions</p>	
<p>the type and frequency of inspections and maintenance required for safety reasons. They must, where appropriate, indicate the parts subject to wear and the criteria for replacement.</p>	<p>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.</p>	
<p>Where a risk of rupture or disintegration remains despite the measures taken,</p>	<p>Where a risk of rupture or disintegration remains despite the measures taken</p>	
<p>the parts concerned must be mounted, positioned and/or guarded in such a way that any fragments</p>	<p>(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</p>	
<p>will be contained, preventing hazardous situations.</p>	<p>will be contained.</p>	

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
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	Both rigid and flexible pipes carrying fluids, particularly those under high pressure, must be able to withstand the foreseen internal and external stresses and must be firmly attached and/or protected	
to ensure that no risk is posed by a rupture.	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 persons:	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 condition,	– 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.	– 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	1.3.3. Risks due to falling or ejected objects	
Precautions must be taken to prevent risks from falling or ejected objects.	Precautions must be taken to prevent risks from falling or ejected objects (e.g. work pieces, tools, cuttings, fragments, waste, etc.).	
1.3.4. Risks due to surfaces, edges or angles	1.3.4. Risks due to surfaces, edges or angles	
Insofar as their purpose allows, accessible parts of the machinery must have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.	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	1.3.5. Risks related to combined machinery	
Where the machinery is intended to carry out several different operations with manual removal of the piece between each operation (combined machinery), it must be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a risk for exposed persons.	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.	For this purpose, it must be possible to start and stop separately any elements that are not protected.	

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1.3.6. Risks related to variations in operating conditions

Where the machinery performs operations under different conditions of use,

it must be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.

1.3.7. Risks related to moving parts

The moving parts of machinery must be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or must, where risks persist, be fitted with guards or protective devices.

All necessary steps must be taken to prevent accidental blockage of moving parts involved in the work. In cases where, despite the precautions taken, a blockage is likely to occur, the necessary specific protective devices and tools must, when appropriate, be provided

to enable the equipment to be safely unblocked.

The instructions and, where possible, a sign on the machinery shall identify these specific protective devices and how they are to be used.

1.3.8. Choice of protection against risks arising from moving parts

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

1.3.8.1. Moving transmission parts

Guards designed to protect persons against the hazards generated by moving transmission parts must be:

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:

The rotational speed of tools is only one of the operating conditions that may vary. The new requirement is given here a far more extended impact.

The terms used were chosen in accordance with the terminology of the European harmonized standards (especially clause 3 of EN ISO 12100-1:2003).

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<ul style="list-style-type: none"> – either fixed guards as referred to in section 1.4.2.1, or – interlocking movable guards as referred to in section 1.4.2.2. <p>Interlocking movable guards should be used where frequent access is envisaged.</p>	<ul style="list-style-type: none"> – 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. <p>Movable guards should be used where frequent access is foreseen.</p>	<p>Section 1.4.2.2 of the new directive (referred to here) defines the "interlocking movable guard".</p> <p>It may be, according to the result of the risk assessment:</p> <ul style="list-style-type: none"> – either an interlocking guard (see 3.25.4 of EN ISO 12100-1:2003) – or an interlocking guard with guard locking (see 3.25.5 of EN ISO 12100-1:2003) <p>The old directive required only an interlocking guard (section 1.4.2.2.A)</p>	
<p>1.3.8.2. Moving parts involved in the process</p> <p>Guards or protective devices designed to protect persons against the hazards generated by moving parts involved in the process must be:</p> <ul style="list-style-type: none"> – either fixed guards as referred to in section 1.4.2.1, or – interlocking movable guards as referred to in section 1.4.2.2, or – protective devices as referred to in section 1.4.3, or – a combination of the above. <p>However, when certain moving parts directly involved in the process cannot be made completely inaccessible during operation owing to operations requiring operator intervention, such parts must be fitted with:</p> <ul style="list-style-type: none"> – fixed guards or interlocking movable guards preventing access to those sections of the parts that are not used in the work, and – adjustable guards as referred to in section 1.4.2.3 restricting access to those sections of the moving parts where access is necessary. 	<p>B. Moving parts directly involved in the process</p> <p>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:</p> <ul style="list-style-type: none"> – 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. <p>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:</p> <ul style="list-style-type: none"> – 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. 	<p>Section 1.4.2.2 of the new directive (referred to here) defines the "interlocking movable guard".</p> <p>It may be, according to the result of the risk assessment:</p> <ul style="list-style-type: none"> – either an interlocking guard (see 3.25.4 of EN ISO 12100-1:2003) – or an interlocking guard with guard locking (see 3.25.5 of EN ISO 12100-1:2003) <p>The old directive required only an interlocking guard with guard locking (section 1.4.2.2.B)</p>	
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1.3.9. Risks of uncontrolled movements

When a part of the machinery has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, must be prevented or must be such that it does not present a hazard.

1.4 REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES

1.4.1. General requirements

Guards and protective devices must:

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

In addition, guards must, where possible, protect against the ejection or falling of materials or objects and against emissions generated by the machinery.

1.4.2. Special requirements for guards

1.4.2.1. Fixed guards

Fixed guards must be fixed by systems that can be opened or removed only with tools.

Their fixing systems must remain attached to the guards or to the machinery when the guards are removed.

Where possible, guards must be incapable of remaining in place without their fixings.

Text from 3.4.1 concerning mobility only

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.

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.

Very close to 3.4.1 of the old directive (which covered hazards connected with the mobility of machinery), the text of 1.3.9 now applies to all machinery. The reader is invited to note the additional requirement, intended to prevent uncontrolled movements. EN 1037:1995 *Prevention of unexpected start-up* also deals with this aspect.

In old 1.4.2.1 the requirement “Guards and protective devices must be securely held in place” applies only to fixed guards. EN ISO 12100-2:2003 clause 5.3.2.2 requires to securely hold in place fixed guards only. EN 953:1997 clause 5.5.4 extends this requirement to all guards. The new requirement is also covered in EN 1760-1:1997 (Pressure sensitive protective devices), clause 4.16.

The requirement “securely held in place” has been moved to clause 1.4.1 and now applies to all guards and protective devices.

EN 953:1997, clause 7.2, recommends that *guard fastenings remain attached to the guard*. This requirement could be uneasy to be applied to all machinery, especially where hygiene and/or seal problems exist.

The new directive requires it more strictly to prevent the losing of unsuitable fixing systems.

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>1.4.2.2. Interlocking movable guards</p> <p>Interlocking movable guards must:</p> <ul style="list-style-type: none"> – as far as possible remain attached to the machinery when open, – be designed and constructed in such a way that they can be adjusted only by means of an intentional action. [See 3rd hyphen of old 1.4.2.2 B] <p>Interlocking movable guards must be associated with an interlocking device that:</p> <ul style="list-style-type: none"> – prevents the start of hazardous machinery functions until they are closed, and – gives a stop command whenever they are no longer closed. <p>Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery functions has ceased, movable guards must be associated with a guard locking device in addition to an interlocking device that:</p> <ul style="list-style-type: none"> – prevents the start of hazardous machinery functions until the guard is closed and locked, and – keeps the guard closed and locked until the risk of injury from the hazardous machinery functions has ceased. <p>Interlocking movable guards must be designed in such a way that the absence or failure of one of their components prevents starting or stops the hazardous machinery functions.</p>	<p>1.4.2.2. Movable guards</p> <p>A. Type A movable guards must:</p> <ul style="list-style-type: none"> – 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. <p>B. Type B movable guards must be designed and incorporated into the control system so that:</p> <ul style="list-style-type: none"> – 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. [See 2nd hyphen of new 1.4.2.2] – 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. [New 1.4.1 covers this requirement] 	<p>This clause has been totally changed. It has been adapted to the terminology and to the specific provisions of EN 1088: 1995 <i>Interlocking devices associated with guards – Principles for design and selection</i>.</p> <p>In the old directive, "Type A" means "interlocking guard without guard locking" and "Type B" means "interlocking guard with guard locking". Both are "interlocking movable guards" and the new directive highlights the concept that, when it is possible to reach the danger zone before the risk due to the hazardous machinery functions has ceased, interlocking movable guards must be associated with a guard locking device.</p> <p>The requirement is now valid for all interlocking movable guards</p> <p>Guards are intended to protect against every type of hazardous functions, not only against the hazards generated by moving parts. This hyphen now applies to all guards.</p>

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<p>1.4.2.3. Adjustable guards restricting access</p> <p>Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work must be:</p> <ul style="list-style-type: none"> – adjustable manually or automatically, depending on the type of work involved, and – readily adjustable without the use of tools. 	<p>1.4.2.3. Adjustable guards restricting access</p> <p>Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work must:</p> <ul style="list-style-type: none"> – 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. [New 1.4.1 (last paragraph) covers this requirement] 	<p>This hyphen now applies to all guards.</p>
<p>1.4.3. Special requirements for protective devices</p> <p>Protective devices must be designed and incorporated into the control system in such a way that:</p> <ul style="list-style-type: none"> – moving parts cannot start up while they are within the operator's reach, – persons cannot reach moving parts while the parts are moving, and – the absence or failure of one of their components prevents starting or stops the moving parts. <p>Protective devices must be adjustable only by means of an intentional action. [See 3rd hyphen of old 1.4.3]</p>	<p>1.4.3. Special requirements for protection devices</p> <p>Protection devices must be designed and incorporated into the control system so that:</p> <ul style="list-style-type: none"> – 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., [See last paragraph of new 1.4.3] – the absence or failure of one of their components prevents starting or stops the moving parts. 	
<p>1.5 RISKS DUE TO OTHER HAZARDS</p> <p>1.5.1. Electricity supply</p> <p>Where machinery has an electricity supply, it must be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented.</p>	<p>1.5. Protection against other hazards</p> <p>1.5.1. Electricity supply</p> <p>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.</p>	

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>The safety objectives set out in Directive 73/23/EEC shall apply to machinery. However, the obligations concerning conformity assessment and the placing on the market and/or putting into service of machinery with regard to electrical hazards are governed solely by this Directive.</p>	<p>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.</p>	<p>This new text clarifies that the safety objectives of Low Voltage Directive apply to machinery to prevent hazard of electrical nature, but for the obligations concerning assessing of conformity and placing on the market and/or putting into service, only the provisions of the Machinery Directive shall be applied. Therefore Article 3 does not fully apply in the case of the Low Voltage Directive.</p>	
<p>1.5.2. Static electricity</p> <p>Machinery must be designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.</p>	<p>1.5.2. Static electricity</p> <p>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.</p>		
<p>1.5.3. Energy supply other than electricity</p> <p>Where machinery is powered by source of energy other than electricity,</p> <p>it must be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy.</p>	<p>1.5.3. Energy supply other than electricity</p> <p>Where machinery is powered by an energy other than electricity (e.g. hydraulic, pneumatic or thermal energy, etc.),</p> <p>it must be so designed, constructed and equipped as to avoid all potential hazards associated with these types of energy.</p>		
<p>1.5.4. Errors of fitting</p> <p>Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.</p> <p>Where necessary, the instructions must give further information on these risks.</p> <p>Where a faulty connection can be the source of risk, incorrect connections must be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.</p>	<p>1.5.4. Errors of fitting</p> <p>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.</p> <p>Any further information that may be necessary must be given in the instructions.</p> <p>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.</p>		
<p>1.5.5. Extreme temperatures</p> <p>Steps must be taken to eliminate any risk of injury arising from contact with or proximity to machinery parts or materials at high or very low temperatures.</p>	<p>1.5.5. Extreme temperatures</p> <p>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.</p>		
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The necessary steps must also be taken to avoid or protect against the risk of hot or very cold material being ejected.

1.5.6. Fire

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

1.5.7. Explosion

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

Machinery must comply, as far as the risk of explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific Community Directives.

1.5.8. Noise

Machinery must be designed and constructed in such a way that risks resulting from the emission of airborne noise are reduced to the lowest level, taking account of technical progress and the availability of means of reducing noise, in particular at source.

The 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 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,
- minimise 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.

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>The level of noise emission may be assessed with reference to comparative emission data for similar machinery.</p>		<p>The basic term "comparative emission data" for all kinds of emissions is defined in sub-clause 3.39 of EN ISO 12100-1:2003 as "set of emission values of similar machines collected for the purpose of comparison".</p>
<p>1.5.9. Vibrations</p> <p>Machinery must be designed and constructed in such a way that risks resulting from vibrations produced by the machinery are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source.</p>	<p>1.5.9. Vibration</p> <p>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.</p>	<p>The new requirement means that manufacturers and their associations may be asked to collect such comparative data.</p>
<p>The level of vibration emission may be assessed with reference to comparative emission data for similar machinery.</p>		<p>The basic term "comparative emission data" for all kinds of emissions is defined in sub-clause 3.39 of EN ISO 12100-1:2003 as "set of emission values of similar machines collected for the purpose of comparison".</p> <p>The new requirement means that manufacturers and their associations may be asked to collect such comparative data.</p>
<p>1.5.10. Radiation</p> <p>Undesirable radiation emissions from the machinery must be eliminated or be reduced to levels that do not have adverse effects on persons.</p>	<p>1.5.10. Radiation</p> <p>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.</p>	<p>The new requirements on radiation remove legal uncertainties and clarify that the directive covers the protection against both ionising and non-ionising radiation, although certain machinery for nuclear purposes are outside the scope of the directive. The interpretation of the old clause 1.5.10 was not unique in all member states and because of that, CEN was not able to publish an harmonized standard dealing with protection against ionising radiation. Only a CEN-report (CEN/TR 14715:2004) covers this topic.</p>
<p>Any functional ionising radiation emissions must be limited to the lowest level which is sufficient for the proper functioning of the machinery during setting, operation and cleaning. Where a risk exists, the necessary protective measures must be taken.</p>		<p>The harmonized standard EN 12198 (parts 1 to 3) covers protection against and measurement of non-ionizing radiation and also defines the term "functional radiation". See also new 1.7.4.2 (v) concerning declaration of emission values in instructions.</p>
<p>1.5.11. External radiation</p> <p>Machinery must be designed and constructed in such a way that external radiation does not interfere with its operation.</p>	<p>1.5.11. External radiation</p> <p>Machinery must be so designed and constructed that external radiation does not interfere with its operation.</p>	

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1.5.12. **Laser radiation**

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

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

1.5.13. **Emissions of hazardous materials and substances**

Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.

Where a hazard cannot be eliminated, the machinery must be so equipped that hazardous materials and substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.

Where the process is not totally enclosed during normal operation of the machinery, the devices for containment and/or evacuation must be situated in such a way as to have the maximum effect.

1.5.14. **Risk of being trapped in a machine**

Machinery must be designed, constructed or fitted with a means of preventing a person from being enclosed within it or, if that is impossible, with a means of summoning help.

1.5.15. **Risk of slipping, tripping or falling**

Parts of the machinery where persons are liable to move about or stand must be designed and constructed in such a way as to prevent persons slipping, tripping or falling on or off these parts.

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,
- visual 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.

Precipitation by water spraying was taken over from the old clause 3.5.3.

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
Where appropriate, these parts must be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.		EN ISO 12100-2:2003 clause 5.5.6 includes "handholds" among the measures for safe access to machinery.
1.5.16. Lightning		
Machinery in need of protection against the effects of lightning while being used must be fitted with a system for conducting the resultant electrical charge to earth.	Text from 4.1.2.8, concerning lifting only <i>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.</i>	In the new directive this requirement is to be applied to all machinery, where relevant, not only to lifting machinery.
1.6. MAINTENANCE	1.6. Maintenance	
1.6.1. Machinery maintenance	1.6.1. <i>Machinery maintenance</i>	
Adjustment and maintenance points must be located outside danger zones. It must be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while machinery is at a standstill.	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, measures must be taken to ensure that these operations can be carried out safely (see section 1.2.5).	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, a connecting device for mounting diagnostic fault-finding equipment must be provided.	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 machinery components which have to be changed frequently	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 safely. Access to the components must enable these tasks to be carried out with the necessary technical means in accordance with a specified operating method.	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 positions and servicing points	1.6.2. Access to operating position and servicing points	
Machinery must be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment and maintenance of the machinery.	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.	

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1.6.3. Isolation of energy sources

Machinery must be fitted with means to isolate it from all energy sources. Such isolators must be clearly identified. They must be capable of being locked if reconnection could endanger persons.

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

In the case of machinery capable of being plugged into an electricity supply, removal of the plug is sufficient, provided that the operator can check from any of the points to which he has access that the plug remains removed.

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

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

1.6.4. Operator intervention

Machinery must be so designed, constructed and equipped that the need for operator intervention is limited. If operator intervention cannot be avoided, it must be possible to carry it out easily and safely.

1.6.5. Cleaning of internal parts

The machinery must be designed and constructed in such a way that it is possible to clean internal parts which have contained dangerous substances or preparations without entering them; any necessary unblocking must also be possible from the outside.

If it is impossible to avoid entering the machinery, it must be designed and constructed in such a way as to allow cleaning to take place safely.

1.6.3. 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.

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.

This new requirement corresponds to clause 5.2 (Note 1) of EN 1037:1995 "Prevention of unexpected start-up".

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>1.7. INFORMATION</p> <p>1.7.1. Information and warnings on the machinery</p> <p>Information and warnings on the machinery should preferably be provided in the form of readily understandable symbols or pictograms. Any written or verbal information and warnings must be expressed in an official Community language or languages, which may be determined in accordance with the Treaty by the Member State in which the machinery is placed on the market and/or put into service and may be accompanied, on request, by versions in any other official Community language or languages understood by the operators. [Compare with 1.7.2 of the old directive]</p> <p>1.7.1.1. Information and information devices</p> <p>The information needed to control machinery must be provided in a form that is unambiguous and easily understood. It must not be excessive to the extent of overloading the operator.</p> <p>Visual display units or any other interactive means of communication between the operator and the machine must be easily understood and easy to use.</p> <p>1.7.1.2. Warning devices</p> <p>Where the health and safety of persons may be endangered by a fault in the operation of unsupervised machinery, the machinery must be equipped in such a way as to give an appropriate acoustic or light signal as a warning.</p> <p>Where machinery is equipped with warning devices these must be unambiguous and easily perceived. The operator must have facilities to check the operation of such warning devices at all times.</p> <p>The requirements of the specific Community Directives concerning colours and safety signals must be complied with.</p>	<p>1.7. Indicators</p> <p>1.7.0. Information devices</p> <p>The information needed to control machinery must be unambiguous and easily understood. It must not be excessive to the extent of overloading the operator.</p> <p>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.</p> <p>1.7.1. Warning devices</p> <p>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.</p> <p>The requirements of the specific Directives concerning colours and safety signals must be complied with.</p>	<p>These new requirements, mainly moved – fundamentally unchanged, but clarified on some points – from the old 1.7.2., now apply to all the information on the machinery, marking included.</p> <p>This new requirement covers the aspect expressed in old 1.2.8.</p>	
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1.7.2. **Warning of residual risks**

Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, must be provided.

1.7.3. **Marking of machinery**

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

- the business name and full address of the manufacturer and, where applicable, his authorised representative,
- designation of the machinery,
- the CE Marking (see Annex III),
- designation of series or type,
- serial number, if any,
- the year of construction, that is the year in which the manufacturing process is completed.

It is prohibited to pre-date or post-date the machinery when affixing the CE marking.

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

Machinery must also bear full information relevant to its type and essential for safe use. Such information is subject to the requirements set out in section 1.7.1.

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

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. [Compare with 1.7.1 of the new directive]

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 Annex III),
- 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.

"designation of the machinery" is a new required marking. It likely means the brand and model name given by the manufacturer.

The user expects that machinery whose year of construction is 200X, can be associated to the state of the art (and harmonised standards) available at that time. Market surveillance authorities have the same expectations.

The requirements set out in section 1.7.1 apply to the marking of machinery only for the information "relevant to its type and essential for safe use".

The term "machinery" also includes interchangeable equipment; therefore, the last sentence of old 1.7.3 has been deleted.

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>1.7.4. <i>Instructions</i></p> <p>All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service.</p> <p>The instructions accompanying the machinery must be either 'Original instructions' or a 'Translation of the original instructions', in which case the translation must be accompanied by the original instructions.</p> <p>By way of exception, the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his authorised representative may be supplied in only one Community language which the specialised personnel understand. [Compare with old 1.7.4 b]</p> <p>The instructions must be drafted in accordance with the principles set out below.</p> <p>1.7.4.1. General principles for the drafting of instructions</p> <p>(a) The instructions must be drafted in one or more official Community languages. The words 'Original instructions' must appear on the language version(s) verified by the manufacturer or his authorised representative.</p> <p>(b) Where no 'Original instructions' exist in the official language(s) of the country where the machinery is to be used, a translation into that/those language(s) must be provided by the manufacturer or his authorised representative or by the person bringing the machinery into the language area in question. The translations must bear the words 'Translation of the original instructions'.</p> <p>(c) The contents of the instructions must cover not only the intended use of the machinery but also take into account any reasonably foreseeable misuse thereof.</p> <p>(d) In the case of machinery intended for use by non-professional operators, the wording and layout of the instructions for use must take into account the level of general education and acumen that can reasonably be expected from such operators.</p>	<p>1.7.4. <i>Instructions</i></p> <p>(a) All machinery must be accompanied by instructions including at least the following:</p> <p>Text from 1.7.4 b (second part): By way of derogation from this requirement, the maintenance instructions for use by specialised personnel employed by the manufacturer or his authorised representative established in the Community may be drawn up in only one of the Community languages understood by that personnel.</p> <p>Text from 1.7.4 b (first part): The instructions must be drawn up in one of the Community languages by the manufacturer or his authorised 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 country 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 authorised representative established in the Community or by the person introducing the machinery into the language area in question.</p> <p>Text from 1.7.4 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.</p>	<p>In accordance with the importance of the instructions, this paragraph has been made more precise and expanded.</p> <p>EN ISO 12100-2:2003 clause 6.1.1 covers this aspect.</p> <p>EN ISO 12100-2:2003 clause 6.1.1 covers this aspect. The concept of "reasonably foreseeable misuse" has been pointed out also in the General Principles in the beginning of Annex I.</p>	
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1.7.4.2. Contents of the instructions

Each instruction manual must contain, where applicable, at least the following information:

- (a) the business name and full address of the manufacturer and of his authorised representative;
- (b) the designation of the machinery as marked on the machinery itself, except for the serial number (see section 1.7.3);
- (c) the EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature;
- (d) a general description of the machinery;
- (e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning;
- (f) a description of the workstation(s) likely to be occupied by operators;
- (g) a description of the intended use of the machinery;
- (h) warnings concerning ways in which the machinery must not be used that experience has shown might occur;
- (i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery is to be mounted;
- (j) instructions relating to installation and assembly for reducing noise or vibration;
- (k) instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators;

– 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). [Moved to new 1.7.4.2 (g)]

Text from 1.7.4 (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

– workstation(s) likely to be occupied by operators,

Text from second hyphen:

foreseen use of the machinery within the meaning of 1.1.2(c),

Text from last sentence of 1.7.4 a

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

Text from 4th hyphen of 1.7.4 (a):

– *assembly, dismantling,*

Text from last sentence of 1.7.4 (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.).

– instructions for safe:

- putting into service,
- use,
- *where necessary, training instructions,*

See comment on clause 1.7.3 for “designation of the machinery”.

Now, a copy (or an abstract) of the EC declaration of conformity is required in the instructions

EN ISO 12100-2:2003 clause 6.5.1 c), first indent, requires a “detailed description of the machine”.

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>(l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;</p> <p>(m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;</p> <p>(n) the essential characteristics of tools which may be fitted to the machinery;</p>	<ul style="list-style-type: none"> - handling, giving the mass of the machinery and its various parts where they are regularly to be transported separately, [Moved to new 1.7.4.2 (p)] - assembly, dismantling, [Moved to new 1.7.4.2 (i)] - adjustment, [Moved to new 1.7.4 (f)] - maintenance (servicing and repair), [Moved to new 1.7.4 (f)] - where necessary, training instructions, [Moved five hyphens above] - where necessary, the essential characteristics of tools which may be fitted to the machinery. <p>Where necessary, the instructions should draw attention to ways in which the machinery should not be used. [Moved to new 1.7.4.2 (h)]</p> <p>(b) The instructions must be drawn up in one of the Community languages by the manufacturer or his authorised 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 country 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 authorised representative established in the Community or by the person introducing the machinery into the language area in question. [Moved to new 1.7.4]</p>	<p>This requirement was not in old 1.7.4, but in old 1.1.2 (b)</p> <p>The undefined term "user" likely means here "the owner / holder" of the machinery (e.g. an employer). EN ISO 12100-2:2003 - 6.5.1 b), last indent - uses the term "user" in the sense of "owner of the machinery" or "employer" but without defining it. In clause 3.57 of EN 60204-1:2006 "Electrical equipment of machinery" there is a definition for user: "entity who utilizes the machine and its associated electrical equipment".</p>

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<p>o) the conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;</p> <p>(p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately; [Compare with the 10th hyphen of old 1.7.4. (a)]</p> <p>(q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;</p> <p>(r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed;</p> <p>(s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;</p>	<p>By way of derogation from this requirement, the maintenance instructions for use by specialised personnel employed by the manufacturer or his authorised representative established in the Community may be drawn up in only one of the Community languages understood by that personnel. [Moved to new 1.7.4.1]</p> <p>(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 [Moved to new 1.7.4.2 (e)]</p> <p>Text from 4th hyphen of 1.7.4 (a):</p> <ul style="list-style-type: none"> – <i>handling, giving the mass of the machinery and its various parts where they are regularly to be transported separately,</i> <p>(d) Any literature describing the machinery must not contradict the instructions as regards safety aspects. The technical documentation describing 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. [Compare with new 1.7.4.3]</p> <p>(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.). [Compare with new 1.7.4.2 (i)]</p>	<p>(r) EN ISO 12100-2:2003 does not address preventive maintenance.</p>
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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>(t) the specifications of the spare parts to be used, when these affect the health and safety of operators;</p> <p>(u) the following information on airborne noise emissions:</p> <ul style="list-style-type: none"> – the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated, – the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 µPa), – the A-weighted sound power level emitted by the machinery, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A). <p>These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.</p> <p>In the case of very large machinery, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery may be indicated.</p> <p>Where the harmonised standards are not applied, sound levels must be measured using the most appropriate method for the machinery. Whenever sound emission values are indicated the uncertainties surrounding these values must be specified.</p> <p>The operating conditions of the machinery during measurement and the measuring methods used must be described.</p>	<p>(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:</p> <ul style="list-style-type: none"> – 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). <p>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.</p> <p>Where the harmonised standards are not applied, sound levels must be measured using the most appropriate method for the machinery.</p> <p>The manufacturer must indicate the operating conditions of the machinery during measurement and what methods have been used for the measurement.</p>	<p>This requirement is not mentioned in EN ISO 12100, but it is common in B and C-type standards: as an example, EN 1760-1:1997 (Pressure sensitive protective devices) – clause 6.2.5 "Maintenance" – requires the use of spare parts approved by the manufacturer.</p> <p>The numerical values are unchanged; the wording has been adapted to the terminology of EN ISO standards (see e.g. EN ISO 4871:1996).</p> <p>The value has been lowered from 85 dB(A) to 80 dB(A).</p>

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<p>Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at a height of 1,6 metre from the floor or access platform. The position and value of the maximum sound pressure must be indicated.</p> <p>Where specific Community Directives lay down other requirements for the measurement of sound pressure levels or sound power levels, those Directives must be applied and the corresponding provisions of this section shall not apply;</p> <p>(v) where machinery is likely to emit non-ionising radiation which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons.</p> <p>1.7.4.3. Sales literature</p> <p>Sales literature describing the machinery must not contradict the instructions as regards health and safety aspects. Sales literature describing the performance characteristics of machinery must contain the same information on emissions as is contained in the instructions.</p>	<p>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 metre from the floor or access platform. The position and value of the maximum sound pressure must be indicated.</p> <p>(g) If the manufacturer foresees that the machinery will be used in a potentially explosive atmosphere, the instructions must give all the necessary information.</p> <p>(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. . [Moved to new 1.7.4.1 (d)]</p> <p>[Text from 1.7.4 (d)] <i>Any literature describing the machinery must not contradict the instructions as regards safety aspects. The technical documentation describing 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.</i></p>		
<p>2. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY</p> <p>Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).</p>	<p>2. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY</p>		
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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>2.1. FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS</p> <p>2.1.1. General</p> <p>Machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products</p> <p>must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion. The following requirements must be observed:</p> <p>(a) materials in contact with, or intended to come into contact with, foodstuffs or cosmetics or pharmaceutical products must satisfy the conditions set down in the relevant Directives. The machinery must be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible disposable parts must be used;</p> <p>(b) all surfaces in contact with foodstuffs or cosmetics or pharmaceutical products, other than surfaces of disposable parts, must:</p> <ul style="list-style-type: none"> – be smooth and have neither ridges nor crevices which could harbour organic materials. The same applies to their joinings, – be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum, – be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the inside surfaces must have curves with a radius sufficient to allow thorough cleaning; <p>(c) it must be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery (if possible, in a 'cleaning' position);</p>	<p>2.1. Agri-foodstuffs machinery</p> <p>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:</p> <p>(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;</p> <p>(b) all surfaces including their joinings must be smooth, and must have neither ridges nor crevices which could harbour organic materials;</p> <p>(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;</p> <p>(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;</p> <p>(e) liquids 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);</p>	<p>The requirements of this chapter now apply to all foodstuffs machinery and also to machinery for cosmetics or pharmaceutical products.</p> <p>A new requirement has been added, stipulating the use of disposable parts where these parts cannot always be cleaned.</p>

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- (d) machinery must be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in areas that cannot be cleaned;
- (e) machinery must be designed and constructed in such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery must be designed and constructed in such a way that continuing compliance with this requirement can be checked.
- (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.

2.1.2. Instructions

The instructions for foodstuffs machinery and machinery for use with cosmetics or pharmaceutical products must indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.

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

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

2.2.1. General

Portable hand-held and/or hand-guided machinery must:

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

- depending on the type of machinery, have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size, arranged in such a way as to ensure the stability of the machinery under the intended operating conditions,
- except where technically impossible, or where there is an independent control device, in the case of handles which cannot be released in complete safety, be fitted with manual start and stop control devices arranged in such a way that the operator can operate them without releasing the handles,
- 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,

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<ul style="list-style-type: none"> – present no risks of accidental starting and/or continued operation after the operator has released the handles. Equivalent steps must be taken if this requirement is not technically feasible, – permit, where necessary, visual observation of the danger zone and of the action of the tool with the material being processed. <p>The handles of portable machinery must be designed and constructed in such a way as to make starting and stopping straightforward.</p>	<ul style="list-style-type: none"> – 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. 		
<p>2.2.1.1. Instructions</p> <p>The instructions must give the following information concerning vibrations transmitted by portable hand-held and hand-guided machinery:</p> <ul style="list-style-type: none"> – the vibration total value <p>to which the hand-arm system is subjected, if it exceeds 2,5 m/s². Where this value does not exceed 2,5 m/s², this must be mentioned,</p> <ul style="list-style-type: none"> – the uncertainty of measurement. <p>These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.</p> <p>If harmonised standards are not applied, the vibration data must be measured using the most appropriate measurement code for the machinery.</p> <p>The operating conditions during measurement and the methods used for measurement, or the reference of the harmonised standard applied, must be specified.</p>	<p>Instructions</p> <p>The instructions must give the following information concerning vibrations transmitted by hand-held and hand-guided machinery:</p> <ul style="list-style-type: none"> – the weighted root mean square acceleration value <p>to which the arms are subjected, if it exceeds 2,5 m/s² as determined by the appropriate test code. Where the acceleration does not exceed 2,5 m/s², this must be mentioned.</p> <p>If there is no applicable test code, the manufacturer must indicate the measurement methods and conditions under which measurements were made</p>	<p>This modification adapts the requirement to the state of the art. Vibration measurement basic standard EN ISO 20643:2005 and also EC Directive 2002/44/EC (Vibration Exposure) require that the principal (emission and exposure) quantity is "vibration total value" which is "the root sum of squares of the values for the three measured axes of vibration". The former (old directive) quantity "weighted root mean square acceleration value" may also refer to a single-axis acceleration value (typically the dominant axis).</p> <p>The standard concerning declaration of uncertainties (for machinery) is EN 12096:1997. In the old directive, the declaration of uncertainties has been voluntary.</p>	
<p>2.2.2. Portable fixing and other impact machinery</p> <p>2.2.2.1. General</p> <p>Portable fixing and other impact machinery must be designed and constructed in such a way that:</p>		<p>This is a completely new chapter. It refers to fixing and other impact machinery irrespective of the source of energy used. Cartridge-operated ones are in the scope of the new directive (see comment on article 1 and recital 6).</p>	
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- energy is transmitted to the impacted element by the intermediary component that does not leave the device,
- an enabling device prevents impact unless the machinery is positioned correctly with adequate pressure on the base material,
- involuntary triggering is prevented; where necessary, an appropriate sequence of actions on the enabling device and the control device must be required to trigger an impact,
- accidental triggering is prevented during handling or in case of shock,
- loading and unloading operations can be carried out easily and safely.

Where necessary, it must be possible to fit the device with splinter guard(s) and the appropriate guard(s) must be provided by the manufacturer of the machinery.

2.2.2.2. Instructions

The instructions must give the necessary information regarding:

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

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

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

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

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;

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>(b) where the machinery is likely to be used in conditions involving the risk of ejection of workpieces or parts of them, it must be designed, constructed, or equipped in such a way as to prevent such ejection, or, if this is not possible, so that the ejection does not engender risks for the operator and/or exposed persons;</p> <p>(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;</p> <p>(d) where the tool is incorporated into a non-fully automated machine, the latter must be designed and constructed in such a way as to eliminate or reduce the risk of accidental injury.</p>	<p>(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;</p> <p>(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;</p> <p>(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.</p>		
<p>3. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO THE MOBILITY OF MACHINERY</p> <p>Machinery presenting hazards due to its mobility must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).</p>	<p>3. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET THE PARTICULAR HAZARDS DUE TO THE MOBILITY OF MACHINERY</p> <p>Machinery presenting hazards due to mobility must be designed and constructed to meet the requirements set out below.</p> <p>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. [See 1st hyphen of 3.1.1 (a) of the new directive]</p> <p>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.). [See 2nd hyphen of 3.1.1 (a) of the new directive]</p> <p>In order to verify that rotary cultivators and power harrows do not present unacceptable risks to the exposed persons, the manufacturer or his authorised representative established within the Community must, for each type of machinery concerned, perform the appropriate tests or have such tests performed.</p>		
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3.1. GENERAL	3.1. General
3.1.1. Definitions	3.1.1. <i>Definition</i>
(a) 'Machinery presenting hazards due to its mobility' means	
<ul style="list-style-type: none"> – machinery the operation of which requires either mobility while working, or continuous or semi-continuous movement between a succession of fixed working locations, or [See 2nd para of chapter 3 of the old directive] 	
<ul style="list-style-type: none"> – machinery which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another. [See 3rd para of chapter 3 of the old directive] 	
(b) 'Driver' means an operator responsible for the movement of a machine. The driver may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control.	'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. <i>Lighting</i>
	<p>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.).</p> <p>[New 1.1.4 covers lighting for all machinery]</p>
	<p>3.1.3. <i>Design of machinery to facilitate its handling</i></p> <p>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.</p> <p>[Moved to new 1.1.5 to apply to all machinery]</p>
3.2. WORK POSITIONS	3.2. Work stations
3.2.1. Driving position	3.2.1. <i>Driving position</i>
	<p>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.</p> <p>[Compare with new 1.2.2]</p>

Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>Visibility from the driving position must be such that the driver can, in complete safety for himself and the exposed persons, operate the machinery and its tools in their foreseeable conditions of use. Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision.</p>	<p>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.</p>	
<p>Machinery on which the driver is transported must be designed and constructed in such a way that, from the driving positions, there is no risk to the driver</p>	<p>Machinery must be so designed and constructed that, from the driving position, there can be no risk to the driver and operators on board</p>	
<p>from inadvertent contact with the wheels and tracks.</p>	<p>from inadvertent contact with the wheels or tracks. [Note that other "operators" are dealt with in new 3.2.3, 2nd para]</p>	
<p>The driving position of ride-on drivers must be designed and constructed in such a way that a driver's cab may be fitted, provided this does not increase the risk and there is room for it. The cab must incorporate a place for the instructions needed for the driver.</p>	<p>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.</p>	
	<p>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. [Compare with new 1.1.7]</p>	
	<p>The materials used for the cab and its fittings must be fire-resistant. [New 1.5.6 applies to fire protection in general]</p>	

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3.2.2. Seating

Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the ground should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4, their seats must be designed or equipped with a restraint system so as to keep the persons in their seats, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems should not be fitted if they increase the risk.

3.2.3. Positions for other persons

If the conditions of use provide that persons other than the driver may occasionally or regularly be transported by the machinery or work on it, appropriate positions must be provided which enable them to be transported or to work on it without risk.

The second and third paragraphs of section 3.2.1 also apply to the places provided for persons other than the driver.

3.2.2. 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. [Moved to new 1.1.8, 2nd para, and new 1.1.6 applies to ergonomic principles in general]

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. [Moved to new 1.1.8, 3rd para]

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. [Moved to new 1.1.8]

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.

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>3.3. CONTROL SYSTEMS</p> <p>If necessary, steps must be taken to prevent unauthorised use of controls. [This is the 1st paragraph of old 3.3.2, with a wider scope]</p> <p>In the case of remote controls, each control unit must clearly identify the machinery to be controlled from that unit.</p> <p>The remote control system must be designed and constructed in such a way as to affect only:</p> <ul style="list-style-type: none"> – the machinery in question, – the functions in question. <p>[New requirements for remote-control also appear in new 3.3.3.]</p> <p>Remote controlled machinery must be designed and constructed in such a way that it will respond only to signals from the intended control units.</p> <p>3.3.1. Control devices</p> <p>The driver must be able to actuate all control devices required to operate the machinery from the driving position, except for functions which can be safely actuated only by using control devices located elsewhere.</p> <p>These functions include, in particular, those for which operators other than the driver are responsible or for which the driver has to leave the driving position in order to control them safely.</p> <p>Where there are pedals, they must be so designed, constructed and fitted as to allow safe operation by the driver with the minimum risk of incorrect operation. They must have a slip-resistant surface and be easy to clean.</p> <p>Where their operation can lead to hazards, notably dangerous movements, the control devices, except for those with preset positions, must return to the neutral position as soon as they are released by the operator.</p> <p>In the case of wheeled machinery, the steering system must be designed and constructed in such a way as to reduce the force of sudden movements of the steering wheel or the steering lever caused by shocks to the guide wheels.</p>	<p>3.3. Controls</p> <p>3.3.1. <i>Control devices</i></p> <p>The driver must be able to actuate all control devices required to operate the machinery from the driving position, except for functions which can be safely actuated only by using control devices located 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.</p> <p>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.</p> <p>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.</p> <p>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.</p>		
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Any control that locks the differential must be so designed and arranged that it allows the differential to be unlocked when the machinery is moving.

The sixth paragraph of section 1.2.2, concerning acoustic and/or visual warning signals, **applies only in the case of reversing.**

3.3.2. Starting / moving

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

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

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

Where it **does not give rise to other risks,** movement of the machinery must depend on safe positioning of the aforementioned parts.

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

3.3.3. Travelling function

Without prejudice to road traffic regulations, self-propelled machinery and its trailers must meet the requirements for slowing down, stopping, braking and immobilisation so as to ensure safety under all the operating, load, speed, ground and gradient conditions allowed for.

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 unauthorised persons from starting the engine. [Moved (in a modified form) to new 3.3, 1st para]

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. stabilisers, jib, etc.), the driver must be provided with the means of checking easily, before moving the machinery, that such devices are in a particular position which allows safe movement.

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

Where it **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 immobilisation so as to ensure safety under all the operating, **load**ing, speed, ground and gradient conditions allowed for **by the manufacturer and corresponding to conditions encountered in normal use.**

In the new directive an acoustic or visual warning signal is required when reversing and no means exist to ensure that none is in the danger zone.

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>The driver must be able to slow down and stop self-propelled machinery by means of a main device. Where safety so requires, in the event of a failure of the main device, or in the absence of the energy supply needed to actuate the main device, an emergency device with a fully independent and easily accessible control device must be provided for slowing down and stopping.</p>	<p>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.</p>		
<p>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.</p>	<p>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.</p>		
<p>Remote-controlled machinery must be equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations:</p> <ul style="list-style-type: none"> – if the driver loses control, – if it receives a stop signal, – if a fault is detected in a safety-related part of the system, – if no validation signal is detected within a specified time. 	<p>Remote-controlled machinery must be designed and constructed to stop automatically if the driver loses control.</p>		
<p>Section 1.2.4 does not apply to the travelling function.</p>	<p>Section 1.2.4 does not apply to the travelling function.</p>		
<p>3.3.4. Movement of pedestrian-controlled machinery</p>	<p><i>3.3.4. Movement of pedestrian-controlled machinery</i></p>		
<p>Movement of pedestrian-controlled self-propelled machinery must be possible only through sustained action on the relevant control device by the driver. In particular, it must not be possible for movement to occur while the engine is being started.</p>	<p>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.</p>		
<p>The control systems for pedestrian-controlled machinery must be designed in such a way as to minimise the risks arising from inadvertent movement of the machine towards the driver, in particular:</p>	<p>The control systems for pedestrian-controlled machinery must be designed to minimise the hazards arising from inadvertent movement of the machine towards the driver. In particular:</p>		
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- crushing,
- injury from rotating tools.

The speed of travel of the machinery must be compatible with the pace of a driver on foot.

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

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

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

3.4.2. Moving transmission parts

By way of exception to section 1.3.8.1, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access.

- (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. [Compare with new 1.3.9.]

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.

[Text from 3.4.8]

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 unauthorised access.

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>3.4.3. Roll-over and tip-over</p> <p>Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery must be fitted with an appropriate protective structure, unless this increases the risk.</p> <p>This structure must be such that in the event of rolling or tipping over it affords the ride-on person(s) an adequate deflection-limiting volume.</p> <p>In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.</p>	<p>3.4.2. Risk of break-up during operation</p> <p>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. [Compare with new 1.4.1. and 1.3.2]</p> <p>3.4.3. Rollover</p> <p>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).</p> <p>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).</p> <p>In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorised representative established within the Community must, for each type of structure concerned, perform appropriate tests or have such tests performed.</p> <p>In addition, the earth-moving machinery listed below with a capacity exceeding 15 kW must be fitted with a rollover protective structure:</p> <ul style="list-style-type: none"> - crawler loaders or wheel loaders, - backhoe loaders, - crawler tractors or wheel tractors, - scrapers, self-loading or not, - graders, - articulated steer dumpers. 	<p>The requirement is extended to apply also to tip-over. Tip-over is a recognised hazard already in some safety standards, and EN/ISO-standards for "TOPS" also exist.</p> <p>This requirement has been changed essentially. Where the risk exists, ROPS/TOPS itself shall be fitted: anchorage points alone are no longer sufficient. The protective structure shall not be fitted whereas this would increase the risk.</p> <p>This removal of the paragraph does not mean that a ROPS is no longer required.</p> <p>As ROPS or TOPS are required for all machinery having the risk of roll-over or tip-over (unless the structure increases the risk) there is no need for this list. The history of the list dates back to the time before the original machinery directive 89/392/EEC when there was a specific directive 86/295/EEC on ROPS (and 86/296/EEC on FOPS) in earth-moving machinery.</p> <p>In principle, it is up to the manufacturer to decide, on the basis of the risk assessment, which vehicles need to be fitted with ROPS.</p>

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3.4.4. *Falling objects*

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk due to falling objects or material, the machinery must be designed and constructed in such a way as to take account of this risk and fitted, if its size allows, with an appropriate protective structure.

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

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

must, for each type of structure concerned, perform appropriate tests or have such tests performed.

3.4.5. *Means of access*

Handholds and steps must be designed, constructed and arranged in such a way that the operators use them instinctively and do not use the control devices to assist access.

3.4.6. *Towing devices*

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

Insofar as the tow bar load so requires, such machinery must be equipped with a support with a bearing surface suited to the load and the ground.

3.4.7. *Transmission of power between self-propelled machinery (or tractor) and recipient machinery*

Removable mechanical transmission devices

linking self-propelled machinery (or a tractor) to the first fixed bearing of recipient machinery must be designed and constructed in such a way that any part that moves during operation is protected over its whole length.

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 authorised representative established within the Community

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.

As regards FOPS, the requirement has been changed essentially: when the risk exists, FOPS has to be fitted, whereas the old 3.4.4 required only anchorage points for FOPS.

The change in the term (see. Art 2 f) raises the question as to whether it implicates a wider scope for this requirement (and for the products listed in Annex IV).

Some language versions of the new directive still use „transmission shaft“, thus limiting this requirement and limiting also the type examination (Annex IV).

Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>On the side of the self-propelled machinery (or tractor), the power take-off to which the removable mechanical transmission device is attached must be protected either by a guard fixed and linked to the self-propelled machinery (or tractor) or by any other device offering equivalent protection.</p>	<p>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.</p>	
<p>It must be possible to open this guard for access to the removable transmission device. Once it is in place, there must be enough room to prevent the drive shaft damaging the guard when the machinery (or the tractor) is moving.</p>		
<p>On the recipient machinery side, the input shaft must be enclosed in a protective casing fixed to the machinery.</p>	<p>On the towed machinery side, the input shaft must be enclosed in a protective casing fixed to the machinery.</p>	
<p>Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machinery. The removable mechanical transmission device must be marked accordingly.</p>	<p>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.</p>	
<p>All recipient machinery, the operation of which requires a removable mechanical transmission device to connect it to self-propelled machinery (or a tractor), must have a system for attaching the removable mechanical transmission device so that, when the machinery is uncoupled, the removable mechanical transmission device and its guard are not damaged by contact with the ground or part of the machinery.</p>	<p>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.</p>	
<p>The outside parts of the guard must be so designed, constructed and arranged that they cannot turn with the removable mechanical transmission device. The guard must cover the transmission to the ends of the inner jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in the case of wide-angle universal joints.</p>	<p>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.</p>	
<p>If means of access to working positions are provided near to the removable mechanical transmission device, they must be designed and constructed in such a way that the shaft guards cannot be used as steps, unless designed and constructed for that purpose.</p>	<p>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.</p>	

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	<p>3.4.8. Moving transmission parts</p> <p>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 unauthorised access. [Moved to new 3.4.2]</p>	
<p>3.5. PROTECTION AGAINST OTHER HAZARDS</p>	<p>3.5. Protection against other hazards</p>	
<p>3.5.1. Batteries</p>	<p>3.5.1. Batteries</p>	
<p>The battery housing must be designed and constructed in such a way as to prevent the electrolyte being ejected on to the operator in the event of rollover or tipover and to avoid the accumulation of vapours in places occupied by operators.</p> <p>Machinery must be designed and constructed in such a way that the battery can be disconnected with the aid of an easily accessible device provided for that purpose.</p>	<p>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.</p> <p>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.</p>	<p>The application of the requirements is now imperative/ mandatory. The limitation “to avoid as far as possible the chance of ...” has been dropped.</p>
<p>3.5.2. Fire</p>	<p>3.5.2. Fire</p>	
<p>Depending on the hazards anticipated by the manufacturer, machinery must, where its size permits:</p> <ul style="list-style-type: none"> – either allow easily accessible fire extinguishers to be fitted, or – be provided with built-in extinguisher systems. 	<p>Depending on the hazards anticipated by the manufacturer when in use, machinery must, where its size permits:</p> <ul style="list-style-type: none"> – either allow easily accessible fire extinguishers to be fitted, – or be provided with built-in extinguisher systems. 	
<p>3.5.3. Emissions of hazardous substances</p>	<p>3.5.3. Emissions of dust, gases, etc.</p>	
<p>The second and third paragraphs of section 1.5.13 do not apply where the main function of the machinery is the spraying of products. However, the operator must be protected against the risk of exposure to such hazardous emissions.</p>	<p>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.</p> <p>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.</p>	

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>3.6. INFORMATION AND INDICATIONS</p> <p>3.6.1. Signs, signals and warnings</p> <p>All machinery must have signs and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, so as to ensure the health and safety of persons. They must be chosen, designed and constructed in such a way as to be clearly visible and indelible.</p> <p>Without prejudice to the provisions of road traffic regulations, machinery with a ride-on driver must have the following equipment:</p> <ul style="list-style-type: none"> – an acoustic warning device to alert persons, – a system of light signals relevant to the intended conditions of use; – where necessary, there must be an appropriate connection between a trailer and the machinery for the operation of signals. <p>Remote-controlled machinery which, under normal conditions of use, exposes persons to the risk of impact or crushing must be fitted with appropriate means to signal its movements or with means to protect persons against such risks. The same applies to machinery which involves, when in use, the constant repetition of a forward and backward movement on a single axis where the area to the rear of the machine is not directly visible to the driver.</p> <p>Machinery must be constructed in such a way that the warning and signalling devices cannot be disabled unintentionally. Where it is essential for safety, such devices must be provided with the means to check that they are in good working order and their failure must be made apparent to the operator.</p> <p>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.</p>	<p>3.6. Indications</p> <p>3.6.1. <i>Signs and warning</i></p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> – 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. <p>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.</p> <p>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.</p> <p>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.</p>	

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3.6.2. **Marking**

The following must be shown legibly and indelibly on all machinery:

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

and, where appropriate:

- maximum drawbar pull provided for at the coupling hook, in Newtons (N),
- maximum vertical load provided for on the coupling hook, in Newtons (N).

3.6.3. **Instructions**3.6.3.1. **Vibrations**

The instructions must give the following information concerning vibrations transmitted by the machinery to the hand-arm system or to the whole body:

- the vibration total value

to which the hand-arm system is subjected, if it exceeds $2,5 \text{ m/s}^2$. Where this value does not exceed $2,5 \text{ m/s}^2$, this must be mentioned,

- the highest root mean square value of weighted acceleration to which the whole body is subjected, if it exceeds $0,5 \text{ m/s}^2$. Where this value does not exceed $0,5 \text{ m/s}^2$, this must be mentioned,

- the uncertainty of measurement.

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

[Compare with 1st para (a) of old 3.6.3]

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: [Compare with 2nd paragraph of new 3.6.3.1]
- the weighted root mean square acceleration value to which the arms are subjected, if it exceeds $2,5 \text{ m/s}^2$; should it not exceed $2,5 \text{ m/s}^2$, this must be mentioned,
 - the weighted root mean square acceleration value to which the body (feet or posterior) is subjected, if it exceeds $0,5 \text{ m/s}^2$; should it not exceed $0,5 \text{ m/s}^2$, this must be mentioned.

As in new 2.2.1.1 for hand-held machinery, the state-of-the-art quantity for mobile machinery (vibration from steering wheel etc.) according to EN 1032:2003, clause 6.4, is "vibration total value". It requires measurements in all 3 axes and the declared quantity is "the root sum of squares of the values for the three measured axes of vibration". In order to declare the old quantity, a measurement in the dominant axis is sufficient.

For whole body measurements, the state-of-the-art quantity according to EN 1032:2003, clause 6.4, is the highest value for the measurements made in all 3 axes.

The standard concerning declaration of uncertainties (for machinery) is EN 12096:1997. In the old directive, the declaration of uncertainties has been voluntary.

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>Where harmonised standards are not applied, the vibration must be measured using the most appropriate measurement code for the machinery concerned.</p> <p>The operating conditions during measurement and the measurement codes used must be described.</p> <p>3.6.3.2. Multiple uses</p> <p>The instructions for machinery allowing several uses depending on the equipment used and the instructions for the interchangeable equipment must contain the information necessary for safe assembly and use of the basic machinery and the interchangeable equipment that can be fitted.</p>	<p>Where the harmonised standards are not applied, the vibration must be measured using the most appropriate method for the machinery concerned.</p> <p>The manufacturer must indicate the operating conditions of the machinery during measurement and which methods were used for taking the measurements;</p> <p>(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.</p>		
<p>4. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS</p> <p>Machinery presenting hazards due to lifting operations must meet all the relevant essential health and safety requirements described in this chapter (see <i>General Principles, point 4</i>).</p> <p>4.1. GENERAL</p> <p>4.1.1. Definitions</p> <p>(a) 'Lifting operation' means a movement of unit loads consisting of goods and/or persons necessitating, at a given moment, a change of level. [Compare with 2nd paragraph of old 4]</p>	<p>4. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET THE PARTICULAR HAZARDS DUE TO A LIFTING OPERATION</p> <p>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.</p> <p>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. [Compare with new 4.1.1 (a)]</p> <p>4.1. General remarks</p> <p>4.1.1. Definitions</p> <p>(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; [Definition moved to art. 2 (d) as it defines the scope; the new definition is wider than the old one]</p>	<p>This part, according with the new definition of "lifting operation", now applies also to the lifting of persons, not only to the lifting of loads.</p> <p>In the definition (a) of "lifting operation", the words "at a given moment" exclude the application to continuously moving lifting machinery (e.g. escalators, paternoster). The definition refers only to "unit loads", thus excluding the lifting of non-coherent or fluid materials (e.g. screw feeders and similar machinery).</p>	
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<p>(b) 'Guided load' means a load where the total movement is made along rigid or flexible guides whose position is determined by fixed points.</p> <p>(c) 'Working coefficient' means the arithmetic ratio between the load guaranteed by the manufacturer or his authorised representative up to which a component is able to hold it and the maximum working load marked on the component.</p> <p>(d) 'Test coefficient' means the arithmetic ratio between the load used to carry out the static or dynamic tests on lifting machinery or a lifting accessory and the maximum working load marked on the lifting machinery or lifting accessory.</p> <p>(e) 'Static test' means the test during which lifting machinery or a lifting accessory is first inspected and subjected to a force corresponding to the maximum working load multiplied by the appropriate static test coefficient and then re-inspected once the said load has been released to ensure that no damage has occurred.</p> <p>(f) 'Dynamic test' means the test during which lifting machinery is operated in all its possible configurations at the maximum working load multiplied by the appropriate dynamic test coefficient with account being taken of the dynamic behaviour of the lifting machinery in order to check that it functions properly.</p> <p>(g) 'Carrier': means a part of the machinery on or in which persons and/or goods are supported in order to be lifted.</p>	<p>(b) 'separate lifting accessories' means accessories which help to make up or use a slinging device, such as eyehooks, shackles, rings, eyebolts, etc.; [This definition has been deleted, as these products are "lifting accessories" according to the new definition]</p> <p>(c) 'guided load' means the load where the total movement is made along rigid or flexible guides, whose position is determined by fixed points;</p> <p>(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;</p> <p>(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;</p> <p>(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;</p> <p>(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.</p> <p>[Text from old 6.1.1, valid for lifting of persons only] <i>For the purposes of this Chapter, 'carrier' means the device by which persons are supported in order to be lifted, lowered or moved.</i></p>	<p>The new definition means carriers for all lifting machinery; chapter 4 is the right place for it, as chapter 4 applies also to lifting operations for machinery lifting persons.</p>	
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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
4.1.2. Protection against mechanical hazards	4.1.2. <i>Protection against mechanical hazards</i>		
4.1.2.1. Risks due to lack of stability	4.1.2.1. Risks due to lack of stability		
Machinery must be designed and constructed in such a way that the stability required by section 1.3.1 is maintained both in service and out of service, including all stages of transportation, assembly and dismantling, during foreseeable component failures and also during the tests carried out in accordance with the instruction handbook. To that end, the manufacturer or his authorised representative must use the appropriate verification methods.	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 authorised representative established within the Community must use the appropriate verification methods; in particular, for self-propelled industrial trucks with lift exceeding 1,80 m, the manufacturer or his authorised representative established within the Community must, for each type of industrial truck concerned, perform a platform stability test or similar test, or have such tests performed.	Actually there is no particular reason to emphasize the stability tests of a certain machinery type. Appropriate verification applies to all machinery as stated. The reason for this particular old requirement is probably in old industrial truck directive 86/663/EEC, which was repealed by the original machinery directive 89/392/EEC as amended by 91/368/EEC.	
4.1.2.2. Machinery running on guide rails and rail tracks	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.	Machinery must be provided with devices which act on the guide rails or tracks to prevent derailment.		
If, despite such devices, there remains a risk of derailment or of failure of a rail or of a running component, devices must be provided which prevent the equipment, component or load from falling or the machinery from overturning.	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	4.1.2.3. Mechanical strength		
Machinery, lifting accessories and their components must be capable of withstanding the stresses to which they are subjected, both in and, where applicable, out of use, under the installation and operating conditions provided for	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.	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.		
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Machinery and lifting accessories must be designed and constructed in such a way as to prevent failure from fatigue and wear, taking due account of their intended use.

The materials used must be chosen on the basis of the intended working environments, with particular regard to corrosion, abrasion, impacts, extreme temperatures, fatigue, brittleness and ageing.

Machinery and lifting accessories must be designed and constructed in such a way as to withstand the overload in the static tests without permanent deformation or patent defect. Strength calculations must take account of the value of the static test coefficient chosen to guarantee an adequate level of safety. That coefficient has, as a general rule, the following values:

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

Machinery must be designed and constructed in such a way as to undergo, without failure, the dynamic tests carried out using the maximum working load multiplied by the dynamic test coefficient. This dynamic test coefficient is chosen so as to guarantee an adequate level of safety: the coefficient is, as a general rule, equal to 1,1.

As a general rule, the tests will be performed at the nominal speeds provided for.

Should the control circuit of the machinery allow for a number of simultaneous movements,

the tests must be carried out under the least favourable conditions, as a general rule by combining the movements concerned.

4.1.2.4. Pulleys, drums, wheels, ropes and chains

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

Drums and wheels must be designed, constructed and installed in such a way that the ropes or chains with which they are equipped can be wound without coming off.

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.

See new 4.1.3, which applies also to static tests.

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>Ropes used directly for lifting or supporting the load must not include any splicing other than at their ends. Splicings are, however, tolerated in installations which are intended by design to be modified regularly according to needs of use.</p>	<p>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).</p>	
<p>Complete ropes and their endings must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 5.</p>	<p>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.</p>	
<p>Lifting chains must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 4.</p>	<p>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.</p>	
<p>In order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of chain and rope used directly for lifting the load and for the rope ends, perform the appropriate tests or have such tests performed.</p>	<p>In order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative established within the Community 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.</p>	
<p>4.1.2.5. Lifting accessories and their components</p>	<p>4.1.2.5. Separate lifting accessories</p>	
<p>Lifting accessories and their components must be sized with due regard to fatigue and ageing processes for a number of operating cycles consistent with their expected life-span as specified in the operating conditions for a given application.</p>	<p>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.</p>	
<p>Moreover:</p>	<p>Moreover:</p>	
<p>(a) the working coefficient of wire-rope/rope-end combinations must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 5. Ropes must not comprise any splices or loops other than at their ends;</p>	<p>(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;</p>	
<p>(b) where chains with welded links are used, they must be of the short-link type. The working coefficient of chains must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;</p>	<p>(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;</p>	

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| <p>(c) the working coefficient for textile ropes or slings is dependent on the material, method of manufacture, dimensions and use. This coefficient must be chosen in such a way as to guarantee an adequate level of safety; it is, as a general rule, equal to 7, provided the materials used are shown to be of very good quality and the method of manufacture is appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety. Textile ropes and slings must not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling;</p> <p>(d) all metallic components making up, or used with, a sling must have a working coefficient chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;</p> <p>(e) the maximum working load of a multilegged sling is determined on the basis of the working coefficient of the weakest leg, the number of legs and a reduction factor which depends on the slinging configuration;</p> <p>(f) in order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of component referred to in (a), (b), (c) and (d), perform the appropriate tests or have such tests performed.</p> | <p>(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;</p> <p>(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;</p> <p>(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;</p> <p>(f) in order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative established within the Community must, for each type of component referred to in (a), (b), (c) and (d) perform the appropriate tests or have such tests performed.</p> |
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4.1.2.6. Control of movements

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

- (a) Machinery must be designed **and constructed** or fitted with devices in such a way that the amplitude of movement of its components is kept within the specified limits. The operation of such devices must, where appropriate, be preceded by a warning.
- (b) Where several fixed or rail-mounted machines can be manoeuvred simultaneously in the same place, with risks of collision, such machinery must be designed and constructed **in such a way as to** make it possible to fit systems enabling these risks to be avoided.

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;

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>(c) Machinery must be designed and constructed in such a way that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine.</p> <p>(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.</p> <p>(e) Holding devices must be designed and constructed in such a way that inadvertent dropping of the loads is avoided.</p>	<p>(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;</p> <p>(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;</p> <p>(e) holding devices must be so designed and constructed that inadvertent dropping of the loads is avoided.</p>		
<p>4.1.2.7. Movements of loads during handling</p> <p>The operating position of machinery must be located in such a way as to ensure the widest possible view of trajectories of the moving parts, in order to avoid possible collisions with persons, equipment or other machinery which might be manoeuvring at the same time and liable to constitute a hazard.</p> <p>Machinery with guided loads must be designed and constructed in such a way as to prevent persons from being injured by movement of the load, the carrier or the counterweights, if any. [See old 4.2.3, 1st para]</p>	<p>4.1.2.7. Handling of loads</p> <p>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.</p> <p>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.</p> <p>4.1.2.8. Lightning</p> <p>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. [Compare with new 1..5.16]</p>	<p>This last requirement now refers also to the risk of contact with the carrier (see also clause 4.1.2.8.3).</p>	
<p>4.1.2.8. Machinery serving fixed landings</p> <p>4.1.2.8.1. <i>Movements of the carrier</i></p> <p>The movement of the carrier of machinery serving fixed landings must be rigidly guided to and at the landings. Scissor systems are also regarded as rigid guidance.</p>		<p>This new clause reflects the fact that construction lifts and lifts with speed under 0.15 m/s are now within the scope of machinery directive; see also new 6.4 concerning the lifting of persons.</p>	
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4.1.2.8.2. Access to the carrier

Where persons have access to the carrier, the machinery must be designed and constructed in such a way as to ensure that the carrier remains stationary during access, in particular while it is being loaded or unloaded.

The machinery must be designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.

4.1.2.8.3. Risks due to contact with the moving carrier

Where necessary in order to fulfil the requirement expressed in the second paragraph of section 4.1.2.7, the travel zone must be rendered inaccessible during normal operation.

When, during inspection or maintenance, there is a risk that persons situated under or above the carrier may be crushed between the carrier and any fixed parts, sufficient free space must be provided either by means of physical refuges or by means of mechanical devices blocking the movement of the carrier.

4.1.2.8.4. Risk due to the load falling off the carrier

Where there is a risk due to the load falling off the carrier, the machinery must be designed and constructed in such a way as to prevent this risk.

4.1.2.8.5. Landings

Risks due to contact of persons at landings with the moving carrier or other moving parts must be prevented.

Where there is a risk due to persons falling into the travel zone when the carrier is not present at the landings, guards must be fitted in order to prevent this risk. Such guards must not open in the direction of the travel zone. They must be fitted with an interlocking device controlled by the position of the carrier that prevents:

- hazardous movements of the carrier until the guards are closed and locked,
- hazardous opening of a guard until the carrier has stopped at the corresponding landing.

[Text from old 4.2.3, 2nd para]

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.

[Text from old 4.2.3 , 1st para]

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.

[Compare with 2nd paragraph of new 4.1.2.7]

“Where necessary” means that, in order to comply with the second paragraph of section 4.1.2.7, a presence-sensing device (for instance) may be used, depending on the findings of the risk assessment.

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>4.1.3. Fitness for purpose</p> <p>When lifting machinery or lifting accessories are placed on the market or are first put into service, the manufacturer or his authorised representative must ensure, by taking appropriate measures or having them taken, that the machinery or the lifting accessories which are ready for use – whether manually or power-operated – can fulfil their specified functions safely.</p> <p>The static and dynamic tests referred to in section 4.1.2.3 must be performed on all lifting machinery ready to be put into service.</p> <p>Where the machinery cannot be assembled in the manufacturer's premises or in the premises of his authorised representative, the appropriate measures must be taken at the place of use. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.</p>	<p>[Text from old 4.2.4, 1st para] <i>When machinery is placed on the market or is first put into service, the manufacturer or his authorised representative established within the Community 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.</i></p> <p>[Text from old 4.1.2.3] <i>The dynamic tests must be performed on machinery ready to be put into service under normal conditions of use.</i></p> <p>[Text from old 4.2.4 2nd para] <i>Where the machinery cannot be assembled in the manufacturer's premises, or in the premises of his authorised representative established within the Community, 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.</i></p>	<p>The specific type of product (in this case "lifting machinery" or "lifting accessory") is indicated when the requirements apply only to it. One should remember that the generic term "machinery" means all products within the scope except partly completed machinery (see article 2).</p> <p>The static and dynamic tests must be performed on all lifting machinery. The reader is invited to note that, in the new requirement, the static test has been added and the sentence "under normal conditions of use" has been cancelled. The conditions for the tests are in the section 4.1.2.3 and may be specified in C standards.</p>	
<p>4.2. REQUIREMENTS FOR MACHINERY WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT</p> <p>4.2.1. Control of movements</p> <p>Hold-to-run control devices must be used to control the movements of the machinery or its equipment. However, for partial or complete movements in which there is no risk of the load or the machinery colliding, the said devices may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.</p>	<p>4.2. Special requirements for machinery whose power source is other than manual effort</p> <p>4.2.1. Controls</p> <p>4.2.1.1. Driving position</p> <p>The requirements laid down in section 3.2.1 also apply to non-mobile machinery.</p> <p>4.2.1.2. Seating</p> <p>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.</p> <p>4.2.1.3. Control devices</p> <p>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 authorising automatic stops at preselected levels without holding a hold-to-run control device.</p>	<p>Concerning old 3.2.1, most of the requirements have been moved to new 1.1.6, 1.1.7 and 1.2.2, which apply to all machinery.</p> <p>Concerning old 3.2.2, the requirements applicable here have been moved to new 1.1.8 which applies to all machinery.</p> <p>See comment on 1.2.5</p>	
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4.2.2. Loading control

Machinery with a maximum working load of not less than 1000 kilograms or an overturning moment of not less than 40 000 Nm must be fitted with devices to warn the driver and prevent dangerous movements in the event:

- of overloading,
 - either as a result of the maximum working load
 - or the maximum working moment due to the load being exceeded, or
- of the overturning moment being exceeded.

4.2.3. Installations guided by ropes

Rope carriers, tractors or tractor carriers must be held by counterweights or by a device allowing permanent control of the tension.

4.2.1.4. Loading control

Machinery with a maximum working load of not less than 1000 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. [Compare with new 4.1.2.7, 2nd para (last sentence) and new 4.1.2.8.3, 2nd para]

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.

[Compare with new 4.1.2.8.2]

4.2.4. Fitness for purpose

When machinery is placed on the market or is first put into service, the manufacturer or his authorised representative established within the Community 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.

[Compare with new 4.1.3]

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>4.3. INFORMATION AND MARKINGS</p> <p>4.3.1. Chains, ropes and webbing</p> <p>Each length of lifting chain, rope or webbing not forming part of an assembly must bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer or his authorised representative and the identifying reference of the relevant certificate.</p> <p>The certificate mentioned above must show at least the following information:</p> <p>(a) the name and address of the manufacturer and, if appropriate, his authorised representative;</p> <p>(b) a description of the chain or rope which includes:</p> <ul style="list-style-type: none"> – its nominal size, – its construction, – the material from which it is made, and – any special metallurgical treatment applied to the material; <p>(c) the test method used;</p> <p>(d) the maximum load to which the chain or rope should be subjected in service. A range of values may be given on the basis of the intended applications.</p> <p>4.3.2. Lifting accessories</p> <p>Lifting accessories must show the following particulars:</p>	<p>Where the machinery cannot be assembled in the manufacturer's premises, or in the premises of his authorised representative established within the Community, 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. [Compare with new 4.1.3.]</p> <p>4.3. Marking</p> <p>4.3.1. <i>Chains and ropes</i></p> <p>Each length of lifting chain, rope or webbing not forming part of an assembly must bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer or his authorised representative established in the Community and the identifying reference of the relevant certificate.</p> <p>The certificate should show the information required by the harmonised standards or, should those not exist, at least the following information:</p> <ul style="list-style-type: none"> – the name of the manufacturer or his authorised representative established within the Community, – the address within the Community of the manufacturer or his authorised representative, as appropriate, – a description of the chain or rope which includes: <ul style="list-style-type: none"> – its nominal size, – 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. <p>4.3.2. <i>Lifting accessories</i></p> <p>All lifting accessories must show the following particulars:</p> <ul style="list-style-type: none"> – identification of the manufacturer, 		
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<ul style="list-style-type: none"> – identification of the material where this information is needed for safe use, 	<ul style="list-style-type: none"> – identification of the material (e.g. international classification) where this information is needed for dimensional compatibility, 	<p>New 1.7.3 Marking of machinery applies to all products. Therefore, the new list of "particulars" has been simplified.</p>
<ul style="list-style-type: none"> – the maximum working load. 	<ul style="list-style-type: none"> – identification of the maximum working load, 	
<p>In the case of lifting accessories on which marking is physically impossible, the particulars referred to in the first paragraph must be displayed on a plate or other equivalent means and securely affixed to the accessory.</p>	<p>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.</p>	<p>The definition of "lifting accessories" is now wider, so there is no need to mention "components".</p>
<p>The particulars must be legible and located in a place where they are not liable to disappear as a result of wear or jeopardise the strength of the accessory.</p>	<p>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 jeopardise the strength of the accessory.</p>	
<h4>4.3.3. Lifting machinery</h4>	<h4>4.3.3. Machinery</h4>	
<p>The maximum working load must be prominently marked on the machinery. This marking must be legible, indelible and in an un-coded form.</p>	<p>In addition to the minimum information provided for in 1.7.3, each machine must bear, legibly and indelibly, information concerning the nominal load:</p>	<p>The generic term "machinery" has been replaced with the specific term "lifting machinery" (see comments on clause 4.1.3).</p>
<p>Where the maximum working load depends on the configuration of the machinery, each operating position must be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the working load permitted for each configuration.</p>	<p>(i) displayed in uncoded form and prominently on the equipment in the case of machinery which has only one possible value;</p>	
<p>Machinery intended for lifting goods only, equipped with a carrier which allows access to persons, must bear a clear and indelible warning prohibiting the lifting of persons. This warning must be visible at each place where access is possible.</p>	<p>(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.</p>	
<p>Machinery intended for lifting goods only, equipped with a carrier which allows access to persons, must bear a clear and indelible warning prohibiting the lifting of persons. This warning must be visible at each place where access is possible.</p>	<p>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.</p>	
<h4>4.4. INSTRUCTIONS</h4>	<h4>4.4. Instruction handbook</h4>	
<h5>4.4.1. Lifting accessories</h5>	<h5>4.4.1. Lifting accessories</h5>	
<p>Each lifting accessory or each commercially indivisible batch of lifting accessories must be accompanied by instructions setting out at least the following particulars:</p>	<p>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:</p>	<p>The requirements in this clause shall be applied in addition to those in clause 1.7.4.</p>

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>(a) the intended use;</p> <p>(b) the limits of use (particularly for lifting accessories such as magnetic or vacuum pads which do not fully comply with section 4.1.2.6(e)); [See the last indent of old 4.4.1]</p> <p>(c) instructions for assembly, use and maintenance;</p> <p>(d) the static test coefficient used.</p>	<p>– normal conditions of use,</p> <p>– instructions for use, assembly and maintenance,</p> <p>– the limits of use (particularly for the accessories which cannot comply with 4.1.2.6 (e)). [See new 4.4.1 (b)]</p>	<p>The additional information in (d) makes it easier to carry out other tests later, e.g. after maintenance or repairs.</p>
<p>4.4.2. Lifting machinery</p> <p>Lifting machinery must be accompanied by instructions containing information on:</p>	<p>4.4.2. Machinery</p> <p>In addition to section 1.7.4, the instruction handbook must include the following information:</p>	<p>The generic term "machinery" has been replaced with the specific term "lifting machinery" (see comments on clause 4.1.3).</p>
<p>(a) the technical characteristics of the machinery, and in particular:</p> <ul style="list-style-type: none"> – the maximum working load and, where appropriate, a copy of the load plate or load table described in the second paragraph of section 4.3.3, – the reactions at the supports or anchors and, where appropriate, characteristics of the tracks, – where appropriate, the definition and the means of installation of the ballast; <p>(b) the contents of the logbook, if the latter is not supplied with the machinery;</p> <p>(c) advice for use, particularly to offset the lack of direct vision of the load by the operator;</p> <p>(d) where appropriate, a test report detailing the static and dynamic tests carried out by or for the manufacturer or his authorised representative;</p> <p>(e) for machinery which is not assembled on the premises of the manufacturer in the form in which it is to be used, the necessary instructions for performing the measures referred to in section 4.1.3 before it is first put into service.</p>	<p>(a) the technical characteristics of the machinery, and in particular:</p> <ul style="list-style-type: none"> – 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; <p>(b) the contents of the logbook, if the latter is not supplied with the machinery;</p> <p>(c) advice for use, particularly to offset the lack of direct sight of the load by the operator;</p> <p>(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.</p>	<p>This means: "the tests required in 4.1.3 (2nd para) for all machinery". "where appropriate" means that this applies only to machinery assembled on the premises of the manufacturer – see also (e) below for machinery not assembled on the premises of the manufacture</p>

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

Machinery intended for underground work must meet **all the essential health and safety requirements** described in this chapter (see **General Principles, point 4**).

5.1. RISKS DUE TO LACK OF STABILITY

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

5.2. MOVEMENT

Powered roof supports must allow for unhindered movement of persons.

5.3. CONTROL DEVICES

The accelerator and brake controls for movement of machinery running on rails must be **hand-operated**. However, **enabling devices** may be foot-operated.

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

5.4. STOPPING

Self-propelled machinery running on rails for use in underground work must be equipped with an **enabling device** acting on the circuit controlling the movement of the machinery **such that movement is stopped if the driver is no longer in control of the movement**.

5.5. FIRE

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

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.

Retained in full in new 1.1.4.

The term "enabling device", as defined in EN ISO 12100-1:2003, clause 3.26.2, has replaced "deadman's control", which was inappropriate.

Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments	
<p>The braking system of machinery intended for use in underground workings must be designed and constructed in such a way that it does not produce sparks or cause fires.</p> <p>Machinery with internal combustion engines for use in underground workings must be fitted only with engines using fuel with a low vaporising pressure and which exclude any spark of electrical origin.</p> <p>5.6. EXHAUST EMISSIONS</p> <p>Exhaust emissions from internal combustion engines must not be discharged upwards.</p>	<p>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.</p> <p>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.</p> <p>5.7. Emissions of dust, gases, etc.</p> <p>Exhaust gases from internal combustion engines must not be discharged upwards.</p>	<p>It should be noted that explosion protection (ATEX) and all kinds of potential ignition sources (electrical and non-electrical) are covered by ATEX-directive 94/9/EC (see new 1.5.7).</p>	
<p>6. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PRESENTING PARTICULAR HAZARDS DUE TO THE LIFTING OF PERSONS</p> <p>Machinery presenting hazards due to the lifting of persons must meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).</p> <p>6.1. GENERAL</p> <p>6.1.1. Mechanical strength</p> <p>The carrier, including any trapdoors, must be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load. [From the 2nd sentence of the 1st para of old 6.1.2]</p> <p>The working coefficients for components set out in sections 4.1.2.4 and 4.1.2.5 are inadequate for machinery intended for the lifting of persons and must, as a general rule, be doubled. [From the 1st paragraph of old 6.1.2].</p>	<p>6. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET THE PARTICULAR HAZARDS DUE TO THE LIFTING OR MOVING OF PERSONS</p> <p>Machinery presenting hazards due to the lifting or moving of persons must be designed and constructed to meet the requirements set out below.</p> <p>6.1. General</p> <p>6.1.1. Definition</p> <p>For the purposes of this Chapter, 'carrier' means the device by which persons are supported in order to be lifted, lowered or moved. [Moved to new 4.1.1 (g); "lowered or moved" being deleted from the new definition]</p> <p>6.1.2. Mechanical strength</p> <p>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.</p> <p>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.</p>	<p>This chapter applies to machinery presenting hazards when lifting persons. Also Part 4 refers to the lifting of persons, but primarily in consideration of the hazards to which are exposed persons who operate around the machinery, while Part 6 refers primarily to the hazards to which are exposed persons who use the machinery to be lifted</p>	
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Machinery intended for lifting persons or persons and goods must be fitted with a suspension or supporting system for the carrier designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk of the carrier falling.

If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.

6.1.2. Loading control for machinery moved by power other than human strength

The requirements of section 4.2.2 apply regardless of the maximum working load and overturning moment, unless

the manufacturer can demonstrate that there is no risk of overloading or overturning.

6.2. CONTROL DEVICES

Where safety requirements do not impose other solutions, the carrier must, as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier.

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

The control devices for these movements must be of the hold-to-run type except where the carrier itself is completely enclosed.

6.1.3. 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.

[See first paragraph of new 6.2]

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.

[See first paragraph of new 6.2]

Hold-to-run control devices are not required if the carrier is fully enclosed. In the old directive, the exception only applied to carriers "serving specific levels".

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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p>6.3. RISKS TO PERSONS IN OR ON THE CARRIER</p> <p>6.3.1. Risks due to movements of the carrier</p> <p>Machinery for lifting persons must be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for persons. [From old 6.4.2]</p> <p>6.3.2. Risk of persons falling from the carrier</p> <p>The carrier must not tilt to an extent which creates a risk of the occupants falling, including when the machinery and carrier are moving. [Compare with old 6.3.3]</p> <p>Where the carrier is designed as a work station, provision must be made to ensure stability and to prevent hazardous movements.</p> <p>If the measures referred to in section 1.5.15 are not adequate, carriers must be fitted with a sufficient number of suitable anchorage points for the number of persons permitted on the carrier. The anchorage points must be strong enough for the use of personal protective equipment against falls from a height.</p> <p>Any trapdoor in floors or ceilings or side doors must be designed and constructed in such a way as to prevent inadvertent opening and must open in a direction that obviates any risk of falling, should they open unexpectedly.</p> <p>6.3.3. Risk due to objects falling on the carrier</p> <p>Where there is a risk of objects falling on the carrier and endangering persons, the carrier must be equipped with a protective roof.</p>	<p>6.3. Risks of persons falling from the carrier</p> <p>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.</p> <p>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.</p> <p>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. [Integrated into 1st para of new 6.3.2]</p> <p>The floor of the carrier must be slip-resistant.</p>	<p>The requirement does not make a protective roof a compulsory requirement. Manufacturers or standards bodies must therefore decide on the basis of the risk assessment.</p>

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<p>6.4. MACHINERY SERVING FIXED LANDINGS</p> <p>6.4.1. Risks to persons in or on the carrier</p> <p>The carrier must be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfil this requirement, the carrier itself must be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless the doors are closed. The doors must remain closed if the carrier stops between landings where there is a risk of falling from the carrier.</p> <p>The machinery must be designed, constructed and, where necessary, equipped with devices in such a way as to prevent uncontrolled upward or downward movement of the carrier. These devices must be able to stop the carrier at its maximum working load and at the foreseeable maximum speed.</p> <p>The stopping action must not cause deceleration harmful to the occupants, whatever the load conditions.</p> <p>6.4.2. Controls at landings</p> <p>Controls, other than those for emergency use, at landings must not initiate movements of the carrier when:</p> <ul style="list-style-type: none"> – the control devices in the carrier are being operated, – the carrier is not at a landing. 	<p>6.4. Risks of the carrier falling or overturning</p> <p>6.4.1. Machinery for the lifting or moving of persons must be designed and constructed to prevent the carrier falling or overturning.</p> <p>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. [Compare with new 6.3.1, which covers this]</p>	<p>The general stability requirements are in the new clauses 4.1.2.1 and 4.1.2.2 which now refer also to lifting of persons.</p> <p>See new 6.3.1 which covers this.</p>
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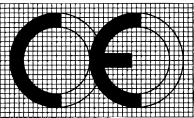
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Directive 2006/42/EC ("new" directive)	Directive 98/37/EC ("old" directive)	Comments
<p data-bbox="145 280 432 309">6.4.3. Access to the carrier</p> <p data-bbox="145 338 576 499">The guards at the landings and on the carrier must be designed and constructed in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons to be lifted.</p> <p data-bbox="145 551 309 580">6.5. MARKINGS</p> <p data-bbox="145 607 520 660">The carrier must bear the information necessary to ensure safety including:</p> <ul data-bbox="145 685 544 790" style="list-style-type: none"> <li data-bbox="145 685 544 739">– the number of persons permitted on the carrier, <li data-bbox="145 763 461 790">– the maximum working load. 	<p data-bbox="584 551 735 580">6.5. Markings</p> <p data-bbox="584 607 983 683">Where necessary to ensure safety, the carrier must bear the relevant essential information.</p>	

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Machinery Directive 2006/42/EC	Comments
<p style="text-align: center;">ANNEX II Declarations</p> <p>1. CONTENT</p> <p>A. EC DECLARATION OF CONFORMITY OF THE MACHINERY</p> <p>This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex I, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.</p> <p>This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.</p> <p>The EC declaration of conformity must contain the following particulars:</p> <ol style="list-style-type: none"> 1. business name and full address of the manufacturer and, where appropriate, his authorised representative; 2. name and address of the person authorised to compile the technical file, who must be established in the Community; 3. description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name; 4. a sentence expressly declaring that the machinery fulfils all the relevant provisions of this Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies. These references must be those of the texts published in the Official Journal of the European Union; 5. where appropriate, the name, address and identification number of the notified body which carried out the EC type-examination referred to in Annex IX and the number of the EC type-examination certificate; 6. where appropriate, the name, address and identification number of the notified body which approved the full quality assurance system referred to in Annex X; 7. where appropriate, a reference to the harmonised standards used, as referred to in Article 7(2); 8. where appropriate, the reference to other technical standards and specifications used; 9. the place and date of the declaration; 10. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative. <p>B. DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY</p> <p>This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex I, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.</p>	<p>A. This is a declaration of conformity for all machinery as listed in Article 1(1) from a to f. There is no more a separate declaration of conformity for safety components.</p> <p>A.2. This is a new requirement to simplify the procedures for market surveillance: a person authorised to compile the technical file must be established in the Community.</p> <p>A.3. The identification of machinery shall be done more clearly – the link between the machinery and the declaration of conformity must be evident.</p> <p>A.4. Now it is clear that only references to directives are required – references to national implementing legislation are not appropriate or required.</p> <p>A.9. Place and date of the declaration were not explicitly required in 98/37/EC, although it is a common practice for this kind of documents.</p> <p>B. The declaration for partly completed machinery is named “declaration of incorporation” for a clear distinction from the declaration for machinery. This declaration shall be drawn up under the same conditions as for machinery.</p>

Machinery Directive 2006/42/EC	Comments
<p>The declaration of incorporation must contain the following particulars:</p> <ol style="list-style-type: none"> 1. business name and full address of the manufacturer of the partly completed machinery and, where appropriate, his authorised representative; 2. name and address of the person authorised to compile the relevant technical documentation, who must be established in the Community; 3. description and identification of the partly completed machinery including generic denomination, function, model, type, serial number and commercial name; 4. a sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives. These references must be those of the texts published in the Official Journal of the European Union; 5. an undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery; 6. a statement that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of this Directive, where appropriate; 7. the place and date of the declaration; 8. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative. 	<p>B.2. See comment A.2. above</p> <p>B.3. See comment A.3. above.</p> <p>B.4. We remind that for partly completed machinery it is not mandatory to fulfil the ESRs of Annex I: it is up to the manufacturer to decide which ESR to apply and to fulfil. It is important for the manufacturer of the final machinery, into which the partly completed machinery will be incorporated, to know which ESRs are applied and fulfilled.</p> <p>B.5. The “relevant information” that may be required by the national authorities is not specified. It may be any kind of information useful for the surveillance of the market. We remind that the relevant technical documentation for the partly completed machinery is required only when one or more essential health and safety requirements are applied and fulfilled.</p>
<p>2. CUSTODY</p> <p>The manufacturer of machinery or his authorised representative shall keep the original EC declaration of conformity for a period of at least 10 years from the last date of manufacture of the machinery.</p> <p>The manufacturer of partly completed machinery or his authorised representative shall keep the original declaration of incorporation for a period of at least 10 years from the last date of manufacture of the partly completed machinery.</p>	<p>Now it is clearly stated that the declarations for both, machinery and partly completed machinery, shall be kept for ten years.</p>
<p style="text-align: center;">ANNEX III CE marking</p> <p>The CE conformity marking shall consist of the initials ‘CE’ taking the following form:</p>  <p>If the CE marking is reduced or enlarged the proportions shown in the above drawing must be respected.</p>	<p>This short annex includes three important new requirements:</p> <ul style="list-style-type: none"> – CE marking must be near the “machinery plate” (or e.g. in that plate) – it must be affixed using the same technique as “machinery plate” – full quality assurance procedure, when used, must be indicated by giving the identification number of notified body <p>(see recital 22)</p>

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. The minimum dimension may be waived for small-scale machinery.

The CE marking must be affixed in the immediate vicinity of the name of the manufacturer or his authorised representative, using the same technique.

Where the full quality assurance procedure referred to in Article 12(3)(c) and 12(4)(b) has been applied, the CE marking must be followed by the identification number of the notified body.

ANNEX IV

Categories of machinery to which one of the procedures referred to in Article 12(3) and (4) must be applied

1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:
 - 1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed;
 - 1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;
 - 1.3. sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;
 - 1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.
2. Hand-fed surface planing machinery for woodworking.
3. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.
4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:
 - 4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;
 - 4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.
5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.
6. Hand-fed tenoning machinery with several tool holders for woodworking.
7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.
8. Portable chainsaws for woodworking.
9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.
10. Injection or compression plastics-moulding machinery with manual loading or unloading.
11. Injection or compression rubber-moulding machinery with manual loading or unloading.
12. Machinery for underground working of the following types:
 - 12.1. locomotives and brake-vans;
 - 12.2. hydraulic-powered roof supports.

Machinery for the production of fireworks and combustion engines used in machinery for underground works have been removed from the list. Other machinery have been added in the list: see following comments.

3. Now only thicknessers "having a built-in mechanical feed device" are covered.

4. This passage has been reworded for a better understanding.

12. Internal combustion engines used in machinery for underground works have been removed. They are not machinery, but partly completed machinery.

Machinery Directive 2006/42/EC	Comments
<p>13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.</p> <p>14. Removable mechanical transmission devices including their guards.</p> <p>15. Guards for removable mechanical transmission devices.</p> <p>16. Vehicle servicing lifts.</p> <p>17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres.</p> <p>18. Portable cartridge-operated fixing and other impact machinery.</p> <p>19. Protective devices designed to detect the presence of persons.</p> <p>20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11.</p> <p>21. Logic units to ensure safety functions.</p> <p>22. Roll-over protective structures (ROPS).</p> <p>23. Falling-object protective structures (FOPS).</p>	<p>15. The guards for removable mechanical transmission devices sold separately, as safety components, are now in this Annex.</p> <p>18. This is new. Portable cartridge operated machinery designed for industrial or technical purpose are now in the scope of the directive (see recital 6 and comment on Article 1.2 d).</p> <p>19. Now all the protective devices designed to detect persons are in this Annex, not only the electro-sensitive ones.</p> <p>20. The specification of these guards has been reworded for a better understanding.</p> <p>21. In 98/37/EC only logic units for two-hand control devices are in the list. This modification is important as electronic and programmable logic units have emerged on the market. It is important that such products provide proper functional safety and reliability whenever performing safety functions.</p>
<p style="text-align: center;">ANNEX V</p> <p style="text-align: center;">Indicative list of the safety components referred to in Article 2(c)</p> <p>1. Guards for removable mechanical transmission devices.</p> <p>2. Protective devices designed to detect the presence of persons.</p> <p>3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in items 9, 10 and 11 of Annex IV.</p> <p>4. Logic units to ensure safety functions.</p> <p>5. Valves with additional means for failure detection intended for the control of dangerous movements on machinery.</p> <p>6. Extraction systems for machinery emissions.</p> <p>7. Guards and protective devices designed to protect persons against moving parts involved in the process on the machinery.</p> <p>8. Monitoring devices for loading and movement control in lifting machinery.</p> <p>9. Restraint systems to keep persons on their seats.</p> <p>10. Emergency stop devices.</p>	<p>This new Annex gives an indicative list of safety components that can be updated in accordance with Article 8 (1)(a).</p> <p>1. These guards are now in Annex IV.</p> <p>2. All these protective devices are now in Annex IV.</p> <p>4. All these logic units are now in Annex IV.</p>

<ol style="list-style-type: none"> 11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges. 12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex I. 13. Systems and devices to reduce the emission of noise and vibrations. 14. Roll-over protective structures (ROPS). 15. Falling-object protective structures (FOPS). 16. Two-hand control devices. 17. Components for machinery designed for lifting and/or lowering persons between different landings and included in the following list: <ol style="list-style-type: none"> (a) devices for locking landing doors; (b) devices to prevent the load-carrying unit from falling or unchecked upwards movement; (c) overspeed limitation devices; (d) energy-accumulating shock absorbers, <ul style="list-style-type: none"> — non-linear, or — with damping of the return movement; (e) energy-dissipating shock absorbers; (f) safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls; (g) electric safety devices in the form of safety switches containing electronic components. 	<p>Although the hazard “tip-over” is dealt with in Annex I clause 3.4.3, TOPS (Tip-Over Protection Structure) is not in this list.</p> <p>It is important to remember that this list of safety components has not to be considered exhaustive.</p> <p>TOPS, according with the definition in Article 2 (c), is a safety component, and there exists even a standard for TOPS (EN 13531:2001 for compact excavators) giving test and performance requirements.</p>
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ANNEX VI

Assembly instructions for partly completed machinery

The assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the final machinery, so as not to compromise safety and health.

The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative.

This new Annex refers to the assembly instructions for partly completed machinery required in Article 13. The requirements concerning the contents of these instructions have been worded in general terms.

Business partners may agree by themselves the language of the instructions.

(We remind that assembly instructions shall not be delivered to the user of the final machinery where the partly completed machinery will be assembled, but shall be stored in the technical file.)

ANNEX VII

A. TECHNICAL FILE FOR MACHINERY

This part describes the procedure for compiling a technical file. The technical file must demonstrate that the machinery complies with the requirements of this Directive. It must cover the design, manufacture and operation of the machinery to the extent necessary for this assessment. The technical file must be compiled in one or more official Community languages, except for the instructions for the machinery, for which the special provisions of Annex I, section 1.7.4.1 apply.

1. The technical file shall comprise the following:
 - (a) a construction file including:
 - a general description of the machinery,
 - the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,

It is important to point out that the procedures for compiling the technical file are now the same for all machineries (in 98/37/EC the procedures are different for annex IV machinery subjected to EC type examination).

The first paragraph clearly states the main purpose of the technical file.

Machinery Directive 2006/42/EC	Comments
<ul style="list-style-type: none"> — full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements, — the documentation on risk assessment demonstrating the procedure followed, including: <ul style="list-style-type: none"> (i) a list of the essential health and safety requirements which apply to the machinery, (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery, — the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards, — any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative, — a copy of the instructions for the machinery, — where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery, — where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery, — a copy of the EC declaration of conformity; <p>(b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of this Directive.</p>	<p>Now the whole risk assessment documentation is required. This is the main change in the content of the technical file. (Directive 98/37/EC requires only the methods adopted to eliminate hazards.) See recital 23. The new EN ISO 14121-1:2007 (resulting from the revision of EN 1050:1996) and the technical report ISO/TR 14121-2:2007 will be important tools both for execution and documentation of the risk assessment process.</p> <p>The declaration of incorporation and the assembly instructions of the partly completed machinery incorporated into the machinery are now required.</p> <p>The EC declaration of conformity of machinery or other products incorporated into the machineries are now required ("other products" are those under directives requiring the CE declaration of conformity).</p> <p>A copy of the EC declaration of conformity is now required</p>
<p>The manufacturer must carry out necessary research and tests on components, fittings or the completed machinery to determine whether by its design or construction it is capable of being assembled and put into service safely. The relevant reports and results shall be included in the technical file.</p> <p>2. The technical file referred to in point 1 must be made available to the competent authorities of the Member States for at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced.</p> <p>The technical file does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. However, it must be capable of being assembled and made available within a period of time commensurate with its complexity by the person designated in the EC declaration of conformity.</p> <p>The technical file does not have to include detailed plans or any other specific information as regards the subassemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the essential health and safety requirements.</p>	<p>Now the relevant reports and results shall be included in the technical file.</p> <p>For the person designated in the EC declaration of conformity as the person authorised to compile the technical file in the Community, see comment in Annex II A2.</p>

3. Failure to present the technical file in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the machinery in question with the essential health and safety requirements.

B. RELEVANT TECHNICAL DOCUMENTATION FOR PARTLY COMPLETED MACHINERY

This part describes the procedure for compiling relevant technical documentation. The documentation must show which requirements of this Directive are applied and fulfilled. It must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the essential health and safety requirements applied. The documentation must be compiled in one or more official Community languages.

It shall comprise the following:

- (a) a construction file including:
- the overall drawing of the partly completed machinery and drawings of the control circuits,
 - full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the partly completed machinery with the applied essential health and safety requirements,
 - the risk assessment documentation showing the procedure followed, including:
 - (i) a list of the essential health and safety requirements applied and fulfilled,
 - (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks,
 - (iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,
 - (iv) any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,
 - (v) a copy of the assembly instructions for the partly completed machinery;
- (b) for series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied.

The manufacturer must carry out necessary research and tests on components, fittings or the partly completed machinery to determine whether by its design or construction it is capable of being assembled and used safely. The relevant reports and results shall be included in the technical file.

This documentation is named "relevant technical documentation" not to be confused with the corresponding "technical file" for machinery.

This documentation shall be compiled by the manufacturer of the partly completed machinery when one or more essential health and safety requirements are applied and fulfilled.

Most of the requirements are similar to those for the technical file of machinery.

Machinery Directive 2006/42/EC	Comments
<p>The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to the competent authorities of the Member States. It does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. It must be capable of being assembled and presented to the relevant authority by the person designated in the declaration for incorporation.</p> <p>Failure to present the relevant technical documentation in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the partly completed machinery with the essential health and safety requirements applied and attested.</p>	
<p style="text-align: center;">ANNEX VIII</p> <p style="text-align: center;">Assessment of conformity with internal checks on the manufacture of machinery</p> <p>1. This Annex describes the procedure by which the manufacturer or his authorised representative, who carries out the obligations laid down in points 2 and 3, ensures and declares that the machinery concerned satisfies the relevant requirements of this Directive.</p> <p>2. For each representative type of the series in question, the manufacturer or his authorised representative shall draw up the technical file referred to in Annex VII, part A.</p> <p>3. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured machinery with the technical file referred to in Annex VII, part A, and with the requirements of this Directive.</p>	<p>This Annex describes the procedure carried out by the manufacturer in accordance with Article 12, Para. 2 for machinery not referred to in Annex IV. The same procedure may be applied to machinery referred to in Annex IV and manufactured in accordance with a harmonized standard (see Article 12, Para 3 (a)).</p>
<p style="text-align: center;">ANNEX IX</p> <p style="text-align: center;">EC type-examination</p> <p>EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative model of machinery referred to in Annex IV (hereafter named the type) satisfies the provisions of this Directive.</p> <p>1. The manufacturer or his authorised representative must, for each type, draw up the technical file referred to in Annex VII, part A.</p> <p>2. For each type, the application for an EC type-examination shall be submitted by the manufacturer or his authorised representative to a notified body of his choice.</p> <p>The application shall include:</p> <ul style="list-style-type: none"> — the name and address of the manufacturer and, where appropriate, his authorised representative, — a written declaration that the application has not been submitted to another notified body, — the technical file. <p>Moreover, the applicant shall place at the disposal of the notified body a sample of the type. The notified body may ask for further samples if the test programme so requires.</p>	<p>In this annex all the procedures for the EC type examinations, and the responsibilities of the notified bodies and of the manufacturers are clearly indicated.</p> <p>1. In the new directive the technical file submitted to the notified body is the same as the technical file required for the assessment of conformity for machinery not referred to in Annex IV. (In directive 98/37 the two procedures require two different types of technical file, specified in two different annexes.)</p>

<p>3. The notified body shall:</p> <p>3.1. examine the technical file, check that the type was manufactured in accordance with it and establish which elements have been designed in accordance with the relevant provisions of the standards referred to in Article 7(2), and those elements whose design is not based on the relevant provisions of those standards;</p> <p>3.2. carry out or have carried out appropriate inspections, measurements and tests to ascertain whether the solutions adopted satisfy the essential health and safety requirements of this Directive, where the standards referred to in Article 7(2) were not applied;</p> <p>3.3. where harmonised standards referred to in Article 7(2) were used, carry out or have carried out appropriate inspections, measurements and tests to verify that those standards were actually applied;</p> <p>3.4. agree with the applicant as to the place where the check that the type was manufactured in accordance with the examined technical file and the necessary inspections, measurements and tests will be carried out.</p> <p>4. If the type satisfies the provisions of this Directive, the notified body shall issue the applicant with an EC type examination certificate. The certificate shall include the name and address of the manufacturer and his authorised representative, the data necessary for identifying the approved type, the conclusions of the examination and the conditions to which its issue may be subject.</p> <p>The manufacturer and the notified body shall retain a copy of this certificate, the technical file and all relevant documents for a period of 15 years from the date of issue of the certificate.</p> <p>5. If the type does not satisfy the provisions of this Directive, the notified body shall refuse to issue the applicant with an EC type-examination certificate, giving detailed reasons for its refusal. It shall inform the applicant, the other notified bodies and the Member State which notified it. An appeal procedure must be available.</p> <p>6. The applicant shall inform the notified body which retains the technical file relating to the EC type-examination certificate of all modifications to the approved type. The notified body shall examine these modifications and shall then either confirm the validity of the existing EC type-examination certificate or issue a new one if the modifications are liable to compromise conformity with the essential health and safety requirements or the intended working conditions of the type.</p> <p>7. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC type-examination certificates. On reasoned request, the Commission and the Member States may obtain a copy of the technical file and the results of the examinations carried out by the notified body.</p> <p>8. Files and correspondence referring to the EC type-examination procedures shall be written in the official Community language(s) of the Member State where the notified body is established or in any other official Community language acceptable to the notified body.</p>	<p>The certificate (and the documentations) shall be retained 15 years from the date of issue. Also if the certificate is not renewed after five years, it shall be retained still ten years from its expiration.</p>
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Machinery Directive 2006/42/EC	Comments
<p>9. Validity of the EC type-examination certificate</p> <p>9.1. The notified body has the ongoing responsibility of ensuring that the EC type-examination certificate remains valid. It shall inform the manufacturer of any major changes which would have an implication on the validity of the certificate. The notified body shall withdraw certificates which are no longer valid.</p> <p>9.2. The manufacturer of the machinery concerned has the ongoing responsibility of ensuring that the said machinery meets the corresponding state of the art.</p> <p>9.3. The manufacturer shall request from the notified body the review of the validity of the EC type-examination certificate every five years. If the notified body finds that the certificate remains valid, taking into account the state of the art, it shall renew the certificate for a further five years. The manufacturer and the notified body shall retain a copy of this certificate, of the technical file and of all the relevant documents for a period of 15 years from the date of issue of the certificate.</p> <p>9.4. In the event that the validity of the EC-type examination certificate is not renewed, the manufacturer shall cease the placing on the market of the machinery concerned.</p>	<p>9. The Notified Bodies shall inform the manufacturer of any change which can have an implication on the validity of the certificates (e.g. the change of the state of the art, the revision or withdrawal of relevant harmonised standards from the Official Journal of the EU, the decisions taken by the competent EU Bodies), and shall withdraw certificates which are no longer valid. The manufacturers of the machinery concerned have the ongoing responsibility of ensuring that the machinery meets the corresponding state of the art. Every five years the manufacturers must request the review of the validity of the EC type-examination certificates and, if the case, they may be renewed for a further five years.</p>
<p style="text-align: center;">ANNEX X Full quality assurance</p> <p>This Annex describes the conformity assessment of machinery referred to in Annex IV, manufactured using a full quality assurance system, and the procedure whereby a notified body assesses and approves the quality system and monitors its application.</p> <p>1. The manufacturer must operate an approved quality system for design, manufacture, final inspection and testing, as specified in point 2, and shall be subject to the surveillance referred to in point 3.</p> <p>2. Quality system</p> <p>2.1. The manufacturer or his authorised representative shall lodge an application for assessment of his quality system to a notified body of his choice.</p> <p>The application shall contain:</p> <ul style="list-style-type: none"> — the name and address of the manufacturer and, where appropriate, his authorised representative, — the places of design, manufacture, inspection, testing and storage of the machinery, — the technical file described in Annex VII, Part A, for one model of each category of machinery referred to in Annex IV which he intends to manufacture, — the documentation on the quality system, — a written declaration that the application has not been submitted to another notified body. 	<p>This Annex describes the new procedure by which a notified body assesses not an individual product, but the manufacturer's quality assurance system for design, manufacture, final inspection and testing of one or more categories of machinery listed in Annex IV. This is a new possibility for the certification of Annex IV machinery. It is already in use in Lifts directive. The lifts with a speed $\leq 0,15$ m/s, which are in Annex IV of this directive (not any more in the scope of Lifts directive), may continue to be certified with this procedure also under the machinery directive as appropriate.</p> <p>The technical file required is that of anyone model of the category of machinery in Annex IV for which the application is lodged. The technical file is required to verify the capacity of the manufacturer to compile the document for the specified category of machinery and whether the contained documents, reports and tests are suitable to ascertain the conformity of the category of machinery with the Directive.</p>

- 2.2. The quality system must ensure conformity of the machinery with the provisions of this Directive. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner, in the form of measures, procedures and written instructions. The documentation on the quality system must permit a uniform interpretation of the procedural and quality measures, such as quality programmes, plans, manuals and records.

It must contain, in particular, an adequate description of:

- the quality objectives, the organisational structure, and the responsibilities and powers of the management with regard to the design and quality of the machinery,
- the technical design specifications, including standards that will be applied and, where the standards referred to in Article 7(2) are not applied in full, the means that will be used to ensure that the essential health and safety requirements of this Directive are fulfilled,
- the design inspection and design verification techniques, processes and systematic actions that will be used when designing machinery covered by this Directive,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
- the inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, and reports on the qualifications of the personnel concerned,
- the means of monitoring the achievement of the required design and quality of the machinery, as well as the effective operation of the quality system.

- 2.3. The notified body shall assess the quality system to determine whether it satisfies the requirements of point 2.2.

The elements of the quality system which conform to the relevant harmonised standard shall be presumed to conform to the corresponding requirements referred to in point 2.2.

The team of auditors must have at least one member who is experienced in the assessment of the technology of the machinery. The assessment procedure shall include an inspection to be carried out at the manufacturer's premises. During the assessment, the team of auditors shall carry out a review of the technical files referred to in point 2.1, second paragraph, third indent to ensure their compliance with the relevant health and safety requirements.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision. An appeal procedure must be available.

- 2.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to ensure that it remains appropriate and effective.

The manufacturer or his authorised representative shall inform the notified body which approved the quality system of any planned change to it.

Machinery Directive 2006/42/EC	Comments
<p>The notified body shall evaluate the proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in point 2.2, or whether a re-assessment is necessary.</p> <p>It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.</p> <p>3. Surveillance under the responsibility of the notified body</p> <p>3.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.</p> <p>3.2. The manufacturer shall, for inspection purposes, allow the notified body access to the places of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, such as:</p> <ul style="list-style-type: none"> — the documentation concerning the quality system, — the quality records provided for in that part of the quality system concerned with design, such as the results of analyses, calculations, tests, etc., — the quality records provided for in that part of the quality system concerned with manufacture, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc. <p>3.3. The notified body shall conduct periodic audits to make sure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report. The frequency of the periodic audits shall be such that a full reassessment is carried out every three years.</p> <p>3.4. Moreover, the notified body may pay the manufacturer unannounced visits. The need for these additional visits and their frequency will be determined on the basis of a visit monitoring system managed by the notified body. In particular, the following factors will be taken into account in the visits monitoring system:</p> <ul style="list-style-type: none"> — the results of previous surveillance visits, — the need to monitor remedial measures, — where appropriate, special conditions attaching to approval of the system, — significant modifications in the organisation of the manufacturing process, measures or techniques. <p>On the occasion of such visits, the notified body may, if necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if a test was carried out, with a test report.</p> <p>4. The manufacturer or his authorised representative shall keep available for the national authorities, for a period of ten years from the last date of manufacture:</p> <ul style="list-style-type: none"> — the documentation referred to in point 2.1, — the decisions and reports of the notified body referred to in point 2.4, third and fourth subparagraphs, and in points 3.3 and 3.4. 	

ANNEX XI

Minimum criteria to be taken into account by Member States for the notification of bodies

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of machines which they inspect, nor the authorised representative of any of these parties. They shall not become involved, either directly or as authorised representatives, in the design, construction, marketing or maintenance of the machines. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.
3. For each category of machinery for which it is notified, the body must possess personnel with technical knowledge and sufficient and appropriate experience to perform a conformity assessment. It must have the means necessary to complete the technical and administrative tasks connected with implementation of the checks in an appropriate manner; it must also have access to the equipment necessary for the exceptional checks.
4. The staff responsible for inspection shall have:
 - sound technical and vocational training,
 - satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
 - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.
5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.
6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.
7. The staff of the body shall be bound to observe professional secrecy with regard to all information obtained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.
8. Notified bodies shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or ensure that they know the situation in respect of relevant standards.
9. Member States may take all necessary measures they regard as necessary in order to ensure that, in the event of cessation of the activities of a notified body, the files of its customers are sent to another body or are made available to the Member State which has notified it.

The minimum requirements are now more specific and have been approximated to those applying to other directives.

The bodies notified under the directive 98/37/EC shall be notified again under the new directive to fulfil these minimum criteria.

8. These new obligations will ensure the technical competence of notified bodies. They must participate in coordination activities for exchange of experience provided for by the Commission in accordance with Article 14 clause 7. They are also obliged to be involved in standardisation process to have a good knowledge on standards against which they have to evaluate machinery.

9. This is a new requirement.

About ETUI-REHS

The Health and Safety Department of the European Trade Union Institute for Research, Education and Health and Safety (ETUI-REHS) aims at promoting high standards of health and safety in European workplaces. It succeeds the former European Trade Union Technical Bureau (TUTB), founded in 1989 by the **European Trade Union Confederation (ETUC)**.

The Health and Safety Department keeps the drafting, transposition and application of European health and safety at work legislation under close review. It set up an Observatory on the application of the European directives to conduct comparative analyses of what changes Community legislation has brought to the different preventive systems of EU countries, and works out common trade union strategies.

The Health and Safety Department provides **expertise** to support the trade union members on the Luxembourg-based Advisory Committee for Health Protection at Work.

It carries out ongoing **research** into fields like risk assessment, the organization of prevention, the gender dimension in workplace health, the participatory design of work equipment, asbestos, stress, and violence in the workplace.

It runs networks of experts in **technical standards development** (ergonomics, safety of machinery) and **dangerous substances** (classification, risk assessment and framing occupational exposure limits).

The Health and Safety Department is an associate member of the European Committee for Standardization (CEN).

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The European Community is not responsible for any use made of the information contained in this publication.

About KAN

The objective of the **Commission for Occupational Health and Safety and Standardization** (Kommission Arbeitsschutz und Normung, **KAN**), is that of ensuring that the greatest possible attention is devoted to OH&S in German, European and international standardization processes. Through its activities, KAN promotes the effective prevention of accidents and occupational diseases, thus assuring a high standard of protection in the working environment, and in turn greater workplace safety.

The goal actively pursued by KAN is for the essential health and safety requirements of European product directives to be adequately supported by harmonized standards.

Based upon the broadest possible consensus among all the groups represented within it, KAN drafts recommendations and position statements on European and international standardization policy and on current and planned standardization projects, in the following areas among others: safety of machinery and electrical equipment; biological, chemical and physical hazards; ergonomics and work organization; personal protective equipment.

To this end, KAN plans and supports studies analyzing areas of standardization, and evaluates the results; analyzes standards from an OH&S perspective, and identifies needs for amendments; maintains close contact with OH&S experts at national, European and international level; holds events for the pooling of information and experience; provides up-to-date information in print and electronic publications.

The Commission comprises five representatives each from employers' organizations, employees' organizations and the state, and one representative each from the industrial BGs and DIN Deutsches Institut für Normung e.V.

Responsibility for KAN lies with **VFA, the Association for the Promotion of Occupational Safety in Europe**. VFA is an association of the industrial BGs, the institutions for statutory accident insurance and prevention. **The German government supports KAN financially in the form of project support.**

