EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Industrial Transformation and Advanced Value Chains
Advanced Engineering and Manufacturing Systems

Guide to application of the Machinery Directive 2006/42/EC

Edition 2.2 – October 2019

(Update of 2nd Edition)

Introduction to the Update of the 2nd Edition

Directive 2006/42/EC is a revised version of the **Machinery Directive**, the first version of which was adopted in 1989. The new Machinery Directive has been applicable since **29th December 2009**. The Directive has the dual aim of harmonising the health and safety requirements applicable to machinery on the basis of a high level of protection of health and safety, while ensuring the free circulation of machinery on the EU market. The revised Machinery Directive does not introduce radical changes compared with the previous versions. It clarifies and consolidates the provisions of the Directive with the aim of improving its practical application.

While the revised Machinery Directive was being discussed by the Council and the European Parliament, the Commission agreed to prepare a new Guide to its application. The purpose of the Guide is to provide explanations of the concepts and requirements of Directive 2006/42/EC in order to ensure uniform interpretation and application throughout the EU. The Guide also provides information about other related EU legislation. It is addressed to all of the parties involved in applying the Machinery Directive, including machinery manufacturers, importers and distributors, Notified Bodies, standardisers, occupational health and safety and consumer protection agencies and officials of the relevant national administrations and market surveillance authorities. It may also be of interest to lawyers and to students of EU law in the fields of the internal market, occupational health and safety and consumer protection.

It should be stressed that only the Machinery Directive and the texts implementing its provisions into national law are legally binding.

The 2nd Edition of the Guide was endorsed by the Machinery Committee on 2 June 2010. In comparison with the 1st Edition, it was completed with comments on Annexes III to XI of the Machinery Directive. Some errors noticed by readers have been corrected. Legal references and terms have been updated in line with the Lisbon Treaty - in particular, where the Directive refers to *'the Community'*, the Guide now refers to *'the EU'*.

Following discussion with the industry, the comments relating to chains, ropes and webbing for lifting purposes in §44, §330, § 340, §341, and §357 have been revised in order to clarify the practical application of the requirements relating to these products.

The 2nd Edition also includes a thematic index to facilitate consultation of the Guide. The numbering of the sections of the Guide is unchanged.

The Guide takes account of the amendment to Directive 2006/42/EC introduced by Regulation (EC) No 569/2009 relating to the regulatory procedure with scrutiny for the Machinery Committee. It also takes account of the provisions of Regulation (EC) No 765/2008 relating to market surveillance, which apply in a complementary way.

The 1st Update to the 2nd Edition of the Guide, further named Edition 2.1, has been completed to include the amendments made to the Machinery Directive by

the Directive 2009/127/EC on Pesticide Equipment and the Regulation (EU) No 167/2013 on the approval and market surveillance of agricultural and forestry vehicles (Tractors). In addition, guidance on "partly completed machinery" and "assemblies" has been added, as well as inserting clarifications and corrections to the concepts of "safety components", "new and used machinery", "marking of machinery". A number of key guidance decisions of the Machinery Working Group have been incorporated into this text.

This Update to the 2nd Edition of the Guide, further named Edition 2.2, contains a number of clarifications and corrections to the concepts of "safety components" and "partly completed machinery", and some edits to ensure coherence with the LVD Guide. There are two newly added paragraphs about the machinery control units (§417) and safety components which are considered to be logic units (§418).

The Guide is published on the Commission's Website EUROPA[1] in English. This updated Edition 2.2 is intended to be a living document, edited and updated with new guidance once approved by the Machinery Working Group. It might be made available in other EU languages, but only the English version will be checked by the Commission. Therefore, in case of doubt, the English version should be taken as the reference.

The Guide can be downloaded and is presented in a printable format. The text of the Directive is presented in boxed red italic type - the comments follow in black type.

The Guide has been prepared with the help of an Editorial Group[2]. The previous Update of the 2nd Edition has been carried out by an external consultant[3] and the Commission, assisted by some of the members of the Editorial Group. This Update has been carried out by the Commission services based on the input from the Editorial Group. The Commission[4] wishes to warmly thank the members of the Editorial Group both for the huge amount of work they have carried out as well as for the efficient, constructive and cooperative spirit in which the drafts have been prepared. In parallel to the work of the Editorial Group, a Machinery Core Group established by Orgalime, including representatives of the main sectors of machinery manufacturing, has provided invaluable input from the industry. The drafts prepared by the Editorial Group have been submitted to the Member States and stakeholders for comments. The Commission

[1] http://ec.europa.eu/growth/sectors/mechanical-engineering/machinery_en

[2] The following people have taken part in the work of the Editorial Group: Lennart Ahnström, Emilio Borzelli, Robert Chudzik, Roberto Cianotti, John Colreavy, Mike Dodds, Cosette Dussaugey, Marcel Dutrieux, Pascal Etienne, Ludwig Finkeldei, Gun Fridfelt, Mikael Holst, Tuiri Kerttula, Andreas Kühn, Thomas Kraus, Patrick Kurtz, Kevin Lane, Leila Martin, Wolfgang Lentsch, Göran Lundmark, Thomas Moessner, Anders Mortensen, Phil Papard, Boguslaw Piasecki, Marc Schulze, Katri Tytykoski, Roger Upfold, Wendy Van Aerschot, Gustaaf Vandegaer, Henk van Eeden, Richard Wilson, Jürg Zwicky.

[3] Phil Papard Consulting.

[4] The Commission representatives: Ian Fraser (until 2013), Felicia Stoica, Mario Gabrielli Cossellu, and Mikhail Simonov.

would also like to thank all those who have made comments. We have tried to take them into account as far as possible.

Of course, the Commission takes full responsibility for the content of the Guide. Readers are invited to communicate any corrections or comments[5] so that they can be taken into account in preparing future updates or a revised 3rd Edition.

Brussels, October 2019

[5] Corrections, comments and suggestions for improvement should be addressed to the functional e-mail box: GROW-MACHINERY@ec.europa.eu.

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(Text with EEA relevance)

PREAMBLE TO THE MACHINERY DIRECTIVE - THE CITATIONS

§1 The citations

The citations included in the preamble to the Machinery Directive indicate the legal basis of the Directive, the opinions expressed by the relevant consultative Committee and the procedure according to which the Directive was adopted.

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.

§2 The legal basis of the Machinery Directive

The legal basis of the Machinery Directive is provided by Article 95 of the EC Treaty (now replaced by Article 114 of the Treaty on the Functioning of the European Union - TFEU) that enables the EU to adopt measures to harmonise the legislation of the Member States in order to ensure the establishment and functioning of the internal market. Such measures must take as a base a high level of protection of the health and safety of people and of the environment.

The Machinery Directive thus has a dual objective: to permit the free movement of machinery within the internal market whilst ensuring a high level of protection of health and safety.

Following the proposal by the Commission, the Machinery Directive was adopted by the European Parliament and the Council, after consulting the Economic and Social Committee, according to the co-decision procedure set out in Article 251 of the EC Treaty (now referred to as the ordinary legislative procedure in Article 294 of the TFEU).

The footnotes to the citation give the references and dates of the successive steps of the procedure. (The Position of the European Parliament of 15 December 2005 was not published in the OJEU).

PREAMBLE TO THE MACHINERY DIRECTIVE - THE RECITALS

§3 The recitals

The recitals introduce the main provisions of the Directive and present the reasons for their adoption. Several of the recitals explain the changes that have been made in the new Machinery Directive compared with Directive 98/37/EC.

The recitals do not have legal force as such and do not usually figure in the national legislation implementing the Directive. However, they help to understand the Directive, in particular, by clarifying the meaning of certain provisions. When interpreting the text of the Directive, the Courts may take the recitals into consideration in order to ascertain the intention of the legislators.

In the following comments, reference is made to the Articles and Annexes of the Directive introduced by each of the recitals. For further explanations, please refer to the comments on the Articles and Annexes concerned.

(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).

§4 The History of the Machinery Directive

The first recital recalls that Directive 2006/42/EC is not an entirely new Directive but is based on Directive 98/37/EC[6] which codified the Machinery Directive 89/392/EEC[7] as amended. Codification means bringing into one legal text the original Directive and its successive amendments:

- Directive 91/368/EEC[8] extended the scope of the Machinery Directive to interchangeable equipment, mobile machinery and machinery for lifting goods. Parts 3, 4 and 5 were added to Annex I.
- Directive 93/44/EEC[9] extended the scope of the Machinery Directive to safety components and machinery for lifting and moving persons. Part 6 was added to Annex I.

[6] OJ L 183, 29.6.1989, p. 9.

[7] 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. OJ L 207, 27.7.1998, p.1.

[8] OJ L 198, 22.7.1991, p. 16.

[9] OJ L 175, 19.7.1993, p. 12.

– Directive 93/68/EEC[10] introduced harmonised provisions relating to the CE-marking.

Directive 98/37/EC was subject to a minor amendment by Directive 98/79/EC relating to the exclusion of medical devices.

Directive 98/37/EC remains in force until 29 December 2009.

Directive 2006/42/EC is termed a recast of the Machinery Directive since the modifications are presented in the form of a new Directive.

Directive 2009/127/EC modified the scope of Directive 2006/42/EC by adding environmental protection risks for "machinery for pesticide application". It introduced a new section in Annex I part 2 to deal with this aspect. Note that it did not extend the scope of the Directive, with respect to the environment, to other types of machinery.

(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.*

§5 The economic and social importance of the Machinery Directive

The second recital underlines the economic and social importance of the dual objectives of the Machinery Directive. The establishment of a harmonised regulatory framework for the design and construction of machinery is of vital economic importance to the European engineering industry. At the same time, safer machinery makes an important contribution to the reduction of the social cost of accidents and damage to health, both in the workplace and in the home.

(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.*

§6 Health and safety

The protection of health and safety is both a fundamental duty and a prerogative of the Member States. Since the Machinery Directive harmonises the health and safety requirements for the design and construction of machinery at EU level, the responsibility of Member States to protect health and safety of people with regard to the risks associated with machinery implies ensuring that the requirements of the Machinery Directive are correctly applied.

[10] OJ L 220, 31.8.1993, p. 1.

(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.

§7 Definitions

The fourth recital underlines the fact that the new Machinery Directive provides a clearer presentation of the scope and includes definitions of the key terms and concepts used in the text. Definitions of terms used in the Directive are given in Article 2 and additional definitions of concepts relating to the essential health and safety requirements are given in sections 1.1.1, 3.1.1 and 4.1.1 of Annex I.

(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.

§8 Inclusion of construction site hoists

Construction site hoists, that were previously excluded from the scope of the Machinery Directive 98/37/EC and the Lifts Directive 95/16/EC, are lifting appliances intended to be temporarily installed for transporting persons or persons and materials to the different levels of a building during construction or repair. The fifth recital explains that such construction site hoists are no longer excluded from the scope of the Machinery Directive. Certain new essential health and safety requirements relating to machinery serving fixed landings have been added to Annex I to deal with specific risks associated with this type of machinery.

With respect to the conformity assessment procedure applicable to construction site hoists, it should also be noted that construction site hoists involving a hazard of falling from a vertical height of more than three metres are included among the devices for the lifting of persons or of persons and goods listed in Annex IV, item 17.

(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.

§9 Inclusion of portable cartridge-operated fixing and other impact machinery

Weapons, including firearms, are excluded from the scope of the Machinery Directive – see §51: comments on Article 1 (2) (d). The sixth recital explains that this exclusion is to be understood in light of the scope of the EU legislation on the control of weapons, which does not apply to equipment designed for industrial or technical purposes only.

Cartridge-operated fixing and other cartridge-operated impact machinery designed for industrial or technical purposes that was excluded from the original Machinery Directive by amending Directive 91/368/EEC, is thus reintroduced into the scope of the new Machinery Directive. In addition, certain essential health and safety requirements relating to specific risks associated with portable fixing and other impact machinery have been added to Annex I. It should be noted that these requirements apply both to cartridge-operated fixing and impact machinery and fixing and impact machinery using other sources of energy – see §280: comments on section 2.2.2 of Annex I. With respect to the conformity assessment of such machinery, it should also be noted that portable cartridge-operated fixing and other cartridge-operated impact machinery is listed in Annex IV, item 18 – see §388: comments on Annex IV, item 18.

For the transitional arrangements mentioned in the last sentence of the sixth recital – see §154: comments on Article 27.

(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).

§10 *Equipment intended for lifting persons with machinery designed for lifting goods*

Exceptional use of machinery designed for lifting goods for the purpose of lifting persons may be subject to national regulations in the framework of provisions implementing Directive 2009/104/EC – see §140: comments on Article 15. Recital 7 implies that equipment placed on the market for such exceptional use with machinery designed for lifting goods is not in the scope of the Machinery Directive. Placing on the market of such equipment may therefore be subject to national regulations.

Equipment for such exceptional use should be distinguished from interchangeable equipment designed to be assembled with lifting machinery in order to confer a new function for lifting persons. Such interchangeable equipment is subject to the machinery Directive[11] – see §388: comments on Annex IV, item 17.

> ***(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).*

§11 *Agricultural and forestry tractors*

The eighth recital refers to the exclusion of agricultural and forestry tractors from the scope of the Machinery Directive for the risks covered by Directive 2003/37/EC. This Directive was replaced by Regulation (EU) No 167/2013 which modified the Machinery Directive to exclude completely Agricultural and Forestry Tractors – see §53: comments on the first indent of Article 1 (2) (e).

> ***(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] See guidance on *Interchangeable equipment for lifting persons and equipment used with machinery designed for lifting goods for the purpose of lifting persons.*

§12 Market surveillance

The term “market surveillance” designates the activity of the authorities of the Member States checking the conformity of products subject to the Directive after they have been placed on the market or put into service and taking the necessary action to deal with non-compliant products. The ninth and tenth recitals introduce several provisions in the new Machinery Directive which establish a stronger legal basis for market surveillance and enforcement action and also provide for the necessary cooperation between the Members States and the Commission in this area – see §93 to §102: comments on Articles 4, §118: comments on Article 9, §122 to §126: comments on Article 11 and §144: comments on Article 19.

> ***(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.*

§13 Formal objection to standards and the safeguard clause

The eleventh recital indicates that the procedure for disputing a harmonised standard (known as a formal objection) and the safeguard procedure for dealing with non-compliant and dangerous products are different procedures that are set out in distinct Articles of the Directive – see §119 to §121: comments on Articles 10, and §122 to §126: comments on Article 11.

> ***(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.*

§14 Regulations on use of machinery

The twelfth recital clarifies the notion of putting into service of machinery that is regulated by the Machinery Directive – see §86: comments on Article 2 (k). Putting into service is to be distinguished from use of machinery that can be regulated by the Member States, in particular, within the framework of the EU legislation on the use of work equipment provided that such national regulations do not conflict with the provisions of this Directive – see §139 and §140: comments on Article 15.

(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.*

§15 Measures to deal with groups of hazardous machinery presenting the same risks

The safeguard procedure set out in Article 11 requires Member States to take the necessary measures to deal with particular models of machinery that fail to comply with the requirements of the Directive and threaten the health and safety of persons. The thirteenth recital introduces a provision which enables measures to be taken at EU level if it becomes clear that an entire group of similar models of machinery give rise to the same risk – see §118: comments on Article 9.

The measures concerned must be submitted to the Machinery Committee according to the regulatory procedure with scrutiny – see §147: comments on Article 22.

(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.*

§16 The state of the art

Recital (14) introduces the concept of 'the state of the art' which shall be taken into account when applying the essential health and safety requirements (EHSRs) set out in Annex I. This concept is very important as it means that the EHSRs are not absolute requirements irrespective of economic cost and technical possibilities available on the market for manufacturers – see §161 and §162: comments on General Principle 3, Annex I.

(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.*

§17 Machinery for consumer use

The Machinery Directive applies both to machinery for use by workers at work and to machinery for use by consumers or providing a service to consumers, i.e. where the consumer either uses the item or would be directly affected by any defect. In general, the design and construction of machinery must take account of the intended use. Recital 15 stresses that the machinery manufacturer must consider whether the machinery is intended to be used by a professional or a non-professional operator or is intended to provide a service to consumers. The Directive includes a specific requirement relating to the drafting of the instructions for machinery intended for use by non-professional operators – see §259: comments on section 1.7.4.1 (d) of Annex I.

> ***(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.*

§18 Partly completed machinery

Recital 16 introduces the concept of partly completed machinery – see §46: comments on Articles 1 (1) (g) and 2 (g). The placing on the market of partly completed machinery is subject to a specific procedure – see §131: comments on Article 13. Partly completed machinery cannot comply fully with the essential health and safety requirements set out in Annex I, since certain of the risks may result from the fact that the machinery is not complete or from the interface between the partly completed machinery and the machinery or assembly of machinery into which it is to be incorporated. However, the manufacturer of partly completed machinery must state, in a Declaration of Incorporation, which of the essential health and safety requirements he has fulfilled – see §385: comments on Annex II 1 B, and §394: comments on Annex VII, B.

> ***(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.*

§19 Trade fairs and exhibitions

Recital 17 introduces the provision that enables manufacturers to exhibit new models of machinery at trade fairs and exhibitions before the conformity of such products with the Machinery Directive has been assessed or to exhibit machinery with certain elements such as, for example, guards removed for demonstration purposes. In such cases, the exhibitor must display an appropriate sign and take adequate safety measures to protect persons from the risks presented by the exhibited machinery – see §108: comments on Article 6 (3).

(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.*

§20 The New Approach and the New Legislative Framework

Recital 18 recalls that the Machinery Directive relies on the regulatory method known as the "New Approach to technical harmonization and standards". The legislation itself sets out the mandatory essential health and safety requirements that products placed on the EU market must fulfil and the procedures for assessing their conformity – see §103: comments on Articles 5 (1) (a), and §163: comments on General Principle 4 of Annex I.

Detailed technical solutions for meeting these essential health and safety requirements are given in European harmonised standards. Application of harmonised standards remains voluntary, but confers a presumption of conformity with the essential health and safety requirements they cover – see §87: comments on Articles 2 (l), and §110: comments on Article 7 (2).

The "New Approach" has been improved and updated by the "New Legislative Framework", through a set of legislative acts such as Regulation (EC) No 765/2008 and Decision 768/2008/EC[12].

(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.

§21 Conformity assessment

Recital 19 refers to the procedures for the person responsible for the CE marking, assessing the conformity of machinery with the essential health and safety requirements

[12] See http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/ and "The 'Blue Guide' on the implementation of EU product rules" http://ec.europa.eu/DocsRoom/documents/12661.

– see §127 to §130: comments on Article 12 – and the rules for the CE marking – see §141: comments on Article 16.

> ***(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.*

§22 Annex IV machinery

The conformity assessment procedure applicable to a given product depends on whether or not it belongs to one of the categories listed in Annex IV which are considered to have a high risk factor or which serve a critical protective function. The different conformity assessment procedures are set out in Annexes VIII, IX and X and the rules for their selection are given in Article 12.

> ***(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 CE-marking

Recitals 21 and 22 introduce the provisions relating to the CE-marking – see §141: comments on Article 16, §250: comments on section 1.7.3 of Annex I, and §387: comments on Annex III.

> ***(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 Risk assessment

Recital 23 refers to the requirement in Annex I on the risk assessment for the machinery which determines the application of the essential health and safety requirements – see §158 and §159: comments on General Principle 1 of Annex I.

(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 technical construction file

The manufacturer's technical construction file referred to in Recital 24 is both a means to enable the market surveillance authorities to check the conformity of machinery after it has been placed on the market and a means for the manufacturer to demonstrate the conformity of his product – see §103: comments on Article 5 (1) (b), §383: comments on Annex II 1 A (2), and §391 to §393: comments on Annex VII A.

(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 Legal remedies

Recital 25 introduces the provisions relating to the rights of manufacturers or other stakeholders subject to decisions taken under the Machinery Directive – see §135: comments on Articles 14 (6), and §145: comments on Article 20.

(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 Enforcement

Recital 26 is a reminder that the national authorities in charge of enforcement of the provisions of the Machinery Directive (the market surveillance authorities) must be able to impose appropriate penalties if those provisions are not correctly applied. The penalties must be foreseen by the national laws and regulations transposing the provisions of the Directive into national law – see §153: comments on Article 26.

(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 Amendment of the Lifts Directive

Recital 27 explains that the new Machinery Directive 2006/42/EC includes an amendment of the Lifts Directive 95/16/EC (replaced by Directive 2014/33/EC as of 20 April 2016) in order to clarify the borderline between the scopes of the two Directives – see §151: comments on Article 24.

(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 Subsidiarity and proportionality

Recital 28 is a justification of the Machinery Directive with respect to the principles of subsidiarity and proportionality set out in Article 5 of the EC Treaty (now Article 5 of the Treaty on European Union – TEU). According to these principles, the EU shall take action only if the same objectives cannot be better achieved by the action of the Member States. It is clear that without the Machinery Directive, manufacturers of machinery would have to apply different rules and procedures for machinery safety in each Member State, which would both constitute a serious obstacle to the internal market and be a less effective means of improving machinery safety.

(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 National correlation tables

Recital 29 refers to an agreement between the European Parliament, the Council and the Commission on improving the quality and transparency of EU law-making. Under the heading of better transposition and application, Member States are encouraged to publish correlation tables showing the relationship between the provisions of the Directive and the measures transposing them into national law. This is important since, while it is the national transposition measures that have force of law, in the dialogue between economic actors, the text of the Machinery Directive itself naturally provides a common reference. A correlation table must also be communicated by the Member States to the Commission together with the text of the measures transposing the Directive into national law – see §153: comments on Article 26.

(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.*

§31 The Machinery Committee

Recital 30 refers to certain measures that can be taken by the Commission after consulting the Machinery Committee – see §116: comments on Articles 8, and §147: comments on Article 22.

THE ARTICLES OF THE MACHINERY DIRECTIVE

Article 1 Scope

1. *This Directive applies to the following products:*

(a) machinery;

(b) interchangeable equipment;

(c) safety components;

(d) lifting accessories;

(e) chains, ropes and webbing;

(f) removable mechanical transmission devices;

(g) partly completed machinery.

2. *The following are excluded from the scope of this Directive:*

(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:

- *agricultural and forestry tractors for the risks covered by Directive 2003/37/EC, with the exclusion of machinery mounted on these vehicles,*
- *motor vehicles and their trailers covered by Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers [(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.*

(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).

Article 2 Definitions

For the purposes of this Directive, 'machinery' designates the products listed in Article 1(1)(a) to (f).

The following definitions shall apply:

(a) 'machinery' means:

– *an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application,*

– *an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion,*

– *an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure,*

– *assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point (g) which, in order to achieve the same*

end, are arranged and controlled so that they function as an integral whole,

- *an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;*

(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;

(c) 'safety component' means a component:

- *which serves to fulfil a safety function,*
- *which is independently placed on the market,*
- *the failure and/or malfunction of which endangers the safety of persons, and*
- *which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.*

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;

. . .

§32 The products covered by the Machinery Directive

Article 1 (1) sets out the scope of the Directive, that is to say the products to which the provisions of the Directive are applicable. Each of the seven categories listed in Article 1 (1), (a) to (g) is subject to a definition given in Article 2, (a) to (g). Consequently, Article 1 must be read together with Article 2. In the following comments, each of the seven

categories of product subject to the Machinery Directive is examined in turn, together with its definition.

> ***Article 2 Definitions***
>
> *For the purposes of this Directive, 'machinery' designates the products listed in Article 1(1)(a) to (f).*
>
> *. . .*

§33 The use of the term 'machinery' in the broad sense

The first product category referred to in Article 1 (1) (a) and defined in Article 2 (a) is machinery. In Article 1 (1) (a) and Article 2 (a) the term *'machinery'* is used in the strict sense. However, the definitions of the product categories set out in Article 2 are preceded by a sentence explaining that the term *'machinery'* is also to be understood in a broad sense to refer to the six product categories referred to in Article 1 (1), (a) to (f).

The obligations set out in the articles of the Directive that apply to machinery shall thus be understood as applying both to machinery in the strict sense referred to in Article 1(1) (a) and also to the products referred to in Article 1(1) (b) to (f): interchangeable equipment, safety components, lifting accessories, chains, ropes and webbing and removable mechanical transmission devices.

This is the case, for example, for the obligations set out in Article 4 (1) on market surveillance, Article 5 (1) relating to placing on the market and putting into service, Article 6 (1) on freedom of movement, Article 7 (1) and (2) on presumption of conformity and harmonised standards, Article 9 on specific measures to deal with potentially hazardous machinery, Article 11 on the safeguard clause, Article 12 on the procedures for assessing the conformity of machinery, Article 15 on installation and use of machinery, Article 16 on CE marking, Article 17 on non-conformity of marking and Article 20 on legal remedies. The obligations set out in these Articles do not apply to partly completed machinery referred to in Article 1 (1) (g).

Where obligations apply to partly completed machinery, this is explicitly stated, for example, in Article 4 (2) on market surveillance, Article 5 (2) relating to placing on the market, Article 6 (2) on freedom of movement and Article 13 on the procedure for partly completed machinery.

Where obligations apply both to machinery in the broad sense and also to partly completed machinery, this is also explicitly stated, for example, in Article 4 (3) on market surveillance and Article 6 (3) on freedom of movement.

In the essential health and safety requirements of Annex I to the Machinery Directive, the term *'machinery'* is generally to be understood in the broad sense to designate any of the product categories referred to in Article 1 (1), (a) to (f). Where certain essential health and safety requirements are applicable to only one or more of these categories, this is explicitly stated or can be inferred from the context. For example, in part 4 of Annex I, certain requirements explicitly apply only to lifting accessories.

§34 Machinery in the strict sense

The product category referred to in Article 1 (1) (a), that is to say machinery in the strict sense, is defined in Article 2 (a). The definition includes five indents. In the following comments, the different elements of each indent of the definition are examined in turn.

Article 2 (a) – first indent

'machinery' means:

– *an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application,*

. . .

§35 The basic definition

The first indent of the definition of *'machinery'* includes the following elements:

. . . *an assembly* **. . .** *consisting of linked parts or components* **. . .**

Products with parts or components that are not linked together in an assembly are not considered as machinery.

This does not preclude the supply of machinery with certain parts disassembled for storage or transport purposes. In such cases, the machinery must be designed and constructed in order to prevent errors of fitting when the separate parts are assembled. This is particularly important if the machinery is intended for untrained non-professional users. The manufacturer must also provide adequate assembly instructions, taking account, where appropriate, of the level of general education and acumen that can reasonably be expected from non-professional users – see §225: comments on section 1.5.4, §259: comments on section 1.7.4.1 (d), and §264: comments on section 1.7.4.2 (i) of Annex I.

. . . *at least one of which moves* **. . .**

Products without moving parts are not considered as machinery.

. . . *fitted with or intended to be fitted with a drive system* **. . .**

The moving parts of machinery are powered by a drive system using one or more sources of energy such as thermal, electric, pneumatic, hydraulic or mechanical energy. The machinery may have a motor using its own source of energy such as thermal energy or energy provided by a battery. It may be connected to one or more external sources of energy such as a supply of electricity or compressed air. Machinery may use mechanical energy supplied by other equipment such as, for example, towed agricultural machinery that is driven by the power take-off of a tractor, or test beds for motor vehicles that are driven by the vehicles being tested; machinery may also be powered by natural sources of energy such as wind or water power.

Usually the manufacturer of complete machinery supplies the machinery fitted with its drive system. However, machines intended to be fitted with a drive system but supplied without it may also be considered as machinery. This provision takes account, for example, of the fact that certain users of machinery prefer to have a homogeneous stock of motors for their machines in order to facilitate maintenance.

For machinery to be supplied without a drive system:

- the manufacturer's risk assessment must take into account all the risks associated with the machinery, including those relating to the drive system to be fitted to the machinery – see §158: comments on General Principle 1 of Annex I;
- the machinery manufacturer must set out in his instructions all the necessary specifications for the drive system to be fitted such as the type, power and means of connection, and provide precise fitting instructions for the drive system – see §264: comments on section 1.7.4.2 (i) of Annex I;
- the conformity assessment of the machinery must cover the specifications of the drive system to be fitted and the fitting instructions;
- the CE-marking on the machinery and the EC Declaration of Conformity that accompanies the machinery must cover the specifications and instructions relating to the drive system to be fitted.

If the above conditions are not fulfilled, machinery without a fully specified drive system must be considered as partly completed machinery (PCM) – see §46: comments on Article 2 (g). In that case, the combination of such partly completed machinery and the drive system must be considered as the final machinery and must be subject to a specific conformity assessment – see §38: comments on the fourth indent of Article 1 (a).

. . . *other than directly applied human or animal effort* ***. . .***

The moving parts of machinery subject to the Machinery Directive must be driven by a source of energy other than directly applied human or animal effort. Machinery driven by directly applied human or animal effort, such as, for example, hand-driven lawn mowers, hand drills or hand-pushed trolleys, which cease to operate as soon as the manual effort is no longer applied, are not subject to the Machinery Directive. Lifting machinery is the only exception to this general rule – see §40: comments on the fifth indent of Article 2 (a).

On the other hand, the Machinery Directive is applicable to machinery driven by manual effort which is not applied directly but stored, for example, in springs or in hydraulic or pneumatic accumulators, so that the machinery can function after the manual effort has ceased.

. . . *which are joined together for a specific application* ***. . .***

Machinery must be useable for a specific application as applying to the complete machine and its intended use. Typical machinery specific applications include, for example, the processing, treatment, or packaging of materials, or the moving of materials, objects or persons.

Article 2 (a) - second indent

. . .

'machinery' means:

. . .

- *an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion,*

. . .

§36 Machinery supplied without connection components

The second indent of the definition of machinery recognises that the characteristics of the components needed to connect a machine on site to the sources of energy and motion may depend on the site where the machinery is to be used or installed. Machinery may therefore be supplied without these components. In that case, the machinery manufacturer must set out in his instructions all the necessary specifications for the safe means of connection – see §264: comments on section 1.7.4.2 (i) of Annex I.

Article 2 (a) – third indent

. . .

'machinery' means:

. . .

— *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,*

. . .

§37 Machinery to be installed on a specific support

The third indent of the definition of machinery refers to machinery intended for installation on a means of transport or in a building or a structure.

Means of transport are, in general, excluded from the scope of the Machinery Directive, but machinery mounted on means of transport are subject to the Machinery Directive - see §54: comments on Article 1 (2) (e). Examples of machinery mounted on means of transport include, for example, loader cranes, tail lifts, tipper bodies, vehicle or trailer-mounted compressors, vehicle-mounted compaction systems, vehicle-mounted concrete mixers, skip loaders, powered winches, tippers, telescopic lifting arms and vehicle-mounted mobile elevating work platforms.

Where such machinery is mounted on road vehicles, road trailers or tractors that are excluded from the scope of the Machinery Directive, the requirements of the Machinery Directive do not apply to the road vehicle, road trailer or tractor itself. However, the requirements of the Machinery Directive apply both to the mounted machinery and to all aspects of the interface between the machinery and the chassis on which it is mounted which may affect the safe travel and operation of the machinery. Machinery mounted on means of transport is therefore distinguished from self-propelled mobile machinery such

as, for example, self-propelled construction machinery or self-propelled agricultural machinery, which is subject to the Machinery Directive in its entirety.

The third indent of the definition of machinery implies that the manufacturer of machinery intended to be installed on a means of transport or installed in a building or a structure is responsible for the conformity of the machinery with the relevant essential health and safety requirements. He must affix the CE-marking on the machinery and draw up and sign the EC Declaration of Conformity. The manufacturer of such machinery must take into account in his risk assessment all the risks associated with the machine, including those relating to installation of the machinery on the chassis of a vehicle or trailer or on a supporting structure – see §158: comments on General Principle 1 of Annex I. The machinery manufacturer shall set out in his instructions the necessary specifications for the supporting structure and provide precise installation instructions – see §264: comments on section 1.7.4.2 (i) of Annex I.

Manufacturers of machinery intended to be installed on means of transport must therefore specify the vehicles or trailers on which the machinery can be safely installed, either by reference to their technical characteristics or, where necessary, by reference to specific models of vehicle.

If a product intended to be installed on a means of transport is not supplied ready to install, for example, if important elements such as the supporting frame or stabilisers are missing, it should rather be considered as partly completed machinery – see §46: comments on Article 2 (g). In that case, the person who assembles the partly completed machinery and the other elements on the means of transport is to be considered as the manufacturer of the final machinery.

Manufacturers of machinery intended to be installed in a building or structure such as, for example, gantry cranes, certain lifts or escalators must specify the characteristics, in particular the load-bearing characteristics, of the structure needed to support the machinery. However, the machinery manufacturer is not responsible for the construction of the building or structure itself – see §262: comments on section 1.7.4.2 (i), and §361: comments on 4.4.2 (a) of Annex I.

The person who installs such a machine on a means of transport or in a building or structure is responsible for carrying out the machinery manufacturers' installation instructions.

The conformity assessment of machinery intended to be installed on a means of transport or in a building or structure covers the machinery itself, the specifications for the supporting structure and the installation instructions. The necessary tests and inspections must be carried out on the machinery installed on its support in order to check the conformity with the essential health and safety requirements. The CE-marking on the machine and the EC Declaration of Conformity that must accompany the machine cover the conformity of the machine itself and the specifications and instructions relating to its installation.

In the case of machinery intended for lifting operations, the manufacturer is responsible for checking the fitness for purpose of the machinery ready to be put into service – see §350 to §352: comments on section 4.1.3, and §361: comments on section 4.4 2 (e) of Annex I.

Certain categories of machinery to be installed in buildings are also subject to Directive 89/106/EC on Construction Products, such as, for example, powered gates, doors, windows, shutters and blinds – see §92: comments on Article 3.

Article 2 (a) – fourth indent

. . .

'machinery' means:

. . .

- *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,*

. . .

§38 Assemblies of machinery

The fourth indent deals with assemblies of machinery consisting of two or more machines or partly completed machines assembled together for a specific application. Assemblies of machinery may be constituted by two units such as, for example, a packaging machine and a labelling machine, or by several units assembled together, for example, in a production line.

The definition of assemblies of machinery indicates that assemblies are arranged and controlled so that they function as an integral whole in order to achieve the same end. For a group of units of machinery or partly completed machinery to be considered as an assembly of machinery, all of these criteria must be fulfilled:

- the constituent units are assembled together in order to carry out a common function, for example, the production of a given product;
- the constituent units are functionally linked in such a way that the operation of each unit directly affects the operation of other units or of the assembly as a whole, so that a risk assessment is necessary for the whole assembly;
- the constituent units have a common control system – see §184: comments on section 1.2.1, and §203: comments on section 1.2.4.4 of Annex I.

A group of machines that are connected to each other but where each machine functions independently of the others is not considered as an assembly of machinery in the above sense.

The definition of assemblies of machinery does not extend to a complete industrial plant consisting of a number of production lines each made up of a number of machines, assemblies of machinery and other equipment, even if they are controlled together by a single production control system. Only if the plant (which may be any combination of machinery, partly completed machinery and other equipment resulting in machinery subject to the Machinery Directive) forms a single integrated line is it subject to the Machinery Directive as an assembly. So for the purpose of applying the Machinery Directive, most industrial plants can be divided into different sections, each of which may be a distinct assembly (of machinery) or even an independent machine (e.g. a mixing vessel). Even a single production line may be divided into separate assemblies and/or

machines if there is no safety related connection between constituent assemblies or machinery.

However, where risks are created by the interfaces with other sections of the plant these must be covered by the installation instructions – see §264: comments on section 1.7.4.2 (i) of Annex I.

It should also be noted that the placing on the market of equipment installed in industrial plants that is not in the scope of the Machinery Directive may be subject to other EU internal market legislation – see §89-92: comments on Article 3.

The person constituting an assembly of machinery is considered as the manufacturer of the assembly of machinery and is responsible for ensuring that the assembly as a whole complies with the health and safety requirements of the Machinery Directive – see § 79: comments on Articles 2 (i). In some cases, the manufacturer of the assembly of machinery is also the manufacturer of the constituent units. However, more frequently, the constituent units are placed on the market by other manufacturers, either as complete machinery that could also operate independently according to the first, second or third indents of Article 2 (a), or as partly completed machinery according to Article 2 (g).

If the units concerned are placed on the market as complete machinery that could also operate independently, they must bear the CE marking and be accompanied by an EC Declaration of Conformity – see §103: comments on Article 5 (1). If they are placed on the market as partly completed machinery, they must not bear the CE-marking, but note that if other legislation providing for CE marking also apply (e.g. ATEX Directive, Radio Equipment Directive, etc.), a CE marking will have been applied, in which case the Declaration of Conformity should state it only covers that legislation. In all cases the partly completed machine must be accompanied by a Declaration of Incorporation under the Machinery Directive together with assembly instructions – see §104: comments on Articles 5 (2), and §131, comments on Article 13.

Assemblies of machinery are subject to the Machinery Directive because their safety depends not just on the safe design and construction of their constituent units but also on the suitability of the units linked together and the safety of the interfaces between them. At the interface modifications to or extra, guarding/protection devices may need to be designed and fitted so that the assembly as a whole is compliant. The risk assessment to be carried out by the manufacturer of an assembly of machinery must therefore cover both the suitability of the constituent units for the safety of the assembly as a whole and the hazards resulting from the interfaces between the constituent units. It must also cover any hazards resulting from the assembly that are not covered by the EC Declaration of Conformity (for machinery) or the Declaration of Incorporation and the assembly instructions (for partly completed machinery) supplied by the manufacturers of the constituent units.

The manufacturer of the assembly of machinery must:

- carry out the appropriate conformity assessment procedure for the assembly of machinery – see §127 to §130: comments on Article 12;

- affix a specific marking (for example, a specific plate) to the assembly of machinery with the information required by section 1.7.3 and, where appropriate, sections 3.6.2, 4.3.3 and 6.5 of Annex I, including the CE marking;
- draw up and sign an EC Declaration of Conformity for the assembly of machinery - see §103: comments on Article 5 (1).
- compile the technical file which must contain the results of the risk assessment and the design details of the interfaces (e.g. guards, linking conveyers, hoppers, feeders and electronic interface devices) between the items. It must also document any modifications that have been made to the constituent units when incorporating the new items into the assembly. The EC Declaration of Conformity for complete machines and the Declaration of Incorporation and the assembly instructions for partly completed machinery incorporated into the assembly of machinery must also be included in the technical file for the assembly of machinery – see §392: comments on Annex VII A 1 (a).

§39 Assemblies comprising new and existing machinery

The Machinery Directive applies to machinery when it is first placed on the market and put into service in the EU. This is, in general, new machinery – see §72: comments on Article 2 (h). Consequently, the assemblies of machinery referred to in the fourth indent of Article 2 (a) are often new assemblies of new machinery. For machinery in service (used at work), the employer must ensure that the conformity and safety of the machinery is maintained throughout its working life, according to the national regulations implementing Directive 2009/104/EC – see §140: comments on Article 15 and following the manufacturer's instructions – see §272, comments on section 1.7.4.2 (r) of Annex I.

Where, one or more of the constituent units of existing assemblies of machinery may be replaced by new units, or new units may be added to an existing assembly of machinery, the question arises as to whether an assembly of machinery comprising new and existing units is, as a whole, subject to the Machinery Directive. It is not possible to give precise criteria for answering this question in each particular case. In doubt, it is therefore advisable for the person constituting such an assembly of machinery to consult the relevant national authorities. However, the following general guidance can be given:

1. If the risk assessment[13] shows that the replacement or the addition of a constituent unit in an existing assembly of machinery does not add a new hazard, nor increase an existing risk, no action is required according to the Machinery Directive for the parts of the assembly that are not affected by the modification. The same applies where there is a new hazard, or an increase in an existing risk, but the existing protective measures present on the assembly before the modification are still sufficient so that the assembly can still be considered safe after modification. However, for those parts of the assembly that are affected by the replacement or the addition of a constituent unit, action under the Machinery Directive will be required. The employer remains responsible for the safety of the whole assembly according to

[13] The risk assessment carried out by the manufacturer, preceding the conformity assessment.

the national provisions implementing Directive 2009/104/EC – see §140: comments on Article 15.

- If the risk assessment[14] for the new unit shows it does not have any safety implications (e.g. by requiring modifications) on the existing assembly and it is a complete machinery that could also operate independently, that bears the CE-marking and is accompanied by an EC Declaration of Conformity, then the addition of this new unit (as a complete machinery) into the existing assembly is to be considered as the installation of the new unit (machinery) and this does not give rise to a new conformity assessment, CE marking or EC Declaration of Conformity for either the new unit (machinery) or the assembly to which is added..
- However, if the new unit to be added to the assembly comprises partly completed machinery (PCM) as defined by Art. 2 (g) , which must be accompanied by a Declaration of Incorporation and assembly instructions, the person incorporating the PCM into the assembly is to be considered as the manufacturer of the new unit (as by incorporating the PCM in the assembly, 'new' machinery is being put into service). He must therefore assess any risks arising from the interface between the PCM, other equipment and the assembly of machinery, fulfil any relevant EHSRs that have not been applied by the manufacturer of the PCM, apply the assembly instructions, draw up an EC Declaration of conformity, compile the technical file for the modified parts of the assembly (essentially how the PCM has been put into service, including any changes to the existing assembly) and affix the CE marking to the new unit as assembled. For example, if a new automatic reel change unit, which is a partly completed machinery, is added to the end of a paper making line which will not affect the main parts of the line, then only the interface design and any modifications to the control system or to the existing assembly will need to be assessed for the purposes of CE marking the unit, as fitted.

2. If the replacement or the addition of new constituent units in an existing assembly of machinery has a substantial impact on the operation or the safety of the assembly as a whole or involves substantial modifications of the assembly, it may be considered that the modification amounts to the constitution of a new assembly of machinery to which the Machinery Directive must be applied. In that case, the whole assembly, including all its constituent units, must comply with the provisions of the Machinery Directive. This may also be required if a new assembly of machinery is constituted from new and second-hand units.

[14] The risk assessment carried out by the manufacturer, preceding the conformity assessment.

Article 2 (a) – fifth indent

. . .

'machinery' means:

. . .

— *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;*

. . .

§40 Manually powered machinery for lifting loads

The fifth indent of the definition of machinery sets out an exception to the general rule that manually powered machinery is excluded from the Machinery Directive. Manually powered machinery intended for lifting loads, whether goods or persons or both, is subject to the Machinery Directive – see §328: comments on section 4.1.1 (a) of Annex I. Examples of such machinery include manually powered hoists and cranes, jacks, lifting tables, pallet and stacker trucks and mobile elevating work platforms. Products which do not lift a load but simply maintain it at a given height are not covered by this definition.

Article 2

. . .

(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;*

§41 Interchangeable equipment

Interchangeable equipment referred to in Article 1 (1) (b) is defined in Article 2 (b). It should be noted that interchangeable equipment is also designated by the term *'machinery'* used in the broad sense – see §33: comments on the first paragraph of Article 2.

In the following comments, the different elements of the definition of interchangeable equipment are examined in turn.

. . . *after the putting into service of machinery or of a tractor* . . .

Interchangeable equipment is equipment that is designed and constructed in order to be assembled with machinery after the basic machinery has been put into service. Equipment that is assembled with machinery by the manufacturer when the machinery is placed on the market and that is not intended to be changed by the user is not considered as interchangeable equipment but is considered as part of the machinery.

One or more items of interchangeable equipment may be supplied by the machinery manufacturer together with the basic machinery or by another manufacturer. In either

case, each item of interchangeable equipment shall be considered as a separate product and must be accompanied by a separate EC Declaration of Conformity, bear the CE marking and be supplied with its own instructions.

> **. . .** *is assembled with that machinery or tractor by the operator himself* **. . .**

The fact that interchangeable equipment is intended to be assembled with the machinery implies that the combination of the basic machinery and the interchangeable equipment functions as an integral whole. Equipment that is used with the machinery but not assembled with it is not to be considered as interchangeable equipment. Equipment that requires significant modifications to the "parent machine" by the user when adding and removing the item or it is not designed to be removed or added on a routine basis, is not regarded as "interchangeable equipment".

> **. . .** *in order to change its function or attribute a new function, in so far as this equipment is not a tool* **. . .**

Interchangeable equipment should not be confused with spare parts that do not change the function of the machinery or attribute a new function to it but that are simply intended to replace worn or damaged parts.

Interchangeable equipment is also distinguished from tools, such as, for example, blades, bits, simple earthmoving buckets, etc. which do not change or attribute a new function to the basic machinery. Tools as such are not subject to the Machinery Directive (although the machinery manufacturer must specify the essential characteristics of tools which may be fitted to the machinery – see §268: comments on section 1.7.4.2 (n) of Annex I.

Examples of interchangeable equipment include equipment assembled with agricultural or forestry tractors for functions such as ploughing, harvesting, lifting or loading, and equipment assembled with earth-moving equipment, for functions such as drilling or demolition. Work platforms intended to be assembled with lifting machinery in order to modify its function for the purpose of lifting persons are interchangeable equipment – see §388: comments on Annex IV, item 17. Other examples of interchangeable equipment are supports intended for assembly with portable hand-held machines to convert them into fixed machines and interchangeable power-feed units for woodworking machinery.

Interchangeable equipment may be placed on the market by the manufacturer of the basic machinery or by another manufacturer. In either case, the manufacturer of the interchangeable equipment must specify in his instructions the machinery with which it can be safely assembled and used, either by reference to the technical characteristics of the machinery or, where necessary, by reference to specific models of machinery. He must also provide the necessary instructions for safe assembly and use of the interchangeable equipment – see §264: comments on section 1.7.4.2 (i) of Annex I.

The manufacturer of the interchangeable equipment must ensure that the combination of the interchangeable equipment and the basic machinery with which it is intended to be assembled fulfils all the relevant essential health and safety requirements of Annex I and must carry out the appropriate conformity assessment procedure.

It should be noted that the assembly of interchangeable equipment with basic machinery may have the effect of creating a combination that belongs to one of the categories of machinery listed in Annex IV. This may be the case, for example, if a support is assembled with hand-held woodworking machine to convert it into fixed machinery such as a circular saw bench or a vertical spindle moulding machine; or when a work platform is assembled with lifting machinery in order to modify its function for the purpose of lifting persons.[15] In such cases, the manufacturer of the interchangeable equipment must carry out a risk assessment for the combination of the interchangeable equipment and the basic machinery and apply one of the conformity assessment procedures foreseen for Annex IV machinery – see §129 and §130: comments on Article 12. The conformity assessment must ensure that the assembly of the interchangeable equipment and the type or types of basic machinery with which it is intended to be assembled complies with all the relevant essential health and safety requirements of Annex I.

The requisite information relating to the conformity assessment of the combination of the interchangeable equipment and the basic machinery shall be mentioned in the EC Declaration of conformity for the interchangeable equipment. The instructions for the interchangeable equipment must also specify the type or types of basic machinery with which the equipment is intended to be assembled and include the necessary assembly instructions – see §264: comments on section 1.7.4.2 (i) and §416: guidance document on interchangeable equipment for lifting persons.

Article 2

. . .

(c) *'safety component' means a component:*

- *which serves to fulfil a safety function,*
- *which is independently placed on the market,*
- *the failure and/or malfunction of which endangers the safety of persons, and*
- *which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.*

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

§42 Safety components

Safety components referred to in Article 1 (1) (c) are defined in Article 2 (c). It should be noted that safety components are also designated by the term *'machinery'* used in the broad sense – see §33: comments on the first paragraph of Article 2.

The safety function serves to fulfil a protective measure to eliminate or, if not possible, to reduce a risk: this action being either inherent in the design or triggered either

[15] See §416: Interchangeable equipment for lifting persons and equipment used with machinery designed for lifting goods for the purpose of lifting persons.

automatically, or through intervention by the operator on the safety component (as is the case with an emergency stop device, seat belt or two-hand control device).

Safety components are considered to be physical devices (like machinery or interchangeable equipment). Software which performs a safety function and which is placed independently on the market is not considered a 'safety component'. However, physical components incorporating software and fulfilling the definition at Art 2 (c) are 'safety components', and may also be 'logic units to ensure safety functions' (item 21, Annex IV – see: §388 Categories of machinery that may be subject to one of the conformity assessment procedures involving a Notified Body).

Many machinery components are critical for the health and safety of persons. However, purely operational components, by virtue of the fourth indent in Article 2 (c) above, are not considered as safety components. Safety components are components intended by the component manufacturer to be fitted to machinery specifically to fulfil a protective role, in addition to any operational duty. Components placed independently on the market that are intended by the component manufacturer for functions that are both safety and operational functions, or that are intended by the component manufacturer to be used either for safety or for operational functions are to be considered as safety components. For example, a hydraulic valve designed and specified as being capable of performing a safety function as well as normal production use, is a "safety component" where other parts of the definition are met. However, a similar valve where the manufacturer markets it only for normal production use would not be considered a safety component. Similarly, a control unit/board delivering safety functions is a "safety component" where the other parts of the definition are met – see §417: Status of machinery control units under the Machinery Directive.

The exclusion of low-voltage switchgear and control gear set out in the fifth indent of Article 1 (2) (k) does not apply to electrical safety components – see §68: comments on Article 1 (2) (k).

The last sentence of the definition refers to the list of safety components given in Annex V. Annex V lists categories of safety component that are commonly fitted to machinery. Examination of the list helps to understand the definition of *'safety component'*. However, the list is indicative, not limitative. In other words, any component that complies with the definition set out in Article 2 (c) is to be considered as a safety component subject to the Machinery Directive, even if it is not it is included in the list given in Annex V.

If, in future, safety components are identified which are not included in the list given in Annex V, for example, innovative safety components, the Commission can adopt an implementing Decision to update the list, after consulting the Machinery Committee according to the Regulatory procedure with scrutiny – see §116: comments on Article 8 (1) (a), and §147: comments on Article 22 (3). However, this procedure is not a requirement for the item to be considered as a "safety component" as this list is only indicative, this guide includes, at paragraph *§*389**,** some other items that meet the definition of "safety components" that are not currently on the list in Annex V.

The second indent of the definition set out in Article 2 (c) implies that only safety components independently placed on the market are subject as such to the Machinery

Directive. Safety components manufactured by a machinery manufacturer to be incorporated in his own machinery are not subject to the Directive as such, although they must enable the machinery to comply with the relevant essential health and safety requirements. It should be noted that when such a manufacturer supplies safety components as spare parts to replace the original safety components on machinery he has placed on the market, they are not subject to the Machinery Directive – see § 48: comments on Article 1 (2) (a).

With respect to the conformity assessment procedure applicable to safety components, it should be noted that certain safety components are listed in Annex IV – see §129 and §130: comments on Article 12, and §388: comments on items 19 to 23 of Annex IV.

Specific guidance on safety fences as a safety component is given in section §411.

Article 2

. . .

(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;*

§43 Lifting accessories

Lifting accessories referred to in Article 1 (1) (d) are defined in Article 2 (d). It should be noted that lifting accessories are also designated by the term *'machinery'* used in the broad sense – see § 33: comments on the first paragraph of Article 2.

Lifting machinery usually has a device for holding the load such as, for example, a hook. Such load holding devices incorporated into lifting machinery are not to be considered as lifting accessories. However, given the varied shape, size and nature of the loads to be lifted, equipment is often placed between the holding device of the lifting machinery and the load, or on the load itself, in order to hold the load during the lifting operation. Such equipment is referred to as a lifting accessory. Products that are independently placed on the market to be incorporated into loads for this purpose are also considered as lifting accessories.

Equipment placed between the holding device of lifting machinery and the load is considered as a lifting accessory, even if it is placed on the market with the lifting machinery or with the load.

The last part of the definition of *'lifting accessories'* states:

> ***. . .*** *slings and their components are also regarded as lifting accessories*

This implies that equipment intended to be used as an independent sling or in a variety of combinations in slings to be made up by a user, for example, to make up a multi-leg sling, is considered as a lifting accessory. On the other hand, components that are intended to be incorporated in slings and that are not intended to be used independently

to make up a sling are not considered as lifting accessories – see §358: comments on section 4.3.2 of Annex I.

The Machinery Committee has drawn up a list of various categories of equipment used for lifting operations, indicating which categories are considered as lifting accessories: see section §412. The list is not exhaustive but is intended to facilitate uniform interpretation and application of the Machinery Directive to lifting accessories.

Lifting accessories are subject to certain specific essential health and safety requirements in Part 4 of Annex I – see §337 to §341: comments on sections 4.1.2.3, 4.1.2.4 and 4.1.2.5, §358: comments on section 4.3.2, and §360: comments on section 4.4.1 of Annex I.

Article 2

. . .

(e) *'chains, ropes and webbing' means chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;*

§44 Chains, ropes and webbing

Chains, ropes and webbing referred to in Article 1 (1) (e) are defined in Article 2 (e).

The products designated by the terms *'chains, ropes and webbing'* are chains, ropes and webbing designed and constructed for incorporation into lifting machinery or lifting accessories for lifting purposes – see §328: comments on section 4.1.1 (a) of Annex I. Chains, ropes or webbing designed for purposes other than lifting are not subject to the Machinery Directive as such. However, chains, ropes or webbing that are designed, constructed and specified by the manufacturer for dual or multiple purposes including lifting purposes are subject to the Directive.

Since chains, ropes and webbing for lifting purposes are among the products designated by the term *'machinery'* used in the broad sense – see §33: comments on the first paragraph of Article 2 - manufacturers of chains ropes and webbing for lifting purposes must fulfil all of the obligations set out in Article 5 (1) – see §103: comments on Article 5 (1).

It should be noted that the products designated by the terms *'chains, ropes and webbing'* are the products placed on the market by the chain, rope or webbing manufacturer in the form of bulk reels, drums, rolls, coils or bundles of chain, rope or webbing. They may be supplied by the chain, rope or webbing manufacturer to distributors, to manufacturers of lifting machinery or lifting accessories, or to users.

The obligations set out in Article 5 (1) apply when the chains, ropes or webbing are first placed on the market. The distributor or user does not become a manufacturer in the sense of the Directive by cutting individual lengths for incorporation into lifting machinery or lifting accessories. Therefore, the obligations set out in Article 5 (1) do not apply again to lengths of chain, rope or webbing cut from the products already placed on the market by the chain, rope or webbing manufacturer. Such lengths are to be considered as components of the lifting machinery or the lifting accessories into which they are incorporated.

However, distributors of chains, ropes and webbing must ensure that the relevant EC Declaration of Conformity, the reference of the certificate setting out the characteristics of the chain, rope or webbing and the manufacturer's instructions are supplied with the cut length of chain, rope or webbing to manufacturers of lifting machinery or lifting accessories or to users – see §83: comments on Article 2 (i), and §357: comments on section 4.3.1 of Annex I.

Article 2

. . .

(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;*

§45 Removable mechanical transmission devices

Removable mechanical transmission devices referred to in Article 1 (1) (f) are defined in Article 2 (f). It should be noted that removable mechanical transmission devices are also designated by the term *'machinery'* used in the broad sense – see §33: comments on the first paragraph of Article 2.

Removable mechanical transmission devices are subject to specific essential health and safety requirements in Part 3 of Annex I – see §319: comments on section 3.4.7 of Annex I.

It should be noted that guards for removable mechanical transmission devices are included as item 1 in the indicative list of safety components set out in Annex V. When they are placed on the market independently, such guards are therefore subject to the Machinery Directive as safety components. However, according to the second sentence of the above definition, when a removable mechanical transmission device is placed on the market together with its guard, it is subject to the Machinery Directive as a single product.

With respect to the conformity assessment procedure, it should also be noted that removable mechanical transmission devices including their guards are listed in Annex IV, item 14, and guards for removable mechanical transmission devices are listed in Annex IV, item 15.

Article 2

. . .

(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;*

§46 Partly completed machinery

Partly completed machinery (PCM) referred to in Article 1 (g) is defined in Article 2 (g). It should be noted that partly completed machinery is not among the products designated by the term *'machinery'* used in the broad sense – see § 33: comments on the first paragraph of Article 2. Partly completed machinery cannot be considered as interchangeable equipment.

The placing on the market of partly completed machinery is subject to a specific procedure – see §104: comments on Article 5 (2), §131: comments on Article 13, §384 and §385: comments on Annex II 1 B, and comments on Annexes VI and VII.

Partly completed machinery subject to the Machinery Directive is a product intended to form machinery that is in the scope of the Machinery Directive after incorporation.

'An assembly which is almost machinery' means that partly completed machinery is a product that is similar to machinery in the strict sense referred in Article 1 (1) (a), that is to say, an assembly consisting of linked parts or components at least one of which moves, but which lacks some elements necessary to perform its specific application. Partly completed machinery must thus undergo further construction in order to become final machinery that can perform its specific application. As an example, industrial robots are usually designed without a specific application until incorporated into the final machinery - see Article 2(g) of the Machinery Directive. The manufacturer of the final machinery takes the necessary measures so that the robot can perform its specific application safely within the assembly. In practice, only an industrial “stand and function alone-robot” provided with both an end-effector and control system so that it can itself perform a specific application, is a complete machinery under the Machinery Directive.

This further construction is not the fitting of a drive system to machinery supplied without a drive system where the drive system to be fitted is covered by the manufacturer's conformity assessment – see §35: comments on the first indent of Article 2 (a) – or the connection on site or with sources of energy or motion – see §36: comments on the second indent of Article 2 (a). Partly completed machinery should also be distinguished from machinery ready to be installed on a means of transport or in a building or a structure – see §37: comments on the third indent of Article 2 (a).

Machinery that meets the definition in the first three indents of Article 2(a) so it can in itself operate independently, performing its specific application – see §35: comments on the first indent of Article 2 (a) – but which only lacks the necessary protective means or safety components, such as guards, is not to be considered as partly completed machinery. Such incomplete machinery does not meet the requirements of the Machinery Directive and must not be CE marked and cannot be placed on the EU/EEA market – see §103: comments on Article 5 (1).

Machinery constructed in situ is not to be considered a PCM because on arrival at site it comprises a number of parts which may not be compliant (unless one or more of those parts meet the definition of a PCM, which includes being specifically intended for incorporation). It is still a machinery to which Machinery Directive applies so it must undergo conformity assessment and CE marking before it is first put into service.

Sometimes complete machinery missing some parts is confused with a PCM. If the missing parts are not constitutional parts of the machinery (e.g. a motor as a source of energy) and do not give rise to substantial impact on the safety of that machinery (so must be considered as part of conformity assessment) and the machinery manufacturer's instructions provide clear information for the installation of the missing parts such that the safety and compliance of the final machinery is guaranteed with the Machinery Directive, then the completion of the machinery can be made later according to those instructions, prior to being put into service for the first time, according to Art 2(a) second indent.

Since partly completed machinery is *'almost machinery'*, it is to be distinguished from machinery components that are not subject to the Machinery Directive as such – see §35: comments on the first indent of Article 2 (a). Machinery components can usually be integrated into a wide range of categories of machinery with different applications.

The second sentence of the definition of partly completed machinery states:

> ***. . .*** *A drive system is partly completed machinery.*

This provision also applies to drive systems ready to be fitted to machinery and not to the individual components of such systems.

For example, an internal combustion engine or a high voltage electric motor placed on the market ready to be fitted, i.e. with the connections necessary for the fitting, to machinery that is subject to the Machinery Directive are to be considered as partly completed machinery. Electric motors that are marketed for a wide variety of uses and hence not specifically designed or equipped for fitting to a particular type of machinery are not partly completed machinery.

It should be noted that most low voltage (50 - 1000 volts a.c. or between 75 and 1500 volts d.c.) electric motors are excluded from the scope of the Machinery Directive and are subject to the Low Voltage Directive 2014/35/EU, unless they are subject to ATEX Directive 2014/34/EU – see §69: comments on Article 1 (2) (k) –, or form part of the drive system discussed above as PCM. It should also be noted that low voltage electric motors for ATEX application are excluded from the LVD. Consequently such motors fall under the scope of the MD – see §69: comments on Article 1 (2) (k).

Machinery Directive does not prescribe requirements for PCM manufacturers to meet the EHSRs of Annex I. However, All EHSRs met by the PCM must be declared on the accompanying Declaration of Incorporation – see § 385: comments on Annex II 1 B. PCMs must be accompanied by assembly instructions which should include the essential information to enable safe incorporation, including, where relevant, for the final machine's control system, the relevant data on safety performance/reliability - see §417: Status of machinery control units under the Machinery Directive. This is particularly important where a control unit/board is an integral part of the PCM and delivers safety functions (note: the control board need not be supplied in the same enclosure as the PCM, but must be marketed as a single PCM product).

Manufacturers of final machinery are advised to check the Declaration of Incorporation, technical specifications and the assembly instructions prior to purchasing, to satisfy themselves that the PCM is suitable for integration into the final machinery.

The Machinery Directive does not apply as such to separate machinery components or subassemblies such as, for example seals, ball-bearings, pulleys, elastic couplings, solenoid valves, hydraulic cylinders, and the like, that do not have a specific application and that are intended to be incorporated into machinery; unless they fulfil one of the other definitions of products, e.g. a safety component, that are in the scope of the Machinery Directive by virtue of Art 2 (b) to (f), or are partly completed machinery as defined by Art. 2(g). The complete machinery incorporating such components must comply with the relevant essential health and safety requirements. The machinery manufacturer must therefore choose components with adequate specifications and characteristics. Component manufacturers may provide customers with relevant technical documentation to allow such subassemblies and components, to be installed correctly and safely. As these items are not in the scope of the Machinery Directive, the component manufacturers are not required to provide any declarations of conformity or to produce a technical file according to Annex VII or assembly instructions to Annex VI.

§47 Products excluded from the scope of the Machinery Directive

The scope of the Machinery Directive set out in Article 1 (1) is limited in two ways:

- Certain products corresponding to the definitions set out in Articles 2 (a) to (g) are explicitly excluded from the scope of the Machinery Directive. The list of explicitly excluded products is set out in Article 1 (2), (a) to (l).
- According to Article 3 – *Specific Directives*, the Machinery Directive does not apply to products listed in Article 1 (1) for the risks covered more specifically by other EU legislation. When these specific Directives cover all the risks associated with the products concerned, such products are entirely excluded from the scope of the Machinery Directive. When the specific Directives only cover certain of the risks associated with the products concerned, as for example ignition sources (according to the ATEX Directive 2014/34/EU), such products remain in the scope of the Machinery Directive for the other risks – see §89 to §91: comments on Article 3.

Article 1 (2)

(a) *Safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery;*

§48 Safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery

The exclusion set out in Article 1 (2) (a) concerns only components identical to components manufactured by the machinery manufacturer and fitted to their own machinery. Such components are not subject to the Machinery Directive as such because they are not placed on the market independently – see §42: comments on Article 2 (c).

When such a machinery manufacturer supplies identical components as spare parts to replace the original components, those spare parts do not thereby become subject to

the Machinery Directive. It is important not to take the term “identical” too far, it should be taken to refer to the identical parameters of the unit. This means the exemption also applies in cases where the exact same components are no longer available and the machinery manufacturer supplies spare parts with the identical safety function and with the identical safety performance as the components that were originally fitted to the machinery.

Article 1 (2)

. . .

(b) *Specific equipment for use in fairgrounds and/or amusement parks;*

§49 Equipment for use in fairgrounds and/or amusement parks

Equipment designed and constructed specifically for use in fairground or amusement parks is excluded from the scope of the Machinery Directive by Article 1 (2) (b). This includes powered seating to contain or restrain a person, or move in response to other stimuli, such as a simulator experience, but only where specifically intended for use in fairgrounds or amusement parks (see also comments on electrically-operated furniture at §64). The design and construction of equipment specifically intended for use in fairgrounds or amusement is not subject to any EU legislation and may therefore be subject to national regulations. It can be noted that there are two European standards for such equipment[16].

Use of such equipment by workers (for example, during erection, dismantling or maintenance operations) is subject to national provisions implementing Directive 2009/104/EC on use of work equipment by workers at work – see §140: comments on Article 15.

Article 1 (2)

. . .

(c) *machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;*

§50 Machinery for nuclear purposes

The exclusion set out in Article 1 (2) (c) concerns machinery specially designed for the purposes of the nuclear power industry or for the production or processing of radioactive materials, the failure of which may result in an emission of radioactivity.

Machinery used in the nuclear power industry, such as fork lift trucks, cranes and generators, which do not give rise to a risk of emission of radioactivity and/or failure of which do not directly generate radioactive emission, are not excluded from the scope of the Machinery Directive.

[16] EN 13814:2004 *Fairground and amusement park machinery and structures - Safety;* EN 13782:2005 *Temporary structures - Tents - Safety.*

The machinery concerned by the exclusion set out in Article 1 (2) (c) is also to be distinguished from machinery incorporating radioactive sources, for example, for the purposes of measurement, non-destructive testing or preventing the accumulation of static electric charge. As they are not designed or used for nuclear purposes and thus are not excluded from the scope of the Machinery Directive – see §232: comments on section 1.5.10 of Annex I.

It should be noted that the use of radioactive sources may be subject to authorisation and control according to the national provisions implementing Directive 96/29/Euratom and Directive 2003/122/Euratom[17].

Article 1 (2)

. . .

(d) *weapons, including firearms;*

§51 Weapons, including firearms

As explained in Recital 6, the exclusion of weapons, including firearms, set out in Article 1 (2) (d), is to be understood in light of the scope of the EU legislation on control of the acquisition and possession of weapons set out in Annex I to Council Directive 91/477/EEC[18]. Section III (b) of that Annex excludes devices designed for industrial or technical purposes provided that they can be used for the stated purpose only.

Consequently, the exclusion of weapons, including firearms, from the scope of the Machinery Directive does not extend to cartridge-operated fixing and other cartridge-operated impact machinery designed for industrial or technical purposes – see §9: comments on Recital 6.

§52 Means of transport

The exclusions relating to various means of transport are set out in the five indents of Article 1 (2) (e). In the following comments, these indents are examined in turn.

[17] Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. OJ L 159, 29.06.1996 p. 1; Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources. OJ L 346, 31.12.2003, p. 57.

[18] OJ L 256, 13.9.1991, p. 51.

Article 1 (2) (e) – first indent[19]

the following means of transport:

. . .

— *agricultural and forestry tractors for the risks covered by Directive 2003/37/EC, with the exclusion of machinery mounted on these vehicles.*

. . .

§53 Agricultural and forestry tractors

The exclusion set out in the first indent of Article 1 (2) (e) concerns agricultural and forestry tractors covered by Regulation 167/2013 on the approval and market surveillance of agricultural and forestry vehicles (Tractors) which replaced Directive 2003/37/EC on 1st January 2016. The amendment brought to Article 1(2)(e) of the Machinery Directive, is removing the reference to the exclusion being only for the risks covered by that Directive. Such tractors supplied under Regulation 167/2013 as of 1 January 2016 are completely excluded from the Machinery Directive. However, there is a two-year transition period where tractors supplied under national legislation implementing Directive 2003/37/EC can still be supplied up to 31st December 2017, and are thus also in scope of the Machinery Directive 2006/42/EC.

This change was made because at the time the new Machinery Directive was adopted; the Tractors Directive did not deal with all the risks associated with the use of tractors. The new Regulation 167/2013 was drafted to cover all risks including those previously covered by the Machinery Directive, and so a complete exclusion could be made. This change was anticipated when the Machinery Directive 2006/42/EC was adopted, the following joint declaration was made by the European Parliament, the Council and the Commission:

> *The Parliament, the Council and the Commission declare that, in order to cover all aspects related to the health and safety of agricultural and forestry tractors in one harmonising Directive, the Directive 2003/37/EC on type-approval of agricultural and forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units needs to be modified so as to address all the relevant risks of the Machinery Directive.*
>
> *Such a modification of Directive 2003/37/EC should include an amendment of the Machinery Directive, in order to delete the expression "for the risks" in Article 1 (2) (e), first indent.*
>
> *The Commission recognises the need to include in the agricultural and forestry tractors directives further requirements for risks not yet covered by these directives. To this end, the Commission is considering appropriate measures that include references to United Nations regulations, CEN and ISO standards and OECD codes.*

[19] Article 1(2)(e) was amended by Regulation (EU) 167/2013 on the approval and market surveillance of agricultural and forestry vehicles.

It is important to note that the exclusion relating to agricultural and forestry tractors applies only to the tractors themselves and not to their trailers, to towed or pushed machinery or to mounted or semi-mounted machinery on the tractor.

Examples of mounted and semi-mounted machinery that are in scope of the Machinery Directive are: telescopic booms; digging equipment; post drivers; cutting devices mounted under tractors and equipment for vegetation maintenance. Where the tractor is designed with such items fitted in the production process, whether an integral part of the tractor or not, they are still considered as being "mounted" and so are in scope of the Machinery Directive. Where the "vehicle" is primarily designed for a task such that it does not meet the definition of an agricultural vehicle in Regulation (EU) No 167/2013, such as some models of telescopic material handler, then it is considered a product under the Machinery Directive.

Trailers and interchangeable towed machinery are in the scope of both Tractors Regulation 167/2013 and the Machinery Directive.

The requirements for the safe road circulation of such trailers and towed machinery are harmonised by Regulation (EU) No 167/2013 while the health and safety requirements of such machinery remain subject to the Machinery Directive.

Article 1 (2) (e) – second indent

. . .

the following means of transport:

. . .

— *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, with the exclusion of machinery mounted on these vehicles,*

. . .

§54 Four-or-more-wheeled road vehicles and their trailers

The exclusion set out in the second indent of Article 1 (2) (e) concerns motor vehicles and their trailers. When Directive 2006/42/EC was adopted, the type-approval of such vehicles was covered by Council Directive 70/156/EEC. As from 29 April 2009, Directive 70/156/EEC is replaced by Directive 2007/46/EC[20] This Directive applies to power-driven vehicles having at least four wheels, with a maximum design speed exceeding 25 km/h, designed and constructed in one or more stages for use on the road, and of systems, components and separate technical units designed and constructed for such vehicles, as well as non-self-propelled vehicles on wheels designed and constructed to the towed by a motor vehicle.

Article 2 (3) of Directive 2007/46/EC foresees the possibility of optional type-approval or individual approval for mobile machinery, while stating that such optional approvals shall

[20] Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles. OJ L 263, 9.10.2007, p. 1.

be without prejudice to the application of the Machinery Directive 2006/42/EC. Consequently, any mobile machinery subject to type-approval or individual approval for circulation on the road remains subject to the Machinery Directive for all risks other than those linked to road circulation.

Vehicles not intended for use on the road such as, for example, off-road quads, ATVs, go-karts, golf-carts buggies and snowmobiles, are subject to the Machinery Directive, unless they are exclusively intended for competition – see §56: comments on Article 1 (2) (e) – fourth indent.

The same is true of vehicles with a maximum design speed not exceeding 25 km/h such as, for example, certain compact road sweepers.

Machinery mounted on road vehicles or trailers such as, for example, loader cranes, tail-lifts, vehicle or trailer-mounted compressors, vehicle-mounted compaction systems, vehicle mounted concrete mixers, skip loaders, powered winches, tipper bodies and vehicle or trailer-mounted mobile elevating work platforms, are subject to the Machinery Directive – see §37: comments on Article 2 (a) – third indent.

Article 1 (2) (e) – third indent

. . .

— *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,*

. . .

§55 Two- and three-wheeled road vehicles

The exclusion set out in the third indent of Article 1 (2) (e) concerns vehicles covered by Directive 2002/24/EC[21] which applies to two or three-wheel motor vehicles, whether twin-wheeled or otherwise, intended to travel on the road.

The exclusion does not apply to vehicles not intended for use on the road such as, for example, off-road motorcycles, which are thus subject to the Machinery Directive unless they are exclusively intended for competition – see §56: comments on Article 1 (2) (e) – fourth indent.

The exclusion does not apply to vehicles with a maximum design speed of less than 6 km/h, pedestrian controlled vehicles, vehicles intended for use by the physically handicapped, off-road vehicles, or electrically power assisted cycles (EPACs or pedelecs) that are outside the scope of Directive 2002/24/EC. These categories of two or three-wheel motor vehicles are therefore subject to the Machinery Directive.

Hoverboards or self-balancing scooters, which commonly have a single or pair of wheels on either side, are also subject to the Machinery Directive unless explicitly covered by the Toys Directive 2009/48/EC[22].

[21] OJ L 124, 9.5.2012, p. 1.

[22] OJ L 170, 30.6.2009, p.1

Article 1 (2) (e) – fourth indent

. . .

— *motor vehicles exclusively intended for competition,*

. . .

§56 Motor vehicles intended for competition

The exclusion set out in the fourth indent of Article 1 (2) (e) concerns motor vehicles intended for competition. Such vehicles are excluded from the scope of the Machinery Directive whether they are intended for road use or for off-road use.

The exclusion concerns vehicles exclusively intended for competition, thus, for example, vehicles intended for leisure use that may also be used for informal competitions are not excluded. The main criterion to be applied to judge whether vehicles are to be considered as exclusively intended for competition is whether they are designed according to the technical specifications laid down by one of the officially recognised racing associations.

For competition motorcycles, competition quads or All-Terrain Vehicles (ATVs) and competition snowmobiles, the technical specifications are laid down by the FIM (Fédération Internationale de Motocyclisme) and its national affiliated federations. To assist market surveillance authorities to distinguish competition models from others, the FIM publishes on its Website the list of competition motorcycles, quads and snowmobiles that comply with its technical specifications and that participate in national or international motor sports competitions organized under the auspices of the international federation and its national affiliates.

Article 1 (2) (e) – fifth indent

. . .

— *means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport;*

§57 Means of transport by air, on water and on rail networks

According to the exclusion set out in the fifth indent of Article 1 (2) (e), the Machinery Directive does not cover any kind of aircraft or means of water-borne transport. This exclusion applies as well to hovercrafts[23].

Craft subject to the Recreational Craft Directive 94/25/EC as amended by Directive 2003/44/EC are excluded from the scope of the Machinery Directive. The Machinery Directive does not therefore apply to inboard and stern-drive engines that are considered as part of the craft.

Concerning "unmanned aerial vehicles" or "drones", they can be considered as covered by the Machinery Directive 2006/42/EC as long as they are not treated as "means of transport", so not in the specific exclusion for aircrafts stated in the Directive (e.g.

[23] Decision of the Machinery Working Group on 5 November 2014.

specially designed and constructed for military or police purposes or designed and constructed for transporting loads, as well as drones covered by the Directive 2009/48/EC for toys). In addition, other EU legislation can apply to drones according to the specific characteristics of the product, such as the Electromagnetic Compatibility (EMC) Directive 2014/30/EU or the Radio Equipment Directive (RED) 2014/53/EC.

However, the Machinery Directive is applicable to outboard engines, with the exception of the requirements that are specifically included in the Recreational Craft Directive 2013/53/EU relating to the owner's manual, the handling characteristics of the craft, the starting of outboard engines and exhaust and noise emissions.

Machinery mounted on water-borne vessels, such as, for example floating cranes, drills, excavators and dredgers, are not excluded from the scope of the Machinery Directive. It should be noted that lifting appliances fitted on a means of transport are subject to the Machinery Directive – see §151: comments on Article 24.

The exclusion of means of transport on rail networks concerns machinery intended for the transport of persons and/or goods on international, national, regional, suburban or urban rail networks or on rail systems connected to such networks. Railway turnouts (also known as points or switches) are not covered by the Machinery Directive[24] and they are subject to Directive 2008/57/EC[25] on the interoperability of the rail system.

On the other hand, machinery intended for use on rail systems not connected to such networks such as, for example, self-propelled machinery running on rails for underground work, are in the scope of the Machinery Directive.

Machinery intended for use on rail networks that is not intended for the transport of persons and/or goods such as, for example, railbound machinery for the construction, maintenance and inspection of the rail track and structures, is also in the scope of the Machinery Directive. The same goes for machinery mounted on railbound vehicles, such as, for example, loader cranes and mobile elevating work platforms.

Article 1 (2)

(f) *Seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;*

§58 Seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units

Seagoing vessels and mobile offshore units such as, for example, mobile drilling rigs, and machinery installed on them are excluded from the scope of the Machinery Directive by Article 1 (2) (f) since they are subject to the Conventions of the International Maritime Organisation.

[24] Decision of the Machinery Working Group on 23 March 2015.

[25] OJ L191, 18.7.2008, p. 1.

Some of the equipment concerned by this exclusion may also be subject to the Marine Equipment Directive 96/98/EC[26] as amended by Directive 2002/75/EC[27].

A mobile offshore unit is an offshore unit that is not intended to be located on the oil field permanently or for the long term, but is designed to be moved from location to location, whether or not it has a means of propulsion or of lowering legs to the seafloor. There are three main types of offshore units for drilling: jack-up; semi-submersible and drill-ship.

However, permanently placed floating units intended for production, such as, for example, FPSOs (Floating Production, Storage and Offloading installations - usually based on tanker designs) and FPPs (Floating Production Platforms - based on semi-submersible vessels) and the machinery installed on such units are not excluded from the scope of the Machinery Directive.

Machinery on permanently placed offshore platforms such as, for example, oil production rigs, and machinery which is designed to be used on both fixed and mobile offshore units is also subject to the Machinery Directive.

Article 1 (2)

(g) *Machinery specially designed and constructed for military or police purposes;*

§59 Machinery for military or police purposes

The exclusion set out in Article 1 (2) (g) applies to machinery specially designed and constructed for defence purposes or for the purpose of maintaining order. Ordinary machinery used by the armed forces or by the police but which is not specially designed for defence purposes or for the purpose of maintaining order is subject to the Machinery Directive.

In some countries, certain fire services belong to the military, however machinery designed for use by such fire-fighters is not thereby considered to be designed and constructed for military purposes and is thus subject to the Machinery Directive.

Article 1 (2)

(h) Machinery specially designed and constructed for research purposes for temporary use in laboratories;

§60 Machinery for research purposes

The exclusion set out in Article 1 (2) (h) was introduced since it was not considered reasonable to submit to the requirements of the Machinery Directive laboratory equipment specially designed and constructed for the needs of particular research projects. Consequently, the exclusion does not apply to machinery permanently installed in laboratories that may be used for general research purposes or to machinery installed

[26] OJ L 46 of 17/2/1997, p. 25.

[27] OJ L 254, 23/9/2002, p. 1.

in laboratories for purposes other than research such as, for example, for testing purposes.

The exclusion only applies to equipment designed and constructed for temporary research use, that is to say, equipment that will cease to be used when the research projects for which it was designed and constructed have been completed.

Article 1 (2)

(i) *Mine winding gear;*

§61 Mine winding gear

The exclusion set out in Article 1 (2) (i) concerns lifts equipping mine shafts. Mine winding gear is also excluded from the scope of the Lifts Directive 95/16/EC. It was considered that such lifts were specific installations the characteristics of which varied according to the site and which gave rise to few obstacles to trade. Mine winding gear thus remains subject to national regulations.

It should be noted that this exclusion concerns installations in the mine shaft. Lifts installed in other parts of a mine are not concerned by the exclusion and thus may be subject to either the Lifts Directive or the Machinery Directive, as the case may be – see §90: comments on Article 3, and §151: comments on Article 24.

Article 1 (2)

(j) *Machinery intended to move performers during artistic performances;*

§62 Machinery intended to move performers during artistic performances

The exclusion set out in Article 1 (2) (j) concerns machinery intended to be used to move performers in the course of the artistic performance. Such equipment is excluded from the scope of the Machinery Directive and the Lifts Directive 95/16/EC, since application of the requirements of these Directives could be incompatible with the artistic function of the equipment concerned – see §151: comments on Article 24.

The exclusion does not apply to machinery intended only to move objects such as, for example, scenery or lighting, or to machinery intended to move persons other than the performers such as, for example, technicians.

It should also be noted that the exclusion does not concern other equipment, such as escalators or lifts, designed for moving persons in theatres or other entertainment premises for purposes not directly linked to the execution of the artistic performance. Such equipment is subject to either the Lifts Directive or the Machinery Directive, as the case may be – see §90: comments on Article 3, and §151: comments on Article 24.

Article 1 (2)

(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:*

— household appliances intended for domestic use,

— audio and video equipment,

— information technology equipment,

— ordinary office machinery,

— low-voltage switchgear and control gear,

— electric motors.

§63 Machinery covered by the Low Voltage Directive

One of the objectives of the revision of the Machinery Directive was to clarify the borderline between the scope of the Machinery Directive and the Low Voltage Directive 2014/35/EU[28] (replacing Directive 2006/95/EC from 20 April 2016) in order to provide greater legal certainty.

Article 1 (2) (k) lists the categories of low voltage electrical and electronic machinery that are excluded from the scope of the Machinery Directive.

Electrical machinery that is not in any of the categories listed in Article 1 (2) (k) (and that is not concerned by one of the other exclusions) is in the scope of the Machinery Directive. When such machinery has an electrical supply within the voltage limits of the Low Voltage Directive (between 50 and 1000 V for alternating current or between 75 and 1500 V for direct current), it must fulfil the safety objectives of the Low Voltage Directive – see §222: comments on section 1.5.1 of Annex I. However, in that case, the manufacturer's EC Declaration of Conformity should not refer to the Low Voltage Directive.

On the other hand, low voltage electrical equipment placed on the market independently for incorporation into machinery is subject to the Low Voltage Directive as such[29].

Article 1 (2) (k) – first indent

. . .

– household appliances intended for domestic use,

. . .

[28] OJ L 96, 29.3.2014, p. 357.

[29] See the *Guidelines on the application of the Directive*, available on http://ec.europa.eu/growth/sectors/electrical-engineering/lvd-directive/.

§64 Household appliances intended for domestic use

Concerning the exclusion mentioned in the first indent of Article 1 (2) (k), several clarifications are necessary:

- the expression *'household appliances'* designates equipment intended for housekeeping functions such as washing, cleaning, heating, cooling, cooking, etc. Examples of household appliances include washing machines, dish washers, vacuum cleaners and machinery for food preparation and cooking, and machinery for domestic personal care, such as hair dryers, shavers, etc. On the other hand, electrical gardening machinery or electrical power tools intended for construction and repair work in the home are not concerned by this exclusion and are subject to the Machinery Directive;
- the exclusion concerns appliances *'intended for domestic use'*, in other words, appliances intended for use by private persons (consumers) in the home environment. Thus appliances for the housekeeping functions mentioned above that are intended for commercial or industrial use are not excluded from the scope of the Machinery Directive;
- electrically operated furniture, such as beds, chairs, tables, storage furniture including kitchen furniture, remain subject to the Machinery Directive as they are not household appliances of the types indicated above. This includes electrically-operated furniture which 'entertains', e.g. by responding to a sound or film track, events in a video game, 'simulates' function such as machinery at shows or exhibitions, or provides a non-medical stimuli (e.g. for relaxation), unless the products are specifically intended for use in fairgrounds or amusement parks – see §49 comments on the exclusion of Article 1 (2) b. However, where provided for medical purposes such that they are within scope of the Directive 93/42/EEC (as amended)[30] concerning medical devices, that Directive applies instead of the Machinery Directive.
- drives for storage furniture (such as the powered movement of kitchen storage unit doors, flaps, drawers and similar applications) and powered table/desk tops may be placed on the market either as:
  - partly completed machinery according to Article 2 (g) if all the provisions of Article 13 are fully applied (see the comments at §46), or
  - as complete machinery according to Article 2 (a) if all the provisions of Article 5 are applied (see the end of §35 - comments on the definition of machinery).
- electrically operated furniture incorporating multiple drives for the opening or closing of doors, drawers or lift-ups (including those in separate units located in the same room) are not to be considered an assembly of machinery unless the criteria of the fourth indent of Article 2 (a) are fully met (see §38 Assemblies of machinery).
-

While it is possible for a consumer to acquire an appliance intended for commercial use or for a commerce to acquire an appliance intended for domestic use, the criterion to be

[30] OJ L 169, 12.7.1993, p. 1.

taken into account for determining the intended use is the use intended and stated by the manufacturer of the appliance in his product information or his Declaration of Conformity. Evidently, this statement must accurately reflect the foreseeable use of the product.

Article 1 (2) (k) – second indent

. . .

- *audio and video equipment,*

. . .

§65 Audio and video equipment

The exclusion mentioned in the second indent of Article 1 (2) (k) concerns equipment such as, for example, radio and television receivers, tape and video players and recorders, CD and DVD players and recorders, amplifiers and loud speakers, cameras and projectors.

Article 1 (2) (k) – third indent

. . .

- *information technology equipment,*

. . .

§66 Information technology equipment

The exclusion mentioned in the third indent of Article 1 (2) (k) concerns equipment used for the processing, conversion, transmission, storage, protection and retrieval of data or information. The equipment concerned includes, for example, computer hardware, communication network equipment and telephone and telecommunication equipment.

The exclusion does not extend to electronic equipment incorporated into machinery such as, for example, programmable electronic control systems, which is considered as an integral part of the machinery subject to the Machinery Directive and must enable the machinery to fulfil the relevant essential health and safety requirements of Annex I to the Directive. Certain devices incorporating information technology equipment may also be subject to the Machinery Directive as safety components.

Article 1 (2) (k) – fourth indent

. . .

- *ordinary office machinery,*

. . .

§67 Ordinary office machinery

The exclusion set out in the fourth indent of Article 1 (2) (k) applies to electrical equipment such as, for example, printers, copiers, fax machines, sorters, binders and staplers.

This exclusion does not concern machinery with similar functions intended for use in industries such as, for example, the printing or paper industries, additive printing machinery for producing 3-dimentional products in home, office, laboratory or similar environments, or production printers (even when for use in office environments).

The exclusion of ordinary office machinery does not extend to electrically powered office furniture which is subject to the Machinery Directive.

Article 1 (2) (k) – fifth indent

. . .

- *low-voltage switchgear and control gear,*

. . .

§68 Low-voltage switchgear and control gear

Low voltage switchgear and control gear referred to in the fifth indent of Article 1 (2) (k) are devices for making and breaking the current in electrical circuits and associated control, measuring and regulating equipment for the control of electrical energy using equipment.

Such equipment is not subject to the Machinery Directive as such. Where such equipment is incorporated into machinery, it must enable the machinery to fulfil the relevant essential health and safety requirements of Annex I to the Machinery Directive.

It should also be noted that this exclusion does not apply to low voltage electrical safety components – see §42: comments on Article 2 (c).

Article 1 (2) (k) – sixth indent

. . .

- *electric motors;*

§ 69 Electric motors

The exclusion set out in the sixth indent of Article 1 (2) (k) implies that electric motors that are in the scope of the Low Voltage Directive 2014/35/EU (that is to say, electric motors with an electricity supply within the voltage limits and that are not listed in Annex II of that Directive) are subject to the Low Voltage Directive only.

An electric motor is a device for converting electrical energy into mechanical energy. The exclusion applies to the motor itself without a specific application and without additional mechanical elements of a drive system.

The exclusion also applies to low voltage electric motor-generators which are similar devices for converting mechanical energy into electrical energy. On the other hand, generator sets, comprising a source of mechanical energy such as, for example, an internal combustion engine, and an electric generator, are subject to the Machinery Directive.

The exclusion does not apply to electric motors that are intended for use in potentially explosive atmospheres and that are subject to the ATEX-Directive 2014/34/EU, because such motors are excluded from the Low Voltage Directive. Electric motors that are intended for use in potentially explosive atmospheres are therefore subject to the Machinery Directive.

Article 1 (2)

(l) *the following types of high-voltage electrical equipment:*

- *switch gear and control gear,*
- *transformers.*

§ 70 High-voltage electrical equipment

The high-voltage electrical equipment excluded by Article 1 (2) (l) comprises switch gear and control gear and transformers forming part of or connected to a high-voltage electricity supply (above 1000 V for alternating current or above 1500 V for direct current).

This high-voltage electrical equipment is not subject to the Machinery Directive as such. Where such equipment is incorporated into machinery, it must enable the machinery to fulfil the relevant essential health and safety requirements of Annex I to the Machinery Directive – see §222: comments on section 1.5.1 of Annex I.

Article 2

(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;*

§ 71 The definition of 'placing on the market'

The term *'machinery'* in the definition of 'placing on the market' is used in the broad sense, that is to say, the definition applies to the placing on the market of any of the products listed in Article 1, (a) to (f) and defined in Article 2 (a) to (f) – see §33: comments on the first paragraph of Article 2 – as well as to partly completed machinery.

The Machinery Directive applies to machinery or partly completed machinery placed on the EU market. It does not apply to products manufactured in the EU with a view to being placed on the market or put into service in countries outside the EU, although certain of these countries may have national regulations based on the Machinery Directive or accept machinery on their market that complies with the Directive.

§ 72 New and used machinery

Machinery is considered as placed on the market when it is made available in the EU for the first time. The Machinery Directive therefore applies to all new machinery placed on

the market or put into service in the EU, whether such machinery is manufactured in the EU or outside the EU.

In general, the Machinery Directive does not apply to the placing on the market of used or second-hand machinery. In some Member States, the placing on the market of used or second-hand machinery is subject to specific national regulations. Otherwise the putting into service and use of second-hand machinery for professional use is subject to the national regulations on the use of work equipment implementing the provisions of Directive 2009/104/EC – see §140: comments on Article 15.

There is one exception to this general rule. The Machinery Directive applies to used or second-hand machinery that was first made available with a view to distribution or use outside the EU when it is subsequently placed on the market or put into service for the first time in the EU.[31] The person responsible for placing on the market or putting into service such used machinery for the first time in the EU, whether he is the manufacturer of the machinery, an importer, a distributor or the user himself, must fulfil all the obligations set out in Article 5 of the Directive.

The question arises as to when a transformation of machinery is considered as construction of new machinery subject to the Machinery Directive. It is not possible to give precise criteria for answering this question in each particular case. In doubt, it is therefore advisable for the person placing such rebuilt machinery on the market or putting it into service to consult the relevant national authorities.

§73 The stage at which the Machinery Directive applies to machinery

The definition of 'placing on the market', together with the definition of 'putting into service' given in Article 2 (k), determines the stage at which machinery must comply with the relevant provisions of the Directive. The manufacturer or his authorised representative must have fulfilled all their obligations relating to the conformity of machinery when it is placed on the market or put into service – see §103: comments on Article 5.

Placing on the market refers to each individual item of machinery or partly completed and not to a model or type. The relevant provisions of Directive 2006/42/EC therefore apply to all items of machinery or partly completed machinery placed on the market as from 29th December 2009 – see §153: comments on Article 26.

The Machinery Directive does not apply to machinery before it is placed on the market or put into service. In particular, machinery transferred by the manufacturer to his authorised representative in the EU in order to fulfil all or part of the obligations set out in Article 5 is not considered to be placed on the market until it is made available with a view to distribution or use – see §84 and §85: comments on Article 2 (j). The same goes for machinery still under construction, transferred by a manufacturer from manufacturing facilities outside the EU with a view to its completion in manufacturing facilities in the EU.

[31] Machinery first placed on the market in countries that subsequently acceded to membership of the European Union is considered as having been placed on the market in the EU.

The manufacturer may need to operate or test the machinery or parts of it during construction, assembly, installation or adjustment before it is placed on the market or put into service. In that case, he must take the necessary precautions to protect the health and safety of operators and other exposed persons when carrying out such operations, in accordance with the national regulations on health and safety at work and on the use of work equipment implementing the provisions of Directives 89/391/EEC and 2009/104/EC – see §140: comments on Article 15. However, the machinery concerned is not required to comply with the provisions of the Machinery Directive until it is placed on the market or put into service.

Particular rules apply to machinery exhibited at trade fairs, exhibitions and demonstrations – see §108: comments on Article 6 (3).

§ 74 The legal and contractual forms of placing on the market

Placing on the market is defined as making machinery available with a view to distribution or use. Making machinery available implies that the machinery will be transferred from the manufacturer to another person such as a distributor or a user. However, it could be that the distribution operation is part of the manufacturer's own business, in which case it is when the item moves from the production area/factory to the distribution warehouse ready to be supplied. There is no restriction as to the legal or contractual form of this transfer.

In many cases, but not exclusively, placing on the market involves a transfer of the ownership of the machinery from the manufacturer to the distributor or user in exchange for payment (for example, sale or hire-purchase). In other cases, placing on the market may take other contractual forms (such as, for example, lease or rental). In such cases, the right to use the machinery is granted in exchange for payment, without transfer of ownership. The Machinery Directive applies to such machinery when it is first subject to a lease or rental contract in the EU. The Machinery Directive does not apply when used machinery that was first placed on the market according to the Machinery Directive is subject to subsequent lease or rental contracts in the EU. Rental or lease of used machinery may be subject to national regulations – see §140: comments on Article 15.

Placing on the market includes any offer for distribution, consumption or use on the EU market which could result in actual supply (e.g. an invitation to purchase, advertising campaigns) and this includes the general offer to supply into the EU on the internet. Therefore, if a machine is offered or advertised for supply (and hence use) on the internet into the EU it is considered as being placed on the market in the same way as a machine may be advertised for supply in a newspaper or magazine, and so the machinery must comply with the Machinery Directive.

Machinery is also considered to be placed on the market if it is made available with a view to distribution or use free of charge (for example, as a gift or a loan).

Placing on the market is considered not to take place where a machine is introduced from a third country in the EU customs territory and has not been released for free

circulation. This includes the cases of products in transit, placed in free zones, warehouses or temporary storage[32].

§ 75 Auctions

Auctions held in free zones

One of the ways in which machinery is placed on the market is through auctions. Such auctions may be held in a free zone[33]. The main purpose of holding auctions in a free zone is to sell new and used machinery from outside the EU for use in countries outside the EU. Machinery sold for that purpose is not considered to be placed on the market in the EU.

On the other hand, the machinery offered for sale at such an auction is considered to be placed on the market or put into service in the EU if and when it leaves the free zone in order to be distributed or used in the EU. If the machinery concerned is new or is used machinery that is placed on the market or put into service in the EU market for the first time, and if the manufacturer of the machinery concerned or his authorised representative has not fulfilled his obligations according to the Machinery Directive, the person who purchases the machinery at the auction and brings it from the free zone into the EU with a view to its distribution or use is to be considered as the person placing the machinery on the market or putting it into service in the EU and must fulfil all the obligations set out in Article 5.

Auctions held outside free zones

If an auction is held in the EU outside a free zone, it can be assumed that the machinery is being offered for sale with a view to its distribution or use in the EU and it is therefore to be considered as placed on the market in the EU.

If machinery offered for sale at an auction held in the EU outside a free zone is new, whether manufactured in or outside the EU, it must comply with the relevant provisions of the Machinery Directive. The same goes for used machinery offered for sale at such an auction if it is placed on the market in the EU for the first time – see §72: comments on Article 2 (h).

If the manufacturer of the machinery concerned or his authorised representative has not fulfilled his obligations according to the Machinery Directive, the person offering the machinery for sale at such an auction (the consignor) is to be considered as the person placing the machinery on the market in the EU and must therefore fulfil all the

[32] See Council Regulation (EEC) No 2913/92 establishing the Community customs code.

[33] The EU has "Free Zones" which allow for temporary storage of goods prior to being exported or re-exported from the customs territory of the EU or brought into another part of the customs territory of the EU – see Articles 155 to 161 of Regulation (EC) No 450/2008 of the European Parliament and of the Council of 23 April 2008 laying down the Community Customs Code (Modernised Customs Code). OJ L 145, 4.6.2008, p. 1. Zone are subject to customs supervision and do not benefit from the free circulation in the internal market. Before benefiting from the free circulation in the internal market, these goods must be declared for release for free circulation. That entails application of commercial policy measures, completion of the other formalities laid down in respect of the importation of goods and the charging of any duties legally due.

obligations of the manufacturer set out in Article 5. These obligations include ensuring that the machinery satisfies the relevant essential health and safety requirements, ensuring that the technical file is available, providing the instructions, carrying out the appropriate conformity assessment procedure, drawing up and signing the EC Declaration of Conformity of the machinery and affixing the CE-marking – see §81: comments on Article 2 (i).

The auctioneer who organises the sale by auction of such machinery offered for sale by consignors is be considered as a distributor and must therefore ensure that the machinery bears the CE marking, is accompanied by the EC Declaration of Conformity drawn up and signed by the manufacturer or his authorised representative and is accompanied by instructions – see §83: comments on Article 2 (i).

§ 76 Placing on the market of assemblies of machinery

Assemblies of machinery that are assembled in user's premises by a person other than the user are considered to be placed on the market when the assembly operations have been completed and the assembly is handed over to the user for use – see §38: comments on Article 2 (a) – fourth indent, and §79: comments on Article 2 (i).

§ 77 Placing on the market of partly completed machinery

Partly completed machinery is considered to be placed on the market when it is made available to a manufacturer of complete machinery or of an assembly of machinery into which it is to be incorporated – see §46: comments on Article 2 (g).

Article 2

(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;*

§ 78 The definition of 'manufacturer'

The obligations created by the Machinery Directive relating to the conformity of machinery and partly completed machinery fall on the manufacturer or his authorised representative. These obligations are summarised in Article 5. The definition of *'manufacturer'*, together with the following definition of 'authorised representative', determine who shall fulfil these obligations. It is important to understand that the term manufacturer used here is not the same as used in general language, this is explained below in § 79.

The term *'machinery'* in the definition of *'manufacturer'* is used in the broad sense, that is to say, the definition applies to the manufacturer of any of the products listed in Article 1,

(a) to (f) and defined in Article 2 (a) to (f) – see §33: comments on the first paragraph of Article 2. The definition also applies to the manufacturer of partly completed machinery.

§ 79 Who is the manufacturer?

A manufacturer can be a natural or legal person, that is to say, an individual or a legal entity such as a company or association. The process of design and construction of machinery or partly completed machinery may involve several individuals or companies, but in this case one of them must take the responsibility, as the manufacturer, for the conformity of the machinery or partly completed machinery with the Directive. However, the term manufacturer in this Directive also can apply to other persons who have the responsibilities for conformity assessment and CE marking – see §81: comments on Article 2 (i).

Since the essential health and safety requirements of the Directive mainly concern the design and construction of machinery, the person who is in the best position to fulfil these requirements is clearly the person who actually designs and constructs the machinery, or who at least controls the design and construction process. In some cases, the manufacturer may design and construct the machinery himself. In other cases, all or part of the design or the construction of the machinery may be carried out by other persons (suppliers or sub-contractors). However, the person who assumes the legal responsibility for the conformity of the machinery or the partly completed machinery with a view to its being placed on the market under his own name or trademark must ensure sufficient control over the work of his suppliers and sub-contractors and possess sufficient information to ensure that he is able to fulfil all his obligations under the Directive as set out in Article 5 – see §105: comments on Article 5 (3).

A person constituting an assembly of machinery is considered as the manufacturer of the assembly – see §38: comments on Article 2 (a). Usually, the elements constituting an assembly of machinery are supplied by different manufacturers, however one person must assume the responsibility for the conformity of the assembly as a whole. This responsibility can be assumed by the manufacturer of one or more of the constituent units, by a contractor or by the user. If a user constitutes an assembly of machinery for his own use he is considered as the manufacturer of the assembly – see §80 below.

§ 80 A person manufacturing machinery for his own use

A person who manufactures machinery for his own use is considered as a manufacturer and must fulfil all the obligations set out in Article 5. In that case, the machinery is not placed on the market, since it is not made available by the manufacturer to another person but used by the manufacturer himself. However, such machinery must comply with the Machinery Directive before it is put into service – see §86: comments on Article 2 (k). The same goes for a user constituting an assembly of machinery for his own use – see §79 above.

§ 81 Other persons who may be considered as manufacturers

The provision set out in the second sentence of the definition of *'manufacturer'* is intended to deal with the situation that arises for certain machinery imported into the EU. If a machinery manufacturer established outside the EU takes the decision to place his

products on the market in the EU, he is able to fulfil his obligations under the Machinery Directive himself or mandate an authorised representative to perform all or part of these obligations on his behalf – see §84 and §85: comments on Article 2 (j). In this case a person purchasing such CE marked machinery from outside the EU does not take on "the manufacturers" duties. On the other hand, the decision to import non-CE marked machinery into the EU may be taken by an importer, distributor or user. In some cases, the machinery may be ordered from an intermediary such as an export company. In other cases, a person may purchase the machinery outside the EU and bring it into the EU himself, order machinery via the Internet, or purchase machinery in a free zone (such as an auction site) with a view to its distribution or use in the EU.

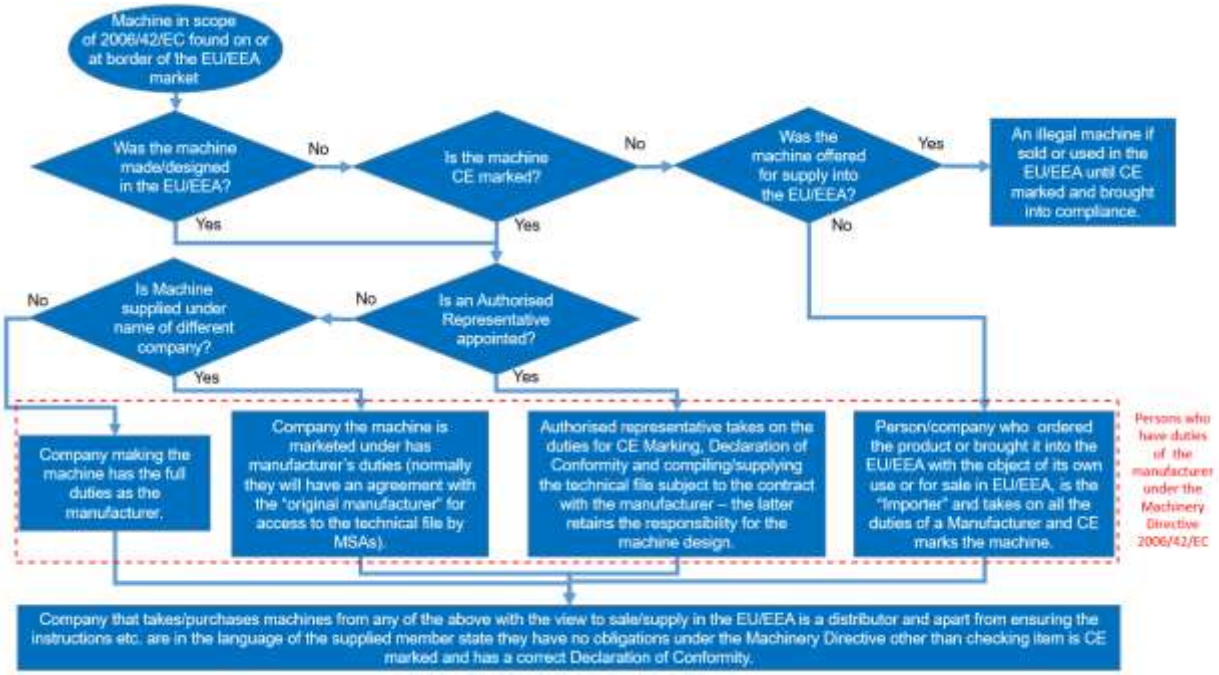
The person placing such machinery on the market in the EU may be able to arrange for the "original manufacturer" to fulfil the obligations according to the Directive, and have the item CE marked. However, if that is not the case, the person placing the machinery on the market in the EU must fulfil these obligations himself. The same goes for a person importing machinery into the EU for his own use. In these cases, the person placing the machinery or partly completed machinery on the EU market or putting machinery into service in the EU is considered as the manufacturer and must therefore fulfil all of the obligations of manufacturer set out in Article 5.

This entails that the person placing the machinery on the market must have the means to satisfy these obligations, which include ensuring that the machinery satisfies the relevant essential health and safety requirements, ensuring that the technical file is available, providing the instructions, carrying out the appropriate conformity assessment procedure, drawing up and signing the EC Declaration of Conformity of the machinery and affixing the CE-marking – see §103 to §105: comments on Article 5.

It should be noted that the provision set out in the second sentence of the definition given in Article 2 (i) cannot be invoked by a manufacturer in the EU or by a manufacturer outside the EU who takes the initiative to place machinery on the EU market, in order to avoid their obligations under the Machinery Directive.

Another case where the duties of a manufacturer rest with a person/company other than who actually designed and made the machine, is where it is marketed and supplied under the distributors name or "brand". This is a common situation with power tools and appliances sold in a number of chain stores and outlets marketed under a "brand" name owned by the store.

The flow chart below illustrates the various economic operators who can take on the duties of the manufacturer of machinery.



§ 82 Machinery modified before it is first put into service

In some cases, machinery is sold to an importer or a distributor who then modifies the machinery at the request of a customer before the machinery is put into service for the first time. If the modifications were foreseen or agreed by the manufacturer and covered by the manufacturer's risk assessment, technical documentation and EC Declaration of Conformity, the original manufacturer's CE marking remains valid. On the other hand, if the modification is substantial (for example, a change of function and/or performance of the machinery) and not foreseen or agreed by the manufacturer, the original manufacturer's CE-marking becomes invalid and has to be renewed – see §72: comments on Article 2 (h). The modifier is then considered as the manufacturer and must fulfil all the obligations set out in Article 5 (1).

§ 83 Distributors

Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products defines 'distributor' as "*any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market*"[34]. The Machinery Directive does not include explicit obligations for distributors of Machinery, unless the distributor is the authorised representative of the manufacturer or is the person placing the machinery on the market – see §81 above.

[34] Article 2 (6) of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

The role of distributors of machinery was clarified by a judgement of the European Court of Justice[35]. The Court judged that national provisions may require distributors to ensure that, before machinery is delivered to the user, it:

- bears the CE marking,
- is accompanied by the EC Declaration of Conformity drawn up and signed by the manufacturer or his authorised representative, translated into one of the official languages of the Member State in which the machinery is placed on the market,
- is accompanied by instructions in the official language or languages of the Member State concerned.

If the manufacturer has not provided original instructions in that or those languages, a distributor who brings the machinery into the language area in question must provide a translation – see §257: comments on section 1.7.4.1 of Annex I. If the Distributor installs the item or has the opportunity to see it in its working configuration, for example if they supply and install industrial equipment, they should be aware of any obvious defect such as missing guards or interlocks that are required to meet the essential health and safety requirements of the Directive. In such cases they should seek to correct the non-compliance with the manufacturer.

A distributor is generally expected to exercise due care with respect to the machinery he supplies, to be aware of the regulations to which it is subject and to refrain from supplying machinery which evidently fails to comply with the requirements of the Machinery Directive. However, the distributor cannot be required to verify himself the conformity of the machinery with the essential health and safety requirements of the Machinery Directive.

In case of doubt about the conformity of machinery, the distributor is expected to cooperate with the market surveillance authorities, for example, by assisting them in establishing contact with the manufacturer or his authorised representative and in obtaining from the latter the necessary information such as the relevant elements of the technical file – see §98: comments on Article 4.

With respect to specific obligations of distributors of chains, ropes and webbing – see §44: comments on Article 2 (e) and §357: comments on section 4.3.1 of Annex I.

Article 2

(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;*

§ 84 The possibility to appoint an authorised representative

The obligations relating to the placing on the market and putting into service of machinery and the placing on the market of partly completed machinery fall on the manufacturer or his authorised representative. The nomination of an authorised

[35] Judgement of the ECJ, 8th September 2005, Case C-40/04.

representative in the EU is a solution available to manufacturers of machinery or partly completed machinery, whether established within or outside the EU, in order to facilitate the accomplishment of their obligations under the Directive. The authorised representative must have a written mandate from the manufacturer that specifies explicitly which of the obligations set out in Article 5 are entrusted to him. The authorised representative is thus different from a commercial agent or distributor.

An authorised representative can be a legal or natural person, that is to say, an individual or a legal entity such as a company or association. He must be established in the EU, in other words, he must have an address in the territory of one of the Member States.

The manufacturer must ensure that his authorised representative is given the means necessary to accomplish all of the obligations that are conferred on him. This is particularly important if the authorised representative is given the task of carrying out the conformity assessment of the machinery – see §105: comments on Article 5 (3).

It is not an obligation for a manufacturer established outside the EU to nominate an authorised representative: such a manufacturer can accomplish all of his obligations directly. However, whether or not such a manufacturer appoints an authorised representative, he must always indicate in the EC Declaration of Conformity or the Declaration of Incorporation the name and address of the person established in the EU who is authorised to compile the technical file or the relevant technical documentation – see §383: comments on Annex II 1 A (2), and §385: comments on Annex II 1 B (2). This duty is limited to putting together the technical information as supplied to this person by the manufacturer and to liaise and facilitate the supply of it to the Market Surveillance Authority who has requested to see the relevant parts of the technical file. They have no technical responsibility for the content of the technical file or have other compliance duties. Thus this person is not to be confused with an authorised representative.

It should also be noted that if the manufacturer has nominated an authorised representative for any of the obligations set out in Article 5, the EC Declaration of Conformity of the machinery or the Declaration of Incorporation of partly completed machinery must include the name and address of both the manufacturer and of his authorised representative – see §383: comments on Annex II 1 A (1), §385: comments on Annex II 1 B (1).

§ 85 The tasks of an authorised representative

A manufacturer can give a mandate to an authorised representative to carry all or part of the obligations mentioned in Article 5.

In the case of machinery, the tasks given by the manufacturer to the authorised representative may therefore include ensuring that the machinery satisfies the relevant essential health and safety requirements, ensuring that the technical file is available, providing the instructions, carrying out the appropriate conformity assessment procedure, drawing up and signing the EC Declaration of Conformity of the machinery and affixing the CE-marking – see §103 to §105: comments on Article 5.

In the case of partly completed machinery, the authorised representative of the manufacturer may be mandated to compile the relevant technical documentation, to

prepare and provide the assembly instructions and to draw up and sign the Declaration of Incorporation of partly completed machinery – see §131: comments on Article 13.

Article 2

(k) *'putting into service' means the first use, for its intended purpose, in the Community, of machinery covered by this Directive;*

§ 86 The definition of 'putting into service'

The Machinery Directive applies to machinery when it is placed on the market and/or put into service. Machinery that is placed on the market in the EU is put into service when it is used in the EU for the first time. This applies to new machines that are completed and tested at the users site (may be referred to as 'in-situ' manufacturing), including both machines the user has built himself or have been built for him by another. Existing machinery originally first put into service outside the EU and moved by the user to his own site in the EU is also subject to the Machinery Directive as it is now being put into service for the first time in the EU. However, 'putting into service' does not apply to existing machinery (which was originally been put into service or placed on the market in the EU) that has had modifications carried out, unless they are so extensive that the machine is considered as new – see §72: comments on Article 2 (h). In such cases, the obligations of the manufacturer with respect to the placing on the market and the putting into service of the machinery are the same.

In the case of machinery manufactured by a person for his own use or an assembly of machinery constituted by the user (that is not placed on the market), the Machinery Directive applies when the machinery or assembly of machinery is first put into service. In other words, such machinery must comply with all the provisions of the Directive before it is first used for its intended purpose in the EU. The machinery may need to be tested as part of the installation and commissioning process for a short and limited period under the full control of the manufacturer, which includes the control of the persons involved in the testing. This process may then result in further modifications being required prior to CE marking and the issuing of the Declaration of Conformity. Only then it can be "cleared" for use or production and handed over to the user. This testing process must not be used for production as a way of getting around the legislation. This testing is considered to be part of the manufacturing process and not being put into service. However, during this period, full compliance must be fulfilled with the requirements of the national legislation that implements Directive 2009/104/EC concerning the minimum health and safety requirements for the use of work equipment by workers at work.

Article 2

(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.*

§ 87 The definition of 'harmonised standard'

Harmonised standards are essential tools for applying the Machinery Directive. Their application is not mandatory. However, when the references of harmonised standards are published in the Official Journal of the European Union, application of their specifications confers a presumption of conformity with the essential health and safety requirements they cover – see §110: comments on Article 7 (2).

Furthermore, harmonised standards provide a good indication of the state of the art that must be taken into account when applying the essential health and safety requirements set out in Annex I – see §162: comments on General Principle 3 of Annex I.

Although the definition of 'harmonised standards' refers to the three European Standardisation Organisations (ESOs), in practice, only two ESOs, CEN and CENELEC, are involved in the development of standards supporting the Machinery Directive – see §112: comments on Article 7 (2).

The remit issued by the Commission mentioned in the definition is generally referred to as a mandate. On 19th December 2006, the Commission issued the mandate M/396 to CEN and CENELEC requesting the ESOs to review the existing body of harmonised standards for machinery in light of Directive 2006/42/EC and to develop the necessary new standards[36].

[36] See the "Standardisation - Mandates" database http://ec.europa.eu/growth/tools-databases/mandates/.

Article 2[37]

(m) *'essential health and safety requirements' means mandatory provisions relating to the design and construction of the products subject to this Directive to ensure a high level of protection of the health and safety of persons and, where appropriate, of domestic animals and property and, where applicable, of the environment. The essential health and safety requirements are set out in Annex I. Essential health and safety requirements for the protection of the environment are applicable only to the machinery referred to in section 2.4 of that Annex.*

§ 88 Essential health and safety requirements

Machinery subject to the Machinery Directive must fulfil the relevant essential health and safety requirements set out in Annex I. The essential health and safety requirements are to be applied in light of the General principles set out in introduction to Annex I – see §157 to §163: comments on the General Principles of Annex I.

The essential health and safety requirements set out in Annex I may be supported by European harmonised standards – see §110 to §114: comments on Article 7 (2) and (3).

Most of the essential health and safety requirements concern primarily the protection of the health and safety of persons, including operators and other exposed persons – see §166: comments on section 1.1.1 of Annex I. They also concern the protection of domestic animals, including pets and livestock, insofar as such animals are liable to be exposed to the hazards generated by the machinery. There are no specific essential health and safety requirements relating to the protection of property, however certain of the essential requirements deal with hazards that are liable to damage property, such as, for example, the fire and explosion hazards.

The only essential health and safety requirements of the Machinery Directive that concern the protection of the environment are those set out in section 2.4 of Annex I which apply to machinery for pesticide application – see §282 to §290: comments on section 2.4 of Annex I. Other categories of machinery may be subject to environmental protection requirements set out in other specific Directives – see §92: comments on Article 3.

Article 3

Specific Directives

Where, for machinery, the hazards referred to in Annex I are wholly or partly covered more specifically by other Community Directives, this Directive shall not apply, or shall cease to apply, to that machinery in respect of such hazards from the date of implementation of those other Directives.

[37] Article 2 (m) was introduced by Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application. OJ L310, 25.11.2009, p. 29.

§ 89 The Machinery Directive and other internal market legislation

According to Article 3, for products in the scope of the Machinery Directive, the provisions of the Machinery Directive may be totally or partially superseded by other EU legislation (Directives or Regulations) that cover all or certain of the hazards concerned more specifically.

This specific legislation may be comprehensive health and safety Directives covering all of the machinery hazards for the products in their scope. According to Article 3, these Directives are to be applied instead of the Machinery Directive for the products in their scope – see §90 below.

In other cases, the overlap between the specific Directives and the Machinery Directive is limited to one or a few hazards. According to Article 3, in these cases the relevant requirements of the specific Directive are to be applied instead of the corresponding essential health and safety requirements of the Machinery Directive – see §91 below.

Besides the specific Directives referred to in Article 3, other EU Directives may apply in a complementary way to machinery in the scope of the Machinery Directive for aspects not covered by the Machinery Directive, such as electromagnetic compatibility or the protection of the environment – see §92 below.

The other EU legislation referred to in the following paragraphs are Directives or Regulations for ensuring the free movement of goods through technical harmonisation based on Article 95 of the EC Treaty (now Article 114 of the TFEU). They do not include Directives based on Article 175 EC (now Article 192 of the TFEU) relating to the protection of the environment, or Directives based on Article 137 EC (now Article 153 of the TFEU) relating to the protection of workers' health and safety. For the relationship between the Machinery Directive and the Directives based on Article 137 EC (Article 153 TFEU) – see §140: comments on Article 15.

The Directives referred to in §90 to §92 may also be applicable to partly completed machinery referred to in Article 1 (g).

It should be noted that when more than one Directive is applicable to machinery, the conformity assessment procedure required by each Directive may be different. In that case, the conformity assessment to be carried out under each Directive concerns only the aspects that are covered more specifically by that Directive.

The CE-marking affixed on the machinery signifies that the machinery complies with all of the applicable EU legislation requiring the CE-marking – see §106: comments on Article 5 (4), and §141: comments on Article 16. Note that although partly completed machinery must not bear the CE mark under the Machinery Directive, it may bear the CE mark if it also comes under other relevant legislation such as ATEX – see §251: comments on Annex I 1.7.3 – 3rd paragraph..

When, in addition to the Machinery Directive, one or more other Directives requiring an EC Declaration of Conformity are applicable to machinery, the manufacturer may draw up a single EC Declaration of Conformity for all of the Directives concerned, providing this Declaration contains all the information required by each Directive. This may not be possible in all cases, since certain Directives specify a particular format for the Declaration of Conformity. In any case, the EC Declaration of Conformity of the

machinery must include a declaration that the machinery complies with the other applicable Directives – see §383: comments on Annex II 1 A (4).

§90 Specific EU legislation that apply instead of the Machinery Directive to machinery that is in their scope

Directive 2014/35/EU[38] (*) **on electrical equipment designed for use within certain voltage limits** **(Low Voltage Directive, LVD)** (*) replacing the previous LVD 2006/95/EC[39] from 20 April 2016	Electrical and electronic products that are any of the categories listed in Article 1(2) (k) of Machinery Directive 2006/42/EC (MD) shall comply with the LVD. Electrical and electronic products that is not in any of the categories listed in Article 1(2) (k) of the MD but meet the definitions of article 2 of the MD, shall comply with the MD. It should be noted that section 1.5.1 of Annex I to the MD requires the electrical aspects of machinery to meet the safety objectives of the LVD. [..] Thus, whilst machinery with an electrical supply, which is not in any of the categories listed in Article 1(2) (k) of MD, shall fulfil the safety objectives of the LVD, the manufacturer's EC Declaration of conformity shall not refer to the LVD but to the MD
Directive 2009/48/EC[40] **on the safety of toys**	The Toys Directive is a comprehensive health and safety Directive, dealing more specifically than the MD with the hazards of machinery intended to be used as toys. In accordance with Article 3, the MD is thus not applicable to machinery that is within the scope of the Toys Directive.
Directive 89/686/EEC[41] (*) **on personal protective equipment** **(PPED)** (*) a new Regulation (EU) 2016/425 on PPE was approved in 2016 and will be applicable from 21.04.2018[42]	The PPED is a comprehensive health and safety Directive, dealing more specifically than the MD with the hazards of machinery intended for use as PPE. In accordance with Article 3, the MD is thus not applicable to machinery that is within the scope of the PPED. It should be noted that products that are subject to the PPED may be fitted to machinery, such as, for example, rigid or flexible guides for personal fall arrest equipment.

[38] OJ L 96, 29.3.2014, p. 357.

[39] OJ L 374, 27.12.2006.

[40] OJ L 170, 30.6.2009 p. 1.

[41] OJ L 399, 30.12.1989 p. 18.

[42] OJ L 81,31.3.2016 p.51.

Directive 93/42/EEC[43] (*) as amended by Directive 2007/47/EC[44] **on medical devices** **(MDD)** (*) a new Regulation (EU) 2017/475 on medical devices was approved in 2017 and will be applicable from 26.05.2020	The MDD is a comprehensive health and safety Directive, dealing more specifically than the MD with the hazards of machinery intended for medical use. In accordance with Article 3, the MD is thus not applicable to machinery that is within the scope of the MDD. It should be noted that Article 3 of the MDD as amended makes any essential health and safety requirements of the MD that are relevant and that are more specific than the ones included in the MDD applicable to medical devices that are machinery, while all the other obligations relating to the placing on the market of such devices, including the conformity assessment procedure and the risk assessment, are set by the MDD only.
Directive 2014/33/EU[45] (*) **on lifts** **(LD)** (*) replacing the previous LD 95/16/EC[46] from 20 April 2016	The LD is a comprehensive health and safety Directive, dealing more specifically than the MD with the hazards of machinery intended for use as a lift and those of safety components for lifts. In accordance with Article 3, the MD is not thus applicable to the lifts or safety components that are within the scope of the LD. It should be noted that section 1.1 of Annex I of the LD makes any relevant essential health and safety requirements of the MD, that are not included in Annex I of the LD, applicable to lifts, while all the other obligations relating to the placing on the market of such lifts, including the conformity assessment procedure, are set by the LD only. The MD applies to lifts that are excluded from the scope of the LD, unless they are also excluded from the scope of the MD – see §47 to §70: comments on Articles 1 (2), and §151: comments on Article 24.

[43] OJ L 169, 12.7.1993 p. 1.

[44] OJ L 247, 21.9.2007 p. 21.

[45] OJ L 96, 29.3.2014, p. 251.

[46] OJ L 213, 7.9.1995, p. 1.

Directive 2000/9/EC[47] (*) **on cableway installations designed to carry persons** (*) a new Regulation (EU) 2016/424 on Cableways was approved in 2016 and should be applicable in 2018	The Cableways Directive is a comprehensive health and safety Directive, dealing more specifically than the MD with the hazards of machinery intended for use as cableways designed to carry persons. In accordance with Article 3, the MD is thus not applicable to cableways designed to carry persons that are within the scope of the Cableways Directive. The MD applies to certain cableways that are outside or excluded from the scope of the Cableways Directive such as, for example, cableways for the transport of goods only and cableways for agricultural, mining or industrial purposes. Other installations that are excluded from the scope of the Cableways Directive are also excluded from the scope of the MD, for example, as means of transport on water or on rail networks or as specific equipment for use in fairgrounds or amusement parks – see §49 and §57: comments on Article 1 (2).
Regulation (EU) No 167/2013[48] **on agricultural and forestry vehicles**	This Regulation covers all identified risks including those previously covered by the Machinery Directive, for agricultural and forestry tractors, and so a complete exclusion from the Machinery Directive could be made. To do this it modified Article 1(2)(e) of the Machinery Directive, removing the reference to the exclusion being only for the risks covered by that Directive. Such tractors supplied under Regulation 167/2013 from 1 January 2016 are completely excluded from the Machinery Directive. However, there is a two-year transition period where tractors supplied under national legislation implementing Directive 2003/37/EC can still be supplied up to 31 December 2017, and are thus also in scope of the Machinery Directive 2006/42/EC.

[47] OJ L 106, 3.5.2000, p. 21.

[48] OJ L 60, 2.3.2013, p. 1.

§91 Specific EU legislation that may apply to machinery instead of the Machinery Directive for specific hazards

Directive 2014/34/EU[49] (*) **on equipment and protective systems intended for use in potentially explosive atmospheres** **(ATEX Directive)** (*) replacing the previous ATEX Directive 94/9/EC[50] from 20 April 2016	In accordance with Article 3, the ATEX Directive applies, for the explosion hazard, to machinery intended for use in potentially explosive atmospheres. The reference to "the specific Community Directives" in the second paragraph of section 1.5.7 of Annex I of the MD is to be understood as a reference to the ATEX Directive. It should be noted that the ATEX Directive does not apply to areas within machinery where a potentially explosive atmosphere may exist or to explosion hazards that are not due to atmospheric conditions[51]. The risk of explosion posed by or within the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery are covered by the MD - see §228: comments on section 1.5.7 of Annex I. A machinery manufacturer may incorporate ATEX equipment, protective systems or components that have already been placed on the market in order to prevent the risk of explosion in areas within the machinery. In that case, the EC Declaration of Conformity of the machinery should not refer to the ATEX Directive but the EC Declarations of conformity of the ATEX equipment, systems or components incorporated into the machinery must be included in the machinery manufacturer's technical file – see §392: comments on Annex VII A 1 (a).
Directive 84/500/EEC[52] **on ceramic articles to come into contact with foodstuffs** **Regulation (EC) No 1935/2004**[53] **on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC** **Directive 2002/72/EC**[54] **on plastic materials and articles intended to come into contact with foodstuffs**	In accordance with Article 3, the EU provisions on materials and articles intended to come into contact with food apply to the relevant parts of foodstuffs machinery. The reference in section 2.1.1 (a) of Annex I of the Machinery Directive to "the relevant Directives" is to be understood as a reference to Directive 84/500/EEC, Regulation (EC) No 1935/2004 and Directive 2002/72/EC.

[49] OJ L 96, 29.3.2014, p. 309.

[50] OJ L 100, 19.4.1994, p. 1.

[51] See the *Guidelines on the application of Directive 2014/34/EU (ATEX Guidelines)*, available on http://ec.europa.eu/growth/sectors/mechanical-engineering/atex/.

[52] OJ L 277, 20.10.1984 p. 12.

Directive 2014/29/EU[55] (*) **on simple pressure vessels** **(SPVD)** (*) replacing the previous SPVD 2009/105/EC[56] from 20 April 2016	In accordance with Article 3, the SPVD applies, for the pressure hazards, to simple pressure vessels manufactured in series within its scope that are incorporated into or connected to machinery. It should be noted that the MD covers the risk of break-up during operation – see §207: comments on section 1.3.2 of Annex I.
Directive 2009/142/EC[57] (*) **on appliances burning gaseous fuels** **(Gas Appliances Directive, GAD)** (*) a new Regulation (EU) 2016/426 on gas appliances was approved in 2016 and will be applicable from 21.04.2018[58]	The GAD applies to appliances burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or washing, including forced draught burners, and to fittings for such appliances. In accordance with Article 3, the GAD also applies, for the hazards that it covers, to gas appliances within its scope that are incorporated into machinery. Appliances specifically designed for use in industrial processes carried out on industrial premises are excluded from the GAD. Such appliances, and other gas appliances excluded from the scope of the GAD, are subject to the MD if they are in its scope or are incorporated into machinery. The MD also applies to gas appliances in the scope of the GAD that have powered moving parts, for hazards that are not covered by the GAD.
Directive 2014/68/EU[59] (*) **on pressure equipment** **(PED)** (*) replacing the previous PED 97/23/EC[60] from 19 July 2016	In accordance with Article 3, the PED is applicable, for the pressure hazards, to pressure equipment within its scope that is incorporated into or connected to machinery. If pressure equipment that has already been placed on the market is incorporated into machinery, the machinery manufacturer's technical file must include the EC Declaration of Conformity of that pressure equipment to the PED – see §392: comments on Annex VII A 1 (a). Pressure equipment classified as no higher than category 1 that is incorporated into machinery in the scope of the MD is excluded from the scope of the PED. The MD is thus fully applicable to such equipment. It should be noted that the MD covers the risk of break-up during operation – see §207: comments on section 1.3.2 of Annex I.

[53] OJ L 338, 13.11.2004 p. 4.

[54] OJ L 220, 15.08.2002 p. 18.

[55] OJ L 96, 29.3.2014, p. 45.

[56] OJ L 264, 8.10.2009, p. 12.

[57] OJ L 330, 16.12.2009, p. 10.

[58] OJ L 81, 31.3.2016, p.99

[59] OJ L 189, 27.6.2014, p. 164.

§ 92 *EU legislation that may apply to machinery, in addition to the Machinery Directive, for hazards they cover more specifically than the Machinery Directive*

Regulation (EU) No 305/2011[61] (*) **on construction products** **(CPR)** (*) replaced the previous CPD 89/106/EEC[62] from 1 July 2013	The CPR sets out requirements relating to the suitability of construction products for the construction works into which they are to be incorporated. The CPR applies, in addition to the Machinery Directive, to machinery designed to be incorporated in a permanent manner in construction works, such as, for example, powered gates, doors, windows, shutters and blinds, ventilation and air-conditioning systems. It should be noted that application of the CPR is possible only when a harmonised technical specification is available.
Regulation (EU) 2016/1628[63] (*) **on requirements relating to gaseous and particulate pollutant emission limits** **(NRMMD)** (*) amending and repealing Directive 97/68/EC[64]	The NRMMD Regulation sets out type-approval requirements and emission limits for the gaseous and particulate emissions of internal combustion engines to be installed in the non-road mobile machinery that is within its scope. Engines installed in non-road mobile machinery must bear the markings referred to in Article 32 to Regulation (EU) 2016/1628 and further specified in its Implementing Regulation (EU) 2017/656, but those Regulations shall not be mentioned in the EC Declaration of Conformity of the machinery.
Directive 2014/53/EU[65] (*) **on radio equipment** **(RED)** (*) replacing the previous R&TTED 1999/5/EC[66] from 13 June 2016	The requirements of the RED with respect to the use of the radio frequency spectrum apply to radio equipment within its scope that is incorporated into machinery, such as, for example, certain remote control devices. It should be noted that the safety of remote control systems for machinery is subject to the MD – see §184: comments on section 1.2.1 of Annex I.

[60] OJ L 181, 9.7.1997, p. 1.

[61] OJ L 88, 4.4.2011, p. 5.

[62] OJ L 40, 11.2.1989, p. 12.

[63] OJ L 252, 16.9.2016, p.53

[64] OJ L 59, 27.2.1998, p. 1.

[65] OJ L 153, 22.5.2014, p. 62.

[66] OJ L 91, 7.4.1999, p. 10.

Directive 2000/14/EC[67] as amended by Directive 2005/88/EC[68] **on the noise emission in the environment by equipment for use outdoors** **(OND)**	The OND sets out environmental noise emission requirements for machinery intended for use outdoors within its scope.[69] It should be noted that the last paragraph of section 1.7.4.2 (u) of Annex I of the MD refers to other Community Directives that address noise. Where machinery is within the scope of the OND, the MD provisions concerning sound power levels do not apply – see §229 and §230: comments on section 1.5.8, and §273: comments on section 1.7.4.2 (u) of Annex I.
Directive 2011/65/EU[70] (*) **on the restriction of the use of certain hazardous substances in electrical and electronic equipment** **(RoHS)** (*) replaced the previous Directive 2002/95/EC[71] from 3 January 2013	The RoHS Directive sets out restrictions on the use of certain hazardous substances in the electrical and electronic equipment belonging to categories 1, 2, 3, 4, 5, 6, 7 and 10 as set out in Annex I A to Directive 2002/96/EC[72] (WEEE). Certain products belonging to these categories may also be in the scope of the Machinery Directive such as, for example, categories 1 – large household appliances that are not intended for domestic use, 6 – electrical and electronic tools, 7 – powered leisure and sports equipment and 10 – automatic dispensers.
Directive 2014/30/EU[73] (*) **on electromagnetic compatibility** **(EMCD)** (*) replacing the previous EMCD 2004/108/EC from 20 April 2016	The EMCD applies to machinery that contains electrical or electronic parts that may generate or be affected by electromagnetic disturbance. The EMCD covers aspects of electromagnetic compatibility related to the functioning of machinery[74]. However, the MD covers the immunity of machinery with respect to safety-related electromagnetic disturbance, whether transmitted by radiation or by wire - see §184: comments on section 1.2.1, and §233: comments on section 1.5.11 of Annex I.

[67] OJ L 162, 3.7.2000, p. 1.

[68] OJ L 344, 27.12.2005, p. 44.

[69] See the *Guidelines for the application of Directive 2000/14/EC*, available on http://ec.europa.eu/growth/sectors/mechanical-engineering/noise-emissions/.

[70] OJ L 174, 1.7.2011, p. 88.

[71] OJ L 37, 13.2.2003, p. 19.

[72] OJ L 37, 13.2.2003, p. 24.

[73] OJ L 96, 29.3.2014, p. 79.

[74] See the *Guide for the EMC Directive 2004/108/EC*, available on http://ec.europa.eu/growth/sectors/electrical-engineering/emc-directive/.

Directive 2009/125/EC[75] (*) **on ecodesign requirements for energy-related products** **(EuP Directive)** (*) replaced the previous Directive 2005/32/EC from 20 November 2010	The EuP Directive provides a framework for the adoption of eco-design requirements for industrial products. The implementing measures adopted in the framework of the EuP Directive may apply to machinery or to equipment to be incorporated into machinery, such as, for example, pumps.

Article 4

Market surveillance

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 and, where applicable, the environment, when properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen*[76].

. . .

§ 93 Market surveillance

Article 4 sets out the obligation of the Member States to ensure that the provisions of the Machinery Directive for machinery and partly completed machinery are correctly applied and that machinery placed on the market and put into service is safe. This Article was changed by Directive 2009/127/EC which amended the Machinery Directive with regard to machinery for pesticide application. The main change was to add "*does not endanger and, where applicable, the environment*", otherwise the application of this Article is not affected.

The term *'machinery'* in Article 4 (1) is used in the broad sense to refer to the product categories referred to in Article 1 (1) (a) to (f) – see §33: comments on the first paragraph of Article 2.

Basic rules for market surveillance are set out in Chapter III of the Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products.[77] The Regulation is directly applicable from 1st January 2010. Its provisions relating to market surveillance are complementary to those of the

[75] OJ L 285, 31.10.2009, p. 10.

[76] Article 4(1) was amended by Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application. OJ L 310, 25.11.2009, p. 29.

[77] Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93. OJ L 218, 13.8.2008, p. 30.

Machinery Directive, in other words, they apply when the Machinery Directive does not include specific provisions having the same objective[78].

The following comments relate both to the provisions of Article 4 of the Machinery Directive and to the complementary provisions included in Chapter III of the Regulation. The relevant provisions of the Regulation are summarised and references are made to the relevant Articles of the Regulation in footnotes, however readers should consult the full text of the Regulation.

The term *'market surveillance'* designates the activities carried out and the measures taken by public authorities to ensure that the products subject to the Directive have been subject to the requisite conformity assessment procedures, that they comply with the applicable essential health and safety requirements and, for complete products, that they are safe.[79] Market surveillance is carried out *when or after* such products are placed on the market or put into service. Market surveillance is thereby distinguished from conformity assessment, which aims to ensure the conformity of products *before* they are placed on the market or put into service.

§ 94 Market surveillance of machinery

The market surveillance of machinery required by Article 4 (1) includes at least the following activities:

- checking that machinery that is placed on the market or put into service bears the CE-marking and is accompanied by a correct EC Declaration of Conformity – see §103: comments on Articles 5 (1), §141: comments on Article 16, §383: comments on Annexes II 1 A, and §387: comments on Annex III;
- ensuring that machinery that is placed on the market or put into service has been subject to the appropriate conformity assessment procedure – see §127 to §130: comments on Article 12;
- checking that machinery that is placed on the market or put into service is accompanied by the necessary information, such as instructions – see §103: comments on Articles 5 (1), and §254 to §256: comments on section 1.7.4 of Annex I;
- where the machinery incorporates partly completed machinery, checking that the assembly instructions of the manufacturer of the partly completed machinery have been correctly followed by the manufacturer of the complete machinery or assembly of machinery;
- monitoring the conformity of machinery that is placed on the market or put into service to ensure that it complies with the essential health and safety requirements that are applicable and does not endanger the health and safety of persons and, where appropriate, domestic animals, property or the environment in the case of pesticides machinery – see §282: comments on EHSR 2.4 on

[78] See Article 15 (2) of Regulation (EC) No 765/2008.

[79] See Article 2 (17) of Regulation (EC) No 765/2008.

Annex I; §103: comments on Article 5 (1), and §160: comments on General principle 2 of Annex I;

- taking appropriate action to ensure that non-compliant products are brought into conformity or withdrawn from the market – see §122 to §126: comments on Articles 11, and §142, comments on Article 17.

The essential health and safety requirements of the Machinery Directive mainly concern the health and safety of persons, including operators and other exposed persons – see §166 and §167: comments on sections 1.1.1 (c) and (d) of Annex I. The essential health and safety requirements apply, also where appropriate, to the health and safety of domestic animals (the use of the word "domestic" has a wide definition and included animals bred for farming, and not just household pets). This may be relevant, for example, to machinery intended for use with, or liable to be in contact with farm animals, horses or pets. The essential health and safety requirements also apply, where appropriate, to the protection of property, for example, against the risks of fire or explosion – see §227 and §228: comments on sections 1.5.6 and 1.5.7 of Annex I.

Market surveillance can be carried out at any stage after the construction of the machinery is complete, as soon as the product concerned has been made available for distribution or use in the EU – see §73: comments on Article 2 (h). Machinery can be examined in the premises of manufacturers, importers, distributors, rental companies, in transit or at the external borders of the EU.

The conformity of machinery may also be checked at the user's premises after it has been put into service, however, in that case, the market surveillance authorities must take care to distinguish the features of the machinery as it was supplied by the manufacturer from features that may result from modifications carried out by the user – see §382: comments on Annex II 1 A. This may be facilitated by examination of the relevant elements of the manufacturer's technical file – see §392: comments on Annex VII A. The conformity of machinery manufactured by the user for his own use may also be checked after it has been put into service – see §86: comments on Article 2 (k).

If the non-conformity of machinery in use creates a risk for users, the national authorities in charge of occupational health and safety may require users to take the necessary measures to protect persons and, in case of serious risk, may forbid the use of the machinery. Such measures may be taken in the framework of national regulations implementing Directive 2009/104/EC on the use of work equipment – see §140: comments on Article 15. However, in such cases, the market surveillance authorities shall also take the necessary action on the basis of the Machinery Directive with respect to the manufacturer of the machinery concerned.

When assessing the conformity of machinery, the market surveillance authorities must take account of the state of the art including, where appropriate, the harmonised standards in force, at the time the machinery was placed on the market – see §161 and §162: comments on General Principle 3 of Annex I.

The market surveillance authorities must take into account the use of the machinery intended by the manufacturer and also reasonably foreseeable misuse – see §171 and §172: comments on sections 1.1.1 (h) and (i) of Annex I.

***Article 4** (continued)*

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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.*

. . .

§ 95 Market surveillance of partly completed machinery

Article 4 (2) requires Member States to carry out market surveillance of partly completed machinery.

Market surveillance of partly completed machinery can be carried out before the partly completed machinery has been incorporated into the final machinery or assembly of machinery. The market surveillance authorities may also carry out checks on machinery or assemblies of machinery into which partly completed machinery has been incorporated. In that case, the market surveillance of the partly completed machinery is an aspect of the market surveillance of the final machinery.

If a non-conformity is detected in the partly completed machinery after it has been incorporated, the market surveillance authorities can check in the technical file for the final machinery whether the Declaration of Incorporation for the partly completed machinery states that the essential health and safety requirement concerned has been applied and fulfilled – see §384: comments on Annex II 1 B. In that case, the market surveillance authorities should address the manufacturer of the partly completed machinery.

Market surveillance of partly completed machinery comprises the following activities:

a) ensuring that partly completed machinery that has been placed on the market has been subject to the appropriate procedure – see §131: comments on Article 13;

b) checking that partly completed machinery that has been placed on the market is accompanied by a correct Declaration of Incorporation. In particular, ensuring that the Declaration of Incorporation includes the declaration as to which essential health and safety requirements have been applied and fulfilled – see §131: comments on Article 13, and §384: comments on Annex II. 1 B;

c) checking that the manufacturer's assembly instructions have drawn up so as to enable the manufacturer of the complete machinery to assemble the partly completed machinery correctly – see §131: comments on Article 13, and §390: comments on Annex VI;

d) monitoring the conformity of the partly completed machinery that has been placed on the market with the essential health and safety requirements that the manufacturer states have been applied and fulfilled – see §385: comments on Annex II B 4. The monitoring of partly completed machinery can be facilitated by referring to the relevant technical documentation – see §394: comments on Annex VII B;

e) taking appropriate measures to deal with partly completed machinery that fails to comply with any of the provisions referred to in (a) to (d) above. Although the

Machinery Directive does not specify the measures to be taken, it is clear that the market surveillance authorities must require the manufacturer of partly completed machinery to bring his product into conformity with the provisions referred to in (a) to (d) above and, failing that, to ensure that the product is withdrawn from the market.

Article 4 (continued)

. . .

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*.

§ 96 Market surveillance authorities

The term *'competent authorities'* designates the authority or authorities of each Member State responsible for carrying out market surveillance on its territory[80]. Articles 4 (3) and 4 (4) require the Member States to designate the authorities that are responsible for carrying out market surveillance and to define their tasks, organisation and powers. The Member States are free to determine how their market surveillance is organised, however the market surveillance system must fulfil certain criteria:

- The market surveillance authorities shall carry out their duties independently, impartially and without bias[81].
- The Member States must provide the market surveillance authorities with adequate resources in terms of staff and budget to carry out their tasks.
- The legal powers to be given to the market surveillance authorities shall include the power to require economic operators to make available the necessary documentation and information and, where justified, to enter the premises of economic operators and take the necessary representative samples of products[82].
- The Member States must ensure that the powers given to the market surveillance authorities are exercised in accordance with the principle of proportionality[83].
- The Member states must take the necessary measures to ensure that the public is aware of the existence, responsibilities and identity of the national market surveillance authorities, as well as how they may be contacted[84].

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[80] See Article 2 (18) of Regulation (EC) No 765/2008.

[81] See Article 19 (4) of Regulation (EC) No 765/2008.

[82] See Article 19 (1) of Regulation (EC) No 765/2008.

[83] See Article 18 (4) of Regulation (EC) No 765/2008.

[84] See Article 17 (2) of Regulation (EC) No 765/2008.

- The market surveillance system must be able to cover the whole range of products subject to the Machinery Directive, including machinery for professional use and machinery intended for use by consumers[85]. In some Member States, a single authority may cover the whole range of products. In other Member States, market surveillance for the Machinery Directive may be shared between, for example, the authority in charge of consumer protection and the authority responsible for occupational health and safety.
- If more than one authority is involved, the Member State must make arrangements to ensure the necessary coordination and communication between them[86].
- The market surveillance authorities must have the facilities to carry out the necessary technical inspection and tests or, at least, they must have access to the necessary facilities as required[87]. The public authorities responsible for market surveillance may entrust certain specific tasks, such as testing or technical inspection of machinery, to competent test or inspection bodies, including private bodies. However, the public market surveillance authorities remain responsible for all market surveillance decisions and measures taken on the basis of tests or inspections carried out on their behalf by such bodies.

§ 97 The market surveillance system

The market surveillance system must include:

- a procedure for dealing with complaints about non-compliant machinery;
- a system for monitoring and acting on reports and data relating to accidents and damage to health due to machinery;
- surveys of particular categories of machinery and inspection or testing of samples;
- adequate means to verify that corrective actions have been effectively carried out;
- means to follow up scientific and technical knowledge concerning health and safety issues relating to machinery.[88]

Obviously, the market surveillance authorities cannot examine all of the products placed on the market, but the level of monitoring of products on the market must be sufficient to ensure that market surveillance activity is perceived by the stakeholders concerned and has a significant impact on the behaviour of the economic operators.

The market surveillance authorities shall take appropriate action when complaints or reports on accidents, incidents or damage to health due to machinery indicate that the

[85] See Article 16 (3) of Regulation (EC) No 765/2008.

[86] See Article 18 (1) of Regulation (EC) No 765/2008.

[87] See Article 19 (1) of Regulation (EC) No 765/2008.

[88] See Article 18 (2) of Regulation (EC) No 765/2008.

machinery concerned does not comply with the essential health and safety requirements of the Machinery Directive.

The market surveillance authorities shall follow up decisions made by the Commission according to the safeguard clause procedure – see §122 to §126: comments on Article 11. The market surveillance authorities shall also follow up information on unsafe products notified under the RAPEX system set up under the General Product Safety Directive[89].

In addition to such reactive action, market surveillance activity shall be organised on the basis of periodic market surveillance programmes which must be regularly reviewed and updated in order to improve their effectiveness. The market surveillance programme for machinery can either be included in a general market surveillance programme or be subject to a sector-specific programme. The market surveillance programmes must be communicated to the other Member States and to the Commission and made known publicly, including by means of electronic communications. The first such communication shall take place by 1st January 2010. Market surveillance programmes must be reviewed at least every fourth year and the results of the review shall be communicated to the other Member States and to the Commission and made available to the public[90].

In order to be most effective, market surveillance activity should be based on risk assessment. Particular attention should be given to product areas where there is evidence of poor application of the provisions of the Directive or where, despite application of the Directive, the rate of accidents or damage to health due to the use of machinery remains high.

In order to optimise the use of resources, cooperation and coordination between the market surveillance authorities of the Member States is necessary – see §144: comments on Article 19. The Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products foresees specific measures to improve such cooperation as well as measures to ensure appropriate cooperation with the competent authorities of third countries[91].

§ 98 The tools for market surveillance

The European Commission has introduced the Information and Communication System for Market Surveillance (ICSMS)[92] which is a databased system that implements Article 23 of Regulation (EC) No 765/2008, as a key tool for market surveillance authorities. The ICSMS system's internal section is confidential and should be used to record the results of market surveillance. In this sense, it provides a tool:

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[89] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. OJ L 11, 15.1.2002, p. 4.

[90] See Article 18 (5) and (6) of Regulation (EC) No 765/2008.

[91] See Articles 24, 25 and 26 of Regulation (EC) No 765/2008.

[92] See http://ec.europa.eu/growth/single-market/goods/building-blocks/icsms/.

- to enable market surveillance authorities to exchange information on products being examined and thus help stop duplication of effort;
- to facilitate the cooperation between market surveillance authorities to bring defective products into compliance; and
- to provide a means to help plan and manage market surveillance campaigns and projects.

The database should be filled in when the investigation of a machine has started so other authorities know of this work and can stop any duplication of effort and to establish cooperation where it is beneficial. As the information in the investigation is obtained, the ICSMS database should be added to. Facilities exist in ICSMS to transfer this information to the necessary forms for both RAPEX and Safeguard Notifications if these are required.

The following sections explain the steps market surveillance can proceed and the information that should be available to assist this process.

The CE marking and the EC Declaration of Conformity

The CE marking affixed to the machinery and the manufacturer's EC Declaration of Conformity that shall accompany the machinery are the first elements that can be checked by the market surveillance authorities – see §141: comments on Articles 16, §385: comments on Annex II 1 A, and §387: comments on Annex III.

In particular, the EC Declaration of Conformity provides essential information to enable the market surveillance authorities to carry out the necessary checks:

- the identity of manufacturer of the machinery and of his authorised representative, where appropriate;
- the person authorised to compile the technical file;
- the conformity assessment procedure that has been followed and the identity of the Notified Body involved, where appropriate;
- the other Directives that have been applied to cover certain hazards more specifically – see §89 to §92: comments on Article 3;
- the harmonised standards or other technical specifications that have been applied, where appropriate.

In order to benefit from the presumption of conformity conferred by the application of harmonised standards, manufacturers must indicate the references of the harmonised standard(s) applied in the EC Declaration of Conformity. However, it should be recalled that the application of harmonised standards remains voluntary – see §110 and §111: comments on Articles 7 (2), §114: comments on Article 7 (3) and §385: comments on Annex II 1 A.

In the case of machinery belonging to one of the categories listed in Annex IV where the manufacturer has followed the procedure for assessment of conformity with internal checks on the manufacture of machinery according to Annex VIII, the manufacturer must indicate the reference(s) of the harmonised standard(s) applied in the EC

Declaration of Conformity, since the application of harmonised standards that cover all of the EHSRs applicable to the machinery is a condition for using that conformity assessment procedure – see §129: comments on Article 12 (3).

Where the reference of a harmonised standard is indicated in the EC Declaration of Conformity, the market surveillance authorities are entitled to consider that the manufacturer has applied the specifications of the standard in full. If the manufacturer has not applied all of the specifications of a harmonised standard, he may still indicate the reference of the standard in the EC Declaration of Conformity, but, in that case, he must indicate which specifications of the standard he has or has not applied.

The instructions

Examination of the instructions that must accompany the machinery may also provide important information for the purposes of market surveillance. The instructions must be provided in the official language or languages of the country of use – see §256: comments on section 1.7.4 of Annex I.

In particular, the instructions must specify the intended use of the machinery, which must be taken into account in the course of any investigation of the conformity of the machinery – see §171: comments on section 1.1.1 (h) of Annex I.

The technical file or the relevant technical documentation

If the market surveillance authorities have a doubt as the conformity of machinery with the essential health and safety requirements, they may request communication of all or part of the manufacturer's technical file – see §393: comments on Annex VII A 2 and 3. In the case of partly completed machinery, the market surveillance authorities may request communication of the manufacturer's relevant technical documentation – see §394: comments on Annex VII B. Such a request can be made at any stage of the market surveillance process.

These provisions have a dual purpose: on the one hand, providing the relevant elements of the technical file or of the relevant technical documentation enables a manufacturer to explain the measures he has taken to deal with the risks associated with the machinery in order to comply with the applicable essential health and safety requirements. On the other hand, the examination of these documents helps the market surveillance authorities to complete their investigation and either dispel or confirm their doubts about the conformity of the machinery concerned. However, it is not necessary for the market surveillance authorities to request these documents if they consider that they already have enough information on which to base their decision.

The request for communication of the technical file or of the relevant technical documentation should indicate the nature of the doubt about the conformity of the machinery concerned and the parts or aspects of the machinery that are subject to investigation. Only the elements of the technical file or the relevant technical documentation that are necessary for the investigation should be requested, so as not to constitute a disproportionate burden for the manufacturer.

Failure to present the technical file for machinery, or the relevant technical documentation for partly completed machinery, in response to such a duly reasoned request may constitute grounds for doubting the conformity of the machinery or the

partly completed machinery – see §393: comments on Annex VII A 3, and §394: comments on Annex VII B (b). In other words, if the manufacturer fails to respond to a duly reasoned request to supply the relevant elements of his technical file or technical documentation, the market surveillance authorities are entitled to decide what action to take on the basis of whatever other evidence is available to them.

§ 99 Documents relating to Annex IV machinery

When machinery belonging to one of the categories listed in Annex IV has been subject to one of the conformity assessment procedures involving a Notified Body, in addition to the requests for documentation mentioned in the preceding paragraph, the market surveillance authorities have the possibility to obtain certain documents from the Notified Body concerned.

EC type-examination

For machinery subject to the EC type-examination procedure set out in Annex IX, the market surveillance authorities may, on request, obtain a copy of the relevant EC type-examination certificate. This enables the authorities, from any Member State, to check that a certificate has really been issued for the machinery concerned. On reasoned request, the market surveillance authorities may obtain a copy of the technical file and the results of the examinations carried out by the Notified Body – see §399: comments on Annex IX 7.

Such requests may be addressed by the market surveillance authority directly to the Notified Body that carried out the EC type-examination. The Notified Body should respond to the national market surveillance authority making the request. In case of difficulties, for example, with respect to language, the market surveillance authorities may seek the assistance of the national authorities responsible for the notification of the Notified Body concerned – see §144: comments on Article 19.

Full quality assurance

In order to check that conformity assessment procedure involving the manufacturer's full quality assurance system has been correctly applied, the market surveillance authorities can request from the manufacturer or his authorised representative communication of the relevant elements of the documentation of the manufacturer's full quality assurance system – see §407: comments on Annex X 4.

§100 Action to deal with non-compliant machinery

Non-compliant CE marking

If a market surveillance authority discovers a non-conformity with respect to the CE-marking, the corrective action to be taken is set out in Article 17. The safeguard clause set out in Article 11 is only to be used if the action taken according to Article 17 fails to put an end to the non-conformity – see §142: comments on Article 17.

Failure to comply with the essential health and safety requirements

If a market surveillance authority discovers that machinery that has been placed on the market fails to comply with the relevant essential health and safety requirements, the authority should first require the manufacturer or his authorised representative to take

the necessary corrective action to bring the machinery into conformity or to withdraw it from the market within a timeframe determined by the market surveillance authority[93]. Such corrective measures should be taken with respect to all items of the machinery that have the same design or construction defect and be applied throughout the EU market.

If the product concerned creates a serious risk, the market surveillance authority shall also require the manufacturer to take appropriate action with respect to machinery that has already been placed on the market or put into service such as, for example, a recall of the product[94]. Where the product possess a serious and immediate risk and there is not ready access or response from the manufacturer, the market surveillance authority may take action to restrict or stop the use and supply of the product urgently through contact with the supply chain and users. In this case the manufacturer should be contacted as soon as possible and asked to correct the non-compliance.

If the necessary corrective actions are not undertaken voluntarily by the manufacturer within the timeframe determined by the market surveillance authority, the Member State must take the necessary measures to ensure that the unsafe products are withdrawn from the market. Such measures must be notified to the Commission and the other Member States in accordance with the safeguard clause – see §123: comments on Article 11.

The market surveillance authorities shall also take appropriate measures to ensure users are alerted, where possible, in cooperation with the economic operators concerned, in order to prevent accidents or damage to health that might result from the defect that has been identified[95].

If machinery presenting a serious risk is withdrawn from the market, whether voluntarily or by means of a restrictive measure, is or brought into conformity by voluntary corrective action, the Member State concerned must inform the other Member States and the Commission in order to enable them to check that the necessary corrective actions are taken throughout the EU – see §144: comments on Article 19. The Rapid Alert System (RAPEX) originally established under the General Product Safety Directive is now used for this purpose[96].

It should be noted that when the market surveillance authorities take a compulsory measure restricting the placing on the market of machinery presenting a serious risk, the notification under the RAPEX system does not remove the obligation for the Member State concerned to notify the measure according to the safeguard clause of the Machinery Directive – see §123: comments on Article 11.

[93] See Article 2 (15) of Regulation (EC) No 765/2008.

[94] See Article 2 (14) and Article 20 of Regulation (EC) No 765/2008.

[95] See Article 19 (2) of Regulation (EC) No 765/2008.

[96] See Article 22 (4) of Regulation (EC) No 765/2008.

§101 Unsafe consumer products

In addition to the provisions of the Machinery Directive and the Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products, certain specific provisions of the General Product Safety Directive apply with respect to machinery intended for or likely to be used by consumers, where the Machinery Directive or the Regulation do not include equivalent provisions.[97] In particular the following provisions are applicable:

- the obligation for distributors to exercise due care and cooperate with the market surveillance authorities[98];
- the obligation for producers and distributors to inform the authorities about unsafe products and to cooperate with the authorities in order to prevent risks to consumers[99];
- certain measures that can be taken by the market surveillance authorities with respect to unsafe products[100].

§102 Controls at the external borders of the EU

In many cases, in particular for mass-produced products imported into the EU from third countries, the most effective way to carry out market surveillance is to check the conformity of such products at the point of entry into the EU market, before they are dispersed throughout the distribution networks of the Member States.

Articles 27 to 29 of Regulation (EC) No 765/2008 which, for this aspect, repeals and replaces Regulation (EEC) No 339/93, provide the legal framework for such controls. These provisions are fully applicable for imported machinery.

Member States must provide the authorities in charge of the control of products entering the EU market (usually, the Customs authorities) with the necessary powers and resources to enable them to carry out, on an adequate scale, appropriate checks on the characteristics of machinery before it is released for free circulation[101].

The necessary cooperation and exchange of information must be organised between these authorities and the authority or authorities in charge of market surveillance for machinery[102]. In particular, market surveillance authorities shall provide authorities in charge of external border controls with information on product categories in which a serious risk or non-compliance has been identified[103].

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[97] See Article 1 (2) (b) of Directive 2001/95/EC and Article 15 (3) of Regulation (EC) No 765/2008.

[98] See Article 5 (2) of Directive 2001/95/EC.

[99] See Article 5 (3) of Directive 2001/95/EC.

[100] See Article 8 of Directive 2001/95/EC.

[101] See Article 27 (1) of Regulation (EC) No 765/2008.

[102] See Article 27 (2) of Regulation (EC) No 765/2008.

[103] See Article 29 (5) of Regulation (EC) No 765/2008.

The authorities in charge of the external border controls shall suspend release of machinery for free circulation within the EU in the following cases:

- if complete machinery does not bear the CE marking and the other markings required by the Machinery Directive or has been affixed with the CE marking in a false or misleading manner, or is not accompanied by the EC Declaration of Conformity signed by the manufacturer or his authorised representative;
- if there is cause to believe that the machinery presents a serious risk to health and safety[104].

The authorities in charge of the external border controls shall suspend release of partly completed machinery for free circulation within the EU in the following cases:

- if the partly completed machinery is not accompanied by a Declaration of Incorporation – see §384: comments on Annex II 1 B;
- if the partly completed machinery is not accompanied by assembly instructions – see §390: comments on Annex VI.

The market surveillance authorities must be immediately informed of any such suspension. They must release the product for free circulation within 3 days unless action has been initiated by the market surveillance authorities. This does not mean the product has to be investigated or tested within these 3 days, but the market surveillance authority has to decide, in this period, if they want to carry out such testing or examination and to inform the border control authority so the product is not released for free circulation. Normally, the market surveillance authority will visit to see the product in the 3-day period to make an initial assessment, but with access to modern communication tools between the authorities, a visit may not always be necessary.

The Regulation sets out the procedures to be followed if the machinery has not been subject to the appropriate conformity assessment procedure, if it fails to comply with the applicable essential health and safety requirements, or if the machinery presents a serious risk[105].

[104] See Article 27 (3) of Regulation (EC) No 765/2008.

[105] See Articles 28 and 29 of Regulation (EC) No 765/2008.

Article 5

Placing on the market and putting into service

1. *Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:*

(a) ensure that it satisfies the relevant essential health and safety requirements set out in Annex I;

(b) ensure that the technical file referred to in Annex VII, part A is available;

(c) provide, in particular, the necessary information, such as instructions;

(d) carry out the appropriate procedures for assessing conformity in accordance with Article 12;

(e) draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery;

(f) affix the CE marking in accordance with Article 16.

. . .

§103 The obligations of machinery manufacturers

Article 5 (1) provides a summary of the obligations to be fulfilled by manufacturers of machinery before placing their products on the market or putting them into service – see § 78 to § 81: comments on Article 2 (i).

It should be noted that the term *'machinery'* is used here in the broad sense. These obligations thus apply to manufacturers of machinery referred to in Article 1 (1) (a) to (f): machinery in the strict sense, interchangeable equipment, safety components, lifting accessories, chains, ropes and webbing and removable mechanical transmission devices - see §33: comments on the first paragraph of Article 2.

All or part of the obligations summarised in Article 5 (1) (a) to (f) can also be fulfilled by the manufacturer's authorised representative – see §84 and §85: comments on Article 2 (j).

In most cases, these obligations must be fulfilled before the machinery is placed on the market in the EU – see §73: comments on Article 2 (h). However, for machinery that is not placed on the market such as, for example machinery manufactured or imported into the EU by a user for his own use, the obligations must be fulfilled before the machinery is put into service – see §80 and §81: comments on Article 2 (i).

Article 5 (1) (c) requires the manufacturer to provide the necessary information and instructions with the machinery. In this regard, it should be noted that providing the necessary information on the machinery and drafting the instructions is considered as part of the design and construction of the machinery and is subject to specific essential health and safety requirements – see §244: comments on section 1.7 of Annex I.

Article 5 (continued)

. . .

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.*

. . .

§104 The obligations of manufacturers of partly completed machinery

Article 5 (2) refers to the obligations of manufacturers of partly completed machinery as defined in Article 2 - see §46: comments on Article 2 (g). The obligations of manufacturers of partly completed machinery are summarised in Article 13 – see §131: comments on Article 13.

Article 5 (continued)

. . .

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.*

. . .

§105 Means of ensuring the conformity of machinery

Article 5 (3) refers to the obligation referred to in Article 5 (1) (d) to carry out the appropriate conformity assessment procedure according to Article 12.

In the case of machinery subject to the procedure for assessment of conformity with internal checks on the manufacture described in Annex VIII, the necessary verifications may be carried out by or on behalf of the manufacturer or his authorised representative. Whether the conformity assessment of the machinery is carried out by the manufacturer himself or entrusted to his authorised representative, the person carrying out the conformity assessment must have, or have access to the necessary means to verify the conformity of the machinery with the applicable health and safety requirements. The means may include, for example, access to the necessary qualified personnel who have knowledge of both the Machinery Directive and relevant standards, access to the necessary information, the competency and the equipment needed to carry out the necessary design checks, calculations, measurements, functional tests, strength tests, visual inspections and checks on information and instructions to ensure the conformity of the machinery with the relevant essential health and safety requirements.

When machinery is designed and constructed according to harmonised standards, the standards normally specify the means to be used to verify the conformity of the

machinery with their specifications[106]. Access to the relevant standards is required in this case.

In the case of machinery belonging to one of the categories listed in Annex IV for which the full quality assurance procedure described in Annex X is used, the means to carry out the necessary verifications must be documented in the manufacturer's full quality assurance system – see §403: comments on paragraph 2.2 of Annex X.

Article 5 (continued)

. . .

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.

§106 CE marking according to other EU legislation

Article 5 (4) concerns the obligation referred to in Article 5 (1) (f): the affixing of the CE marking. Article 5 (4) is a reminder that other EU legislation (Regulations or Directives) providing for the affixing of the CE marking may be applicable to machinery or partly completed machinery (note that although under the Machinery Directive a CE mark must not be placed on partly completed machinery, it may carry a CE mark due to other relevant EU legislation applying such as ATEX – see §251: comments on Annex I 1.7.3 – 3rd paragraph**)**. In that case, the manufacturer must ensure that he has fulfilled his obligations according to all of the EU legislation applicable to his product before affixing the CE marking – see §89 to §92: comments on Article 3.

Besides the CE marking of machinery as proof of their compliance with the relevant EU Directives and Regulations requiring CE-marking, other mandatory affixing and marking may be required by EU legislation[107].

[106] See clause 6.8 *"Verification of the safety requirements and/or protective/risk reduction measures"* of CEN Guide 414:2004 *Safety of machinery - Rules for the drafting and presentation of safety standards.*

[107] See the Blue Guide on the implementation of EU products rules 2016, sections 4.5.1.7. and 4.5.2.

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.*

. . .

§107 Free movement of machinery and partly completed machinery

Article 6 (1) and (2) set out obligations intended to fulfil one of the fundamental objectives of the Machinery Directive: the free movement of machinery and partly completed machinery within the single market.

In Article 6 (1), the term *'machinery'* is used in the broad sense to designate all of the products referred to in Article 1 (1) (a) to (f) – see §33: comments on the first paragraph of Article 2.

According to the obligations set out in Article 6, the Member States may not impose any requirements or procedures for the placing on the market of machinery or partly completed machinery or the putting into service of machinery, for the hazards covered by the Machinery Directive, other than those set out in that Directive.

The obligation to allow free movement of machinery and partly completed machinery that complies with the Directive does not prevent Member States from regulating the installation and use of machinery within certain limits – see §139 and §140: comments on Article 15.

By virtue of the Agreement on the European Economic Area (EEA)[108], machinery and partly completed machinery that complies with the Machinery Directive also benefits from free movement in Iceland, Liechtenstein and Norway. The same is true in Switzerland by virtue of the Mutual Recognition Agreement (MRA) with the EU[109], and in Turkey, Andorra and San Marino by virtue of the Customs Union Agreements between the EU and these countries[110].

[108] http://www.efta.int/legal-texts/eea.

[109] http://ec.europa.eu/growth/single-market/goods/international-aspects/mutual-recognition-agreements/.

[110] http://ec.europa.eu/taxation_customs/customs/customs_duties/rules_origin/customs_unions/.

Article 6 (continued)

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.*

§108 Trade fairs, exhibitions and demonstrations

Trade fairs, exhibitions and demonstrations provide an opportunity for machinery manufacturers, importers and distributors to promote new and innovative products. The provisions of Article 6 (3) are intended to ensure that the Machinery Directive does not constitute an obstacle to the promotion of such products – see §19: comments on Recital 17. In some cases, the companies concerned may wish to see whether their products interest potential customers before carrying out the relevant conformity assessment procedure. In other cases, the procedure may not have been completed at the time the machinery is put on display. Manufacturers, importers or distributors may also wish to exhibit products that are not intended for the EU market. Products may also be displayed with certain guards or protective devices removed in order to show their operating characteristics more clearly.

According to Article 6 (3), such practices are authorised. However, in order to provide clear information to potential customers and avoid unfair competition with exhibitors of products that are in conformity with the Machinery Directive, products that are not in conformity with the provisions of the Directive must be accompanied by a visible sign. This must clearly indicate that they are not in conformity and will not be available for supply into the EU until they have been brought into conformity. It is helpful for the organisers of Trade Fairs to remind exhibitors of their obligation in this respect.

The Machinery Directive does not specify a particular format or wording for this sign. The following wording can be suggested for machinery that the manufacturer intends to bring into conformity and place on the market in the EU:

> ***The machinery displayed is not in conformity with the Machinery Directive 2006/42/EC.***
>
> ***Visitors are informed that the machinery will be made available in the European Union only once it has been brought into conformity.***

The necessary precautions must be taken during exhibitions and demonstrations in order to ensure the safety of the demonstrators and the public, particularly if products are shown with guards or protective devices removed. With respect to the health and safety of demonstrators or other employees of the exhibitors, the necessary measures must be taken in accordance with the national provisions implementing the relevant EU Directives on the protection of the health and safety of workers.

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.*

. . .

§109 Presumption of conformity conferred by the CE marking and the EC Declaration of Conformity

Article 7 (1) explains the role of the CE marking and the EC Declaration of Conformity as "passports" facilitating the free movement of machinery in the single market referred to in Article 6 (1).

The EC Declaration of Conformity must accompany the machinery. This implies that the EC Declaration of Conformity must be supplied with the machinery by the manufacturer when the machinery is placed on the market and it must be passed on by other economic operators, such as importers or distributors, to the user of the machinery – see §83: comments on Article 2 (i).

It should be underlined that the obligation set out in Article 7 (1) for the Member States to regard machinery bearing the CE-marking and accompanied by an EC Declaration of Conformity as complying with the Machinery Directive does not affect the duty of the Member States to carry out market surveillance to ensure that products bearing the CE-marking and accompanied by an EC Declaration of Conformity really comply with the requirements of the Machinery Directive and their duty to ensure that non-compliant products bearing the CE-marking are withdrawn from the market – see §93 and §94: comments on Articles 4 (1), §122 to §126: comments on Article 11, and §142: comments on Article 17.

Article 7 (continued)

. . .

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.*

. . .

§110 The presumption of conformity conferred by the application of harmonised standards

The reference to European standards is a key element of the "New Approach to technical harmonization and standards" that is followed in the Machinery Directive. The Directive sets out the mandatory essential health and safety requirements for machinery while detailed technical specifications for fulfilling these essential health and safety requirements are given in European harmonised standards – see §87: comments on

Article 2 (l).

Once a European harmonised standard has been adopted, the European standardisation organisation communicates it to the European Commission so that the references of the standard can be published in the Official Journal of the European Union (OJEU).

Once the reference of a harmonised standard has been published in the OJEU, application of its specifications confers a presumption of conformity with the essential health and safety requirements covered by the standard. This presumption of conformity exists from the date on which the reference of the standard is first published in the OJEU. The presumption of conformity ceases when the standard is replaced by a new or revised standard on the “date of cessation of presumption of conformity” that is specified in the OJEU for machinery placed on the market after that date – see §114: comments on Article 7 (3).

It is important to understand that the presumption of conformity only extends to the essential health and safety requirements covered by the harmonised standard. Annex Z (in CEN standards) will indicate which essential health and safety requirements are covered. The manufacturer will need to carry out a risk assessment and compliance procedure for the risk areas associated to the relevant essential health and safety requirements. For Annex IV machinery (broad sense) the harmonised standards approach cannot be used if the standard does not cover all relevant essential health and safety requirements of the Directive.

It should be noted that, following formal objection, the references of certain standards may be published in the OJEU with a warning withdrawing the presumption of conformity for certain parts of the standard – see §121: comments on Article 10.

Application of draft European standards (identified by the prefix "prEN") or European standards the references of which have not been published in the OJEU does not confer a presumption of conformity with the essential health and safety requirements of the Machinery Directive.

Information about the subject of the standard (the category of machinery or the aspect of machinery safety covered by the standard) can be found in the clause of the standard relating to its scope. Additional information on the essential health and safety requirements of the Machinery Directive dealt with (or not dealt with) by the standard is provided in an informative Annex “Z” to the standard, which indicates as well the supported legislation and the relevant standardisation request.

Where a standard or part of a standard is referred to by a normative reference in a European harmonised standard, the specifications of the standard or parts of the standard referred to become part of the harmonised standard and their application confers a presumption of conformity with the essential health and safety requirements they cover. This remains true, even if the standard referred to is no longer in force (unless its reference has been withdrawn from the OJEU following a formal objection - see §121: comments on Article 10). On the other hand, application of the latest version of the standard referred to also confers a presumption of conformity with the essential health and safety requirements concerned, provided its reference has been published in the OJEU.

The presumption of conformity conferred by the application of a harmonised standard is not absolute, since the conformity of the standard itself can be challenged – see §119 to §121: comments on Article 10. However, the presumption of conformity conferred by the application of a harmonised standard gives a certain legal certainty for the manufacturer, since he does not have to provide further proof of conformity with the essential health and safety requirements covered by the standard.

Furthermore, in the case of categories of machinery listed in Annex IV, application of a harmonised standard that covers all the essential health and safety requirements that are applicable to the machinery enables the manufacturer to carry out the conformity assessment of the machinery without recourse to a Notified Body – see §129: comments on Article 12 (3).

It should be noted that, although the application of harmonised standards facilitates the risk assessment, it does not entirely dispense the machinery manufacturer from the obligation to carry out a risk assessment for the machinery – see §159: comments on General Principle 1 of Annex I.

Even when a given essential health and safety requirement is covered by a harmonised standard, a machinery manufacturer remains free to apply alternative specifications. The voluntary nature of harmonised standards is intended to prevent technical standards being an obstacle to the placing on the market of machinery incorporating innovative solutions.

However, a harmonised standard provides an indication of the state of the art at the time it was adopted. In other words, the harmonised standard indicates the level of safety which can be expected of a given type of product at that time. A machinery manufacturer who chooses to apply other technical specifications must be able to demonstrate that his alternative solution is in conformity with the EHSRs of the Machinery Directive and provides a level of safety that is at least equivalent to that afforded by application of the specifications of the harmonised standard – see §161 and §162: comments on General Principle 3 of Annex I.

When a manufacturer chooses not to apply harmonised standards or to apply only parts of a harmonised standard, he must include in the technical file the risk assessment undertaken and the steps taken to comply with the essential health and safety requirements – see §392: comments on Annex VII A 1 (a). In such a case, the reference of the harmonised standard should not be listed as such in the manufacturer's EC Declaration of Conformity, but the Declaration may indicate which parts or clauses of a harmonised standard have been applied – see §383: comments on Annex II A 1 (7).

§111 The classification of machinery standards

Machinery standards are classified into three types, A, B and C. The purpose of this classification is to enable the authors of standards for particular categories of machinery to refer to horizontal standards providing well tried technical solutions. The horizontal A and B-type standards can also help manufacturers designing machinery for which C-type standards are not available.

The nature of the presumption of conformity conferred by application of the harmonised standards of these three types must be distinguished:

A-type standards

A-type standards specify basic concepts, terminology and design principles applicable to all categories of machinery. Application of such standards alone, although providing an essential framework for the correct application of the Machinery Directive, is not sufficient to ensure conformity with the relevant essential health and safety requirements of the Directive and therefore does not give a presumption of conformity.

For example, the application of standard EN ISO 12100[111] ensures that the risk assessment is carried out according to the requirements of General Principle 1 of Annex I, but it is not sufficient to show that the protective measures taken by the manufacture to deal with the hazards presented by the machinery comply with the relevant essential health and safety requirements of Annex I.

B-type standards

B-type standards deal with specific aspects of machinery safety or specific types of safeguard that can be used across a wide range of categories of machinery. Application of the specifications of B-type standards confers a presumption of conformity with the essential requirements of the Machinery Directive that they cover when a C-type standard or the manufacturer's risk assessment shows that a technical solution specified by the B-type standard is adequate for the particular category or model of machinery concerned.

Application of B-type standards that give specifications for safety components that are independently placed on the market confers a presumption of conformity for the safety components concerned and for the EHSRs covered by the standards – see §42, comments on Article 2 (c).

C-type standards

C-type standards provide specifications for a given category of machinery such as, for example, mechanical presses, combine harvesters or compressors. The different types of machinery belonging to the category covered by a C-standard have a similar intended use and present similar hazards. C-type standards may refer to A or B-type standards, indicating which of the specifications of the A or B-type standard are applicable to the category of machinery concerned. When, for a given aspect of machinery safety, a C-type standard deviates from the specifications of an A or B-type standard, the specifications of the C-type standard take precedence over the specifications of the A or B-type standard.

Application of the specifications of a C-type standard confers a presumption of conformity with the essential health and safety requirements of the Machinery Directive covered by the standard provided that the manufacturer has determined in his risk

[111] EN ISO 12100:2010 *Safety of machinery - General principles for design - Risk assessment and risk reduction* (ISO 12100-1:2010).

assessment that the scope and the significant hazards covered by the standard correspond with his actual machinery[112].

Certain C-type standards are organised as a series of several parts, Part 1 of the standard giving general specifications applicable to a family of machinery and other parts of the standard giving specifications for specific categories of machinery belonging to the family, supplementing or modifying the general specifications of Part 1. For C-type standards organised in this way, the presumption of conformity with the essential requirements of the Machinery Directive is conferred by application of the general Part 1 of the standard together with the relevant specific part of the standard.

§112 The development of harmonised standards for machinery

Harmonised standards for machinery are developed by the Technical Committees (TCs) of the European Standardisation Organisations, CEN and CENELEC. The TCs are constituted by representatives mandated by the national member organisations of CEN and CENELEC. The TCs involved in developing standards supporting the Machinery Directive include the following:

CEN

TC 10	Lifts, escalators and moving walks
TC 33	Doors, windows, shutters
TC 47	Atomising oil burners and their components - Function - Safety - Testing
TC 98	Lifting platforms
TC 114	Safety of machinery
TC 122	Ergonomics
TC 123	Lasers and photonics
TC 131	Gas burners using fans
TC 142	Woodworking machines - Safety
TC 143	Machine tools - Safety
TC 144	Tractors and machinery for agriculture and forestry
TC 145	Plastics and rubber machines
TC 146	Packaging machines - Safety
TC 147	Cranes - Safety
TC 148	Continuous handling equipment and systems - Safety
TC 149	Power-operated warehouse equipment
TC 150	Industrial trucks – safety
TC 151	Construction equipment and building material machinery - Safety
TC 153	Machinery intended for use with foodstuffs and feed
TC 168	Chains, ropes, webbing, slings and accessories - Safety
TC 169	Light and lighting
TC 182	Refrigerating systems, safety and environmental requirements
TC 186	Industrial thermo processing - Safety
TC 188	Conveyor belts
TC 192	Fire and Rescue service equipment
TC 196	Machines for underground mines - Safety
TC 197	Pumps
TC 198	Printing and paper machinery - Safety
TC 200	Tannery machines and plants - Safety

[112] Further practical guidance is provided by CEN ISO/TR 22100-1:2017 Safety of machinery - Relationship with ISO 12100 - Part 1: How ISO 12100 relates to type-B and type-C standards (ISO/TR 22100-1:2015)

TC 202 Foundry machinery
TC 211 Acoustics
TC 213 Cartridge operated hand-held tools - Safety
TC 214 Textile machinery and accessories
TC 221 Shop fabricated metallic tanks and equipment for storage tanks and for service stations
TC 231 Mechanical vibration and shock
TC 232 Compressors, vacuum pumps and their systems
TC 255 Hand-held, non-electric power tools - Safety
TC 256 Railway applications
TC 270 Internal combustion engines
TC 271 Surface treatment equipment - Safety
TC 274 Aircraft ground support equipment
TC 310 Advanced manufacturing technologies and their applications
TC 313 Centrifuges - Safety requirements
TC 322 Equipments for making and shaping of metals - Safety requirements
TC 354 Non-type approved light motorized vehicles for the transportation of persons and goods and related facilities
TC 397 Project Committee - Baling presses - Safety requirements
TC 429 Project Committee - Food hygiene - Commercial warewashing machines - Hygiene requirements and testing
TC 433 Entertainment Technology - Machinery, equipment and installations

CENELEC

TC 44X Safety of machinery – electro technical aspects
TC 61 Safety of household and similar electrical appliances
TC 116 Safety of hand-held and transportable motor-operated electric tools
TC 88 Wind turbine systems

Draft standards are prepared by Working Groups (WGs) set up by the relevant TC. The WGs are made up of experts nominated by the national standardisation organisations. The draft standard (prEN) prepared by the WG is sent by the TC to the national standardisation organisations who circulate the draft to interested parties at national level for comments (public enquiry). Public enquiry is combined with a majority weighted vote of national standardisation organisations. The comments received are sent back to the TC and examined by the WG in order to improve the draft if relevant Depending on the outcome of the vote and upon TC decision it is possible to publish the standard straight after the enquiry. In case there are technical changes to be made to the draft standard after enquiry, a separate weighted majority vote by the national standardisation organisations is needed for adoption.

Many European harmonised standards are now developed within the framework of the agreements relating to cooperation between CEN and the International Standardisation Organisation (ISO) or between CENELEC and the International Electrotechnical Commission (IEC). The agreement between CEN and ISO is known as the Vienna Agreement. The agreement between CENELEC and IEC is known as the Frankfurt Agreement (former Dresden Agreement). When these agreements are applied, the draft standards may be prepared by the TCs and WGs of ISO or IEC. However, before being adopted as European harmonised standards, they are subject to the enquiry and adoption procedures of CEN or CENELEC, which are normally carried out in parallel with the ISO or IEC procedures.

The reference material on the technical cooperation between CEN and ISO as well as CENELEC and IEC is available on CEN and CENELEC website.

§113 The identification of harmonised standards

Draft European standards are identified by a reference number preceded by the prefix “prEN”, followed by the date of the draft. Such draft European standards are made publicly available at the Public Enquiry stage.

Once the standard has been adopted by CEN or CENELEC, it is identified by the same number preceded by the prefix “EN”, and followed by the date (year) of adoption. When a standard is amended or revised and the new version bears the same number, the date of adoption makes it possible to distinguish the new version of the standard from the previous version.

When a CEN standard is identical to an international standard adopted by ISO, the European and International standards have the same number and the reference of the harmonised standard has the prefix “EN ISO”. A CENELEC standard identical or based on an IEC standard has also an identical EN number. However, for both European Standardisation Organisations, the reference of the corresponding ISO or IEC standard is indicated in brackets after the title of the European standard.

The national member organisations of CEN and CENELEC must give the harmonised standard the status of a national standard without any alteration. In the reference of the national version of a harmonised standard, the prefix “EN” is preceded by the prefix used to identify national standards in the country concerned. Harmonised standards are published by the national standardisation organisations of the EU Member States with the following prefixes:

“ÖNORM EN” in Austria
“NBN EN” in Belgium
“БДС EN” in Bulgaria
“HRN EN” in Croatia
“CYS EN” in Cyprus
“ČSN EN” in the Czech Republic
“DS EN” in Denmark
“EVS EN” in Estonia
“SFS EN” in Finland
“NF EN” in France
“DIN EN” in Germany
“EN” in Greece
“MSZ EN” in Hungary
“IS EN” in Ireland
“UNI EN” in Italy
“LVS EN” in Latvia
“LST EN” in Lithuania
“EN” in Luxembourg
“MSA EN” in Malta
“NEN EN” in the Netherlands
“PN EN” in Poland
“NP EN” in Portugal
“SR EN” in Romania
“STN EN” in Slovakia
“SIST EN” in Slovenia
“UNE EN” in Spain
“SS EN” in Sweden
“BS EN” in the United Kingdom

The same standards are published with the following prefixes in EFTA countries:

“IST EN” in Iceland
“NS EN” in Norway
“SN EN” in Switzerland

In some cases, the date included in the reference of the national version of the harmonised standard is later than the date included in the reference of the standard

published in the OJEU, due to the fact that the publication of the standard at national level may have occurred in the following year.

In the EC Declaration of Conformity of machinery, the European harmonised standards applied by the manufacturer may be identified using either the national reference, with one of the national prefixes listed above, or the reference as listed the in OJEU with the prefix "EN" only – see §383: comments on Annex II 1 A (7).

Article 7 (continued)

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3. *The Commission shall publish in the Official Journal of the European Union the references of the harmonised standards.*

. . .

§114 Publication of the references of harmonised standards in the OJEU

Consolidated lists of harmonised standards are published in the C-series of the OJEU in the form of a Commission communication in the framework of the implementation of the Machinery Directive. The list is regularly updated when the references of new or revised standards are communicated to the European Commission by CEN and CENELEC.

CEN and CENELEC communicate the references several times a year, usually quarterly.

The list published in the OJEU includes the following 5 columns:

Column 1 indicates the European standardisation organisation that has adopted the standard: CEN or CENELEC;

Column 2 indicates the reference of the standard, that is to say, its number, the date of its adoption by CEN or CENLEC and its title;

If the standard has been amended, the reference of the amended version of the standard is indicated. Once the references of such amended standards have been published in the OJEU, the amended version of the standard confers presumption of conformity with the relevant essential health and safety requirements of the Machinery Directive;

Column 3 indicates the date on which the reference of the standard was first published in the OJEU. This is the date from which application of the standard confers a presumption of conformity with the essential health and safety requirement it covers;

Column 4 gives the references of the superseded standard. This column is only used if there was already a harmonised standard dealing with the same subject when the new or revised standard was adopted. In most cases, the superseded standard is an earlier version of a standard that has been revised;

Column 5 indicates the date of cessation of presumption of conformity of the superseded standard. This column is only used when the reference of a

superseded standard is given in the fourth column. The date of cessation of presumption of conformity is fixed by the Commission. In general, the date of cessation of presumption of conformity is the same as the date fixed by CEN or CENELEC for the withdrawal of the superseded standard by the national standardisation organisations.

The new standard confers a presumption of conformity as from the date on which its reference is published in the OJEU, while the superseded standard continues to confer a presumption of conformity until the date of cessation of presumption of conformity indicated in the fifth column. During the period between the two dates (the transition period) the specifications of either the new standard or the superseded standard confer a presumption of conformity with the essential health and safety requirements they cover.

Under the line listing of a particular standard it may be added a “warning” that either limits the presumption of conformity in some way, such as not applying it to certain sections of the standard, or pointing out that the standard does not address certain essential health and safety requirements in an appropriate manner. Such warnings have followed a formal objection. In cases of more fundamental concerns raised in a formal objection then the whole reference in the OJEU may be removed and with it the presumption of conformity.

Article 7 (continued)

. . .

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.*

§115 Participation of the social partners in standardisation

Standardisation is based on a consensus between the interested parties. The parties interested in machinery standards include, for example, machinery manufacturers, users of machinery such as employers, workers and consumers, occupational health and safety institutions, Notified Bodies, other relevant NGOs and public authorities. Rules for the participation of the interested parties are usually subject to national provisions relating to the organisation of standardisation; for example, a fee may be charged to participate depending on the individual national standardisation organisation.

Article 7 (4) sets out a specific requirement for Member States to ensure that appropriate measures are taken to enable the social partners, that is to say the representatives of employers and employees, to have an influence on the standardisation process at national level. It is up to Member States to decide what measures are appropriate and how they are put into effect.

However, societal stakeholders as defined in Annex III to the Regulation (EU) 1025/2012 and SMEs, can also participate at European level directly with the European Standardisation Organisations (Articles 5 and 6 of Regulation (EU) 1025/2012).

Article 8 [113]

Specific measures

1. *The Commission may take any appropriate measure relating to the following:*

(a) updating of the indicative list of safety components in Annex V referred to in Article 2 (c);

(b) restricting the placing on the market of machinery referred to in Article 9.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22 (3).

. . .

§116 Measures subject to the Regulatory Committee Procedure

Article 8 (1) sets out the two cases in which the Commission can adopt measures after consulting the Machinery Committee according to the Regulatory procedure with scrutiny – see §147: comments on Article 22 (3).

– Article 8 (1) (a) enables the Commission to update the indicative list of safety components set out in Annex V, for example, by adding to the list further examples of components that correspond to the definition given in Article 2 – see §42: comments on Article 2 (c). This may be done if it appears that certain existing safety components have been omitted from the list or if new safety components are developed.

– Article 8 (1) (b) enables the Commission to adopt a measure restricting the placing on the market of machinery presenting risks due to the shortcomings of a harmonised standard, presenting the same risk as machinery subject to a justified safeguard action or at the request of a Member State – see §118: comments on Article 9.

Article 8 (continued)

. . .

2. *The Commission, acting in accordance with the procedure referred to in Article 22(2), may take any appropriate measure connected with the practical application of this Directive, including measures necessary to ensure cooperation of Member States with each other and with the Commission, as provided for in Article 19(1).*

§117 Measures subject to the Advisory Committee procedure

[113] Article 8 was amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny (PRAC) - Adaptation to the regulatory procedure with scrutiny - Part Four. OJ L 188, 18.7.2009, p.14.

Article 8 (2) enables the Commission to take any appropriate measure connected with the practical application of the Machinery Directive after consulting the Machinery Committee according to the Advisory procedure – see §147: comments on Article 22 (2). It also provides a legal basis for Commission support for the organisation of administrative cooperation (AdCo) between the market surveillance authorities of the Member States. This has now been implemented and support such as interpretation and funding for travel and accommodation for the official representative of a member states is now given by the Commission – see §144: comments on Article 19 (1).

Article 9[114]

Specific measures to deal with potentially hazardous machinery

1. *When, in accordance with the procedure referred to in Article 10, the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery with technical characteristics presenting risks due to the shortcomings in the standard or to make such machinery subject to special conditions.*

When, in accordance with the procedure referred to in Article 11, the Commission considers that a measure taken by a Member State is justified, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery presenting the same risk by virtue of its technical characteristics or to make such machinery subject to special conditions.

2. *Any Member State may request the Commission to examine the need for the adoption of the measures referred to in paragraph 1.*

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.*[115]

Taking due account of the results of this consultation, it shall adopt the necessary measures.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).

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[114] Article 9 (3) was amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny (PRAC) - Adaptation to the regulatory procedure with scrutiny - Part Four. OJ L 188, 18.7.2009, p.14.

[115] Article 9 (3) 2nd indent was amended by Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application. OJ L 310, 25.11.2009, p. 29.

§ 118 Measures to deal with unsafe machinery presenting similar risks

The safeguard clause set out in Article 11 requiring the Member States to take appropriate measures to deal with unsafe machinery bearing the CE marking, applies to particular models of machinery. Article 9 enables the Commission to adopt measures to prohibit or restrict the placing on the market all models of machinery presenting risks due to the same technical characteristics. This article was amended by Directive 2009/127/EC which expanded the application from just persons to add "where appropriate, of domestic animals and property and, where applicable, of the environment". The meaning of "where applicable, of the environment" restricts the application of this article to the potential or actual effect on the environment to that caused by "pesticides application machinery" and does not increase the scope in this respect to any other type of machinery.

Such measures can be adopted in the following circumstances:

Following a formal objection to a harmonised standard according to Article 10

The first circumstance is linked to the procedure set out in Article 10 for disputing a harmonised standard. When a formal objection is made against a harmonised standard, the Commission may adopt a decision withdrawing or restricting the presumption of conformity conferred by application of the standard on the grounds that certain of its specifications fail to satisfy the relevant essential health and safety requirements – see §121: comments on Article 10. Following such a decision, it may be considered necessary, in order to protect the health and safety of persons, to ensure that machinery designed according to the defective standard is withdrawn from the market or subject to certain restrictions.

Following a safeguard action according to Article 11

The second circumstance is linked to the safeguard clause procedure set out in Article 11. Following the notification of a measure taken by a Member State to prohibit or restrict the placing on the market of a particular model of unsafe machinery, the Commission adopts a decision stating whether or not it considers the measure to be justified – see §123: comments on Article 11 (3). Following such a decision, the Commission may adopt a Decision requiring all Member States to take the appropriate measures, in order to protect the health and safety of persons, to ensure that any other machinery having the same defect as the model subject to the original national measure should be withdrawn from the market or subject to certain restrictions i.e. similar to the action taken in the MS instigating the safeguard action.

At the request of the Member State

Article 9 (2) gives the Member States the possibility to initiate the process by requesting the Commission to examine the need for measures 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.

Before taking such measures, the Commission shall consult the interested parties. Since, the measures do not just concern a single manufacturer but may have consequences for all of the manufacturers of a given category of machinery, it is clear that organisations representing machinery manufacturers at EU level must be consulted.

In general, the consultation of the interested parties is organised in the framework of the Machinery Working Group – see §148: comments on Article 22. The measure is then adopted after consultation of the Machinery Committee according to the Regulatory procedure with scrutiny – see §147: comments on Article 22 (3).

This system has been used, for example, to require Member States to prohibit the placing on the market of flail-type cutting attachments for portable hand-held brush cutters[116].

Article 10

Procedure for disputing a harmonised standard

Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission or the Member State shall bring the matter before the committee set up by Directive 98/34/EC, setting out the reasons therefor. The committee shall deliver an opinion without delay. In the light of the committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union.

§119 Formal objections to harmonised standards

The application of harmonised standards the references of which are published in the OJEU confers a presumption of conformity with the essential health and safety requirements they cover – see §110: comments on Article 7 (2). However, according to Articles 10 and 11 the presumption of conformity can be challenged:

- Article 10 requires a Member State or the Commission to refer a harmonised standard to the Committee set up by Regulation 1025/2012[117] if they have evidence that certain essential health and safety requirements covered by the standard are not adequately fulfilled by its specifications.
- If the safeguard procedure set out in Article 11 is used and the Member State concerned considers that the non-conformity of the machinery subject to the restrictive measure is due to a shortcoming in a harmonised standard applied by the manufacturer, the standard concerned is also referred to the Regulation 1025/2012 Committee – see §124: comments on Article 11 (4).

To avoid the need for such formal objections, the Member States are encouraged to follow the development of harmonised standards and to make their concerns known to CEN or CENELEC before harmonised standards are adopted. Participation in

[116] Commission Decision of 19 January 2012 requiring Member States to prohibit the placing on the market of flail-type cutting attachments for portable hand-held brush cutters. OJ L 18, 21.1.2012, p. 5.

[117] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation (OJ L 316, 14.11.2012, p. 12) lays down procedures, among others, for objections to standards and sets up a committee to consider these. It took over this function with amendments (deletions) to Directive 98/34/EC.

standardization by market surveillance authorities is foreseen at national level by article 7 of Regulation EU 1025/2012. The comments to draft standards are expected to be made during Enquiry stage directly by market surveillance authorities or via national mirror committees. If the information is received at a late stage of the standards development process (for example after a Formal Vote), it cannot always be integrated directly, but could be processed after the publication of the given standard, possibly resulting in an amendment or revision. By the same token, the standardisation organisations are encouraged to take due account of the concerns of the Member States when developing and adopting harmonised standards.

However, a Technical Committee needs to receive structured, concrete and adequately detailed technical and legal information in order to be able to address the concerns and develop a proper technical solution to the issue.

Only the Member States and the Commission have the possibility to make a formal objection against a harmonised standard. If other interested parties consider that a harmonised standard has serious shortcomings, they may draw the matter to the attention of the national authorities or the Commission and ask them to take appropriate action.

§120 The procedure for formal objections

A formal objection can be introduced when a harmonised standard has been adopted by the European Standardisation Organisation and its reference been communicated to the Commission for publication in the OJEU. A formal objection can also be introduced at any time after the publication of the reference of the harmonised standard in the OJEU.

The formal objection must be communicated by the Member State to the Commission via its Permanent Representation to the EU, indicating the reference of the standard concerned, the specifications of the standard that are considered to be defective and the grounds for the objection.

The formal objection is first discussed within the Machinery Working Group – see §148: comments on Article 22 - where the other Member States, the representatives of CEN or CENELEC and other interested parties are invited to express their opinions. The outcome of the discussion in the Machinery Working Group is reported by the Commission to the Regulation 1025/2012 Committee. This Committee is then consulted on a draft Commission Decision. The Decision is then adopted by the Commission and published in the L series of the OJEU.

§121 The outcome of a formal objection

The Commission Decision on a formal objection to a harmonised standard can take several forms:

- if the formal objection is not sustained, the Commission adopts a Decision to publish the reference of the standard in the OJEU, or to maintain the reference of the standard in the OJEU if it has already been published;

– if the formal objection is sustained, the Commission may decide not to publish the reference of the standard in the OJEU, or to withdraw the reference of the standard from the OJEU if it has already been published;

– if the shortcomings of the standard only concern certain specifications and the rest of the standard is considered adequate, the Commission may decide to publish the reference of the standard in the OJEU (or maintain the reference of the standard in the OJEU if it has already been published) with a warning restricting the presumption of conformity conferred by application of the standard.

When the reference of a harmonised standard is published in the OJEU with a warning restricting the presumption of conformity, this implies that the application of the specifications of the standard that are not subject to the restriction continue to confer a presumption of conformity with the essential health and safety requirements they cover. However, in order to comply with the essential health and safety requirements that are not fulfilled by the standard, the manufacturer must carry out a full risk assessment, choose adequate protective measures to deal with the hazards concerned and justify his choice in his technical file – see §392: comments on Annex VII A 1 (a). As the standard used does not carry a complete presumption of conformity, and the product concerned is listed in Annex IV then the procedure for assessment of conformity with internal checks on the manufacture of machinery, provided for in Annex VIII is not possible and either 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, or the full quality assurance procedure provided for in Annex X will need to be used.

When the Commission adopts a Decision not to publish the reference of a standard in the OJEU, to withdraw a reference of a standard from the OJEU or to publish or to maintain the reference of a standard in the OJEU with a restriction, the Commission gives a mandate to the European Standardisation Organisation to revise the standard concerned in order to remedy the shortcomings that have been identified.

Article 11[118]

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.*

. . .

[118] Article 11 was amended by Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application. OJ L 310, 25.11.2009, p. 29.

§122 The safeguard clause

The safeguard clause is foreseen in paragraph (10) of Article 95 of the EC Treaty (now Article 114 of the TFEU) on which the Machinery Directive is based – see §2: comments on the citations:

> *"The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure".*

Article 11 sets out the procedure to be followed when the market surveillance authorities of a Member State discover that the presumption of conformity conferred by the CE-marking and the EC Declaration of Conformity is not founded – see §109: comments on Article 7 (1). This Article was modified by the Directive 2009/127/EC to also apply "where applicable the environment" but only for machinery for pesticide application.

The safeguard procedure set out in Article 11 applies to machinery in the broad sense, in other words, it can be applied to any of the products listed in Article 1 (1), (a) to (f). It is not applicable to partly completed machinery.

When machinery is found not to comply with the applicable health and safety requirements despite the presence of the CE-marking, the Member State should first contact the manufacturer, his authorised representative or the person responsible for placing the machinery on the market and require him to bring the product into conformity or withdraw it from the market within a timeframe determined by the market surveillance authority – see §78 to §84: comments on Article 2 (i) and (j), and §100: comments on Article 4.

If the product is brought into conformity or withdrawn from the market voluntarily, there is no need to take the restrictive measures referred to in Article 11 (1) and consequently there is no legal basis for recourse to the safeguard procedure. However, if the machinery concerned presents a serious risk, Regulation (EC) No 765/2008 requires the Member State concerned to inform the Commission and the other Member States of the action taken using the RAPEX system[119].

In all cases where corrective action is taken by the manufacturer, it is important for the Member State concerned to inform the market surveillance authorities of the other Member States so that they can ensure that the necessary corrective measures are taken throughout the EU – see §100: comments on Article 4. This information can be communicated in the framework of the Machinery AdCo Group – see §144: comments on Article 19 and by using the Information Communication System for Market Surveillance (ICSMS) which is owned and operated by the Commission and implemented by Article 23 of Regulation (EC) No 765/2008 which foresaw the establishment of a General EU information support system. If the non-conformity subject to corrective action taken by the manufacturer results from a deficiency in the harmonised standard applied, the Member State must also take action with respect to

[119] See Articles 20 and 22 of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93. OJ L 218, 13.8.2008, p.30.

the harmonised standard, if necessary by means of the formal objection procedure – see §119 to §121: comments on Article 10.

If voluntary measures to bring the product into conformity are not taken within the timeframe determined by the market surveillance authorities and if the non-conformity is liable to endanger the health and safety of persons or, where appropriate, domestic animals or property, or for pesticides machinery, the environment, the safeguard procedure set out in Article 11 must be followed.

Article 11 (1) describes the measures to be taken by the national market surveillance authorities. The measures may include suspending or prohibiting the placing on the market of the machinery and/or the putting into service of the machinery, or making these operations subject to certain restrictions. The form and content of the measures is a matter for the Member State concerned, but the measures must be both sufficient to protect the health and safety of persons and proportionate to the risk involved.

According to Article 21 (3) of Regulation (EC) No 765/2008, before such measures are taken, the interested parties must be given the opportunity to express their views unless this is not possible because of urgency. If measures are taken without the interested parties being heard, they must be given the opportunity to express their views as soon as possible.

According to Article 20 of the Regulation, in the case of machinery presenting a serious risk requiring rapid intervention, Member States may also order the recall of machinery already placed on the market, both in the supply chain and in service, in order to protect the health and safety of users.

The measure taken by the Member State according to Article 11 (1) must state the exact grounds on which it is based and 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 – see §145: comments on Article 20.

The decision taken by the Member State shall be published – see §143: comments on Article 18 (3).

Article 11 (continued)

. . .

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.

. . .

§123 The safeguard procedure

Article 11 (2) and (3) set out the procedure to be followed at EU level when a national measure is taken in accordance with Article 11 (1). The measure must be notified by the Member State concerned to the European Commission, indicating the reasons for the measure. The notification shall be transmitted to the Commission by the Permanent Representation of the Member State concerned. At the same time, the other Member States must be informed. The information can be communicated through the Machinery AdCo Group using the CIRCABC system – see §146: comments on Article 21. The Machinery AdCo Group has developed a special form to help Member States to transmit the necessary information. This form can be generated with much of the information filled in from the ICSMS system, completed and printed.

Note that Article 11 only applies to CE marked products that do not conform to the Machinery Directive. If a machine is found on the EU/EEA market that is not CE marked and which may be also non-compliant in other respects, the competent Member State Authority (MSA) should take appropriate action to ensure the machine is brought into compliance and CE marked or have it withdrawn from the market.

The notification should clearly indicate the essential health and safety requirements with which the machinery fails to comply and explain the nature of the risks to which these non-conformities give rise. If the market surveillance authorities have assessed the conformity of the machinery with reference to the specifications of a harmonised standard, the relevant clauses of the standard should also be indicated.

In order to enable the Commission to carry out its enquiry without delay, the national authorities should transmit all relevant documents with the notification. Relevant documents may include:

- photos or drawings of the machinery concerned showing the CE marking and the defects concerned;

- a copy of the EC Declaration of Conformity;
- the EC type-examination certificate or the certificate of approval of the manufacturer's full quality assurance system (if applicable);
- the relevant elements of the manufacturer's technical file if they are available;
- the relevant extracts from the manufacturer's instructions;
- reports of any tests or inspections on which the measure is based;
- details of any correspondence exchanged with the parties concerned, such as the manufacturer or his authorised representative, the importer or the distributor of the machinery, or the Notified Body involved.

The Commission services then examine the notification and the supporting documents and consult the parties concerned in order to consider whether or not the measure taken by the Member State is justified. The parties concerned include the authorities of the Member State that has notified the measure, the manufacturer of the machinery concerned or his authorised representative and, where applicable, the Notified Body involved in the conformity assessment of the machinery. An opportunity is given to the parties concerned to meet the Commission services to present their observations if they so wish.

If necessary, the Commission may seek independent expert advice in order to assess the file and, in some cases, to inspect the machinery concerned or carry out tests. The Commission then adopts a Decision which is communicated to the Member State which took the initial measure, to the other Member States, and to the manufacturer or his authorised representative. The Commission's Decision is published in the Official Journal of the European Union – see §143: comments on Article 18 (3).

If the Commission decides that the measure taken by the Member State is justified, the other Member States shall take the measures necessary to ensure the protection of the health and safety of persons with respect to the non-compliant machinery. If, on the other hand, the Commission decides that the measure taken by the Member State is not justified, the measure shall be withdrawn.

It should be noted that Decision No 768/2008 of the European Parliament and the Council of 9 July 2008 on a common framework for the marketing of products, sets out a “safeguard procedure” that is intended to become the system for all relevant “CE marking” Directives and Regulations. A number of such legislation has now been revised to follow this Decision. However, the Machinery Directive 2006/42/EC has not yet been revised and the procedure described in Article 11 must be used until the Machinery Directive is so revised and aligned to the New Legislative Framework.

Article 11 (continued)

. . .

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.*

. . .

§124 Shortcomings in harmonised standards

Article 11 (4) is applicable when the non-conformity notified according to Article 11 (1) and (2) is due to a shortcoming in the harmonised standard applied by the manufacturer. In that case, in addition to the procedure set out in Article 11 (3), a formal objection must be lodged either by the Member State concerned or by the Commission, according to the procedure set out in Article 10 – see §119 to §121: comments on Article 10.

Article 11 (continued)

. . .

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.*

. . .

§125 Action against the person who has affixed the CE marking

The provisions set out in Article 11 (1) to (4) deal with the measures to be taken with respect to products that bear the CE marking and that are liable to compromise the health and safety of persons and, where appropriate, domestic animals or property, or the environment in the case of pesticides machinery.

In addition to those measures, Article 11 (5) requires the Member State to take appropriate action with respect to the person who has affixed the CE marking on a non-compliant product and thereby taken the responsibility for placing the product on the market or putting it into service – see §141: comments on Article 16. That person may be the manufacturer his authorised representative or another person taking the responsibility for placing the product on the market who is considered as a manufacturer – see §78 to §81: comments on Article 2 (i).

The appropriate action shall be determined by the Member States according to the provisions implementing the Machinery Directive into national law. In general, the market surveillance authorities should first require the manufacturer or his authorised representative to take the measures necessary to put an end to the non-conformity. If the necessary measures are not taken within the timeframe determined by the market surveillance authorities, appropriate sanctions must be applied – see §150: comments on Article 23.

In such cases, the Member States must inform the Commission and the Commission shall inform the other Member States. For this purpose, the ICSMS system foreseen in Article 23 of Regulation (EC) No 765/2008 shall be used.

For non-conformities relating to the CE marking or the EC Declaration of Conformity – see §142: comments on Article 17.

Article 11 (continued)

. . .

6. *The Commission shall ensure that Member States are kept informed of the progress and outcome of the procedure.*

§126 Information on the safeguard procedure

According to Article 11 (6), the Commission shall keep the Member States informed of the progress and outcome of the safeguard procedure. The relevant information is provided to the Member States in the framework of the Machinery AdCo Group – see §144: comments on Article 19.

The Commission's Decision is published in the Official Journal of the European Union – see §143: comments on Article 18 (3).

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.*

. . .

§127 Conformity assessment of machinery

Article 12 concerns the conformity assessment procedure that must be carried out by the manufacturer of machinery or his authorised representative before placing machinery on the market and/or putting it into service – see §103: comments on Article 5 (1). The conformity assessment procedure is mandatory, however, for certain categories of machinery, the manufacturer can choose between several alternative procedures. The following paragraphs set out the conditions under which the different conformity assessment procedures can be used.

Article 12 *(continued)*

. . .

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.*

. . .

§128 Categories of machinery not listed in Annex IV

Article 12 (2) sets out the conformity assessment procedure to be used for all categories of machinery other than those listed in Annex IV. The procedure to be followed is the procedure for assessment of conformity with internal checks on the manufacture of machinery, sometimes referred to as *"Supplier's Declaration of Conformity"* or *"first party attestation"*[120] – see §395: comments on Annex VIII. This procedure does not involve the intervention of a Notified Body. However, the manufacturer or his authorised representative is free to seek any independent advice or assistance he needs in order to carry out the conformity assessment of the machinery. He may carry out the checks, inspections and tests and inspections needed to assess the conformity of the machinery himself or entrust them to any competent body of his choice. The relevant technical reports shall be included in the technical file – see §392: comments on Annex VII A 1 (a), sixth indent.

It should be noted that there are no Notified Bodies for categories of machinery other than those listed in Annex IV. Manufacturers of non-Annex IV machinery may seek advice or assistance from Bodies that are notified for certain categories of Annex IV machinery. However, in that case, the body is not acting as a Notified Body and must not use the identification number assigned to it by the Commission on any documents relating to such activity – see §133: comments on Article 14.

***Article 12** (continued)*

. . .

3. Where the machinery is referred to in Annex IV and manufactured in accordance with the harmonised standards referred to in Article 7(2), and provided that those standards cover all of the relevant essential health and safety requirements, the manufacturer or his authorised representative shall apply one of the following procedures:

(a) the procedure for assessment of conformity with internal checks on the manufacture of machinery, provided for in Annex VIII;

(b) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3;

(c) the full quality assurance procedure provided for in Annex X.

. . .

§129 Annex IV machinery designed to harmonised standards that cover all the applicable essential health and safety requirements

Article 12 (3) sets out the three alternative conformity assessment procedures that may be applied to categories of machinery listed in Annex IV designed and constructed in

[120] The concept of "Suppliers Declaration of Conformity" is explained in standard EN ISO/IEC 17050-1:2010 *Conformity assessment - Supplier's Declaration of Conformity* - Part 1: *General requirements* (ISO/IEC 17050-1:2004, corrected version 2007-06-15); however, application of this standard does not confer a presumption of conformity with the requirements of the Machinery Directive.

accordance with harmonised standards. For the procedures set out in Article 12 (3) to be applicable, the following three conditions must be fulfilled:

- the machinery concerned must be in the scope of one or more harmonised C-type standards, (exception is made for safety components independently placed on the market within the scope of one or more harmonised B-type standards- - see §111), the references of which have been published in the OJEU – see §110: comments on Article 7 (2);
- the harmonised standard or standards concerned must cover all of the essential health and safety requirements that are applicable to the machinery as determined by the risk assessment – see §159: comments on General Principle 1; Note that some harmonised standards do not cover all the EHSRs either due to a warning in the OJEU or by design, in the latter case this will be stated in Annex Z. The manufacturer must therefore check that the standard/s do cover all the applicable EHSR by checking both the most recent publication in the OJEU and Annex Z;
- the machinery must be designed and constructed fully in accordance with the harmonised standards concerned.

When these three conditions are fulfilled, the manufacturer can choose the procedure referred to in Article 12 (3) (a) or one of the alternative procedures referred to in Article 12 (3) (b) and (c).

The procedure referred to in Article 12 (3) (a) - assessment of conformity with internal checks on the manufacture of machinery - is identical to the procedure referred to in Article 12 (2) that is applicable for categories of machinery not listed in Annex IV.

The procedure referred to in Article 12 (3) (b) requires the manufacturer to submit the model of machinery to an EC type-examination by a Notified Body in order to ensure that it complies with the EHSRs that are applicable. The conformity of the machinery subsequently produced according to the model examined by the Notified Body is then assessed by the manufacturer himself by means of internal checks – see §396 to §400: comments on Annex IX, and §395: comments on Annex VIII 3.

The procedure set out in Article 12 (3) (c) requires the manufacturer to have a full quality assurance system covering the design, manufacture, final inspection and testing of machinery. The system must be assessed and approved by a Notified Body to ensure that it is adequate to ensure the design and manufacture of machinery that complies with the EHSRs that are applicable. The Notified Body must also monitor the correct application of the full quality assurance system – see §401 to §407: comments on Annex X.

The manufacturer or his authorised representative in the EU can request an EC type-examination of a model of machinery or the assessment of a full quality assurance system from any Notified Body of his choice in the EU, provided the Notified Body concerned is notified for the conformity assessment procedure and for the category of machinery concerned – see §133: comments on Article 14. However, a request for an EC type-examination for a given model of machinery or a request for the assessment of

a given full quality assurance system can only be lodged with a single Notified Body – see §397: comments on Annex IX 2.1, and §402: comments on Annex X 2.1.

An EC type-examination certificate or a decision approving a full quality assurance system issued by a Notified Body is valid throughout the EU.

Article 12 (continued)

. . .

4. Where the machinery is referred to in Annex IV and has not been manufactured in accordance with the harmonised standards referred to in Article 7(2), or only partly in accordance with such standards, or if the harmonised standards do not cover all the relevant essential health and safety requirements or if no harmonised standards exist for the machinery in question, the manufacturer or his authorised representative shall apply one of the following procedures:

(a) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3;

(b) the full quality assurance procedure provided for in Annex X.

§130 Other Annex IV machinery

Article 12 (4) sets out the 2 conformity assessment procedures that may be applied for categories of machinery listed in Annex IV when the one or more of the three conditions for applying Article 12 (3) are not fulfilled. Consequently, the procedures referred to in Article 12 (4) apply in the following cases:

- where harmonised standards covering the type of machinery concerned are not available;
- where the harmonised standards applied by the manufacturer do not cover all the essential health and safety requirements applicable to the machinery concerned;
- where the manufacturer of the machinery concerned has not applied or has only partially applied the relevant harmonised standards.

In such cases, the procedure for assessment of conformity with internal checks on the manufacture of machinery cannot be used and, consequently, one of the two procedures involving a Notified Body must be followed. The manufacturer can still refer to specific clauses of a harmonised standard to prove compliance with one or more requirements of the Directive.

Article 13

Procedure for partly completed machinery

1. *The manufacturer of partly completed machinery or his authorised representative shall, before placing it on the market, ensure that:*

   (a) the relevant technical documentation described in Annex VII, part B is prepared;

   (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.

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.*

§131 Procedure for partly completed machinery

Article 13 (1) sets out the procedure to be followed for the placing on the market of partly completed machinery referred to in Article 1 (1) (g) – see §384 and §385: comments on Annex II 1 B, §390: comments on Annex VI, and §394: comments on Annex VII B.

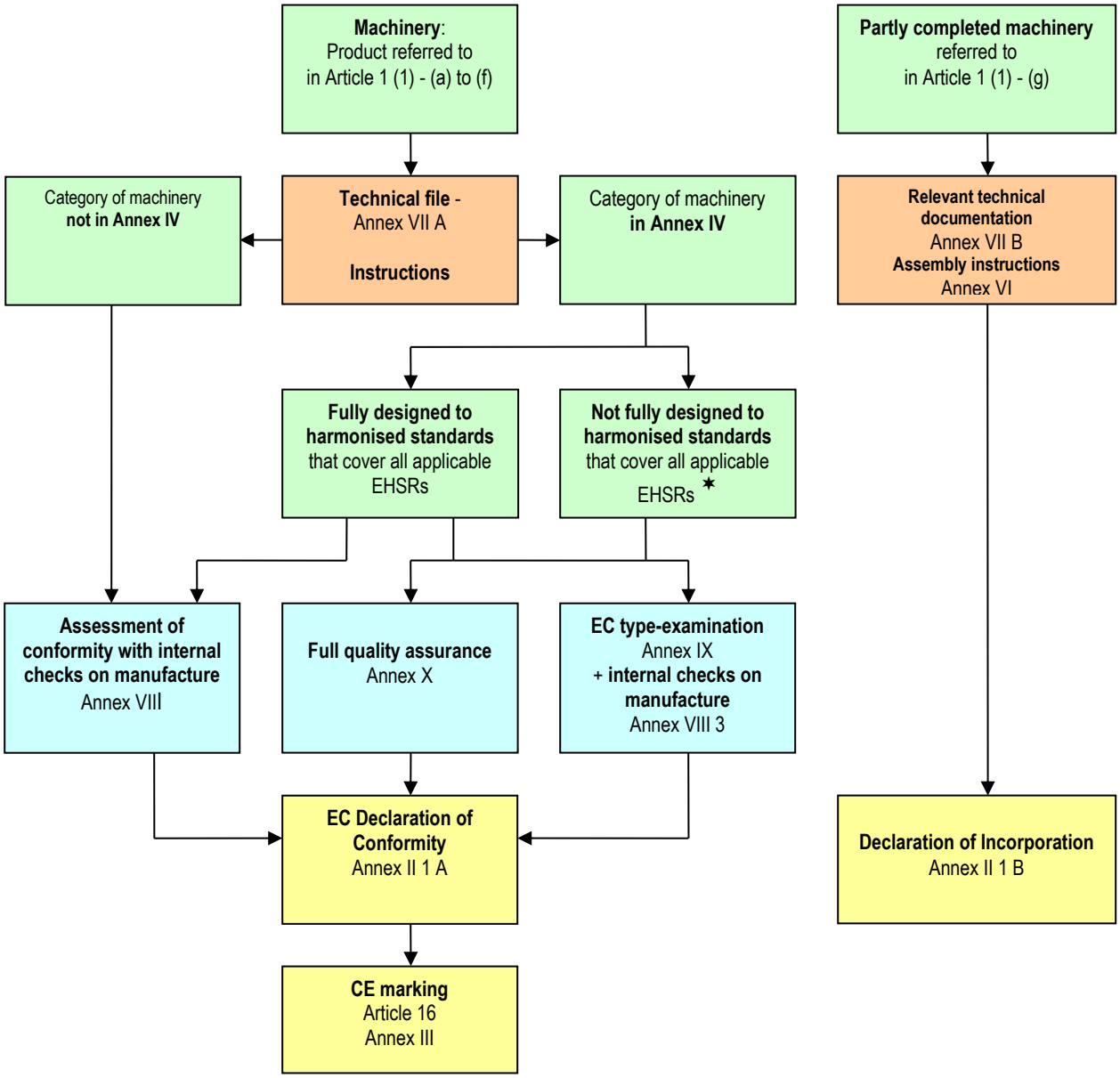
Article 13 (2) aims to ensure that the assembly instructions and the Declaration of Incorporation drawn up by the manufacturer of partly completed machinery are made available to the manufacturer of the final machinery into which the partly completed machinery is incorporated. This is so they can both apply the assembly instructions and include them and the Declaration of Incorporation in the technical file for the final machinery – see §392: comments on the eighth indent of Annex VII A 1 (a).

In general, this implies that the Declaration of Incorporation and a copy of the assembly instructions must be supplied with each item of partly completed machinery. However, in cases where a manufacturer of partly completed machinery supplies a batch of identical products to an identified manufacturer of final machinery, it is not necessary for the manufacturer of the partly completed machinery to supply the Declaration of Incorporation and the assembly instructions with each item, provided he ensures that the manufacturer of the final machinery has received these documents with the first delivery of products belonging to the batch and makes it clear that the Declaration of Incorporation and the assembly instructions apply to all of the items of partly completed machinery belonging to the batch.

Where the partly completed machinery (or part of it) is subject to other EU legislation in addition to the Machinery Directive, the conformity with the other Directives or Regulations concerned must also be declared.

§132 *Diagram of the procedures for the placing on the market of machinery and partly completed machinery*

The following diagram summarises the procedures set out in Article 12 and 13:



✶ Harmonised standards are not available, the harmonised standards do not cover all the applicable EHSRs or the harmonised standards are not applied or are only partially applied.

Colour code: Product category | Documents | Procedure | Declaration – marking

Article 14

Notified bodies

1. *Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the assessment of conformity for placing on the market referred to in Article 12 (3) and (4), together with the specific conformity assessment procedures and categories of machinery for which these bodies have been appointed and the identification numbers assigned to them beforehand by the Commission. Member States shall notify the Commission and other Member States of any subsequent amendment.*
2. *The Member States shall ensure that the notified bodies are monitored regularly to check that they comply at all times with the criteria set out in Annex XI. The notified body shall provide all relevant information on request, including budgetary documents, to enable the Member States to ensure that the requirements of Annex XI are met.*
3. *Member States shall apply the criteria set out in Annex XI in assessing the bodies to be notified and the bodies already notified.*
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.*
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.*

. . .

§133 Notified Bodies

Article 14 sets out the provisions relating to Notified Bodies. Notified Bodies are independent, third-party conformity assessment bodies entrusted with the conformity assessment procedures referred to in Article 12 (3) and (4) for the categories of machinery listed in Annex IV. The term "notified" refers to the fact that such Bodies are notified by the Member States to the Commission and to the other Member States. Before a conformity assessment body is notified, it must be assigned an identification number (with 4 digits) by the Commission. A given Body has a single identification number and may be notified under one or several EU Directives.

Under the Machinery Directive, bodies can only be notified for conformity assessment of the categories of machinery listed in Annex IV. Bodies that have been notified may also provide conformity assessment services to manufacturers of other categories of machinery. However, in such cases, the bodies must make it clear to their customers that they are not acting as Notified Bodies and must not use the identification number assigned to them by the Commission on any documents relating to such activity – see §128: comments on Article 12 (2). It is important that there is no conflict of interest when they carry out work as a Notified Body, so if they undertake consultancy work involving

the design of a product that is listed under Annex IV then another Notified Body should be appointed for the conformity assessment process.

The assessment, appointment and monitoring of the Notified Bodies is the exclusive responsibility of the Member States.

The notification is carried out using the Commission's online information system NANDO (New Approach Notified and Designated Organisations). This site lists all of the European Notified Bodies as well as third country bodies designated under formal agreements such as Mutual Recognition Agreements (MRAs), the European Economic Area Agreement (EEA) and Agreements on Conformity Assessment and Acceptance of Industrial Products (ACAAs).

When notifying a body for conformity assessment according to the Machinery Directive, the notifying authority of the Member State concerned must indicate the category of machinery for which the Body has been designated. A Notified Body may be designated to assess the conformity of one or more of the categories of machinery listed in Annex IV.

The notification must also indicate for which conformity assessment procedure or procedures the Body has been designated. A Notified Body may be designated for one or both of the following two procedures referred to in Article 12:

- the EC type-examination procedure - Article 12 (3) (b) and Article 12 (4) (a) – Annex IX;
- the full quality assurance procedure – Article 12 (3) (c) and Article 12 (4) (b) – Annex X.

Before lodging a request for conformity assessment with a Notified Body, it is therefore important to check in NANDO that the Notified Body concerned has been notified according to the Machinery Directive for the category of machinery and for the conformity assessment procedure concerned – see §129: comments on Article 12 (3).

§134 Assessment and monitoring of Notified Bodies

Article 14 (3) refers to the criteria set out in Annex XI to be used when assessing the bodies to be notified – see §408: comments on Annex XI. Member States are strongly encouraged to use accreditation as a means for assessing Notified Bodies. Regulation (EC) No 765/2008 requires each Member State to appoint a single accreditation body to evaluate whether assessment bodies are competent to carry out specific conformity assessment activities. Each national accreditation body is subject to peer evaluation organised by the European Cooperation for Accreditation (EA)[121].

Article 14 (5) refers to the relevant harmonised standards that can be used to assess Notified Bodies and their laboratories. The relevant harmonised standards are EN ISO/IEC 17020, 17021 and 17025[122].

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[121] Regulation (EC) No 765/2008, Articles 3 to 14.

[122] EN ISO/IEC 17020:2012 *General criteria for the operation of various types of bodies performing inspection*: EN ISO/IEC 17021:2011 *Conformity assessment - Requirements for bodies providing audit and certification of management systems* (Revised in June 2015 as a family of five standards 17021:2015-

According to Article 14 (2), the Member States must also monitor the Notified Bodies in order to ensure that they continue to fulfil the criteria set out in Annex XI. When accreditation is used for the initial assessment of a Notified Body, the accreditation is usually granted for a limited period of time. The monitoring of the Notified Body can therefore be carried out by means of periodic audits in view of renewal of the accreditation.

Article 14 (continued)

. . .

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.

. . .

§135 Withdrawal of certificates or decisions issued by Notified Bodies

Article 14 (6) sets out the duties of a Notified Body in the following cases:

- The Notified Body is informed that machinery placed on the market covered by an EC type-examination certificate or by a decision approving a manufacturer's full quality assurance system fails to comply with the applicable essential health and safety requirements or is unsafe.

  This may be the case, for example, if the machinery concerned is the subject of a measure notified under the safeguard procedure according to Article 11 or by a measure taken to deal with potentially hazardous machinery according to Article 9.

- The notified Body is informed that the manufacturer is failing to comply with his obligations under an approved full quality assurance system.

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1 to 5 – bodies have 2 years before they full supersede the 2011 version); EN ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories* (ISO/IEC 17025:2005); EN ISO/IEC 17025:2005/AC:2006. See Commission communication in the framework of the implementation of the Regulation (EC) No 765/2008 of the European Parliament and of the Council, Decision 768/2008/EC of the European Parliament and of the Council, Regulation (EC) No 761/2001 of the European Parliament and of the Council (Publication of titles and references of harmonised standards). OJ C 136, 16.6.2009, p. 8.

This may be the case, for example, following a periodic audit of the full quality assurance system or following an unannounced visit to check the proper functioning of such a system – see §406: comments on Annex X 3.

The measures to be taken by the Notified Body in such cases depend on the seriousness of the non-conformity and of the risks involved. However, if the appropriate corrective measures are not taken by the manufacturer within the imparted timeframe, the relevant EC type-examination certificate or Decision of approval of a full quality assurance system must be suspended or withdrawn.

When a certificate or decision of approval is suspended or withdrawn, the Notified Body must inform the market surveillance authorities in the Member State in which they are established so that any measures needed to deal with non-compliant or unsafe machinery can be taken. The national authorities shall inform the other Member States and the Commission if action is needed to deal with non-compliant or unsafe machinery outside their territory.

The third paragraph of Article 14 (6) states that an appeal procedure shall be available. A manufacturer must be able to appeal against a decision of a Notified Body to refuse to issue, to suspend, to withdraw or not to renew an EC type-examination certificate - see §399 and §400: comments on Annex IX 5 and 9. A manufacturer must also be able to appeal against a decision not to approve a full quality assurance system, to withdraw or suspend such an approval or to place restrictions on it – see §404 and §406: comments on Annex X 2.3 and 3. The manufacturer must first make a reasoned request to the Notified Body to reconsider its decision. If that fails and if the manufacturer continues to disagree with the decision, he must be able to lodge an appeal. The form of the appeal and the procedure to be followed depends on the national provisions regulating the activity of the Notified Bodies.

Article 14 (continued)

. . .

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.*

. . .

§136 Exchange of experience between the notifying authorities

The exchange of experience between the authorities responsible for assessing and monitoring of the Notified Bodies foreseen in Article 14 (7) is organised in the framework of the Machinery Working Group – see §148: comments on Article 22.

§137 The coordination of Notified Bodies

The exchange of experience between the Notified Bodies is organised in the framework of a European Coordination of Notified Bodies for Machinery, NB-M. The purpose of NB-M is to discuss problems arising in the course of the conformity assessment procedures and to harmonise the practice of the Notified Bodies. In some cases, Notified Bodies are

represented by a national coordination group set up in their country. Participation in coordination activities is one of the criteria for the notification of bodies – see §408: comments on Annex XI.

NB-M is divided into a number of groups that cover the different categories of machinery listed in Annex IV. These are called *Vertical Groups* (VGs).

There are currently 13 VGs that meet as necessary to deal with the following subjects:

VG1	Woodworking machinery
VG2	Meatworking machinery
VG3	Presses for cold-working metals
VG4	Injection or compression moulding machines
VG5	Machines for underground work
VG6	Household waste collection skips (RCVs)
VG7	Removable transmission shafts
VG8	Vehicles servicing lifts
VG9	Lifting persons devices
VG 11	Safety components
VG 12	ROPS and FOPS
VG 13	Full quality assurance
VG 14	Portable cartridge-operated fixing and other impact machinery

In addition, NB-M has a *Horizontal Committee* that supervises and coordinates the work of the Vertical Groups and deals with issues common to all of the Notified Bodies. The Horizontal Committee meets twice a year, under the chairmanship of an elected representative of one of the Notified Bodies. Representatives of the European Commission and of three Member States chosen by the Machinery Working Group take part in these meetings as observers.

The European Commission contributes to the functioning of NB-M by financing the technical secretariat, which prepares the work of the Group, and the administrative secretariat, which organises the meetings and manages the circulation of documents.

NB-M adopts so-called *"Recommendations for Use"* (RfUs) which provide agreed answers to questions that have been discussed in the Vertical Groups. In general, RfUs are established where no relevant harmonised standard is available or where the relevant harmonised standard does not provide a sufficiently precise answer to a certain question. When a relevant harmonised standard is adopted or when the harmonised standard is revised accordingly, the RfU is withdrawn. The RfUs are approved by the NB-M Horizontal Committee then communicated to the Machinery Working Group for endorsement. The RfUs that have been endorsed by the Machinery Working Group are published on the Commission's Website EUROPA. The RfUs are not legally binding but, once they have been agreed by NB-M and have been endorsed by the Machinery Working Group, they are to be considered as an important reference for ensuring uniform application of the Machinery Directive by the NBs.

Article 14 (continued)

. . .

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.

§138 Withdrawal of notification

Article 14 (8) obliges Member States to withdraw their notification of a body which no longer meets the criteria listed in Annex XI or which seriously fails to fulfil its responsibilities. The obligation to withdraw a notification that is no longer justified is a consequence of the obligation for the Member States to monitor the activity of the bodies they have notified in order to ensure that they are carrying out their tasks correctly – see §134: comments on Article 14 (2).

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.

§139 National regulations on the installation and use of machinery

The Machinery Directive applies to the design, construction, placing on the market or putting into service of machinery – see §71 to §77: comments on Article 2 (h), and §86: comments on Article 2 (k). For these aspects, the Directive ensures the total harmonisation of the regulations in force throughout the EU. In other words, the Member States may not introduce national provisions that go beyond, overlap with or contradict the provisions of the Directive.

Article 15 indicates that Member States remain free to regulate the installation and use of machinery in accordance with the relevant provisions of EU law, providing these regulations do not have the effect of restricting the free movement of machinery that complies with the provisions of the Machinery Directive – see §6: comments on Recital 3, and §107: comments on Article 6 (1).

Thus national regulations on the installation and use of machinery or their application must not lead to the modification of machinery that complies with the Machinery Directive. This presupposes that machinery placed on the market really complies with the requirements of the Directive. If users or the national authorities consider that an item of machinery placed on the market is not sufficiently safe and that the applicable

essential health and safety requirements have not been correctly applied, the machinery should be reported to the market surveillance authorities, while the necessary measures are taken to ensure the safety of persons – see §100: comments on Article 4.

The following are some examples of the subjects that may be covered by national rules on the installation and use of machinery:

- the installation of machinery in certain areas, such as, for example, the installation of cranes in urban areas or the installation of wind generators in the countryside;
- the use of mobile machinery in certain areas, such as, for example, the use of off-road vehicles in areas open to the public or the use of certain types of agricultural machinery close to dwellings or public roads;
- the circulation of mobile machinery on public roads;
- the use of machinery at certain times, such as, for example, restrictions on the use of lawnmowers during the weekend;
- the use of certain kinds of machinery by people under a certain age.

§140 National regulations on the health and safety of workers

Particular mention must be made of the national regulations implementing the provisions of the EU Directives relating to health and safety at work. These Directives are based on Article 137 of the EC Treaty (now Article 153 of the TFEU) relating to the protection of workers' health and safety. They set out minimum requirements, which means that Member States remain free to maintain or adopt more stringent requirements if they see fit. Consequently, it is necessary to consult the national regulations in force in each Member State in order to identify the relevant obligations. The most important Directives relating to the use of machinery are:

- Directive 89/391/EEC[123] on the safety and health of workers at work. This is known as the "Framework" Directive, since it sets out the basic obligations of employers and workers relating to health and safety at work and provides the framework for a series of individual Directives dealing with specific aspects of health and safety or specific hazards;
- Directive 2009/104/EC[124] on the use of work equipment by workers at work. This is the second individual Directive adopted under the "Framework" Directive.

Although the concept of work equipment is broader than that of machinery, machinery for professional use constitutes an important category of work equipment. The national

[123] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work. OJ L 183, 29.6.1989.

[124] Directive 2009/104/EC of the European Parliament and of the Council of 16 September 2009 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). OJ L 260, 3.10.2009, p. 5. Directive 2009/104/EC is a codified version of Directive 89/655/EEC and amending Directives 95/63/EEC, 2001/45/EC and 2007/30/EC.

regulations implementing the provisions of Directive 2009/104/EC always apply to the use of machinery at work. In this respect, Directive 2009/104/EC can be considered as a measure complementary to the Machinery Directive.

According to Directive 2009/104/EC, employers are required to make available to workers work equipment that is suitable for the work to be carried out and which complies with the provisions of any relevant EU Directive which is applicable to it.[125] Consequently, all new machinery made available to workers must comply with the Machinery Directive and any other EU Directives that may be applicable – see §89 to §92: comments on Article 3.

The provisions of Directive 2009/104/EC are applicable to machinery in service in workplaces. During the lifetime of the machinery, the employer must take the measures necessary to ensure that machinery in service is kept, by means of adequate maintenance, at a level such that it complies with the provisions that were applicable when it was first made available in the undertaking or establishment[126]. This does not mean that the machinery must be maintained in an "as new" condition, since it is subject to wear. But the necessary maintenance must be carried out to ensure that it continues to comply with the applicable health and safety requirements. To do so, the employer must follow the manufacturer's instructions – see § 272: comments on section 1.7.4.2 (r) of Annex I.

Thus machinery that was subject to the provisions of the Machinery Directive when it was first made available must be maintained in a state of conformity with the essential health and safety requirements of the Machinery Directive that were applied when it was first placed on the market or put into service.

This also applies whenever machinery is modified by the user during the course of its lifetime, unless the modifications are so substantial that the modified machinery must be considered as new machinery and be subject to a new conformity assessment according to the Machinery Directive – see §72: comments on Article 2 (h).

Annex I of Directive 2009/104/EC sets out minimum technical requirements applicable to work equipment in service. These minimum requirements are applicable to machinery put into service before the Machinery Directive became applicable[127].They are not applicable to machinery placed on the market or put into service according to the Machinery Directive.

Directive 2009/104/EC also includes provisions relating to:

- the initial inspection of work equipment the safety of which depends on installation conditions, after installation and before being put into service;
- the inspection of such work equipment after assembly at a new site or in a new location, for example when tower cranes are moved to a new site;

[125] See Directive 2009/104/EC, Articles 4 (1) (a).

[126] See Directive 2009/104/EC, Article 4 (2).

[127] See Directive 2009/104/EC, Article 4 (1) (a) (ii) and (b).

- periodic and special inspections and, where appropriate, testing of work equipment exposed to conditions causing deterioration which is liable to result in dangerous situations[128].

In the case of lifting machinery, the initial inspections, for which the employer is responsible, must be distinguished from the measures to check the fitness for purpose of the machinery, which are the responsibility of the machinery manufacturer – see §350 to §352: comments on section 4.1.3 of Annex I.

Other provisions of Directive 2009/104/EC deal with:

- the restriction of the use and/or the maintenance of work equipment involving a specific risk to designated workers;
- taking account of ergonomic principles;
- information, instructions and training for workers on the use of work equipment;
- consultation of workers and workers' participation[129].

In addition, Annex II of Directive 2009/104/EC sets out specific rules for the use of certain categories of work equipment, including mobile work equipment, work equipment for lifting goods and work equipment for lifting persons – see §10: comments on Recital 7.

The instructions supplied by the manufacturer with machinery constitute an essential tool to enable employers to apply the provisions implementing Directive 2009/104/EC – see §254: comments on section 1.7.4 of Annex I.

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.*

§141 The CE marking

The provisions on the CE marking of machinery set out in the Machinery Directive apply together with the provisions of Regulation (EC) 765/2008 setting out the General Principles of the CE marking which apply in a complementary way. The following comments are based on Article 16 and Annex III of the Machinery Directive and on

[128] See Directive 2009/104/EC, Article 5.

[129] See Directive 2009/104/EC, Articles 6 to 10.

Article 2 (20) and Article 30 of Regulation (EC) 765/2008. The obligations relating to the CE marking apply to the manufacturer, his authorised representative or the person responsible for placing the machinery on the market – see §78 to §85: comments on Article 2 (i) and (j).

Regulation (EC) 765/2008 defines *'CE marking'* as a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing. By affixing or having affixed the CE marking, the manufacturer indicates that he takes responsibility for the conformity of the product.

- the CE marking consists of the initials ‘CE’ with the graphic form shown in Annex III;
- 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 to the machinery visibly, legibly and indelibly in the immediate vicinity of the name of the manufacturer or his authorised representative, using the same technique – see §250: comments on section 1.7.3 of Annex I;
- 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 that has approved the manufacturer's full quality assurance system – see §133: comments on Article 14.

The CE marking shall be the only marking which attests the conformity of the product with the applicable requirements of the relevant EU harmonisation legislation providing for its affixing. Article 16 (3) requires the Member States to forbid the affixing on machinery of markings, signs or inscriptions which are likely to mislead third parties as to the meaning or form of the CE markings or both.

Markings which are likely to mislead third parties as to the form of the CE marking might be, for example, the letters 'EC' or 'EEC', with a graphic form similar to that shown in Annex III, or the initials 'CE' with a graphic form different from that shown in Annex III. Markings which are likely to mislead third parties as to the meaning of the CE marking are markings, other than the CE marking, that signify that the machinery complies with the applicable EU legislation.

The measures to be taken in cases of non-conformity of marking are set out in Article 17.

Article 17

Non-conformity of marking

1. *Member States shall consider the following marking not to conform:*

(a) the affixing of the CE marking pursuant to this Directive on products not covered by this Directive;

(b) the absence of the CE marking and/or the absence of the EC declaration of conformity for machinery;

(c) the affixing on machinery of a marking, other than the CE marking, which is prohibited under Article 16 (3).

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.*

§142 Non conformity of marking

The safeguard clause set out in Article 11 sets out the measures to be taken when machinery bearing the CE marking is discovered to be unsafe. Article 17 sets out the measures to deal with cases of formal non-conformity with the provisions of the Machinery Directive, where there is no indication that the machinery concerned is unsafe. These measures are in line with the obligation of the Member States to ensure the correct implementation of the regime governing the CE marking and to take appropriate action in the event of improper use of the marking set out in Article 30 (6) of Regulation (CE) 765/2008.

Article 17 (1) defines the three cases that are considered to constitute non-conformity of marking. Article 17 (2) states that Member States shall take the necessary measures to require economic operators to put an end to such infringements. The nature of the measures is left to the discretion of the Member States. Such measures do not have to be notified to the Commission or to the other Member States. The penalties for infringements against the provisions of the Machinery Directive must include penalties for non-conformity of marking – see §150: comments on Article 23.

Article 17 (3) sets out the procedure to be followed in case the measures taken to put an end to the infringements referred to in Article 17 (1) are not effective. In that case, the safeguard procedure set out in Article 11 must be followed.

Article 18

Confidentiality

1. *Without prejudice to existing national provisions and practices in the area of confidentiality, Members States shall ensure that all parties and persons concerned by the application of this Directive are required to treat as confidential information obtained in the execution of their tasks. More particularly business, professional and trade secrets shall be treated as confidential, unless the divulging of such information is necessary in order to protect the health and safety of persons.*
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.*

§143 Confidentiality and transparency

The parties and persons concerned by the provisions set out in Article 18 include the administrations of the Member States, the Commission and the Notified Bodies. In particular, the authorities of the Member States and the services of the Commission may require manufacturers to communicate elements of the technical file for machinery or of the relevant technical documentation for partly completed machinery which contain professional and trade secrets. The officials of the public administrations or agencies concerned and any other bodies or institutions acting on their behalf must respect the confidentiality of such information obtained or received in the course of application of the Machinery Directive. Similarly, Notified Bodies must respect the confidentiality of information obtained or received while carrying out the conformity assessment procedures for which they are responsible – see §408: comments on Annex XI 7.

Article 18 (2) indicates that the obligation of confidentiality does not prevent the transmission of information between the Member States and to the Commission in the framework of the cooperation foreseen in Article 19 (Machinery AdCo Group) or to using the internal section of ICSMS to which access is appropriately restricted. The obligation of confidentiality does not apply to the communication of information between the Notified Bodies and to the communication of information by the Notified Bodies to the Member States – see §135: comments on Article 14 (6), §399: comments on Annex IX 5 and 7, and §407: comments on Annex X 4.

The confidentiality obligation does not preclude the issuing of public warnings when this is necessary in order to protect the health and safety of persons.

Article 18 (3) sets out a particular requirement for transparency relating to any decisions taken by the Member States and by the Commission in accordance with Articles 9 and 11. The decisions concerned include:

- the measures taken by the Commission requiring Member States to prohibit or restrict the placing on the market of potentially hazardous machinery according to Article 9 (1);

- the measures taken by the Member States to withdraw from the market, to prohibit the placing on the market and/or putting into service or to restrict the free movement of machinery that is liable to compromise the health and safety of persons and, where appropriate, domestic animals, property, or the environment for pesticide machinery, according to Article 11 (1) (the safeguard clause);
- decisions taken by the Commission on safeguard clauses according to Article 11 (3).

Article 19

Cooperation between Member States

1. *Member States shall take the appropriate measures to ensure that the competent authorities referred to in Article 4(3) cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly.*
2. *The Commission shall provide for the organisation of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive.*

§ 144 Machinery AdCo Group

Article 19 (1) requires the Member States to organise cooperation between the national market surveillance authorities and to transmit to each other the necessary information. Cooperation is essential in this area since, while CE-marked machinery is able to move freely within the single market, surveillance is carried out by each of the Member States.

Article 19 (2) gives the Commission the responsibility of providing for the organisation of an exchange of experience between the market surveillance authorities.

The practical application of Article 19 is carried out in the framework of the Machinery Administrative Cooperation Group (Machinery AdCo Group). This is a forum for the exchange of information between the market surveillance authorities of the Member States and the Commission. The Machinery AdCo Group usually meets twice a year and is chaired in turn by representatives of the Member States. The meetings are restricted to the representatives of the Member States and the Commission and the proceedings and documents of the AdCo Group are confidential, since they frequently refer to specific cases under investigation. However other stakeholders may be invited to take part in AdCo meetings as experts, to an “open” section of the meeting only, to contribute on particular topics when such confidential information is not discussed.

Where the Machinery AdCo reaches a view on the interpretation or added guidance on the Directive, this is then transmitted to the Machinery Working Group for its discussion and agreement. If approved by the Machinery Working Group, the Commission will either integrate the agreed changes in the guide or publish them on the EUROPA machinery web site.

The main activities of the Machinery AdCo Group are:

- sharing information and experience of market surveillance activity;
- promoting best practices and optimising the use of resources;
- ensuring that corrective measures to deal with non-compliant and unsafe machinery are applied in all Member States;
- providing information on the progress and outcome of the safeguard procedure and following-up safeguard clause decisions;
- following-up decisions on specific measures to deal with potentially hazardous machinery;
- planning and organising joint market surveillance projects.

Article 20

Legal remedies

Any measure taken pursuant to this Directive which restricts the placing on the market and/or putting into service of any machinery covered by this Directive shall state the exact grounds on which it is based. Such a measure shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time limits to which such remedies are subject.

§ 145 Reasons for decisions and appeals

Article 20 applies to any measures taken by the authorities of the Member States restricting the placing on the market and/or the putting into service of machinery, whether they are taken on the basis of Article 11 (the safeguard clause), Article 9 (specific measures to deal with potentially hazardous machinery) or Article 17 (non-conformity of marking). The Member State is required to have a procedure in place by which an economic operator can have access to a legal remedy in case of dispute. There should be clear time limits that the operator has to raise such a case against a restrictive action.

Article 21

Dissemination of information

The Commission shall take the necessary measures for appropriate information concerning the implementation of this Directive to be made available.

§146 Information sources

Information relevant to the implementation of the Machinery Directive is publicly available online on the machinery pages of the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG Growth) section of the Commission's website EUROPA.

In particular, the following information is available on EUROPA:

- the legal text and the consolidated text of the Machinery Directive;
- a list of contact points in the Member States for implementation of the Directive;
- the list of references of harmonised standards for machinery;
- the list of Notified Bodies for machinery;
- the Recommendations for Use adopted by the European coordination of Notified Bodies for Machinery (NB-M) that have been endorsed by the Machinery Working Group;
- guidance documents approved by the Machinery Working Group and the present Guide to application of Directive 2006/42/EC;
- the consolidated minutes, including decisions, of all the meetings of the Machinery Working Group held since 1997.

Article 22 [130]

Committee

1. *The Commission shall be assisted by a committee, hereinafter referred to as the 'Committee'.*
2. *Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.*
3. *Where reference is made to this paragraph, Articles 5a(1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.*

§147 The Machinery Committee

Article 22 foresees the setting up of the Committee, called the Machinery Committee, which is composed of representatives of the Member States and chaired by a representative of the Commission. The Committee adopts its own rules of procedure on the basis of standard rules published in the OJEU. The European Parliament is informed of the agendas of the meetings of the Committee and of any draft measures that are submitted to it and receives the results of voting and summary records of the meetings.

The Machinery Committee has two distinct roles:

- ***an advisory role***

The advisory role of the Machinery Committee, set out in Article 8 (2), is to advise the Commission on any appropriate measure connected with the practical application of the

[130] Article 22 was amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny (PRAC) - Adaptation to the regulatory procedure with scrutiny - Part Four. OJ L 188, 18.7.2009, p.14.

Machinery Directive, including measures necessary to ensure cooperation of Member States with each other and with the Commission as provided for in Article 19 (1). The measures concerned cannot involve the amendment of the Directive or the adoption of Decisions supplementing the provisions of the Directive. Therefore, these measures consist mainly in providing guidance on the correct and uniform application of the provisions of the Directive.

- ***a regulatory role***

The regulatory role of the Machinery Committee is to give its opinion on measures proposed by the Commission, which amend or supplement the provisions of the Directive. According to Article 8 (1) (a) and (b), only two subjects can be the subject of such measures:

a) updating of the indicative list of safety components in Annex V – see §42: comments on Article 2 (c);

b) restriction of the placing on the market of potentially hazardous machinery – see §118: comments on Article 9.

The opinion of the Machinery Committee is expressed by means of votes of the representatives of the Member States within the Committee, weighted as for votes of the Council according to Article 205 of the EC Treaty (now Article 238 of the TFEU).

Before such measures are adopted by the Commission, they are submitted to the European Parliament and the Council for scrutiny. The European Parliament or the Council may oppose the draft measures proposed by the Commission on the grounds that they exceed the implementing powers provided for in the Directive, that they are not compatible with the aim or the content of the Directive or do not respect the principles of subsidiarity or proportionality. In case of such opposition, the Commission can submit an amended draft or make a legislative proposal. If there is no opposition from the European Parliament and the Council within three months, the Commission adopts the measure.

§148 The Machinery Working Group

The Machinery Working Group is set up by the Machinery Committee in order to allow observers from industry, users (workers and consumers representation organisations) standardisation and the Notified Bodies to take part in the discussion of problems relating to the practical application of the Machinery Directive. In practice, the Machinery Working Group is the most frequently used forum to discuss the application of the Directive at EU level. Like the Machinery Committee, the Machinery Working Group is chaired by a representative of the Commission and composed of representatives of the Member States. Representatives of EFTA countries, candidate countries and countries with formal agreements with the EU are also present as observers.

Associations of machinery manufacturers at European level participate as observers and are invited to attend meetings in order to present information and views on specific issues that are under discussion. Representatives of the European standardisation organisations are also present to provide information and to respond to the questions raised by the Member States relating to standards. The Notified Bodies are represented

by the European Coordination of Notified Bodies for Machinery (NB-M) which reports on the work of the Coordination, takes note of the opinion of the Machinery Working Group on the Recommendations for Use submitted to the Working Group for endorsement and submits questions to the Working Group relating to the interpretation of the Directive. Trades unions and representatives of consumer protection organisations are also invited to express the views of the final users of machinery.

The topics most frequently discussed by the Machinery Working Group are:

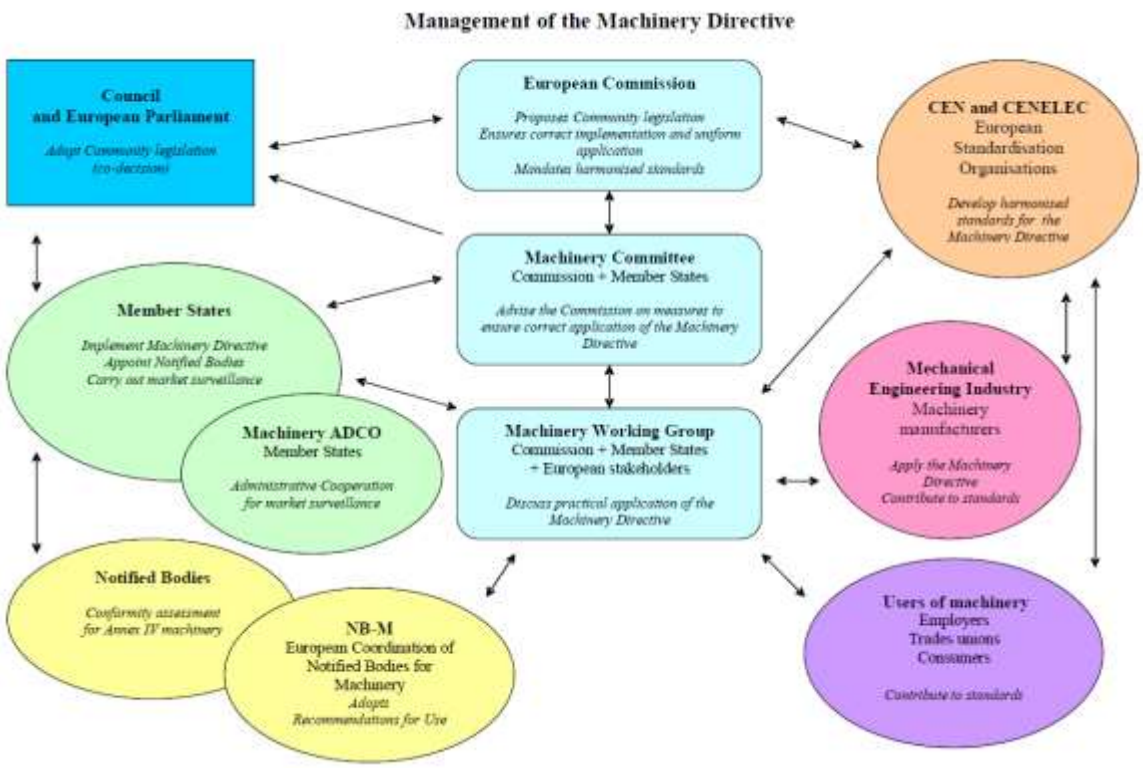
- clarification of the scope of the Directive and the conformity assessment procedures with respect to particular categories of products;
- concerns relating to the development of harmonised standards for machinery;
- opinions on formal objections against harmonised standards – see §120: comments on Article 10.

The Machinery Working Group meets twice or three times a year in Brussels. Working documents for the meetings of the Machinery Working Group are circulated to members of the Group on the Machinery Directive section of the Commission online information system CIRCABC. Organisations representing machinery stakeholder at European level have access to these documents. Other stakeholders can request the documents from their respective representative organisations. Care should be taken not to take the positions expressed in working documents or discussion papers as representing the views of the Commission or of the Machinery Working Group.

The minutes of meetings of the Machinery Working Group are published on the machinery pages of the Commission's website EUROPA, once they have been corrected and approved at the following meeting.

§149 Diagram of institutions dealing with the Machinery Directive

The following diagram indicates the roles of the different institutions, entities and groups involved in proposing, adopting, transposing, applying and enforcing the Machinery Directive:



Article 23

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 29 June 2008 and shall notify it without delay of any subsequent amendment affecting them.

§150 Penalties for infringements against the provisions of the Directive

The national provisions implementing the Machinery Directive must be legally binding and infringements against those provisions must therefore be sanctioned by appropriate penalties.

The possible infringements may include the following:

- failure to apply the applicable conformity assessment procedure for machinery – see §127 to §130: comments on Articles 12;
- failure to apply the procedure for partly completed machinery – see §131: comments on Article 13;

- non-conformity of marking – see §142: comments on Article 17;
- failure of machinery to comply with the essential health and safety requirements set out in Annex I;
- missing or incomplete technical file - see §103: comments on Article 5, and §391 to §393: comments on Annex VII A;
- missing or incomplete instructions (including the necessary translation) - see §103: comments on Article 5, and §254 to §256: comments on section 1.7.4 of Annex I;
- failure to comply with the measures foreseen in Article 11 (safeguard clause) and Article 9 (specific measures to deal with potentially hazardous machinery).

It is up to each Member State to fix the type and the level of the penalties for such infringements. Article 23 states that the penalties must be effective, proportionate and dissuasive, in line with the Jurisprudence of the European Court of Justice.

Article 24

Amendment of Directive 95/16/EC

Directive 95/16/EC is hereby amended as follows:

1. *in Article 1, paragraphs 2 and 3 shall be replaced by the following:*
2. *'For the purposes of this Directive, "lift" shall mean a lifting appliance serving specific levels, having a carrier moving along guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal, intended for the transport of:*
   - *persons,*
   - *persons and goods,*
   - *goods alone if the carrier is accessible, that is to say a person may enter it without difficulty, and fitted with controls situated inside the carrier or within reach of a person inside the carrier.*

   Lifting appliances moving along a fixed course even where they do not move along guides which are rigid shall be considered as lifts falling within the scope of this Directive.

   A "carrier" means a part of the lift by which persons and/or goods are supported in order to be lifted or lowered.
3. *This Directive shall not apply to:*
   - *lifting appliances whose speed is not greater than 0,15 m/s,*
   - *construction site hoists,*
   - *cableways, including funicular railways,*
   - *lifts specially designed and constructed for military or police purposes,*
   - *lifting appliances from which work can be carried out,*

— *mine winding gear,*

— *lifting appliances intended for lifting performers during artistic performances,*

— *lifting appliances fitted in means of transport,*

— *lifting appliances connected to machinery and intended exclusively for access to workstations including maintenance and inspection points on the machinery,*

— *rack and pinion trains,*

— *escalators and mechanical walkways.';*

2. in Annex I, point 1.2 shall be replaced by the following:

1.2. 'Carrier

The carrier of each lift must be a car. This car must be designed and constructed to offer the space and strength corresponding to the maximum number of persons and the rated load of the lift set by the installer.

Where the lift is intended for the transport of persons, and where its dimensions permit, the car must be designed and constructed in such a way that its structural features do not obstruct or impede access and use by disabled persons and so as to allow any appropriate adjustments intended to facilitate its use by them.'

§151 The borderline between the Machinery Directive and the Lifts Directive

Article 24 of Directive 2006/42/EC introduces an amendment to the Lifts Directive 95/16/EC (replaced by Directive 2014/33/EU from 20 April 2016) with the purpose of better defining the borderline with the Machinery Directive – see §28: comments on Recital 27.

On the one hand, Article 24 (1) modifies the definition of *'lift'* given in Article 1 (2) of the Lifts Directive, replacing the term '*car'* with the term *'carrier'.* This implies that the nature of the carrier is not a criterion for application of the Lifts Directive. At the same time, Article 24 (2) modifies the essential health and safety requirement set out in section 1.2 of Annex I to the Lifts Directive in order to specify that the carrier of lifts subject to that Directive must be a car. It should also be noted that section 3.1 of Annex I to the Lifts Directive requires lift cars to be completely enclosed.

On the other hand, Article 24 (1) modifies the list of exclusions set out in Article 1 (3) of the Lifts Directive, adding the exclusion of lifting appliances whose speed is not greater than 0,15 m/s. Consequently, low-speed lifts are subject to the Machinery Directive – see §344: comments on section 4.1.2.8 and §377: comments on section 6.4 of Annex I.

With respect to the modified list of exclusions from the Lifts Directive, the following items should also be noted:

Construction site hoists are excluded from the scope of the Lifts Directive. They are no longer excluded from the scope of Directive 2006/42/EC and are thus subject to the Machinery Directive as from 29th December 2009 – see §8: comments on Recital 5.

The following are excluded from the Lifts Directive and are subject to the Machinery Directive:

- lifting appliances from which work can be carried out;
- 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;
- escalators and mechanical walkways.

Cableways are all excluded from the scope of the Lifts Directive. In accordance with Article 3, while the Machinery Directive is not applicable to cableways designed to carry persons that are covered by the Cableways Directive 2000/9/EC, it does apply to certain cableways that are outside or excluded from the scope of the Cableways Directive – see §90: comments on Article 3.

The following are excluded from both the Lifts Directive and the Machinery Directive:

- lifts specially designed and constructed for military or police purposes – see §59: comments on Article 1 (2) (g);
- mine winding gear – see §61: comments on Article 1 (2) (i);
- lifting appliances intended for lifting performers during artistic performances – see §62: comments on Article 1 (2) (j);
- rack and pinion trains on rail networks - §57: comments on the fifth indent of Article 1 (2) (e).

Article 25

Repeal

Directive 98/37/EC is hereby repealed as from 29 December 2009. [131]

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.

§152 Repeal of Directive 98/37/EC

Directive 2006/42/EC replaced Directive 98/37/EC. Directive 98/37/EC was repealed on 29th December 2009, at which date the provisions of Directive 2006/42/EC became applicable.

The second paragraph of Article 25 means that from 29th December 2009, references to the Machinery Directive in other EU legislation remain valid and shall be understood as references to Directive 2006/42/EC. Where such references are made to specific provisions of the Directive, the references shall be read as referring to the equivalent

[131] Subject to a corrigendum published in OJ L 76, 16.3.2007, p. 35.

provisions indicated in the correlation table given in Annex XII. Such references are updated when the legislation concerned is revised.

Article 26

Transposition

1. *Member States shall adopt and publish the provisions necessary to comply with this Directive by 29 June 2008 at the latest. They shall forthwith inform the Commission thereof.*

They shall apply those provisions with effect from 29 December 2009.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. *Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive, together with a table showing how the provisions of this Directive correspond to the national provisions adopted.*

§153 Transposition and application of the provisions of the Directive

EU Directives are addressed to the Member States who are thereby instructed to adopt the necessary provisions transposing them into national law. It is these national provisions that create binding obligations for economic operators. According to Article 288 of the TFEU (former Article 249 EC), the Directive is binding as to the result to be achieved but leaves to the national authorities the choice of form and methods. However, since the Machinery Directive is based on Article 95 of the EC Treaty (now Article 114 of the TFEU) that foresees measures to harmonise provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market, the latitude given to the Member States is, in practice, rather limited. In particular, the essential health and safety requirements for the design and construction of machinery and the conformity assessment procedures applicable must be the same in all the Member States.

The Member States were given 2 years following the entry into force of the Directive to adopt the necessary provisions. These provisions become applicable eighteen months later, on 29th December 2009. Until that date, Directive 98/37/EC continued to apply.

The references of the texts transposing the provisions of the Directive into the national law of the Member States, that have been communicated to the Commission according to the obligation set out in Article 26 (2), are presented on the EUR-Lex website[132].

[132] http://eur-lex.europa.eu/.

Article 27

Derogation

Until 29 June 2011 Member States may allow the placing on the market and the putting into service of portable cartridge operated fixing and other impact machinery which are in conformity with the national provisions in force upon adoption of this Directive.

§154 Transition period for portable cartridge operated fixing and other impact machinery

As a general rule, since manufacturers have a period of three and a half years between the entry into force of Directive 2006/42/EC and the application of its provisions during which to adapt their products where necessary, it was not considered necessary to foresee a transition period. However, by way of derogation to the general rule, Article 27 foresees a transition period of eighteen months for portable cartridge operated fixing machinery and other portable cartridge operated impact machinery during which Member States may allow the placing on the market of products that comply with the national provisions in force previously. These national provisions are either those implementing the Convention of 1st July 1969 on the Reciprocal Recognition of Proofmarks on Small Arms (the CIP convention), in the case of Member States that are signatories to that Convention, or, in other Member States, existing national regulations – see §9: comments on Recital 6.

It should be noted that the transition period was a facility open to Member States, not an obligation. Consequently, portable cartridge operated fixing machinery and other portable cartridge operated impact machinery that complied with the Machinery Directive benefited for free movement in the EU from 29th December 2009. Such machinery that complied with the national provisions in force previously could only be placed on the market in those Member States that allow this. As from 29 June 2011, all such machinery must comply with the Machinery Directive.

Article 28

Entry into force

This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Union.

§ 155 Date of entry into force of the Directive

Article 28 sets out the date of entry into force of Directive 2006/42/EC. Since the Directive was published in the OJEU on 9th June 2006, it entered into force on 29th June 2006. The date of entry into force is the date at which the Directive acquires a legal existence and should not be confused with the date of application of the provisions of the Directive which is 29th December 2009 – see §153: comments on Article 26 (1).

Article 29

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 17 May 2006.

For the European Parliament	*For the Council*
The President	*The President*
J. BORRELL FONTELLES	*H. WINKLER*

§ 156 Addressees and signatories of the Directive

The Directive is addressed to the Member States, since the transposition of the provisions of the Directive into national law is necessary in order to create binding legal obligations for the economic operators.

The Directive is signed by the Presidents of the European Parliament and of the Council since it was adopted by these Institutions according to the co-decision procedure foreseen in Article 251 of the EC Treaty (now referred to as the ordinary legislative procedure in Article 294 of the TFEU) – see §2: comments on the citations.

ANNEX I

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

GENERAL PRINCIPLES

§157 The General Principles

The essential health and safety requirements (EHSRs) set out in Annex I are introduced by four General Principles. The first one, dealing with risk assessment, explains a basic requirement of Annex I to identify the hazards and assess the risks associated with machinery in order to identify and apply the relevant EHSRs. The other General Principles are essential for understanding the status and the implications of the EHSRs.

These General Principles must be taken into account when applying each of the EHSRs to the design and construction of machinery.

GENERAL PRINCIPLES

1. *The manufacturer of machinery or his authorised representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.*

By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorised representative shall:

— *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).*

. . .

§158 Risk assessment

According to General Principle 2, the EHSRs are only applicable when the corresponding hazard exists for the machinery in question. In order to identify these hazards, taking into account all phases of the foreseeable lifetime of the machinery, the manufacturer or his authorised representative must ensure that a risk assessment is

carried out according to the iterative process described in General Principle 1. For the terms 'hazard' and 'risk' – see §164: comments on section 1.1.1 (a), and §168: comments on section 1.1.1 (e).

The risk assessment may be carried out by the manufacturer himself, by his authorised representative or by another person acting on their behalf. If the risk assessment is carried out on behalf of the manufacturer by another person, the manufacturer remains responsible for the risk assessment and the implementation of the necessary protective measures during the design and construction of machinery – see §78 to §81: comments on Article 2 (i), and §83 and §84: comments on Article 2 (j).

The second sentence of the first paragraph of General Principle 1 states that the machinery must then be designed and constructed taking into account the results of the risk assessment. Risk assessment is described as an iterative process because each risk reduction measure envisaged to deal with a particular hazard must be evaluated to see if it is adequate and does not generate new hazards. If this is not the case, the process must be carried out anew. This implies that the risk assessment process must be carried out in parallel with the design process of the machinery.

The last indent of the second paragraph underlines that the risk reduction measures to deal with the identified hazards are to be given an order of priority, according to the principles of safety integration – see §174: comments on section 1.1.2 (b).

The risk assessment and its outcome must be documented in the Technical file for machinery – see §392: comments on Annex VII A 1 (a).

Standard EN ISO 12100 (A-type standard) explains the general principles for risk assessment of machinery[133].

§159 Risk assessment and harmonised standards

The process of risk assessment is facilitated by the application of harmonised standards, since C-type standards for machinery identify the significant hazards that are generally associated with the category of machinery concerned and specify protective measures to deal with them. However, the application of harmonised standards does not entirely dispense the machinery manufacturer from the obligation to carry out a risk assessment.

A manufacturer who applies the specifications of a C-type standard must ensure that the harmonised standard is appropriate to the particular machinery concerned and covers all of the risks it presents. As a starting point, Annex Z and the entry of the reference in the OJEU should be checked to ensure that the standard's presumption of conformity does not exclude any essential health and safety requirements. If the machinery concerned presents hazards that are not covered by the harmonised standard, a full risk assessment is required for those hazards and appropriate protective measures must be taken to deal with them.

[133] EN ISO 12100: 2010 *Safety of machinery - General principles for design. Risk assessment and risk reduction* (ISO 12100-1:2010).

Furthermore, where harmonised standards specify several alternative solutions without defining criteria for choice between them, the choice of the appropriate solution for the machinery concerned must be based on a specific risk assessment. This is particularly important when applying B-type standards – see §111: comments on Article 7 (2).

GENERAL PRINCIPLES (continued).

. . .

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.*

. . .

§160 The applicability of the essential health and safety requirements

General Principle 2 must be borne in mind when reading each of the EHSRs set out in Annex I. The EHSRs are usually expressed without qualification. However, they are only applicable when they are relevant and necessary. In other words, an EHSR applies when the hazard concerned is present on the particular model of machinery concerned. The first sentence of General Principle 2 also underlines that, when identifying the hazards for a given model of machinery, not just the intended conditions of use but also foreseeable abnormal situations must be taken into account. Foreseeable abnormal situations are those arising from reasonably foreseeable misuse - see §172: comments on section 1.1.1 (i).

The second sentence sets out an exception to General Principle 2, since the requirements set out in sections 1.1.2, 1.7.3 and 1.7.4 are applicable to all machinery.

GENERAL PRINCIPLES *(continued)*

. . .

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.*

. . .

§161 The state of the art

General Principle 3 is critical for a correct understanding of how to apply the essential health and safety requirements (EHSRs). It first recalls that the EHSRs, when they are applicable to a given model of machinery, are legally binding. This is clear from the terms of Article 5 (a) setting out the obligations of machinery manufacturers. In this respect, it is important to distinguish the EHSRs of Annex I from the specifications of

harmonised standards, the application of which is voluntary – see §110: comments on Article 7 (2).

The EHSRs set out in Annex I are usually expressed without qualification. The second sentence of General Principle 3 recognises that it may not always be possible to satisfy certain EHSRs fully, given the current state of the art. In such cases, the machinery manufacturer must strive to fulfil the objectives set out in the EHSRs to the greatest extent possible.

The notion of *"the state of the art"* is not defined as such in the Machinery Directive. However, it is clear from Recital 14 (see §16: comments) that the notion of *'the state of the art'* includes both a technical and an economic aspect. In order to correspond to the state of the art, the technical solutions adopted to fulfil the EHSRs must employ the most effective technical means that are available at the time for a cost which is reasonable taking account of the total cost of the category of machinery concerned and the seriousness of the harm the risk reduction is required to address. For example the cost of compliance will be more relevant for the risk of minor fully recoverable injuries, but to reduce the risk of a fatal injury the cost "barrier" will be extremely high, when an adequate technical solution that already exists is not applied, for risks leading to a fatal injury.

Manufacturers of machinery cannot be expected to use solutions that are still at the research stage or technical means that are not generally available on the market. On the other hand, they must take account of technical progress and adopt the most effective technical solutions that are appropriate to the machinery concerned when they become available for a reasonable cost.

"The state of the art" is thus a dynamic concept: the state of the art evolves when more effective technical means become available or when their relative cost diminishes. Thus a technical solution that is considered to satisfy the EHSRs of the Directive at a given time may be considered inadequate at a later time, if the state of the art has evolved.

A machinery manufacturer can only take account of the state of the art at the time the machinery is constructed. If an evolution of the state of the art makes it possible to approach the objectives set out in the EHSRs more closely, a manufacturer producing a series of machines according to the same design must upgrade his design accordingly (while taking account of the time necessary for the redesign and the corresponding changes in the production process).

§162 Harmonised standards and the state of the art

Harmonised standards provide technical specifications that enable machinery manufacturers to comply with the EHSRs. Since harmonised standards are developed and adopted on the basis of a consensus between the interested parties, their specifications provide a good indication of the state of the art at the time they are adopted. The evolution of the state of the art is reflected in later amendments or revisions of harmonised standards. The evolution of the state of the art may mean a standard becomes outdated and is in need of a revision; the revision cycle (normally 5 years) should address this aspect, but in some cases the standard's presumption of conformity may need to be withdrawn or limited – see §119: comments on Article 10.

In this respect, the level of safety afforded by the application of a harmonised standard provides a benchmark that must be taken into account by all manufacturers of the category of machinery covered by the standard, including those who choose to employ alternative technical solutions. A manufacturer who chooses alternative solutions must be able to demonstrate that these solutions are in conformity with the EHSRs of the Machinery Directive, taking account of the current state of the art. Consequently, such alternative solutions must provide a level of safety that it is at least equivalent to that afforded by application of the specifications of the relevant harmonised standard – see §110: comments on Article 7 (2).

When harmonised standards are not available, other technical documents may provide useful indications for applying the EHSRs of the Machinery Directive. Such documents include, for example, international standards, national standards, draft European standards, the Recommendations for Use issued by the European Coordination of Notified Bodies – see §137: comments on Article 14 (7) – or guidelines issued by professional organisations. However, application of such technical documents does not confer a presumption of conformity with the EHSRs of the Machinery Directive – see §383: comments on Annex II 1 A (8).

GENERAL PRINCIPLES *(continued)*[134]

. . .

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. Essential health and safety requirements for the protection of the environment are applicable only to the machinery referred to in section 2.4.*

§163 The structure of Annex I

General principle 4 explains the structure of Annex I. The EHSRs set out in Part 1 of Annex I must be taken into account by manufacturers of all categories of machinery. With the exception of sections 1.1.2, 1.7.3 and 1.7.4 which are always applicable, the EHSRs set out in the other sections of Part 1 are applicable when the manufacturer's risk assessment shows that the hazard concerned is present.

Parts 2 to 6 of Annex I deal with the following specific hazards:

Part 2 hazards specific to certain categories of machinery:
- foodstuffs machinery,

[134] General principle 4 was amended by Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application. OJ L 310, 25.11.2009, p. 29.

- machinery for cosmetics or pharmaceutical products,
- hand-held and hand-guided machinery,
- portable fixing machinery and other portable impact machinery,
- machinery for working wood and material with similar characteristics,
- machinery for pesticide application;

Part 3 hazards due to the mobility of machinery;

Part 4 hazards due to lifting operations;

Part 5 hazards specific to machinery intended for underground work;

Part 6 hazards due to the lifting of persons.

The relevance of the EHSRs set out in each of these parts depends on whether a given model of machinery belongs to one or more of the categories of machinery concerned by Parts 2 or 5 or whether the manufacturer's risk assessment show that the machinery presents one or more of the specific hazards referred to in Parts 3, 4 and 6 – see §160: comments on General Principle 2. For example, a mobile elevating work platform is subject to requirements set out in Parts 1, 3, 4, and 6. A hand-held circular saw for woodworking is subject to requirements set out in Parts 1 and 2.

In some cases, the EHSRs set out in Parts 2 to 6 are supplementary to EHSRs set out in the other parts of Annex I dealing with the same type of hazard. This is indicated in the comments on the sections concerned.

1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

1.1 GENERAL REMARKS

1.1.1 Definitions

For the purpose of this Annex:

(a) 'hazard' means a potential source of injury or damage to health;

. . .

§164 Hazard

The term *'hazard'* is used in the context of risk assessment with a meaning which may be different from everyday usage. In the context of risk assessment, *'hazard'* refers to a potential source of harm. The presence of a hazard is an inherent feature of the machinery and is independent of whether or not any injury or damage to health is actually likely to occur. For example, the presence in the machinery of parts at a high temperature is a potential source of injuries, such as burns, or of damage to health, such as heat stress-related illness; the presence in the machinery of sharp blades is a potential source of injuries such as cuts or amputation. During the phase of hazard identification, a hazard must be considered to be present, even if the part of the machinery presenting the hazard is inaccessible.

Hazards can be identified by their physical origin (for example, mechanical hazard, electrical hazard) or by the nature of the potential injury or damage to health (for example, cutting hazard, crushing hazard, repetitive strain hazard, or electric shock hazard).

General Principle 1 requires the manufacturer to identify the hazards that are inherent to the machinery or that can be generated by its use, and the associated hazardous situations. A hazardous situation is a circumstance, an event or a sequence of events in which a person is exposed to a hazard. Hazardous situations can range in duration from a sudden event to a circumstance that is permanently present during use of the machinery.

***1.1.1 Definitions** (continued)*

. . .

(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;

. . .

§165 Danger zone

The concept of *'danger zone'* makes it possible to locate the places where persons may be exposed to a hazard. In the case of risks involving contact with moving parts of the machinery, for example, the danger zone is limited to the proximity of the hazardous parts. In the case of other risks, such as, for example, the risk of being hit by objects ejected from the machinery or the risk of exposure to noise emissions or emissions of hazardous substances from the machinery, the danger zone may include substantial areas in the environment of the machinery.

One of the most effective ways to prevent risks is to design machinery so as to avoid the need for persons to enter danger zones – see §189: comments on section 1.2.2, and §239: comments on section 1.6.1.

***1.1.1 Definitions** (continued)*

. . .

(c) 'exposed person' means any person wholly or partially in a danger zone;

. . .

§166 Exposed person

The definition of the term *'exposed person'* is very broad. Operators are one category of potentially exposed person – see §167: comments on section 1.1.1 (d). However, persons who do not have any direct involvement with the machinery may be present in a danger zone, particularly if the danger zones include areas in the environment of the machinery. In the case of machinery for professional use, such persons may be, for example, other employees of the company where the machinery is used or bystanders. In the case of machinery used on construction sites, on public roads or in urban areas, potentially exposed persons may include members of the public in the street or in

buildings nearby. In the case of machinery such as agricultural machinery or machinery intended for use by consumers in the home or in the garden, potentially exposed persons may be family members including children. The EHSRs aim to prevent risks for all exposed persons. Consequently, the manufacturer's risk assessment must include an assessment of the likelihood of operators and of any other persons being in a danger zone.

***1.1.1 Definitions** (continued)*

. . .

(d) 'operator' means the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving machinery;

. . .

§167 Operator

The definition of *'operator'* gives the term a very broad sense. In the Machinery Directive, the term is used to designate all persons with specific tasks involving the machinery and is not limited to production operators. Operators include all the different persons dealing with the machinery in the various phases of its lifetime - see §173: comments on section 1.1.2 (a). In the case of machinery intended for use at the workplace, the operators may be professionals who may or may not have been specially trained. In the case of machinery designed for use by consumers, the operators using the machinery are non-professional and must be assumed not to have been specially trained – see §259: comments on section 1.7.4.1 (d). It should be noted that certain kinds of machinery are placed on the market for both professional use and for use by consumers.

***1.1.1 Definitions** (continued)*

. . .

(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;

. . .

§168 Risk

Like the term *'hazard'*, the term *'risk'* is used in the Machinery Directive with a more precise sense than in everyday use. The existence of a risk depends on the hazards generated by the machinery and also on the interface between the machinery and the operators and other exposed persons. A hazard may be present on machinery, but if no person is liable to be exposed to that hazard, there is no risk.

Risks may be characterised by reference to the hazard or hazardous situation concerned (such as, for example, a risk due to contact with moving parts, a risk due to contact with hot surfaces, a risk due to noise emissions or emissions of hazardous substances); risks may also be characterised by reference to their possible

consequences (such as, for example, a crushing risk, a cutting risk, a risk of being burnt, a risk of loss of hearing).

The third step of the process of risk assessment is to estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence – see §158: comments on General Principle 1. The estimation of the risk is based on a combination of these two factors. The most serious risks involve a combination of a high probability of occurrence and the possibility of fatal or severe injury or damage to health. However, a low probability of occurrence may still result in a serious risk if fatal or severe injuries or damage to health may result. Risks must therefore be evaluated on a case-by-case basis, taking account of the fact that risks may be different in the phases of the lifetime of the machinery, depending on the operations concerned and the state of the machinery during each phase – see §173: comments on section 1.1.2 (a).

Market surveillance authorities (MSAs) should use risk assessment to determine the level of appropriate action to take to deal with the risk and to inform other MSAs of high risk machinery on the EU market using the Rapid Alert System (RAPEX). A risk assessment procedure[135] has been developed to assist in this process as well as a guideline on how the system should be used. This system was developed for consumer products but it is also applicable to industrial machinery. However, at the moment it is under review mainly to expand its scope to deal with Directives and Regulations where the risk is not primarily with respect to health and safety of persons.

***1.1.1 Definitions** (continued)*

. . .

(f) 'guard' means a part of the machinery used specifically to provide protection by means of a physical barrier;

. . .

§169 Guard

The term *'guard'* is used for parts of the machinery specifically designed to fulfil a protective function. Other parts of the machinery that fulfil a primarily operational function, such as, for example, the frame of the machinery, may also fulfil a protective function but are not referred to as guards.

Guards are defined as providing protection by means of a physical barrier such as, for example, a casing, a shield, a cover, a screen, a door, an enclosure or a fence. The term *'physical barrier'* implies that a guard is constituted by a solid material such as, for example, steel or plastic, to be chosen according to the protection required. The materials used may be continuous or perforated and may be rigid or flexible.

Guards are one of the means that can be used to prevent access to danger zones in or around machinery. In many cases, the guard acts as a barrier in both directions in order

[135] "How to use the RAPEX Risk Assessment Guidelines Application": http://ec.europa.eu/consumers/consumer-safety/rag/help/RAG.pdf.

to protect against two or more risks simultaneously. For example, a guard may be fitted both to prevent persons entering a danger zone and also to prevent ejected objects or fluids, noise emissions, radiation or hazardous substances from reaching persons in the environment of the machinery.

The Machinery Directive distinguishes three main kinds of guards: fixed guards, interlocking moveable guards and adjustable guards restricting access – see §217: comments on section 1.4.2 of Annex I.

When placed independently on the market, guards are considered as safety components – see §42: comments on Article 2 (c) and §389: comments on Annex V (1) (3) and (7).

***1.1.1 Definitions** (continued)*

. . .

(g) 'protective device' means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard;

. . .

§170 Protective devices

Protective devices are distinguished from guards since they do not constitute a physical barrier between the exposed person and the danger zone but reduce risks by preventing exposure to the hazard by other means. Protective devices include, for example, two-hand control devices, sensitive protective equipment such as pressure-sensitive mats and sensitive edges, trip bars and trip wires, and opto-electronic protective devices such as light curtains, laser scanners or camera-based safeguarding systems – see §221: comments on section 1.4.3 of Annex I.

When placed independently on the market, protective devices are considered as safety components – see §42: comments on Article 2 (c) and §389: comments on Annex V (2) and (7).

***1.1.1 Definitions** (continued)*

. . .

(h) 'intended use' means the use of machinery in accordance with the information provided in the instructions for use;

. . .

§171 Intended use

The first step of the risk assessment process described in General Principle 1 is to determine the limits of the machinery, which include the intended use of the machinery. Machinery is not necessarily safe for all possible uses: for example, the manufacturer of machinery intended for working metal has usually not designed the machinery for safely working wood and *vice versa*; for example, the manufacturer of a mobile elevating work platform usually has not designed the machine to be safely used as a crane. The manufacturer's risk assessment and the design and construction of the machinery must

therefore be based on specified use or uses. The specification of the intended use of the machinery must cover, where appropriate, the different operating modes and phases of use of the machinery – see §173: comments on section 1.1.2 (a).

In particular, the parameters on which the safe use of the machinery depends and their limits must be precisely specified. Such parameters include, for example, the maximum load for lifting machinery; the maximum slope on which mobile machinery can be used without loss of stability; the maximum wind-speed in which machinery can be safely used outdoors; the maximum dimensions of workpieces and the type of material that can be safely processed by a machine tool.

The intended use of the machinery is the use defined and described in the manufacturer's instructions – see §263: comments on section 1.7.4.2 (g).

***1.1.1 Definitions** (continued)*

. . .

(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.

§172 Reasonably foreseeable misuse

The first step of the risk assessment process described in General Principle 1 also requires the manufacturer to take account of reasonably foreseeable misuse of machinery. The machinery manufacturer cannot be expected to take account of all possible misuse of the machinery. However, certain kinds of misuse, whether intentional or unintentional, are predictable on the basis of experience of past use of the same type of machinery or of similar machinery, accident investigations and knowledge about human behaviour – see §173: comments on sections 1.1.2 (a), §175: comments on section 1.1.2 (c), and §263: comments on section 1.7.4.2 (h).

The "A" type standard EN ISO 12100:2010 gives the following examples of the kinds of misuse or readily predictable human behaviour that may have to be taken into account:

- loss of control of the machine by the operator;
- reflex behaviour of a person in case of malfunction, incident or failure during the use of the machine;
- behaviour resulting from lack of concentration or carelessness;
- behaviour resulting from taking the line of least resistance in carrying out a task;
- behaviour resulting from pressures to keep machinery running in all circumstances;
- the behaviour of certain persons such as children.

Such behaviour can result in a range of misuse situations, such as, for example, using a crane or a MEWP without deploying the stabilisers; leaving the door open on an

earthmoving truck in hot weather thereby defeating the air filtering and noise control equipment; two people operating a press designed for use by a single person.

Particular attention must be given to factors that may lead to the removal, disabling or defeating of guards and protective devices – see §216: comments on section 1.4.1.

1.1.2 Principles of safety integration

(a) Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.

The aim of 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.

. . .

§173 Principles of safety integration

Section 1.1.2, setting out the principles of safety integration, sometimes referred to as *safety by design*, is a key section of Annex I. Section 1.1.2 sets out a basic methodology for designing and constructing safe machinery which is fundamental to the approach of the Machinery Directive[136]. General Principle 2 states that this EHSR is applicable to all machinery. When applying the other EHSRs, the principles of safety integration set out in section 1.1.2 must always be followed.

Section 1.1.2 (a) first states that machinery must be fitted for its function. The Machinery Directive is primarily concerned with safety and does not contain any specific requirements relating to the performance of machinery. It is generally considered that the performance of machinery is a matter to be left to the market and that users will select machinery with performance characteristics appropriate to their needs. However, the aptitude of machinery to fulfil its function correctly does affect safety in so far as inadequate functioning of the machinery may lead to hazardous situations or be conducive to misuse.

Section 1.1.2 (a) then sets out the general objective that machinery must be designed and constructed so that it can be operated, adjusted and maintained without putting persons at risk. The term *'persons'* covers both operators and any other exposed persons – see §166 and §167: comments on sections 1.1.1 (c) and (d). In order to achieve this objective, the manufacturer must consider both the intended conditions of use, but also any reasonably foreseeable misuse of the machinery – see §172: comments on section 1.1.1 (i).

The second paragraph of section 1.1.2 (a) sets out the objective of preventing risks throughout the foreseeable lifetime of the machinery, including the phases of transport,

[136] EN ISO 12100-1:2003 + A1:2009 - *Safety of machinery - Basic concepts, general principles for design* - Part 1: *Basic terminology, methodology* (ISO 12100-1:2003); EN ISO 12100-2:2003 + A1:2009 - *Safety of machinery - Basic concepts, general principles for design* - Part 2: *Technical principles* (ISO 12100-2:2003).

assembly, dismantling, disabling and scrapping. On the one hand, this requirement implies that safety related components and assemblies must be sufficiently strong and durable – see §207: comments on section 1.3.2, §339 to §341: comments on sections 4.1.2.3, 4.1.2.4, 4.1.2.5, and §369: comments on section 6.1.1 - and that adequate instructions must be given for the maintenance and replacement of components subject to fatigue and wear – see §272: comments on section 1.7.4.2 (r). On the other hand, this paragraph requires the manufacturer to address not only the risks generated during operation, setting and maintenance of the machinery but also during the other phases of its lifetime:

- ***transport***

Measures to prevent the risks associated with the transport of machinery include, for example:

- the design of machinery to facilitate its handling – see §180: comments on section 1.1.5;
- measures to ensure the stability of the machinery during transport – see §206: comments on sections 1.3.1, and comments on section 4.1.2.1;
- measures to ensure adequate mechanical strength during transport – see §338: comments on section 4.1.2.3;
- providing instructions for safe transport – see §269 and §270: comments on sections 1.7.4.2 (o) and (p).

Such measures are particularly important for machinery intended to be transported between successive sites during its lifetime.

- ***assembly and dismantling***

Design of machinery to facilitate assembly and dismantling is also particularly important in the case of machinery intended for temporary installation on successive sites during its lifetime. The measures to be taken include, for example:

- preventing errors of fitting – see §225: comments on section 1.5.4;
- providing adequate instructions, including guide markings on the machine – see §264 and §269: comments on sections 1.7.4.2 (i) and (o).

- ***disabling and scrapping***

The Machinery Directive does not include requirements relating to the disposal, recycling or reuse of machinery components or materials when machinery is scrapped.

The measures referred to in the second paragraph to prevent risks during the disabling and scrapping of the machinery at the end of its lifetime are those that can be taken by the machinery manufacturer. Such measures may include, for example, ensuring that parts containing hazardous substances are suitably and indelibly marked, ensuring that hazardous substances contained in the machinery can be safely evacuated and ensuring that any stored energy can be safely dissipated when the machinery is disabled, in order to avoid hazards during scrapping – see §178: comments on section 1.1.3.

1.1.2 Principles of safety integration *(continued)*

. . .

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

— *eliminate or reduce risks as far as possible (inherently safe machinery design and construction),*

— *take the necessary protective measures in relation to risks that cannot be eliminated,*

— *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.*

. . .

§174 The 3-step method

Section 1.1.2 (b) sets out the approach that must be adopted when determining the measures to be taken to deal with the risks that have been identified and assessed by means of the risk assessment described in General Principle 1. This hierarchy of measures explained below is a one of the most important requirements of the Directive. The three successive steps are put in an order of priority, often referred to as the *3-step method*:

- *Step 1 = first priority - Inherently safe design measures*
- *Step 2 = second priority - Technical protective measures*
- *Step 3 = third priority - Information for users*

This order of priority must be adhered to when selecting measures to deal with a given risk in order to satisfy the corresponding EHSR. Consequently, the manufacturer must exhaust all the possible inherently safe design measures before resorting to protective measures. Similarly, he must exhaust the possible protective measures before relying on warnings and instructions to operators. Application of the 3-step method must also take due account of the state of the art – see §161: comments on General Principle 3.

– ***Step 1 = first priority***

The first priority is given to inherently safe design measures because they are more effective than protective measures or warnings. Some examples of inherently safe design measures are, for example:

- eliminating the hazard altogether, for example, replacing flammable hydraulic fluid with a non-flammable type, removing risk of falls by having maintenance points easily accessible at ground level rather than at height. – see §178: comments on section 1.1.3;
- designing the control system and control devices in order to ensure safe functioning – see §184 to §185: comments on sections 1.2, and §297 and §298: comments on section 3.3;

- ensuring the inherent stability of machinery by its shape and the distribution of masses – see §206: comments on sections 1.3.1;
- ensuring that accessible parts of the machinery do not have sharp edges or rough surfaces – see §209: comments on section 1.3.4;
- ensuring sufficient distance between moving and fixed parts of the machine to avoid the risk of crushing – see §212: comments on section 1.3.7;
- placing the operator so they have all round direct vision of danger areas;
- avoiding accessible surfaces with extreme temperatures – see §226: comments on section 1.5.5;
- reducing emissions of noise, vibrations, radiation or hazardous substances at source – see §229: comments on section 1.5.8, §231: comments on section 1.5.9, §232: comments on section 1.5.10, and §235: comments on section 1.5.13;
- reducing, where possible, the speed and the power of moving parts or the travel speed of the machinery itself;
- locating hazardous parts of machinery in inaccessible places – see §212: comments on section 1.3.7;
- locating adjustment and maintenance points outside danger zones – see §239: comments on section 1.6.1 of Annex I.

- ***Step 2 = second priority***

When it is not possible to eliminate hazards or sufficiently reduce risks by inherently safe design measures, the second priority is given to technical protective measures to prevent persons from being exposed to the hazards. Some examples of technical protective measures are, for example:

- guards: fixed guards, interlocking moveable guards with guard locking where necessary or adjustable guards restricting access – see §218 to §220: comments on sections 1.4.2.1 to 1.4.1.3;
- protective devices – see §221: comments on section 1.4.3;
- insulation of live electrical parts – see §222: comments on section 1.5.1;
- enclosure of sources of noise – see §229: comments on section 1.5.8;
- damping of vibrations – see §231: comments on section 1.5.9;
- containment or evacuation of hazardous substances – see §235: comments on section 1.5.13;
- devices to compensate the lack of direct visibility – see §294: comments on section 3.2.1;
- protective structures against the risk of rolling or tipping over or the risk of falling objects – see §315 and §316: comments on sections 3.4.3 and 3.4.4;
- stabilisers – see §335: comments on sections 4.1.2.1.

– ***Step 3 = third priority***

Finally, for the residual risks that cannot be adequately reduced by inherently safe design measures or by technical protective measures, information must be given to exposed persons, in the form of warnings, signs and information on the machinery, and to users in the instructions so that the necessary precautions and measures can be taken by the users[137]. Some examples of such warnings and instructions are:

- Information or warnings on the machinery in the form of symbols or pictograms – see §245: comments on section 1.7.1;
- warning acoustic or light signals – see §248: comments on section 1.7.1.2;
- indicating of the mass of machinery or parts thereof which must be handled with lifting equipment during the different phases of its foreseeable lifetime – see comments on section – see §253: comments on section 1.7.3;
- warning against the use of machinery by certain persons such as, for example, young people under a certain age or height – see §263: comments on section 1.7.4.2 (g);
- information relating to the safe assembly and installation of the machinery – see §264: comments on section 1.7.4.2 (i);
- specifying the need to provide the necessary information and training to operators – see §266: comments on section 1.7.4.2 (k).
- information on the complementary protective measures to be taken in the workplace – see §267: comments on section 1.7.4.2 (l);
- specifying the need to provide the appropriate personal protective equipment to operators and ensure that it is used – see §267: comments on section 1.7.4.2 (m)[138].

Providing warnings and instructions for use is considered as an integral part of the design and construction of the machinery. However, the fact that this third step is the last in the order of priority given in section 1.1.2 (b) means that warnings and instructions must not be a substitute for inherently safe design measures and technical protective measures when these are possible, taking into account the state of the art.

[137] Such measures are subject to the national provisions implementing Directive 89/391/EEC as amended on the introduction of measures to encourage improvements in the safety and health of workers at work (the "Framework" Directive) and to the individual Directives adopted within this framework – see §140, comments on Article 15.

[138] The provision of personal protective equipment at the workplace is subject to the national provisions implementing Council Directive 89/656/EEC on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace.

1.1.2 Principles of safety integration *(continued)*

. . .

(c) When designing and constructing machinery and when drafting the instructions, the manufacturer or his authorised representative must envisage not only the intended use of the machinery but also any reasonably foreseeable misuse thereof.

The machinery 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.

. . .

§175 Preventing abnormal use

Section 1.1.2 (c) follows logically from section 1.1.2 (a). Since the machinery manufacturer must envisage both the intended use of the machinery and also reasonably foreseeable misuse – see §172: comments on section 1.1.1 (i) – measures must also be taken to prevent foreseeable abnormal use that would engender a risk. These measures must be chosen according to the order of priority set out in section 1.1.2 (b). Thus the manufacturer must as far as possible prevent foreseeable abnormal use by technical means. Example of such means include, for example:

- providing means for restricting the operation of the machinery or of certain control devices to authorised persons – see §204: comments on section 1.2.5, and §297: comments on section 3.3;
- designing machinery to prevent errors of fitting – see §225: comments on section 1.5.4;
- fitting devices to prevent the travel of mobile machinery when the driver is not at the controls – see §304: comments on section 3.3.2;
- fitting devices to prevent the operation of machinery unless stabilisers are in position – see §335: comments on section 4.1.2.1;
- fitting devices to prevent the overloading of lifting machinery – see §354: comments on sections 4.2.2, and §370: comments on section 6.1.2.

Where there remains a residual risk of foreseeable misuse that cannot be entirely prevented by such technical means, appropriate warnings must be given on the machinery – see §249: comments on section 1.7.2 – and in the instructions – see §263: comments on section 1.7.4.2 (h).

***1.1.2 Principles of safety integration** (continued)*

. . .

(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.

. . .

§176 Constraints due to the use of PPE

Section 1.1.2 (d) deals with a particular aspect of the intended use of machinery. Machinery operators may be required to wear or carry personal protective equipment (PPE) to deal with residual hazards generated by the machinery itself, such as, for example, hearing protectors to protect against noise emissions or eye protectors to protect against the risk of projections of hazardous substances or objects. They may also be required to use PPE to protect against hazards that are not generated by the machinery but which are present in the environment in which the machinery is used. For example, machinery operators may have to wear protective footwear to protect their feet against shocks and sharp objects on the construction site or in the workplace where the machinery is used. Machinery operators may have to wear protective gloves, clothing and footwear if the machinery is used in cold or hot atmospheres or in adverse weather conditions.

The design and construction of the machinery and, in particular, the design, positioning and dimensions of the control devices, must take account of the constraints to which the operator is likely to be subject due to such use of PPE. For example, on machinery designed to be used in cold conditions, the spacing, size and design of foot-pedals should be such as to accommodate the wearing of large boots – see §300: comments on section 3.3.1.

***1.1.2 Principles of safety integration** (continued)*

. . .

(e) Machinery must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.

§177 Special equipment and accessories

Section 1.1.2 (e) does not require machinery manufacturers to supply standard tools and equipment required for adjustment and maintenance operations (screwdrivers, spanners, wrenches, hoists and the like) that may be used with different kinds of machinery. However, if the safe adjustment, maintenance or use of the machinery requires the use of equipment or accessories that are specific to machinery concerned, such equipment or accessories must be made available by the machinery manufacturer with the machinery. Such special equipment may include, for example, devices for the removal of parts of the machinery for cleaning purposes or devices for feeding or loading and unloading workpieces.

1.1.3 Materials and products

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

§178 Materials and products used

The requirement set out in section 1.1.3 deals with several kinds of risk:

a) Risks due to materials or products used to construct the machinery such as, for example, metals, plastics, textiles or paints.

   Attention must be given to risks for the health and safety of operators or other exposed persons due to contact with these materials or, for example, due to hazardous substances that may be emitted by these materials when they heat up, are disturbed or are subject to wear. As far as possible, these risks must be prevented by the choice of innocuous materials for the construction of the machinery.

b) Risks due to materials or products used by the machinery such as fuels, lubricants, hydraulic fluids, chemicals, battery electrolyte, water, steam, compressed air and so on.

   Such risks can be eliminated or reduced by designing the machinery to use innocuous materials or products or by substituting hazardous materials or products with less hazardous ones. The manufacturer's instructions must specify the appropriate materials or products to be used with the machinery. Where risks remain, protective measures must be taken to protect operators against exposure to hazardous materials or products used by the machinery, for example, by ensuring that they are inaccessible or adequately contained. Where necessary, appropriate warnings must be given on the machinery and in the instructions.

   The second sentence of section 1.1.3 underlines particular aspects that must be considered when fluids are used. The measures to be taken to prevent risks due to filling, use, recovery or draining of fluids include, for example, the appropriate location and design of tanks and reservoirs and of their filling and draining points and the fitting of a retention tray under hydraulic equipment if leaks cannot be entirely prevented. When tanks are pressurised, they must be provided with means of reducing them to a safe pressure and of checking the pressure prior to the opening of filling or draining points.

c) Risks due to materials or products worked, processed or transformed by the machinery, such as metals, rubber, plastics, wood, foodstuffs, cosmetics and so on.

   The manufacturer of the machinery must take account of the materials to be worked by the machinery and take measures to prevent risks due to hazards such as, for example, sharp edges, splinters, ejected fragments or hot or cold materials.

d) Risks due to materials or products created during the use of the machinery. Such materials may either be the intended products of the machinery or by-products or waste such as, for example, chips, shavings, fumes or dust.

It should be noted that the reference in section 1.1.3 to *"risks due to … products created during the use"* of the machinery does not concern the product safety of products produced by machinery.

Certain aspects of the risks mentioned in (a) to (d) above are subject to specific EHSRs – see §208: comments on section 1.3.3 on risks due to falling or ejected objects, §226: comments on section 1.5.5 on extreme temperatures, §227: comments on section 1.5.6 on the risk of fire, § 228: comments on section 1.5.7 on the risk of explosion, and §235: comments on section 1.5.13 on emissions of hazardous materials and substances.

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.

§179 Integral lighting

The machinery manufacturer is entitled to assume that the ambient lighting in the place of use is of normal intensity. Normal intensity can be judged, for example, by taking into account the levels for indoor and outdoor workplaces indicated in standards EN 12464, parts 1 and 2[139].

The first paragraph of section 1.1.4 requires the manufacturer to provide lighting integral to the machinery when normal ambient lighting is likely to be inadequate to ensure safe operation of the machinery. Such lighting may be necessary, for example, at work stations that are likely to be in the shade or in enclosed or covered work stations or cabs. Such lighting may also be necessary where the visual tasks of the operators require a higher level of luminance than is likely to be provided by the ambient lighting. The third paragraph of section 1.1.4 adds the requirement for integral lighting for internal parts to which access is frequently required for inspection, adjustment and maintenance purposes.

The second paragraph of section 1.1.4 concerns the design of the integral lighting, to ensure that it does not generate other hazards.

[139] EN 12464-1:2002 2011 *Light and lighting - Lighting of work places* - Part 1: *Indoor work places;* EN 12464-2:2014 *Lighting of work places* - Part 2: *Outdoor work places.*

Specifications for integral lighting are given in standard EN 1837[140].

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.*

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

— *either be easily moveable, or*

— *be equipped for picking up and moving safely.*

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

§180 Handling of machinery and parts of machinery

The requirements set out in section 1.1.5 are to be applied in the light of an analysis of the different phases of the lifetime of the machinery concerned – see §173: comments on section 1.1.2 (a).

Section 1.1.5 applies to 'machinery or each component part thereof'. This does not mean that all parts of machinery must be designed for safe handling, but only those parts of the machinery, or the machinery itself, which may have to be handled separately.

Portable hand-held and/or hand guided machinery is subject to specific requirements – see §278: comments on section 2.2.1.

Handling of machinery or parts of machinery is frequently carried out during phases other than normal operation such as, for example, transport, loading and unloading, assembly, installation, dismantling, setting or maintenance. A hand-held power tool intended for consumer use, for example, must be packaged so that it can be safely transported, stored during distribution and carried home by the consumer. A machine tool, for example, must be packaged for transport to the user's premises and designed

[140] EN 1837:1999+A1:2009 *Safety of machinery - Integral lighting of machines.*

and constructed so that it can be safely loaded, transported, unloaded and moved to the place of installation. Heavy parts of machinery such as, for example the mould of an injection moulding machine or the die of a metal working press, may need to be changed frequently, depending on the work to be carried out.

Machinery intended to be installed on successive sites during its lifetime, such as, for example, tower cranes, must be designed so that their elements can be safely handled during assembly and disassembly and safely loaded and attached on the means of transport between installation sites. Special attention should be given to parts that may become unstable during transport, for example, on a lorry travelling on uneven ground. Loading instructions are required and, in some cases, extra equipment may be needed ensure stability during transport, such as, for example, a transport support frame.

The third and fourth paragraphs of section 1.1.5 distinguish machinery or component parts that cannot be safely moved by hand from machinery or parts that can be safely moved by hand. When evaluating whether machinery or parts of machinery fall into one or other category, account should be taken of national regulations implementing the provisions of Directive 90/269/EEC[141] and of the criteria given in the relevant harmonised standards[142].

When designing machinery or parts of machinery to be safely moved or lifted by hand, sharp edges must be avoided. Particular attention must be given to the required posture of the operator[143].

1.1.6 Ergonomics

Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic principles such as:

- *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.*

[141] Council Directive 90/269/EEC of 29 May 1990 on the minimum health and safety requirements for the manual handling of loads where there is a risk particularly of back injury to workers (fourth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC). OJ L 156, 21.6.1990, p. 9.

[142] EN 1005-2:2003+A1:2008 *Safety of machinery - Human physical performance* - Part 2: *Manual handling of machinery and component parts of machinery.*

[143] EN 1005-4: 2005+A1: 2008 *Safety of machinery - Human physical performance* - Part 4: *Evaluation of working postures and movements in relation to machinery*.

§181 Ergonomic principles

The requirements set out in section 1.1.6 refer to ergonomics. The discipline of ergonomics can be defined as follows:

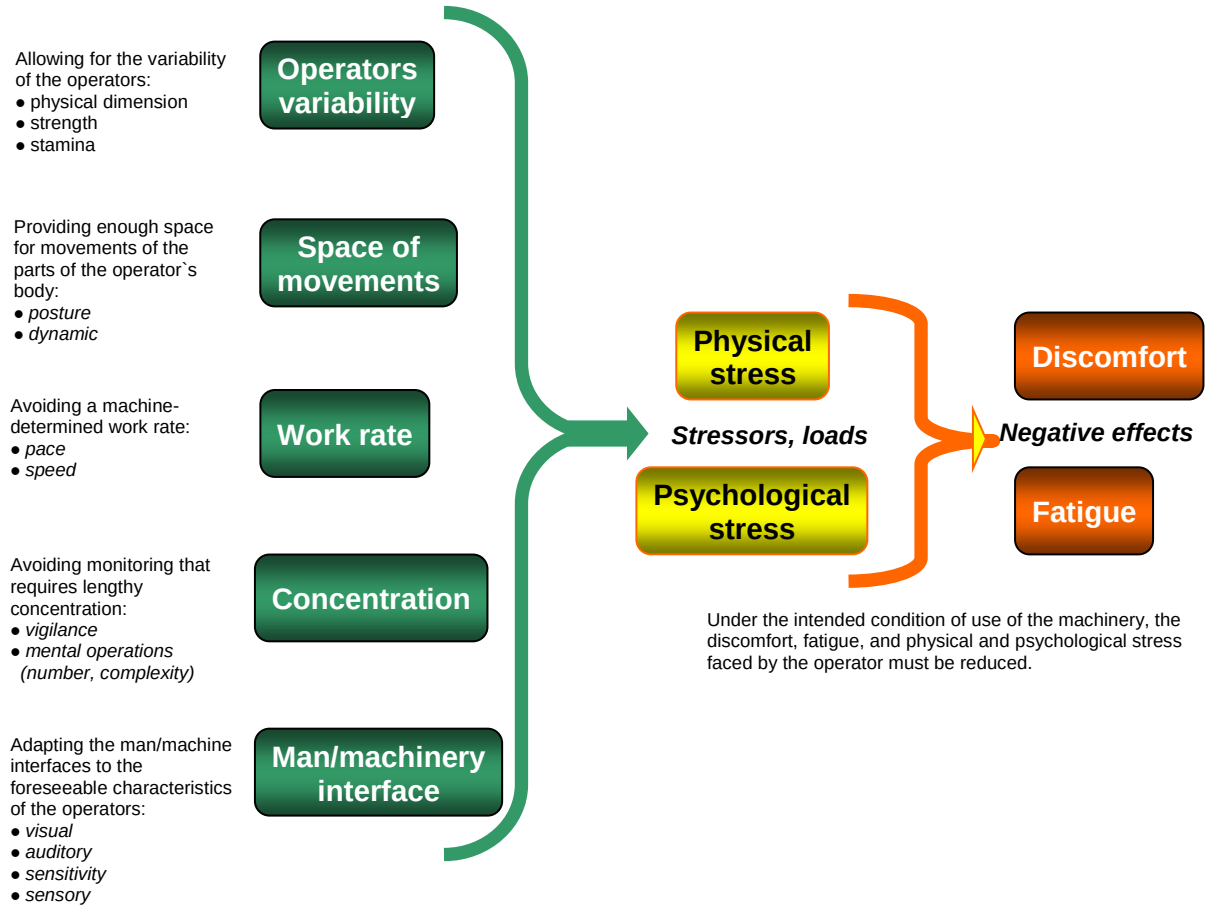
> *"Ergonomics (or the study of human factors) is the scientific discipline concerned with the understanding of interactions among human and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance"*[144].

The ergonomic aspects referred to in section 1.1.6 can be distinguished into two groups. The first group includes ergonomic factors that have to be taken into account when designing machinery. Five factors are listed in the indents of section 1.1.6, however it should be underlined that this list is not exhaustive but is intended to draw the attention of manufacturers to certain important aspects of ergonomic principles.

The second group, listed in the first sentence of section 1.1.6, includes negative effects that can be caused by these factors. Good design reduces the negative effects of these factors on persons whereas inadequate design is likely to give rise to discomfort, fatigue or physical or psychological stress. These effects may, in turn, give rise to musculoskeletal disorders and other ill-health effects, for example. They also can be a factor that makes injury accidents more likely.

[144] EN ISO 6385: 2004 *Ergonomic principles in the design of work systems* (ISO6385:2004).

The following diagram illustrates requirements set out in section 1.1.6:



Ergonomic factors **Possible negative consequences**

Guidance on the practical application of ergonomic principles to the design and construction of machinery is given in a family of harmonised standards developed by CEN TC 122 *Ergonomics*. The relationship between these standards and the ergonomic factors listed above is presented in a separate table and in series of information sheets.

In addition to the general requirement set out in section 1.1.6, ergonomic principles must also be taken into account when applying the essential health and safety requirements (EHSRs) set out in a number of other sections of Annex I to the Machinery Directive 2006/42/EC. For example, the following EHSRs include important ergonomic aspects:

EHSRs applicable to all machinery:

- Lighting (section 1.1.4),
- Handling of machinery or parts of machinery (section 1.1.5),
- Operating positions (sections 1.1.7 and 1.1.8),
- Control devices (section 1.2.2),
- Extreme temperatures (section 1.5.5),

- Noise (section 1.5.8),
- Vibrations (section 1.5.9),
- Radiation (section 1.5.10),
- Emissions of hazardous materials and substances (section 1.5.13),
- Risk of tripping, slipping and falling (section 1.5.15),
- Machinery maintenance (section 1.6.1),
- Access to operating positions and servicing points (section 1.6.2),
- Operator intervention (section 1.6.4),
- Information (section 1.7);

Supplementary EHSRs for portable hand-held and/or hand guided machinery:

- General requirements (section 2.2.1),
- Instructions - vibrations (section 2.2.1.1);

Supplementary EHSRs for the mobility of machinery:

- Driving positions (section 3.2.1),
- Seating (section 3.2.2),
- Positions for other persons (section 3.2.3),
- Control devices (section 3.3.1),
- Starting/moving (section 3.3.2),
- Movement of pedestrian controlled machinery (section 3.3.4),
- Means of access (section 3.4.5),
- Signs, signals and warnings (section 3.6.1),
- Instructions - vibrations (section 3.6.3.1);

Supplementary EHSRs for lifting operations:

- Movement of loads during handling (section 4.1.2.7),
- Access to the carrier (sections 4.1.2.8.2),
- Control of movements (section 4.2.1);

Supplementary EHSRs for the lifting of persons:

- Control devices (section 6.2),
- Access to the carrier (section 6.4.3).

A guidance document on the application of essential health and safety requirements on ergonomics, as approved by the Machinery Working Group, is available on EUROPA website for machinery[145] and to be noted that it is in process to be revised and updated.

1.1.7 Operating positions

The operating position must be designed and constructed in such a way as to avoid any risk due to exhaust gases and/or lack of oxygen.

If the machinery is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery itself gives rise to a hazardous environment, adequate means must be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.

Where appropriate, the operating position must be fitted with an adequate cabin designed, constructed and/or equipped to fulfil the above requirements. The exit must allow rapid evacuation. Moreover, when applicable, an emergency exit must be provided in a direction which is different from the usual exit.

§182 Operating positions in hazardous environments

Operating positions are the places on or at the machinery where operators, as defined in section 1.1.1 (d), carry out their tasks. The manufacturer's instructions must describe the workstation(s) likely to be occupied by operators – see §262: comments on section 1.7.4.2 (f).

The requirement set out in the first paragraph of section 1.1.7 applies mainly to machinery with internal combustion engines. This requirement implies, firstly, that the emission of hazardous exhaust gases must be reduced as far as possible. For example, in the case of machinery designed to be used in enclosed spaces, appropriate systems for the extraction or filtering of exhaust gases must be fitted. Secondly, where there remains a risk of exposure to hazardous exhaust gases, means must be provided to ensure that operators do not inhale such gases and are provided with an adequate supply of breathable air.

The second paragraph of section 1.1.7 is more general and requires operators to be protected against any risks due to the foreseeable use of the machinery in a hazardous environment. Such risks may include, for example, exposure to hot and cold atmospheres, to risks due to noise, radiation, humidity, adverse weather conditions or atmospheres polluted by hazardous substances. This section also covers the risk of electric shock due to overhead lines in the operating area (e.g. agricultural spray machines working under such lines). The manufacturer must therefore take account of the intended and foreseeable conditions of use of the machinery. For example, if the machinery is placed on the market in a country with a mild climate, it might not be necessary to provide protection against extremely cold weather, whereas protection against dust or heat might be needed. Special consideration needs to be given to machinery that generates hazardous substances, such as dust, fume or toxic aerosols,

[145] http://ec.europa.eu/growth/sectors/mechanical-engineering/machinery/

by its very operation; examples are machinery for rock crushing and screening, machinery for grain handling, agricultural spray machinery and paint spray booths.

The third paragraph of section 1.1.7 refers to one of the means that can be used to ensure that operating positions are protected. *'Cabin'* in this paragraph is a generic term for an enclosed operating position such as, for example, a cab on mobile machinery or an enclosed control panel on fixed industrial machinery. In order to fulfil the requirements set out in the first two paragraphs of section 1.1.7, the cabin or enclosure must be provided with the necessary means of purifying and conditioning the air entering the enclosure and preventing inward leaks, for example, by maintaining a positive pressure differential with the outside atmosphere. As well as ensuring protection against hazardous environments, such enclosures can also be designed and constructed to protect operators against exposure to noise emissions – see §229: comments on section 1.5.8. On some mobile machinery, the cab may include a structure to protect against the risk of rolling or tipping over or the risk due to falling objects or both – see §315 and §316: comments on sections 3.4.3 and 3.4.4.

It should be noted that operator's cabins which are an integrated part of a building (e.g. for concrete batching plant or asphalt mixing plant) are not covered by the Machinery Directive, being subject to national regulations, unless they are provided by the manufacturer as part of machinery when placed on the market. However, the control panels provided by the manufacturer shall comply with the Machinery Directive.

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.

§183 Seating and the provision of seats

The requirement set out in section 1.1.8 deals with a specific aspect of the interface between the operator and the machinery that can be a source both of discomfort, fatigue and damage to health if badly designed – see §181: comments on section 1.1.6.

The first paragraph of section 1.1.8 requires machinery to be designed to enable seats to be installed, *'where appropriate and where the working conditions so permit'*. Machinery manufacturers must therefore consider whether operators are likely to be more comfortable and to carry out all or part of their tasks more easily and efficiently

when seated[146]. Where this is the case, the work station, in other words, the place at the machinery where the operators are to be seated, must be designed so that the necessary seats can be installed. This implies paying attention, in particular, to the height of the work surfaces, to the location and design of the control devices and the other parts of the machinery to which the operators must have access and to the space provided for the seat itself and for the operators upper and lower limbs.

The second paragraph of section 1.1.8 is applicable when the operator is intended to sit during operation and the operating position is an integral part of the machinery, in other words, when the operator's seat is not to be installed on the floor next to the machinery but on part of the machinery itself. In that case, the seat must be provided with the machinery.

The second and third paragraphs of section 1.1.8 set out requirements for the seat. The seat must be designed to enable the operator to maintain a stable position taking account of the foreseeable conditions of use including, in particular, foreseeable movements of the machinery.

The relevant parameters of the seat itself such as the height, width, depth and angle of the seat, the position of the backrest and, where appropriate, the position of the arm and footrests, must be adjustable to take account of the variability of operators' physical dimensions. The position of the seat relative to the position of the control devices, including foot-pedals, to be used by the operator must also be adjustable. This can be achieved by allowing for adjustment of the position of the seat, of the control devices or both[147].

For machinery where the seated operator may be exposed to vibration due to the functioning of the machinery itself or due to the movement of the machinery on uneven ground, the provision of a seat with an appropriate damped suspension system is one way to reduce the risk of exposure of seated operators to whole body vibration – see §231: comments on section 1.5.9[148].

[146] EN 1005-4: 2005+A1:2008 *Safety of machinery - Human physical performance* - Part 4: *Evaluation of working postures and movements in relation to machinery*.

[147] See EN ISO 14738:2008 *Safety of machinery - Anthropometric requirements for the design of workstations at machinery* (ISO 14738:2002, including Cor 1:2003 and Cor 2:2005).

[148] See, for example, EN ISO 7096:2008 *Earth-moving machinery - Laboratory evaluation of operator seat vibration* (ISO 7096:2000).

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.*

Particular attention must be given to the following points:

- *the machinery must not start unexpectedly,*
- *the parameters of the machinery must not change in an uncontrolled way, where such change may lead to hazardous situations,*
- *the machinery must not be prevented from stopping if the stop command has already been given,*
- *no moving part of the machinery or piece held by the machinery must fall or be ejected,*
- *automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded,*
- *the protective devices must remain fully effective or give a stop command,*
- *the safety-related parts of the control system must apply in a coherent way to the whole of an assembly of machinery and/or partly completed machinery.*

For cable-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication.

§184 Safety and reliability of control systems

The control system of machinery is the system which responds to input signals from parts of the machinery, from operators, from external control equipment or any combination of these and generates corresponding output signals to the machinery actuators, causing the machine to perform in the intended manner. Control systems can use different technologies or combinations of technologies such as, for example, mechanical, hydraulic, pneumatic, electric, or electronic technologies. The use of electronic control systems that are programmable have been and are now much more common since the Directive came into force.

The design and construction of the control system in order to ensure safe and reliable functioning of the machinery are key factors in ensuring the safety of the machinery as a

whole. Operators must be able to ensure that the machinery functions safely and as expected at all times.

The requirements set out in section 1.2.1 apply to all parts of the control system that, in the event of a fault or a failure, can lead to hazards due to unintended or unexpected behaviour of the machinery. They are of particular importance for the design and construction of the parts of the control system related to safety functions such as, for example, the parts of the control system related to interlocking and guard-locking devices for guards, to protective devices or to emergency stop controls, since a failure of safety related parts of the control system is liable to give rise to a hazardous situation when the corresponding safety function is next required to operate. Certain safety functions may also be operational functions, such as, for example, a two-hand start control device.

The first paragraph of section 1.2.1 and its 4 indents set out the basic requirements for the reliability and safety of control systems. The second paragraph of section 1.2.1 and its 7 indents describe the main hazardous events and situations that must be avoided.

According to the first indent of the first paragraph of section 1.2.1, control systems must be able to withstand intended operating stresses and external influences, taking into account foreseeable abnormal situations – see §160: comments on General Principle 2, and §175: comments on section 1.1.2 (c). The control system must thus be able to withstand the mechanical effects generated by operation of the machinery itself or by its environment such as, for example, shocks, vibrations, and abrasion. Control systems must be able to withstand the effects of the internal and external conditions under which the machinery is intended to function such as, for example, humidity, extreme temperatures, corrosive atmospheres and dust. The correct functioning of control systems must not be affected by electromagnetic radiation, whether generated by parts of the machinery itself or by external elements in the conditions in which the machinery is intended to be used – see §233: comments on section 1.5.11.

The second and third indents of the first paragraph of section 1.2.1 deal with the behaviour of the control system in case of a fault or error in the hardware or software. These requirements take account of the possibility of faults occurring in the control system due, for example, to the failure of a mechanical, hydraulic, pneumatic or electrical component or to an error in the software of a programmable system. Control systems must be designed and constructed so that, if such faults or errors occur, they do not lead to hazardous situations such as those described in the second paragraph of section 1.2.1 – see also §205: comments on section 1.2.6.

The hazardous functions of the machinery can be brought under control, for example, by stopping the function, removing power from the function or preventing the hazardous action of the function. If the relevant functions of the machinery are able to continue despite the occurrence of a fault or a failure, for example, by means of a redundant architecture, there must be a means of detecting the fault or failure so that the necessary action can be taken to achieve or maintain a safe state.

The means to be used to fulfil this requirement depend on the type of control system, on the part of the control system concerned and on the risks that could arise in case of its failure.

The concepts that can be used include:

- The exclusion or reduction of the probability of faults or failures which may affect the safety function by recourse to particularly reliable components and by applying well-tried safety principles, such as, for example, the principle of the positive mechanical action of a component on another component;
- The use of standard components with a check on the safety functions at suitable intervals by the control system;
- The redundancy of parts of the control system such that a single fault or failure does not lead to the loss of the safety function. Technical diversity of the redundant elements can be used to avoid common cause failures;
- Automatic monitoring to ensure that faults or failures are detected and that the necessary protective measures are initiated to prevent the risk concerned. The protective measures may include the stopping of the hazardous process, preventing the re-start of this process or the triggering of an alarm.

These concepts can be applied in different combinations.

The level of performance required for a given safety related part of the control system depends on the level of the risk for which the safety function is intended and is to be determined on the basis of the manufacturer's risk assessment. C-type standards for particular categories of machinery provide guidance on the level of performance required for the different safety related parts of the control system.

The achievement of the required level of performance for safety related parts of control systems must be validated, taking account both of the hardware and software aspects of such systems.

Specifications for the design of safety-related parts of control systems are given in standards EN ISO 13849-1[149] and standard EN 62061[150].

The fourth indent of the first paragraph of section 1.2.1 deals with reasonably foreseeable human error during operation. In order to satisfy this requirement, control systems must, as far as possible, be designed with error tolerance. This involves measures such as the detection of errors and providing appropriate feedback to the operator to facilitate the correction of errors.

General principles for human interaction with machinery to minimise operator errors are given in standard EN 894-1[151].

The third paragraph of section 1.2.1 covers a particular hazard associated with cable-less control systems, such as, for example, remote control systems using radio, optical

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[149] EN ISO 13849-1:2008 *Safety of machinery - Safety-related parts of control systems* - Part 1: *General principles for design* (ISO 13849-1:2006).

[150] EN 62061:2005+A2:2015 *Safety of machinery - Functional safety of safety-related electrical, electronic and programmable electronic control systems* (IEC 62061:2005+A2:2015).

[151] EN 894-1:1997+A1:2008 *Safety of machinery - Ergonomic requirements for the design of displays and control actuators* - Part 1: *General principles for human interactions with displays and control actuators.*

or sonar signals: incorrect signals or loss of communication between the control devices and the machinery to be controlled. It should be noted that section 3.3 provides supplementary requirements for remote control systems for mobile machinery.

1.2.2 Control devices

. . .

§185 Control devices

Control devices are parts of the control system which detect input signals given by the operators, usually by means of hand or foot pressure. There are many different kinds of control devices including, for example, push-buttons, levers, switches, knobs, sliders, joy-sticks, hand wheels, pedals, keyboards and tactile screens. Control devices may be located on the machinery itself or, in the case of remote controls, may be located at a distance from the machinery and be linked to the machinery, for example, by means of wires, or by means of radio, optical or sonar signals.

Application of the requirements set out in section 1.2.2 requires particular attention to ergonomic principles, since control devices are at the interface between the machinery and the operators – see §181: comments on section 1.1.6.

Specifications relating to the requirements set out in the following paragraphs of section 1.2.2 are given in the standards of the EN 894 series[152] and the standards of the EN 61310 series[153].

In addition to the general requirements for control devices set out in section 1.2.2, the following sections of Annex I provide supplementary requirements for control devices for certain categories of machinery or for certain risks:

- portable hand-held and/or hand-guided machinery - sections 2.2.1 and 2.2.2.1;
- mobility of machinery - section 3.3;
- lifting operations – section 4.2.1;
- machinery for underground work - section 5.3;
- machinery for lifting persons - sections 6.2 and 6.4.2.

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[152] EN 894-1:1997+A1:2008 *Safety of machinery - Ergonomic requirements for the design of displays and control actuators* - Part 1: *General principles for human interactions with displays and control actuators;* EN 894-2:1997+A1:2008 *Safety of machinery - Ergonomics requirements for the design of displays and control actuators* - Part 2: *Displays*; EN 894-3:2000+A1:2008 *Safety of machinery - Ergonomics requirements for the design of displays and control actuators* - Part 3: *Control actuators.*

[153] EN 61310-1:2008 *Safety of machinery - Indication, marking and actuation* - Part 1: *Requirements for visual, acoustic and tactile signals* (IEC 61310-1:2007); EN 61310-2:2008 *Safety of machinery - Indication, marking and actuation - Part 2: Requirements for marking* (IEC 61310-2:2007); EN 61310-3:2008 *Safety of machinery - Indication, marking and actuation* - Part 3: *Requirements for the location and operation of actuators* (IEC 61310-3:2007).

1.2.2 Control devices (continued)

. . .

Control devices must be:

– *clearly visible and identifiable, using pictograms where appropriate,*

. . .

§186 Identification of control devices

The first indent of section 1.2.2 on the visibility and clear identification of control devices, aims to enable operators to use the devices without hesitation and avoid unintended commands due to operators confusing one control device with another. Since operators are often liable to perform different tasks and use several different machines in the course of their activity, it is important for manufacturers to identify control devices using, as far as possible, standardised colours, shapes and pictograms so that operators are not surprised when they change tasks or move from one machine to another. If the function of a control device is obvious from its standard shape and location such as, for example, a steering wheel or handlebars on mobile machinery, additional means of identification are not required.

If the controls are identified by means of written or verbal information, this information is subject to the language requirements relating to information and warnings on the machinery – see §245: comments on section 1.7.1.

1.2.2 Control devices (continued)

. . .

– *positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity,*

. . .

§187 Positioning of control devices

The second indent of section 1.2.2 requires manufacturers to take account of ergonomic principles when positioning control devices on the machinery, to ensure that the devices are clearly visible to operators and that they can be reached and used efficiently and safely, without the need to adopt awkward postures.

The positioning of the control devices must take account of the tasks to be carried out by the operators and of the corresponding operating modes, of the position and characteristics of work stations or operating positions, of whether operators are likely to be standing or seated and of the need for operators to observe certain parts of the machinery while using the control devices.

The layout of control devices should also take account of the position of the parts of the machinery affected by its use, following commonly accepted conventions. For example, a device controlling parts of the machinery to the right of the operator should be positioned on the right of the operating position; a device controlling an upward

movement should be positioned above a button controlling a downward movement and so on.

Where control devices have to be operated in a given sequence, they should be arranged in that sequence. Devices controlling related functions should be grouped together and devices controlling unrelated functions should be clearly separated.

The control devices that are likely to be used most frequently or that need to be used continuously should be positioned within the central area of the operator's field of vision and within the immediate reach envelope where they can be reached without bending. Where necessary, this may require the provision of means of adjusting the position of the control devices to accommodate the variation of the body dimensions of operators.

1.2.2 Control devices (continued)

. . .

– *designed in such a way that the movement of the control device is consistent with its effect,*

. . .

§188 Movement of control devices

The requirement set out in the third indent of section 1.2.2 deals with two principles for the design of control devices which are to ensure conformity with the expectations of users and to comply with common practice in order to avoid hazardous situations and errors. The requirement applies to the movements of control devices such as, for example, levers or hand wheels.

Wherever possible, the direction of movement of such devices should be consistent with the direction of the movement controlled by their use. In the case of control devices controlling other parameters, the direction of movement of the device should correspond to commonly accepted conventions such as, for example, the convention that turning a device clockwise increases the value of the parameter concerned and turning the device anti-clockwise reduces it.

Particular attention should be given to the design of control devices in machinery where the operating position is able to rotate with respect to the rest of the machinery, with the result that the direction of certain movements controlled by the control devices is inverted.

1.2.2 Control devices (continued)

. . .

– *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,*

. . .

§189 Location of and positioning of control devices

The location and positioning of control devices outside the danger zones, required by the fourth and fifth indents of section 1.2.2, is one of the ways of avoiding the exposure of operators to hazards – see §165: comments on section 1.1.1 (b). This requirement must be applied taking account not only of areas where there is a risk of direct contact with hazardous elements of the machinery but also of areas where there may be risks due to ejected objects or emissions from the machinery. Ways to fulfil these requirements include, for example, locating the control devices at a sufficient distance from moving parts – see §212: comments on section 1.3.7 – or locating control devices behind a screen or inside an adequate cabin – see §182: comments on section 1.1.7.

Where it is necessary to derogate from this general rule, for example, in cases where control devices have to be provided within a danger zone for setting or maintenance purposes, the requirement set out in the fourth indent can be fulfilled by providing a setting or maintenance mode, the selection of which triggers particular protective measures such as, for example, low speed and/or incremental movement - see §204: comments on section 1.2.5. The provision of emergency stop devices within danger zones is also an exception to the general rule – see §202: comments on section 1.2.4.3.

1.2.2 Control devices (continued)

. . .

– *designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate action,*

. . .

§190 Preventing inadvertent operation of control devices

The requirement set out in the sixth indent of section 1.2.2 aims to avoid inadvertent operation of control devices. Inadvertent operation can result from various causes, such as, for example, accidental contact between a part of the operator's body or of his or her clothing and a control device, unintentional operation of two adjacent control devices (for example, pushing two buttons or levers with one hand or two pedals with one foot), a control device being caught on an obstacle in the environment of the machinery or use of a control device as a hand hold for access to the operating position – see §317: comments on section 3.4.5.

Such risks must be assessed for the different phases of the foreseeable lifetime of the machinery, taking account of the operators' tasks and the corresponding operation modes, and must be prevented by appropriate design measures. Such measures include, for example:

- designing the control devices with sufficient resistance to avoid inadvertent operation by slight pressure;
- positioning the control devices in a recess or surrounding them with a collar;

- positioning and/or guarding control devices, to prevent contact with parts of the operator's body or clothing and to prevent them from being caught on obstacles in the environment of the machinery;
- fitting control devices, the operation of which requires two independent actions;
- fitting control devices with a lock.

Where there is a risk arising from an operator falling onto or being pressed against the controls, then means to prevent dangerous movement of the machine should be taken. A number of fatal accidents have occurred with a variety of machinery such as MEWPs; loader cranes; and interchangeable digging equipment. If such a risk cannot be eliminated by the controls' location and mode of operation, then other means must be taken such as designing the controls with a trip feature when excessive pressure is used or fitting other trip devices.

1.2.2 Control devices (continued)

. . .

– *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.*

. . .

§191 Strength of control devices

The requirement set out in the seventh indent of section 1.2.2 concerns the mechanical strength of control devices. Breakage of control devices can result in a hazardous situation due to the inability to control the function concerned. Such a breakage can also itself result in injury.

In applying this requirement, the foreseeable conditions of use during the different phases of the foreseeable lifetime of the machinery and the different tasks and operating modes involved must be taken into account – see §207: comments on section 1.3.2. This is particularly important for emergency stop devices which have to be operated rapidly and are often designed to be hit – see §202: comments on section 1.2.4.3.

1.2.2 Control devices (continued)

. . .

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.

. . .

§192 Control devices to perform different actions

The requirement set out in the second paragraph of section 1.2.2 applies where a single control device is able to control several different functions.

For example, certain control devices may perform different actions depending on the operating or control mode selected. Control devices may perform different actions depending on the interchangeable equipment fitted to the machinery. Certain joy-stick type control devices can control different actions by means of fore and aft movements, side to side movements and twisting movements, and the effects of the different movements of the joy-stick can be varied using top buttons or trigger switches incorporated in the device.

Use of such control devices can facilitate the control of certain categories of machinery by reducing the number and amplitude of the necessary hand and arm movements. However, it is particularly important when designing such devices to ensure that the effects of the various movements of the device are clearly identified and that the devices are designed to avoid confusion between the different actions that can be performed. Where necessary to avoid confusion, two separate actions must be necessary to control a given function.

The requirement set out in the second paragraph of section 1.2.2 also applies to so-called numerically controlled machinery or machinery with a programmable electronic control system, where the input signals are given by means of a keyboard or tactile screen. One way to avoid errors is for the software to indicate the action to be performed and require confirmation by the operator before the output signal is sent to the machinery actuators.

1.2.2 Control devices (continued)

. . .

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.

. . .

§193 Control devices and ergonomic principles

The requirement set out in the third paragraph of section 1.2.2 implies that the characteristics of control devices must take account of the various parameters of the operators' tasks, including, for example:

- the accuracy required in positioning the control device;
- the speed of setting required;
- the force required to operate the device.

Attention must be paid to the visibility of the control devices and to the ability of operators to reach and use them efficiently and safely in all task situations and operating modes, without having to adopt awkward postures. The layout of control devices, the travel distance of the moving parts of the devices and the force required to operate the devices must take account of the nature of the action to be performed, of the functional anatomy of the human hand or foot and the body dimensions of the operator population. In the case of control devices used frequently or continuously, the design of the devices

must avoid repetitive movements involving awkward postures or excessive hand span that may contribute to musculoskeletal disorders.

Where hold-to-run control devices are required, they must be designed to reduce the constraints for operators as far as possible – see §301: comments on section 3.3.1, §353: comments on section 4.2.1, and §371: comments on section 6.2.

The space between control devices must be sufficient to reduce the risk of unintentional operation, without thereby demanding unnecessary movements. Particular attention should be given to whether operators are likely to use PPE such as protective gloves or protective footwear – see §176: comments on section 1.1.2 (d).

The arrangement and layout of control devices must also take account of human capacities for information processing, with respect to attention, perception and cognition.

1.2.2 Control devices (continued)

. . .

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

. . .

§194 Indicators and displays

The requirement set out in the fourth paragraph of section 1.2.2 requires machinery to be fitted with the necessary indicators to enable operators to carry out their various tasks. These include, for example, indicators to inform operators on the value of the relevant parameters of the machinery (such as, for example, the speed, load, temperature or pressure of parts of the machinery) and on the effects of their action on the control devices, when this is not obvious.

Indicators may also provide warnings to operators when the relevant parameters exceed the safe range of values. Such indicators may be associated with limiting devices that trigger certain actions when safe parameters are exceeded. The indicators may also be used in combination with a specific mode of operation such as low speed or incremental operation.

Commonly used indicators include digital displays and screens, analogical displays such as dials and gauges, as well as tactile and auditory indicators. Indicators can be an integral part of the control devices themselves or independent. If they are independent, they must be designed and positioned so that they can be easily read and understood by the operators from the control position when using the related control devices. In particular, indicators must be designed to facilitate the rapid detection of abnormal behaviour of the machinery.

Indicators and displays are subject to the requirements set out in sections 1.7.1, 1.7.1.1, and 1.7.1.2 relating to information and warnings on the machinery, information devices and warning devices. In particular, any written or verbal information provided by indicators or displays is subject to the language requirements set out in section 1.7.1 – see §245 to §248: comments on sections 1.7.1, 1.7.1.1 and 1.7.1.2.

1.2.2 Control devices (continued)

. . .

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.

. . .

§195 Visibility of danger zones during starting

In accordance with section 1.1.2 (b), the first measure should be the elimination or reduction of the risk, for example, by designing the machinery so that persons do not need to enter the danger zones of the machinery – see §239: comments on section 1.6.1 – or by fitting guards and/or protective devices to detect the presence of persons in the danger zone and prevent starting as long as persons are present. But such measures are not always possible.

If there is a risk that persons may enter the danger zones, the requirement set out in the fifth and sixth paragraphs of section 1.2.2 aim to enable the operator to ensure that no-one is in the danger zones of the machinery before starting the machinery. The persons concerned may be other production operators or other exposed persons such as maintenance operators. In the case of danger zones in the environment of the machinery, the possible exposed persons may include bystanders – see §165: comments on section 1.1.1 (b).

If it is not possible to design the machinery so that the operator controlling the start of the machinery has adequate direct vision of the danger zones from the control position, indirect vision aids can be provided, such as, for example, mirrors or closed circuit television (CCTV).

In this respect, it should be noted that supplementary requirements relating to visibility from the driving position of mobile machinery are set out in section 3.2.1.

Where it is not possible to ensure effective direct or indirect visibility of the danger zones from the control positions, for example due to the extent of the danger zone on a long field conveyor, the starting of the machinery must be preceded by an acoustic or visual warning signal (or both) with sufficient time between the warning signal and the start or movement of the machinery to allow any exposed persons to leave the danger zones or, if that is not possible, exposed persons must have means to prevent the machinery from starting, such as, for example, an emergency stop control in the danger zone – see §202: comments on section 1.2.4.3.

Specifications for acoustic and visual warning signals are given in standard EN 981[154].

[154] EN 981:1996+A1:2008 *Safety of machinery - System of auditory and visual danger and information signals*.

When maintenance operations may be carried out in danger zones of machinery, specific means must be provided for preventing the unexpected start of the machinery or parts of the machinery – see §241: comments on section 1.6.3.

1.2.2 Control devices (continued)

. . .

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.

. . .

§196 Location of control positions

The requirement set out in the seventh paragraph of section 1.2.2 aims to ensure that the position from which the operator controls the operation of the machinery is outside the danger zones of the machinery and located, as far as possible, so that the operator can ensure that other persons are not exposed to risks.

Particular attention should be given to this requirement when considering the use of moveable control devices such as pendant controls or remote controls. The risk assessment must take account of the risk that the operator may control the machinery from a hazardous position, such as, for example, a zone where there is a risk of being crushed or hit by falling or ejected objects.

1.2.2 Control devices (continued)

. . .

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.

. . .

§197 Multiple control positions

The requirements set out in the eighth paragraph of section 1.2.2 concerns machinery provided with two or more control positions intended to be used in turn, either by a single operator or by two or more operators, to carry out different tasks or control the machinery during different phases of its operation. In order to avoid confusion or contradictory commands, the control devices at each control position must be linked to the control system in such a way that the use of one control position precludes the use of the others, except for stop controls and emergency stops.

1.2.2 Control devices (continued)

. . .

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.

§198 Multiple operating positions

The last paragraph of section 1.2.2 applies to machinery provided with two or more operating positions that can be used simultaneously. This is typically the case for assemblies of machinery where different constituent units of the assembly have their own operating position – see §38: comments on the fourth indent of Article 2 (a). The overall control system of such an assembly and the attribution of control functions to the different operating positions must be designed so that commands given at one operating position do not hinder or create a hazardous situation for operators at other operating positions. Particular precautions must be taken if the operation of one element of the assembly automatically starts the operation of another element – see §199: comments on section 1.2.3.

1.2.3 Starting

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

The same requirement applies:

- *when restarting the machinery after a stoppage, whatever the cause,*
- *when effecting a significant change in the operating conditions.*

However, the restarting of the machinery or a change in operating conditions may be effected by voluntary actuation of a device other than the control device provided for the purpose, on condition that this does not lead to a hazardous situation.

For machinery functioning in automatic mode, the starting of the machinery, restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation.

Where machinery has several starting control devices and the operators can therefore put each other in danger, additional devices must be fitted to rule out such risks. If safety requires that starting and/or stopping must be performed in a specific sequence, there must be devices which ensure that these operations are performed in the correct order.

§199 Control of starting

The requirements set out in section 1.2.3 aim to prevent unintended or unexpected starting, which are common causes of serious accidents involving machinery.

The basic requirement set out in the first paragraph of section 1.2.3 is that machinery shall only start when the operator gives a start command by using a specific start control device. This requirement applies to the initial start of machinery at the beginning of a period of operation.

According to the second paragraph of section 1.2.3, this basic requirement also applies when restarting the machinery after a stoppage or when effecting a significant change in the operating conditions such as, for example, the adjustment of the speed of the machinery.

Thus, for example, as a general rule, starting must not be initiated by the closing of an interlocking moveable guard, by the release of a stop control or by the release of an emergency stop control – see §200 to §202: comments on section 1.2.4.

However, according to the third paragraph of section 1.2.3, the requirement for a specific start or restart control device does not apply to restarting or changing the operating conditions if the use of another device than the specific start control device does not lead to a hazardous situation.

Thus, for example, it is exceptionally possible to control the initiation of certain functions of machinery by the closure of an interlocked guard (control guard) or by the withdrawal of a person or the detected part of a person from the sensing field of a protective device. This feature can be useful for ergonomic reasons, in order to avoid the need for repeated action on the start control device on machinery with a short work cycle. However, these exceptional solutions can only be applied if the machinery is designed and constructed with adequate compensatory protective measures to prevent the risk of unintended or unexpected starting.

Specifications for the exceptional recourse to control guards or of protective devices used for cycle initiation are given in standard EN ISO 12100[155].

The fourth paragraph of section 1.2.3 permits a second exception to the general rule set out in the first paragraph, in cases where the starting of the machinery, the restarting after a stoppage or after a change in operating conditions is triggered automatically, provided that this does not lead to a hazardous situation. This requirement implies that automatic starting and restarting must be possible only when the necessary means to protect persons against the risks associated with the automatically controlled functions are in place and operating correctly.

The requirements set out in the fifth paragraph of section 1.2.3 are supplementary to the requirements set out in the eighth and ninth paragraphs of section 1.2.2.

Machinery may be fitted with several start control devices because it is provided with several control positions intended to be used at different times or for different tasks. In such cases, the control system must be designed to ensure that only one start control can be used at a time, in accordance with the eighth paragraph of section 1.2.2.

Several start control devices may also be provided on machinery, especially assemblies of machinery, having several operating positions for different constituent units. In that case the overall control system of the assembly must be designed to ensure that use of one of the start control devices does not give rise to a hazardous situation for the other operators. Similarly, the overall control system must be designed to ensure that elements of the machinery that must be started or stopped in a given order can only be started or stopped in that order and that incorrect start or stop control signals are ineffective.

Specifications for preventing unexpected start-up of machinery are given in standard EN 1037[156].

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[155] EN ISO 12100:2010 *Safety of machinery - General principles for design. Risk assessment and risk reduction* (ISO 12100:2010) – see clauses 5.2.5.3 and 5.3.2.5.

It should be noted that, in addition to the general requirements relating to starting set out in section 1.2.3, supplementary requirements for starting relating to the mobility of machinery are set out in section 3.3.2.

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.

§200 Normal stop control devices

The requirement set out in section 1.2.4.1 aims to ensure that operators can stop machinery safely at all times. Apart from the need to stop the machinery safely for operational reasons, it is also essential for operators to be able to stop machinery in case of malfunctioning that might lead to a hazardous situation.

The second paragraph applies to machinery with two or more workstations. In some cases, a single operator may control the whole of the machinery from different control positions, depending on his tasks and on the phase of operation. In other cases, different parts of the machinery may be controlled by different operators. The stop control device provided at each workstation may stop all of the machinery or only a part of the machinery where this can be done without risk – see §203: comments on section 1.2.4.4. If necessary, the stop control device shall stop the relevant parts of the complex machinery in a sequential procedure – see §199: comments on section 1.2.3.

The requirement set out in the third paragraph of section 1.2.4.1 is a requirement for the design of the control system that is particularly important in the case of machinery with several workstations, since it prevents a start command given by one operator from overriding a stop command given by another operator. It also aims to ensure that a stop command can be given, even in case of a failure of the start control in the sense of a maintained start command.

The requirement, set out in the last paragraph of section 1.2.4.1, that, once the machinery or its hazardous functions have stopped, the energy supply to the actuators concerned must be cut off, aims to prevent the risk of unintended starting following a stop command that might be caused by a fault or failure in the control system. This means that stopping can either be achieved by immediate removal of power to the machine actuators, or with power available to the machine actuators to achieve the stop and then removal of power once the stop has been achieved.

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[156] EN 1037:1995+A1:2008 *Safety of machinery - Prevention of unexpected start-up*.

It should be noted that, in addition to the general requirements for stopping set out in section 1.2.4.1, supplementary requirements for stopping for the travelling function of mobile machinery are set out in section 3.3.3.

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.

§201 Operational stop

Section 1.2.4.2 recognises that, for operational reasons, for example, in order to permit an easier or more rapid restart of the machinery, it may be necessary to provide, in addition to the normal stop control required by section 1.2.4.1, a stop control that does not cut off the energy supply to the actuators. Since, in that case, a failure in the control system could lead to an unintended start, the control system must include the means of monitoring the stop condition in order to ensure that the machinery remains at a stop until it is intentionally restarted using the start control device. The part of the control system relative to the monitoring is to be considered as a safety related part of the control system that must have an adequate level of performance – see §184: comments on section 1.2.1.

1.2.4.3 Emergency stop

Machinery must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted.

The following exceptions apply:

- *machinery in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken,*
- *portable hand-held and/or hand-guided machinery.*

The device must:

- *have clearly identifiable, clearly visible and quickly accessible control devices,*
- *stop the hazardous process as quickly as possible, without creating additional risks,*
- *where necessary, trigger or permit the triggering of certain safeguard movements.*

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

The emergency stop function must be available and operational at all times, regardless of the operating mode.

Emergency stop devices must be a back-up to other safeguarding measures and not a substitute for them.

§202 Emergency stop devices

An emergency stop device comprises a specific control device linked to the control system that gives a stop command and the components or systems necessary to stop the hazardous functions of machinery as quickly as possible, without creating any further risks.

Emergency stop devices are intended to enable operators to stop the hazardous functions of machinery as quickly as possible if, despite the other protective measures taken, a hazardous situation or event arises. The emergency stop does not itself provide protection, which is why the last sentence of section 1.2.4.3 stresses that fitting an emergency stop device is a back-up to other safeguarding measures such as guards and protective devices, not a substitute for them. However, an emergency stop can enable operators to prevent a dangerous situation from resulting in an accident or at least reduce the severity of the consequences of an accident. An emergency stop may also enable operators to prevent malfunctioning of the machinery from damaging the machinery.

The first paragraph of section 1.2.4.3 requires machinery to be fitted, as a general rule, with one or more emergency stop devices. The second paragraph of section 1.2.4.3 sets out two exceptions where emergency stop devices are not required. The first exception is where an emergency stop device would not reduce the risk compared with the normal stop control or would create new risks. This may be the case, for example, if it is not possible to obtain a significantly quicker stop than is obtained by the normal stop control without creating further risks, such as, for example, the loss of stability or the risk of break-up of parts of the machinery. In cases where an emergency stop control is not provided, the normal stop control device must be clearly identifiable, clearly visible and quickly accessible, also for people not familiar with the machine, so that it can be used to stop the machinery in an emergency. The second exception concerns portable hand-held and/or hand-guided machinery – see §278: comments on section 2.2.1.

The third and fourth paragraphs of section 1.2.4.3 set out requirements for the design of emergency stop devices:

- Firstly, the emergency stop control devices must be clearly identifiable and clearly visible. This is important because, in an emergency situation, a split-second reaction may be crucial. Usually, emergency stop control devices are red against a yellow background.
- Secondly, emergency stop control devices must be quickly accessible. This requirement has consequences for both the choice of the type of control device and the number and location of control devices to be fitted.

  Frequently, emergency stop control devices are hand-operated mushroom-type buttons. However, where there is a risk that the operator may have difficulty to reach the emergency stop, for example, if both of the operator's hands may be caught up, foot-operated emergency stop control devices, or bars that can be operated by other parts of the body may be preferable.

  On machinery where the danger zones extend over a long distance, for example, on continuous handling machinery such as conveyors, emergency stop controls can be activated by wires or ropes.

  Since emergency stop control devices must be quickly accessible, the number and the location of the devices to be fitted must be decided taking account of the size and configuration of the machinery, the number of operators, the location of the danger zones and the location of the workstations and maintenance points. In particular, it may be necessary to additionally fit emergency stop control devices within danger zones that are not visible to the operator starting the machinery or in areas of machinery where persons might be trapped, in order to enable any exposed persons to prevent starting if they cannot leave the danger zone in time – see §195: comments on the sixth paragraph of section 1.2.2.
- The second indent of the third paragraph specifies that the emergency stop device must stop the hazardous process as quickly as possible, without creating additional risks. The means to fulfil this requirement depend on the characteristics of the machinery. In some cases, an immediate cut-off of the energy supply to the actuators is sufficient. Where a controlled stop is necessary, the actuators may

remain under power during the stopping process and the energy supply may be cut off once stopping is achieved. In some cases, to avoid creating additional risks, it may be necessary to maintain the power supply to certain components even after stopping is achieved, for example, to prevent parts of the machinery from falling.

– The third indent of the third paragraph refers to cases where actions other than the stopping of the machinery may also be needed to avoid or remove the hazardous situation. For example, once the machinery has stopped, it may be necessary to open or to permit the opening of points where parts of the operator's body may be caught or trapped. In such cases, the emergency stop device must be designed to trigger such actions automatically or, at least, to permit such actions to be controlled. Where necessary for safety, certain functions of the machinery shall not be stopped (such as, for example cooling systems, or dust extractors).

The requirement set out in the fourth paragraph of section 1.2.4.3 aims to prevent the risk of inadvertent restarting of the machinery after the emergency stop device has been activated. This requirement can be met by fitting emergency stop devices of the 'lock-in' type needing a specific deliberate action to disengage them. The disengagement of the emergency control device must not restart the machinery but only permit the restarting of the machinery using the normal start control device – see §199: comments on section 1.2.3.

The fifth paragraph of section 1.2.4.3 requires the emergency stop function to be available and operational at all times, regardless of the operating mode – see §204: comments on section 1.2.5.

Specifications for emergency stops are given in standard EN ISO 13850[157].

Specific guidance on emergency stop devices are given in section §413.

1.2.4.4 Assembly of machinery

In the case of machinery or parts of machinery designed to work together, the machinery must be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery itself but also all related equipment, if its continued operation may be dangerous.

§203 Stop controls for assemblies of machinery

The requirement set out in section 1.2.4.4 must be applied according to the risk assessment carried out by the manufacturer of an assembly of machinery – see §38: comments on the fourth indent of Article 2 (a). The possibility of a normal stop control stopping only certain of the constituent units of an assembly of machinery permitted by section 1.2.4.2 does not apply if continued operation of other elements of the machinery may give rise to a hazardous situation. Similarly, where it is important for operators of one unit of an assembly of machinery to be able to stop related units of the assembly in

[157] EN ISO 13850:2015 *Safety of machinery - Emergency stop - Principles for design* (ISO 13850:2015).

an emergency, the emergency stop devices must act on all the related parts of the assembly.

If an assembly of machinery is divided into different zones controlled by different normal stop controls and emergency stop devices, these zones must be clearly defined and it must be clearly indicated which elements of the assembly of machinery belong to which zone. The interfaces between zones shall be designed in such a way that continued operation in one zone cannot give rise to hazardous situations in other zones which have been stopped.

1.2.5 Selection of control or operating modes

The control or operating mode selected must override all other control or operating modes, with the exception of the emergency stop.

If machinery has been designed and constructed to allow its use in several control or operating modes requiring different protective measures and/or work procedures, it must be fitted with a mode selector which can be locked in each position. Each position of the selector must be clearly identifiable and must correspond to a single operating or control mode.

The selector may be replaced by another selection method which restricts the use of certain functions of the machinery to certain categories of operator.

If, for certain operations, the machinery must be able to operate with a guard displaced or removed and/or a protective device disabled, the control or operating mode selector must simultaneously:

- *disable all other control or operating modes,*
- *permit operation of hazardous functions only by control devices requiring sustained action,*
- *permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked sequences,*
- *prevent any operation of hazardous functions by voluntary or involuntary action on the machine's sensors.*

If these four conditions cannot be fulfilled simultaneously, the control or operating mode selector must activate other protective measures designed and constructed to ensure a safe intervention zone.

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

§204 Mode selection

Section 1.2.5 deals with risks that may arise when machinery is designed with several control or operating modes. In some cases, machinery may be designed with specific control modes, for example, for setting or maintenance operations. In other cases, different operating modes are foreseen, for example, for operation with manual or

automatic feeding of workpieces. Mobile machinery may be designed to be controlled by a ride-on driver or by remote control.

The first paragraph of section 1.2.5 applies in all such cases and requires the different control or operating modes to be exclusive of each other, except for the emergency stop function, which must be available whichever control or operating mode is selected.

The second paragraph of section 1.2.5 applies to operating modes requiring different protective measures and work procedures having a different impact on safety. For example, for an operating mode with manual feeding of workpieces, safeguarding with interlocking moveable guards or with protective devices, such as optoelectronic protective devices or two-hand control devices, may be appropriate. For an operating mode with automatic feeding, the use of a two-hand control device as the main means of safeguarding will probably not be acceptable.

Setting or maintenance modes may enable certain functions of the machinery to be controlled with guards open or with protective devices muted or by means of a special control device such as a pendant control or a remote control device, instead of the control devices used for normal operation.

In these cases, each position of the mode selector must correspond to a single control or operating mode and it must be possible to lock the mode selector device in each position, while the device must be provided with the necessary indicators to make it clear to operators which control or operating mode has been selected – see §194: comments on the fourth paragraph of section 1.2.2.

The third paragraph of section 1.2.5 permits, as an alternative to a physically lockable selector, that selection of a control or operating mode such as, for example, a setting or maintenance mode, may be restricted to specially trained and authorised operators by other means, such as, for example, an access code.

The means used for restriction of access to the operating modes should achieve the necessary level of safety taking into account the reasonably foreseeable misuse. Where any failure in the means used for mode selection can result in danger, it must be considered an integral part of the safety-related control system.

The fourth paragraph of section 1.2.5 sets out four conditions that must be simultaneously fulfilled for machinery to be provided with a control or operating mode where the guards are open or protective devices are muted:

- The first condition aims to rule out any use of the other control or operating modes during use of this mode;
- The second condition aims to ensure that the operator retains full control of hazardous functions at all times;
- The third condition requires the disabling of the normal protective means to be compensated by other protective measures such as, for example, reduced speed and/or incremental operation of the moving parts. Safeguarding shall be maintained for hazardous parts to which access is not required;
- The fourth condition requires the mode selector not only to disable all other control modes but also to disable any sensors on the machinery that might otherwise trigger

movements or other hazardous functions of the machinery or parts of the machinery during the operation concerned.

The fifth paragraph of section 1.2.5 applies if it is necessary to provide an operational mode with certain of the normal protective means disabled and where one or more of the four conditions set out in the fourth paragraph cannot be fulfilled. In that case, the machinery must be provided with other protective means to ensure that the zone in which the operator is intended to intervene is safe. Such a safe zone may be limited by active optoelectronic protective devices. However, the use of easily defeateable devices, such as a pressure sensitive operator mat are not suitable. It should be underlined that these means must be integrated in the design and construction of the machinery and that it is not sufficient, in such a case, to rely solely on the manufacturer's instructions, on warnings on the machinery or on the training of the operators.

1.2.6 Failure of the power supply

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

Particular attention must be given to the following points:

- *the machinery must not start unexpectedly,*
- *the parameters of the machinery must not change in an uncontrolled way when such change can lead to hazardous situations,*
- *the machinery must not be prevented from stopping if the command has already been given,*
- *no moving part of the machinery or piece held by the machinery must fall or be ejected,*
- *automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded,*
- *the protective devices must remain fully effective or give a stop command.*

§205 Failure of the power supply

Section 1.2.6 deals with hazardous situations that may arise in case of the failure of the power supply or following such a failure. The first paragraph sets out the basic requirement that the interruption of the power supply, the re-establishment of the power supply after an interruption or any fluctuation of the power supply must not lead to a dangerous situation. The power supply may be interrupted as a result of a local or general electricity power cut or as a result the failure of other power sources such as steam, compressed air, hydraulic fluid and so on. Fluctuations in the power supply may include variations in the voltage or frequency of the electricity supply, variations in the pressure of steam, compressed air and hydraulic fluid, and so on.

In order to fulfil this requirement, the manufacturer's risk assessment must include an analysis of the possible behaviour of the machinery in such cases and the machinery must be designed and constructed to prevent hazardous situations from resulting. The

six indents of the second paragraph of section 1.2.6 draw attention to certain common hazardous situations which may occur in the event of the failure of the power supply. It must be underlined that this list is only indicative. It can also be noted that these hazardous situations are the same as those mentioned in the second paragraph of section 1.2.1 with respect to the safety and reliability of control systems, thus certain of the necessary design measures may be common to both requirements.

- The first indent refers to the risk of unexpected start of the machinery. This situation is most likely to occur when the power supply is re-established after an interruption. The control system must therefore be designed to ensure that the interruption of the power supply automatically prevents any start until the machinery is restarted using the start control device.
- The second indent refers to cases where a power supply is necessary to maintain certain parameters of the machinery such as, for example, pressure or temperature, within safe limits. In certain cases, it may be necessary to provide a reserve power supply for that purpose. In addition, related data may be saved for use when re-establishing the power supply.
- The third indent applies to the parts of the control system controlling stop and emergency stop functions. The control system must be designed so that, once a stop command has been given, it remains effective even if the power supply is interrupted.
- The fourth indent requires machinery to be designed so that moving parts or pieces held by the machinery do not fall or are not ejected in case of failure of the power supply. This may be achieved by clamps, brakes, locking devices, check valves and so on that operate by removal of power or, if that is not possible, by a source of stored energy such as, for example, a spring or a reservoir of compressed air.

  In this respect, it should be noted that a specific requirement applies to lifting operations – see §342: comments on section 4.1.2.6 (c).
- The fifth indent requires the machinery to be designed so that the moving parts can be stopped safely in case of failure of the power supply. Where energy is required to stop the moving parts safely, it may be supplied from a source of stored energy. In certain cases, it may be necessary to provide a reserve power supply to enable the moving parts of the machinery to be stopped safely.
- The last indent requires protective devices to be designed so that they remain effective in the absence of the power supply or so that a stop command is automatically triggered if the power supply is interrupted.

1.3 PROTECTION AGAINST MECHANICAL HAZARDS

1.3.1 Risk of loss of stability

Machinery and its components and fittings must be stable enough to avoid overturning, falling or uncontrolled movements during transportation, assembly, dismantling and any other action involving the machinery.

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

§206 Stability

The first paragraph of section 1.3.1 requires the manufacturer to ensure the stability of the machinery and its components and fittings during the different phases of the foreseeable lifetime of the machinery – see §173: comments on section 1.1.2 (a).

Factors to be taken into account include, for example, the shape of the machinery and its base, the characteristics of the surface or structure on which the machinery is intended to be used, mounted or installed, the weight distribution, dynamic effects due to movements of the machinery itself, of its parts or of elements processed or held by the machinery, the effects of vibrations, of external forces such as wind pressure and of weather conditions such as snow and ice.

Where the stability of the machinery depends on conditions of use such as, for example, the slope, terrain or loading, the conditions in which the machinery meets the requirement of stability must be specified in the manufacturer's instructions – see §264 and §269: comments on sections 1.7.4.2 (i) and (o).

The second paragraph of section 1.3.1 refers to cases where the stability of the machinery requires particular measures to be taken when it is used or installed. In such cases, the necessary provisions for anchorage must be incorporated in the design and construction of the machinery and the measures to be taken by the user or installer must be specified in the manufacturer's instructions – see §264: comments on section 1.7.4.2 (i), and §269: comments on section 1.7.4.2 (o). This section applies, in particular, to all machines which are intended to be regularly moved from a jobsite to another (e.g. earth moving machinery or tower crane).

It should be noted that, in addition to the general requirements relating to stability set out in section 1.3.1,

- supplementary requirements relating to the stability of portable machinery are set out in section 2.2.1;
- supplementary requirements relating to the stability of mobile machinery are set out in sections 3.4.1 and 3.4.3;
- supplementary requirements relating to the stability of machinery for lifting are set out in sections 4.1.2.1 and 4.2.2;

– supplementary requirements relating to the stability of powered roof supports for underground work are set out in section 5.1;

– supplementary requirements relating to the stability of machinery for lifting persons are set out in section 6.1.2.

1.3.2 Risk of break-up during operation

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

The durability of the materials used must be adequate for the nature of the working environment foreseen by the manufacturer or his authorised representative, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion.

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

Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned must be mounted, positioned and/or guarded in such a way that any fragments will be contained, preventing hazardous situations.

Both rigid and flexible pipes carrying fluids, particularly those under high pressure, must be able to withstand the foreseen internal and external stresses and must be firmly attached and/or protected to ensure that no risk is posed by a rupture.

Where the material to be processed is fed to the tool automatically, the following conditions must be fulfilled to avoid risks to persons:

– *when the workpiece comes into contact with the tool, the latter must have attained its normal working condition,*

– *when the tool starts and/or stops (intentionally or accidentally), the feed movement and the tool movement must be coordinated.*

§207 Break-up during operation

Hazards associated with break-up during operation may be due, for example, to the collapse of the machinery itself or of its parts, or to the uncontrolled movement or ejection of parts of the machinery due to the failure of components or sub-assemblies. The first two paragraphs of section 1.3.2 aim to prevent the break-up of parts of the machinery during operation by means of the use of appropriate constituent materials, and by means of the appropriate design and construction of components and assemblies in order to resist the stresses to which they will be subjected during operation. In some cases, harmonised standards provide specifications for the materials, design, construction and testing of certain critical parts. In other cases, fulfilling these requirements must be achieved by respecting sound engineering principles and practices.

The second paragraph of section 1.3.2 draws attention to the importance of taking account of the conditions under which the machinery is intended to be used during the

different phases of its lifetime – see §173: comments on section 1.1.2 (a). Certain conditions of use may affect the resistance of certain materials and assemblies such as, for example, extreme heat or cold, corrosive atmospheres, humidity or radiation. Overspeed, for example, of rotating tools, can give rise to a risk of break-up and must therefore be prevented in such cases. The conditions of use for which the machinery has been designed and their limits must be indicated in the manufacturer's instructions – see §263: comments on section 1.7.4.2 (g).

Where fatigue is a significant factor, the manufacturer must take account of the expected lifetime of the machine and the nature of the functions that it is expected to perform, taking into account the number of operational cycles to which the component or assembly concerned will be subject during its lifetime.

The third paragraph of section 1.3.2 takes account of the fact that certain machinery parts subject to wear that can lead to break-up may have to be periodically inspected by the user and repaired or replaced as necessary. The manufacturer's instructions must indicate the type of checks to be carried out on such parts (for example, visual checks, functional checks or tests), the frequency of such checks (for example, in terms of number of operational cycles or duration of use) and the criteria for the repair or replacement of the parts concerned – see §272: comments on section 1.7.4.2 (r).

The fourth paragraph of section 1.3.2 deals with cases where, despite the use of appropriate materials and assemblies, there is a residual risk of rupture or disintegration during operation. In such cases, the necessary measures must be taken to prevent fragments from reaching persons. This can be achieved by mounting and positioning the parts liable to break up so that fragments are contained by other parts of the machinery such as, for example, the frame, or by fitting appropriate guards. Whether the containment of the fragments is achieved by functional parts of the machinery or by guards, parts concerned must be strong enough to resist the energy of the ejected fragments – see §169: comments on section 1.1.1 (f), and §216: comments on section 1.4.1.

The fifth paragraph of section 1.3.2 deals with the specific risks associated with pipes and hoses containing fluids, particularly those under high pressure such as, for example, those used in fluid power systems. On the one hand, such pipes and hoses must be designed and mounted so that they can withstand the internal pressures and other stresses to which they may be subject. On the other hand, where there is a residual risk of rupture, they must be located or shielded to prevent ejected fluids from creating a risk for persons and adequately attached to prevent the whiplash effect.

It should be noted that some of this equipment may be subject, for the pressure risk, to the Pressure Equipment Directive 97/23/EC – see §91: comments on Article 3.

General specifications for hydraulic and pneumatic pipes and hoses are given in standards EN ISO 4413 and EN ISO 4414[158].

[158] EN ISO 4413:2010 *Hydraulic fluid power. General rules and safety requirements for systems and their components*; EN ISO 4414:2010 *Pneumatic fluid power. General rules and safety requirements systems and their components.*

The last paragraph of section 1.3.2 deals with the specific risks associated with machinery using tools designed to operate safely at a particular range of speeds, where contact between the processed material and the tool at lower or higher speeds can give rise to a risk of break-up of the tool or of the material. There must be no contact between the workpiece and the tool until normal working conditions are achieved. For the same reason, the speed of the tool must be automatically coordinated with the feed movement during each starting and stoppage of the tool.

It should be noted that, in addition to the general requirements relating to the risk of break-up during operation set out in section 1.3.2,

- supplementary requirements relating to the mechanical strength of machinery for lifting are set out in sections 4.1.2.3, 4.1.2.4 and 4.1.2.5;
- supplementary requirements relating the mechanical strength of machinery for lifting persons are set out in section 6.1.1.

1.3.3 Risks due to falling or ejected objects

Precautions must be taken to prevent risks from falling or ejected objects.

§208 Falling or ejected objects

The requirement set out in section 1.3.3 deals with risks of injury due to contact with falling or ejected objects such as workpieces or fragments of workpieces, tools or fragments of tools, waste, chips, splinters, swarf, stones and so on. Wherever possible, the design and construction of the machinery must prevent objects falling or being ejected towards persons. However, where this cannot be entirely achieved, the necessary protective measures must be taken. Protective measures include the fitting of guards to prevent ejected objects from reaching persons or the enclosure of the operating positions – see §182: comments on section 1.1.7. Where such protective measures may not be fully effective, the machinery manufacturer must specify, in the instructions, the need to provide and use appropriate personal protective equipment, such as, for example eye protectors – see §267: comments on section 1.7.4.2 (m).

It should be noted that, in addition to the general requirement relating to risks due to falling or ejected objects set out in section 1.3.3,

- supplementary requirements relating to splinter guards for portable fixing and other impact machinery are set out in section 2.2.2.1;
- supplementary requirements relating to the risk of ejection of workpieces or parts of them for machinery for working wood and material with similar physical characteristics are set out in section 2.3 (b);
- supplementary requirements relating to protection against falling objects for mobile machinery are set out in section 3.4.4;
- supplementary requirements relating to the risk due to falling or dropping of the load for lifting machinery are set out in section 4.1.2.6;

- supplementary requirements relating to the risk due to the load falling off the carrier of lifting machinery serving fixed landings are set out in section 4.1.2.8.4;
- supplementary requirements relating to the risk due to objects falling on the carrier of machinery for lifting persons are set out in section 6.3.3.

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.

§209 Sharp edges and angles and rough surfaces

The requirement set out in section 1.3.4 concerns the risk of scrapes, cuts and bruises due to contact with sharp edges and angles, or contact with rough surfaces.

The factors to be taken into account when assessing this risk include:

- the accessibility of the parts concerned;
- their location with respect to operating positions, control devices and maintenance points;
- the parts of the body that are liable to come into contact;
- the type of action likely to cause contact such as, for example, access, keeping one's balance, observation, stepping back and so on.

Particular attention should be paid to the edges of movable guards.

General guidance on reducing risks due to sharp edges and angles and rough surfaces is given in standard EN ISO 12100-2[159], while some C-type standards define the minimum radius of accessible edges.

1.3.5 Risks related to combined machinery

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

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

§210 Combined machinery

The requirement set out in section 1.3.5 applies to combined machinery such as, for example, combined woodworking machinery. The first paragraph requires the manufacturer to ensure that the elements of the machinery designed to carry out each

[159] EN ISO 12100-2:2003+A1:2009 *Safety of machinery - Basic concepts, general principles for design* - Part 2: *Technical principles* (ISO 12100-2:2003) – clause 4.2.1.

different operation or function can be used separately without the other elements creating a risk.

For elements that are not, or not completely protected, the second paragraph of section 1.3.5 supplements the requirements set out in sections 1.2.3, 1.2.4.1 and 1.2.4.2.

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.

§211 Variations in operating conditions

The requirement set out in section 1.3.6 concerns machinery that can operate under different conditions of use such as, for example, with different kinds of tools, at different speeds or feeding rates, with different materials or under different environmental conditions. In such cases, the selection of the desired condition of use must be clear to the operators and, where necessary, must also trigger the corresponding protective measures. Involuntary or unintended selection must be prevented by the design of the control devices if this can lead to hazardous situations - see §124: comments on section 1.2.5.

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.

§212 Moving parts

The first paragraph of section 1.3.7 deals with one of the primary causes of accidents involving machinery. Contact with moving parts of machinery can cause injury due to impact, abrasion, cutting or severing, shearing, stabbing or puncture, crushing, entanglement and drawing-in or trapping.

Several measures can be taken to eliminate hazards or reduce risks due to contact with moving parts without recourse to guards or protective devices.

In some cases, risks can be avoided or reduced by the design of the moving parts themselves, for example, by limiting the actuating force so that the actuated part does

not generate a mechanical hazard, or by limiting the mass and/or speed of the moving parts and hence their kinetic energy.

Moving parts can be located in places where they are normally inaccessible to persons, such as, for example, inside the frame of the machinery, at a sufficient height or at a sufficient distance from protective structures to ensure that they cannot be reached.

Dimensions for safety distances are given in standard EN ISO 13857[160].

Sufficient gaps can be provided between moving parts and fixed parts or other moving parts to prevent the risks of crushing, shearing or drawing in.

Dimensions for the necessary gaps to prevent risks of crushing are given in standard EN 349[161].

Where it is not possible to prevent risks due to moving parts by the design of the parts themselves or by means of safety distances or gaps, access to such parts must be prevented by means of guards or protective devices.

The second and third paragraphs of section 1.3.7 deal with the problem of the blockage of moving parts involved in the work. Even if a blockage does not itself create a dangerous situation, the occurrence of blockages often requires operators to intervene quickly in order to avoid damage and loss of production, thereby increasing the likelihood of dangerous intervention. Manufacturers must therefore design machinery as far as possible to prevent blockages and, where they cannot be completely prevented, provide the means to enable moving parts to be safely unblocked, preferably without the need to remove guards. The means for unblocking must be identified by a sign on the relevant part of the machinery, whilst the operating method to be followed in such cases must be specified in the manufacturer's instructions – see §271: comments on section 1.7.4.2 (q). If special equipment is required for that purpose, it must be provided with the machinery – see §117: comments on section 1.1.2 (e).

[160] EN ISO 13857:2008 *Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs* (ISO 13857:2008).

[161] EN 349:1993+A1:2008 *Safety of machinery - Minimum gaps to avoid crushing of parts of the human body*.

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:

– *either fixed guards as referred to in section 1.4.2.1, or*

– *interlocking movable guards as referred to in section 1.4.2.2.*

Interlocking movable guards should be used where frequent access is envisaged.

§213 Moving transmission parts

Moving transmission parts include, for example, gears, belts, ropes and chains together with their associated pulleys and cogs and sprockets and transmission shafts and their couplings.

Since moving transmission parts are not directly involved in the process, it is generally possible to prevent access to them completely during normal operation. Where guards are necessary to achieve this, the choice of guards depends on whether access is required frequently for maintenance operations such as setting, adjustment and cleaning. If frequent access is required, interlocking movable guards should be fitted – see §217: comments on section 1.4.2.

In addition to the general requirement set out in section 1.3.8.1, supplementary requirements for removable mechanical transmission devices linking machinery or a tractor to recipient machinery are set out in section 3.4.7.

An exception to the general requirement set out in section 1.3.8.1, relating to moving parts in the engine compartment of mobile machinery, is set out in section 3.4.2.

1.3.8.2 Moving parts involved in the process

Guards or protective devices designed to protect persons against the hazards generated by moving parts involved in the process must be:

- *either fixed guards as referred to in section 1.4.2.1, or*
- *interlocking movable guards as referred to in section 1.4.2.2, or*
- *protective devices as referred to in section 1.4.3, or*
- *a combination of the above.*

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

- *fixed guards or interlocking movable guards preventing access to those sections of the parts that are not used in the work, and*
- *adjustable guards as referred to in section 1.4.2.3 restricting access to those sections of the moving parts where access is necessary.*

§214 Moving parts involved in the process

Section 1.3.8.2 describes the type of guards or protective devices to be used to prevent access to moving parts involved in the process. Where it is necessary to prevent access to moving parts involved in the process, wherever possible, guards or protective devices must be fitted to prevent access completely during the hazardous movements.

The choice between fixed guards, interlocking movable guards, protective devices or a combination of them must take account of the risk assessment, of the frequency with which access is required and of ergonomic aspects such as the effort required to repeatedly open and close a movable guard – see §217: comments on section 1.4.2.

Protective devices may not provide adequate protection where other risks such as, for example, risks due to ejected objects, extreme temperatures or radiation are present – see §221: comments on section 1.4.3.

The second paragraph of section 1.3.8.2 deals with cases where access to the danger zone cannot be completely prevented, for example, in the case of machinery where the material or workpiece to be processed is manually fed. In such cases, it is necessary to fit a combination of fixed or interlocking movable guards for the sections of the moving parts to which access is not required during normal operation and adjustable guards restricting access to the sections of the moving parts where access is necessary – see §220: comments on section 1.4.2.3.

It should be noted that several categories of machinery with manual feed or loading and unloading of material or workpieces are listed in Annex IV – see §129 and §130: comments on Article 12 (3) and (4), and §388: comments on Annex IV.

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.

§215 Uncontrolled movements

The requirement set out in section 1.3.9 is complementary to the requirement set out in section 1.2.4 relating to stopping. Where there is a risk due to uncontrolled movement of the moving parts of machinery after they have been stopped, the necessary braking systems, locking devices, or systems to monitor the stop condition must be fitted to prevent uncontrolled movements or limit them so that they do not create a risk – see §201: comments on section 1.2.4.2.

It should be noted that, in addition to the general requirement set out in section 1.3.9, supplementary requirements relating to uncontrolled movements of mobile machinery are set out in section 3.4.1; supplementary requirements relating to the risk of uncontrolled movements of lifting machinery are set out in section 4.1.2.6.

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.

§216 General requirements for guards and protective devices

Section 1.4.1 sets out general requirements for guards and protective devices. Specific requirements for the three main types of guards and for protective devices are set out in sections 1.4.2.1, 1.4.2.2, 1.4.2.3 and 1.4.3.

The first indent of section 1.4.1 requires guards and protective devices to have sufficient mechanical strength, taking account both of the hazards they protect against and of the intended conditions of use. For example, where it is foreseeable that an operator could fall or step on the guard. Where a particularly high degree of resistance is required, in particular for guards intended to protect against falling or ejected objects, the relevant harmonised standards specify the design criteria and, where necessary, the tests to be carried out.

The second indent of section 1.4.1 requires guards and protective devices to be securely held in place. This is particularly important when safety depends on the distance between the guard and the hazardous part of the machinery.

The third indent of section 1.4.1 states that guards or protective devices shall not give rise to any additional hazard. For example, the opening or closing of a movable guard must not create a crushing or shearing hazard. Where necessary in order to avoid excessive or repeated effort, the opening and closing of movable guards shall be powered or assisted, for example, by springs or hydraulic or pneumatic cylinders.

The fourth indent of section 1.4.1 requires that guards and protective devices shall not be easy to by-pass or render non-operational. This requirement is particularly relevant for the interlocking devices of movable guards and for protective devices.

The fifth indent of section 1.4.1 requires guards and protective devices to be situated at an adequate distance from the danger zone.

Adequate distances for protective devices are given in standard EN 999[162]. For guards with openings, safety distances with respect to the dimensions and shape of the openings are given in standard EN ISO 13857[163].

The location of setting, adjustment and other maintenance points outside the danger zones can avoid the need to remove guards for routine maintenance operations – see §239: comments on section 1.6.1.

The sixth indent of section 1.4.1 requires guards and protective devices to be designed and constructed, as far as possible, so that they do not constitute an obstacle for operators by obstructing the view of the production process. Failure to take this aspect into account increases the risk that guards and protective devices will be defeated or removed by the operators. The visibility of the work process can be improved, for example, by fitting transparent guards, CCTV or, where there are no risks due to ejected objects or emissions, by fitting guards with openings or protective devices – see §221: comments on section 1.4.3.

The seventh indent of section 1.4.1 states that the design and construction of guards and protective devices must take account of the need for access to the danger zones, whether during normal operation of the machinery or for maintenance purposes. The guards and protective devices must restrict access to the area where the work has to be

[162] EN 999:1998+A1:2008 *Safety of machinery - The positioning of protective equipment in respect of approach speeds of parts of the human body.*

[163] EN ISO 13857:2008 *Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs* (ISO 13857:2008).

carried out. The location of setting, adjustment and maintenance points outside the danger zones can avoid the need to remove guards for routine operations – see §239: comments on section 1.6.1.

The second paragraph of section 1.4.1 underlines that guards can often provide protection against several hazards simultaneously and must be designed and constructed accordingly – see §169: comments on section 1.1.1 (f).

Guards and protective devices designed to protect persons against moving parts involved in the process on the machinery, when independently placed on the market, are safety components – see §42: comments on Article 2 (c), §389: comments on Annex V and §411: comments on when safety fences are safety components.

1.4.2 Special requirements for guards

§217 Special requirements for guards

The requirements set out in section 1.4.2 apply to guards as defined in section 1.1.1, in other words, to the parts of the machinery specifically designed to provide protection by means of a physical barrier – see §169: comments on section 1.1.1 (f).

The Machinery Directive distinguishes three main kinds of guards: fixed guards, interlocking movable guards and adjustable guards restricting access. In general, fixed guards should be fitted when access to the zone protected by the guard is not required or is not frequently required. If access to the zone protected by the guard is required frequently, interlocking movable guards shall be fitted. Adjustable guards restricting access may be fitted to protect parts of the machinery involved in the process to which access cannot be completely prevented during use. For the choice of guards for protection against risks arising from moving parts – see §213 and §214: comments on sections 1.3.8.1 and 1.3.8.2.

Criteria for the choice of guards, taking account of the frequency of access required, and for the design of guards are given in standard EN 953[164].

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.

[164] EN 953:1997+A1:2009 *Safety of machinery - Guards - General requirements for the design and construction of fixed and movable guards*.

§218 Fixed guards

Section 1.4.2.1 sets out three requirements for the first type of guards: fixed guards. The requirements set out in section 1.4.2.1 are complementary to the general requirements for guards and protective devices set out in section 1.4.1.

If the zone protected by a fixed guard does not need to be accessed or if the necessary access can be obtained by another route, fixed guards can be permanently fixed, for example, by welding, riveting or gluing. On the other hand, if it is necessary to open or remove a fixed guard, the first paragraph of section 1.4.2.1 requires that it must only be possible to open or remove the fixing systems with tools. This requirement aims to restrict the removal of fixed guards to competent or authorised persons by an intended action needing some thought and time. Fixed guards may thus be fixed, for example, by means of bolts, screws or other fasteners that can only be removed by using tools such as keys or wrenches. The choice of fixing system and tools must be considered in light of the risk assessment. Fixings that can be quickly loosened or removed such as, for example, wing nuts, or quick-release fasteners, must not be used.

The second indent of section 1.4.2.1 requires the fixing systems for fixed guards to remain attached to the guards or to the machinery when the guards are removed. This requirement aims to reduce risks due to loss of one or more of the fixings when guards are removed, for example, for maintenance purposes. This can lead to the guards not being replaced, being only partially fixed in place or fixed with replacement fixings that do not have adequate strength, so that the guard cannot adequately perform its protective function, for example, where containment of ejected parts is necessary.

Application of this requirement depends on the manufacturer's assessment of the risk concerned. The requirement applies to any fixed guards that are liable to be removed by the user with a risk of loss of the fixings, for example, to fixed guards that are liable to be removed during routine cleaning, setting or maintenance operations carried out at the place of use. The requirement does not necessarily apply to fixed guards that are only liable to be removed, for example, when the machinery is completely overhauled, is subject to major repairs or is dismantled for transfer to another site. For the same reason, it may not be necessary to apply the requirement to the casings of machinery intended for use by consumers, where the manufacturer’s instructions specify that the repairs requiring removal of these casings are only to be carried out in a specialist repair workshop. In that case, fixing systems should be used that are not easy to remove.

The requirement set out in the third paragraph of section 1.4.2.1 aims to prevent the situation where the operators are unaware that a fixed guard has not been properly fixed in place or have failed to replace the guard correctly. Where possible, fixed guards should automatically come away from their fixed position when the fixings are loosened.

As a general rule, building structures (e.g. walls, pillars, etc.) where a machine is installed cannot be considered as guards (fences) of the machinery itself. However, their characteristics may be sufficient in order to prevent workers to access to dangerous parts of the machines or the dangerous areas. In these cases, the structures may replace the installation of additional guards.

For a particular machinery installation such structures can form part of the essential safety package for that installation provided that the machinery manufacturer:

– has assessed that they are suitable for the application; and

– recorded this in the machine's technical file; and

– indicated in the instructions that the installation is unique because of its reliance on building walls for safety; and

– warned in the instructions of the risks that may arise if the building walls are modified, moved or removed, or the machinery is re-located, because the current configuration of the building walls is part of the safe machine layout; and

– specifies in the instructions the fencing requirements for the safety of the machinery if it is moved to another location to ensure it meets the requirements of Directive 2009/104/EC when in use.

1.4.2.2 Interlocking movable guards

Interlocking movable guards must:

– *as far as possible remain attached to the machinery when open,*

– *be designed and constructed in such a way that they can be adjusted only by means of an intentional action.*

Interlocking movable guards must be associated with an interlocking device that:

– *prevents the start of hazardous machinery functions until they are closed and*

– *gives a stop command whenever they are no longer closed.*

Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery functions has ceased, movable guards must be associated with a guard locking device in addition to an interlocking device that:

– *prevents the start of hazardous machinery functions until the guard is closed and locked, and*

– *keeps the guard closed and locked until the risk of injury from the hazardous machinery functions has ceased.*

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.

§219 Interlocking movable guards

Section 1.4.2.2 sets out requirements for the second type of guards: interlocking movable guards. The requirements set out in section 1.4.2.2 are complementary to the general requirements for guards and protective devices set out in section 1.4.1.

The two indents of the first paragraph of section 1.4.2.2 set out the requirements for the movable guards themselves. Unlike fixed guards, movable guards must, whenever possible, remain fixed to the machinery when the guards are open. For example, they can be hinged or slide along fixed guides. Their adjustment must be possible only by means of an intentional action in order to prevent, for example, the distance between the

guard and the danger zone from being modified unintentionally during opening or closing.

The two indents of the second paragraph of section 1.4.2.2 set out the requirements for the interlocking device which must be fitted to all movable guards.

The two indents of the third paragraph of section 1.4.2.2 set out the requirements for the guard locking device that must be fitted, in addition to the interlocking device, where there is a possibility of the operator reaching the danger zone before the hazardous machinery functions have ceased. This is often the case when the moving parts of the machinery take some time to stop after a stop command has been given (long run down time). It may also be the case for other hazards such as, for example, extreme temperatures or emissions of hazardous substances.

The parameters given in standard EN 999 can help to determine whether an interlocking movable guard must be fitted with a guard locking device[165].

The last paragraph of section 1.4.2.2 concerns the integration of the interlocking and guard locking devices fitted to movable guards into the control system of the machinery. This requirement is a particular application of the general requirement relating to the safety and reliability of control systems – see §184: comments on section 1.2.1.

Specifications for interlocking and guard locking devices for guards are given in standard EN ISO 14119:2013[166].

Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in items 9, 10 and 11 of Annex IV, when independently placed on the market, are considered as safety components – see §42: comments on Article 2 (c), and §389: comments on Annex V. They are also listed in Annex IV (20).

Specific guidance on guards for drilling machines is provided in section §414.

.1.4.2.3 Adjustable guards restricting access

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

- *adjustable manually or automatically, depending on the type of work involved, and*
- *readily adjustable without the use of tools.*

§220 Adjustable guards restricting access

The two indents of section 1.4.2.3 set out requirements for the third type of guards: adjustable guards restricting access. The requirements set out in section 1.4.2.3 are complementary to the general requirements for guards and protective devices set out in section 1.4.1.

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[165] EN 999:1998+A1:2008 *Safety of machinery - The positioning of protective equipment in respect of approach speeds of parts of the human body.*

[166] EN ISO 14119:2013 *Safety of machinery - Interlocking devices associated with guards - Principles for design and selection.*

Adjustable guards restricting access are to be fitted, in particular, on machinery with manual feed of material or workpieces, where it is not possible to completely prevent access to the danger zone around the tools.

In order to reduce the risk of contact with the hazardous functions as far as possible, it is important to facilitate the adjustment of the guard according to the dimensions of the workpieces concerned. Where this does not give rise to an additional risk, the guard can be designed and constructed so that its position adapts automatically to the dimension of the workpiece. Otherwise, it must be possible for the operator to adjust the position of the guard quickly and easily, without the use of a tool.

1.4.3 Special requirements for protective devices

Protective devices must be designed and incorporated into the control system in such a way that:

- *moving parts cannot start up while they are within the operator's reach,*
- *persons cannot reach moving parts while the parts are moving, and*
- *the absence or failure of one of their components prevents starting or stops the moving parts.*

Protective devices must be adjustable only by means of an intentional action.

§221 Protective devices

Section 1.4.3 sets out requirements for protective devices, such as optoelectronic protective devices, two-hand control devices etc. The requirements set out in section 1.4.3 are complementary to the general requirements for guards and protective devices set out in section 1.4.1.

The requirements for protective devices are similar to those for interlocking movable guards, since they have the same purpose of ensuring that operators do not come into contact with moving parts while they are moving.

It should be noted that, since protective devices do not constitute a physical barrier, they are not appropriate where protection is required against hazards such as, for example, ejected objects, extreme temperatures, noise emissions, radiation or emissions of hazardous substances.

- Specifications for pressure sensitive devices are given in standards EN ISO 13856, parts 1 to 3[167];
- specifications for two-hand control devices are given in standard EN 574[168];

[167] EN ISO 13856-1:2013 *Safety of machinery - Pressure sensitive protective devices* - Part 1: *General principles for the design and testing of pressure sensitive mats and pressure sensitive floors*; EN ISO 13856-2: *Safety of machinery - Pressure sensitive protective devices* - Part 2: *General principles for the design and testing of pressure sensitive edges and pressure sensitive bars*; EN ISO 13856-3: *Safety of machinery - Pressure sensitive protective devices* - Part 3: *General principles for the design and testing of pressure sensitive bumpers, plates, wires and similar devices*.

– specifications for electro-sensitive protective devices are given in standard EN 61496-1[169].

1.5 RISKS DUE TO OTHER HAZARDS

1.5.1 Electricity supply

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

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.

§222 Electricity

Section 1.5.1 deals with risks due to the use of electrical energy. Electrical energy may be transformed into mechanical energy by an electric motor or used, for example, to generate heat or radiation for the process. Static electricity is also used in certain processes such as, for example, painting, the separation of materials or the precipitation of emissions.

The main risks associated with electrical energy are electric shock due to direct contact with live parts (accidental contact with parts that are normally live) or indirect contact (contact with parts that have become live due to a fault) and burns, fire or explosion due to electric sparks or to the overheating of electrical equipment.

The first paragraph of section 1.5.1 requires the machinery manufacturer to take the necessary measures to prevent all hazards of an electrical nature. This general requirement applies whatever the voltage of the electrical supply.

The second paragraph of section 1.5.1 makes the safety requirements of the Low Voltage Directive (LVD) 2014/35/EU (formerly Directive 2006/95/EC as amended) applicable to machinery, also all relevant harmonised Standards listed under the LVD are therefore applicable to machinery. The second sentence of this paragraph makes it clear that the procedures of the LVD relating to the placing on the market and putting into service are not applicable to machinery subject to the Machinery Directive. This means that the Declaration of conformity for machinery subject to the Machinery Directive shall not refer to the LVD.

It should be recalled that certain categories of low voltage electrical equipment are excluded from the scope of the Machinery Directive – see §63: comments on Article 1 (2) (k).

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[168] EN 574:1996+A1:2008 *Safety of machinery - Two-hand control devices - Functional aspects - Principles for design.*

[169] EN 61496-1:2013 *Safety of machinery - Electro-sensitive protective equipment* - Part 1: *General requirements and tests* (IEC 61496-1:2012).

General specifications for the design of the electrical equipment of machinery are given in EN 60204-1[170]; specifications for high voltage electrical equipment of machinery are given in standard EN 60204-11[171]. Specifications for electrical equipment are also given in many standards for specific categories of machinery.

In addition to the general requirements set out in section 1.5.1, supplementary requirements relating to batteries for mobile machinery are set out in section 3.5.1.

1.5.2 Static electricity

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

§223 Unwanted static electricity

Section 1.5.2 deals with risks due to unwanted static electric charge that can build up in machinery or machinery parts, mainly due to friction between the parts of the machinery or between the machinery and workpieces, materials or fluids used or produced by the machinery. Static charge may also be created in ungrounded metal parts by induction in an electric field.

When a person comes into contact with or approaches a charged part, an electric discharge current can flow through the body to the earth. The resulting physiological effects depend mainly on the size of the contact area, the amount of discharge energy and the amplitude and frequency of the current. These effects can be merely annoying or painful or can have life-threatening consequences. The effect of surprise can contribute to the risk of an accident. Discharge of static electricity can also ignite a fire or trigger an explosion – see §227 and §228: comments on sections 1.5.6 and 1.5.7. Discharge of static electricity can also damage electronic circuits in control systems or impede their correct functioning, leading to hazardous situations.

Various techniques can be used to prevent the build-up of unwanted static charges, such as, for example, replacing insulating materials with dissipative or conductive materials, avoiding a dry atmosphere or creating an ionised atmosphere in the areas concerned. The safe discharge of static charges can be achieved, for example, by bonding and earthling conductive machinery parts.

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[170] EN 60204-1:2006+A1:2009 *Safety of machinery - Electrical equipment of machines* - Part 1: *General requirements* (IEC 60204-1:2005 (Modified)).

[171] EN 60204-11:2000 *Safety of machinery - Electrical equipment of machines* - Part 11: *Requirements for HV equipment for voltages above 1 000 V a.c. or 1 500 V d.c. and not exceeding 36 kV* (IEC 60204-11:2000).

1.5.3 Energy supply other than electricity

Where machinery is powered by source of energy other than electricity, it must be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy.

§224 Energy supply other than electricity

Sources of energy other than electricity include, for example, hydraulic, pneumatic, mechanical and thermal energy. The energy may be produced by the machinery itself, for example, by means of an electrically driven hydraulic pump or compressor or by an internal combustion engine, or it may be taken from an external source such as, for example, a supply of compressed air or the power take-off of a tractor. Mechanical energy may also be supplied by other equipment such as, for example, a vehicle test bed that is driven by the vehicle being tested. Energy may also be taken from natural sources such as the wind or moving water. Each type of energy is associated with specific hazards such as, for example, overpressure and internal or external leakage in hydraulic or pneumatic systems, or overheating and gaseous emissions in internal combustion engines.

Section 1.5.3 requires machinery manufacturers to assess and prevent all of the risks due to such energy sources.

Standard EN ISO 4413:2010 gives general specifications for hydraulic power systems[172]; standard EN ISO 4414:2010 gives general specifications for pneumatic power systems[173].

In addition to the general requirement set out in section 1.5.3, supplementary requirements relating to internal combustion engines for machinery intended for underground working are set out in section 5.5.

[172] EN ISO 4413:2010 *Hydraulic fluid power - General rules and safety requirements for and their components.*

[173] EN ISO 4414:2010 *Pneumatic fluid power. General rules and safety requirements for systems and their components*

1.5.4 Errors of fitting

Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

Where necessary, the instructions must give further information on these risks.

Where a faulty connection can be the source of risk, incorrect connections must be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.

§225 Errors of fitting

The first paragraph of the requirement set out in section 1.5.4 deals with risks that may be created when parts are fitted to the machinery during the installation of machinery or when they are refitted following the transfer of the machinery to a new site or following their removal for maintenance purposes.

This requirement applies to machinery parts that are foreseen to be fitted or removed and refitted by or under the control of the user. Correct fitting of other parts must be ensured by the manufacturer's own production system.

Where incorrect fitting or refitting is foreseeable and can give rise to a risk, it must be prevented, as far as is practicable, by the design and construction of the machinery and of the parts concerned and their fixing systems. For example, a matching asymmetrical shape of the part to be fitted and of the recipient part of the machinery can ensure that the part cannot be fitted in the wrong way. Use of distinct fixing systems for parts that are liable to be confused can ensure the same effect. Where a design solution is not practicable, the necessary indications to avoid errors of fitting must be marked on the machinery parts or their housings.

The second sentence of the first paragraph of section 1.5.4 makes the same requirements applicable to moving parts, such as, for example, chains or belts, that must be fitted in a given direction.

Markings to avoid errors of fitting are subject to the requirements set out in section 1.7.1 relating to information and warnings on the machinery.

According to the second paragraph of section 1.5.4, where necessary, the manufacturer's instructions must give further information on the measures taken to avoid errors of fitting, and, where appropriate, provide explanations of the information marked on the parts concerned – see §264: comments on section 1.7.4.2 (i).

The third paragraph of section 1.5.4 deals with the specific case of the risk of errors of connection. The types of connection concerned may include, for example, the connection of the machinery to supplies of energy or fluids, or the connection of the control system of towed machinery to the control system of self-propelled machinery or a tractor.

The approach to this risk is the same as for the prevention of errors of fitting in general. As far as practicable, errors of connection that can give rise to a risk must be avoided by the design of the elements to be connected, for example, by using different diameters, threads or connecting systems. Markings such as colour codes are useful but are not a substitute for design measures. However, if design measures are not practicable, the necessary information must be marked on the elements to be connected and, where appropriate, on the means of connection.

1.5.5 Extreme temperatures

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

The necessary steps must also be taken to avoid or protect against the risk of hot or very cold material being ejected.

§226 Extreme temperatures

Contact with or proximity to hot machinery parts or hot materials used or produced by machinery can cause discomfort, pain and burns. Contact with very cold parts or materials can cause numbness or frostbite. Repeated exposure to cold can cause damage to nerves or vessels.

Wherever possible, risks due to contact with or proximity to parts of machinery or materials used or produced by machinery at high or very low temperatures must be reduced by avoiding the generation of dangerous temperatures. Where this is not possible, the necessary protective measures must be taken to avoid dangerous contact with or proximity to the areas concerned, either by locating them at a sufficient distance from positions normally reachable by persons or by fitting guards or other protective structures with the necessary thermal insulation.

The requirement set out in the second paragraph of section 1.5.5 is complementary to the requirement set out in section 1.3.3 relating to the risk of ejected objects. Where guards are fitted to protect against the risk of ejection of hot or very cold materials, they must be designed to resist the temperatures concerned – see §216: comments on section 1.4.1.

Standards EN ISO 13732, parts 1 and 3[174] provide guidance on the assessment of the risk of injury due to contact with hot and cold surfaces respectively. Guidance is also given in CENELEC Guide 29[175].

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[174] EN ISO 13732-1:2008 +*Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces* - Part 1: *Hot surfaces* (ISO 13732-1:2006); EN ISO 13732-3:2008 *Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces* - Part 3: *Cold surfaces* (ISO 13732-3:2005).

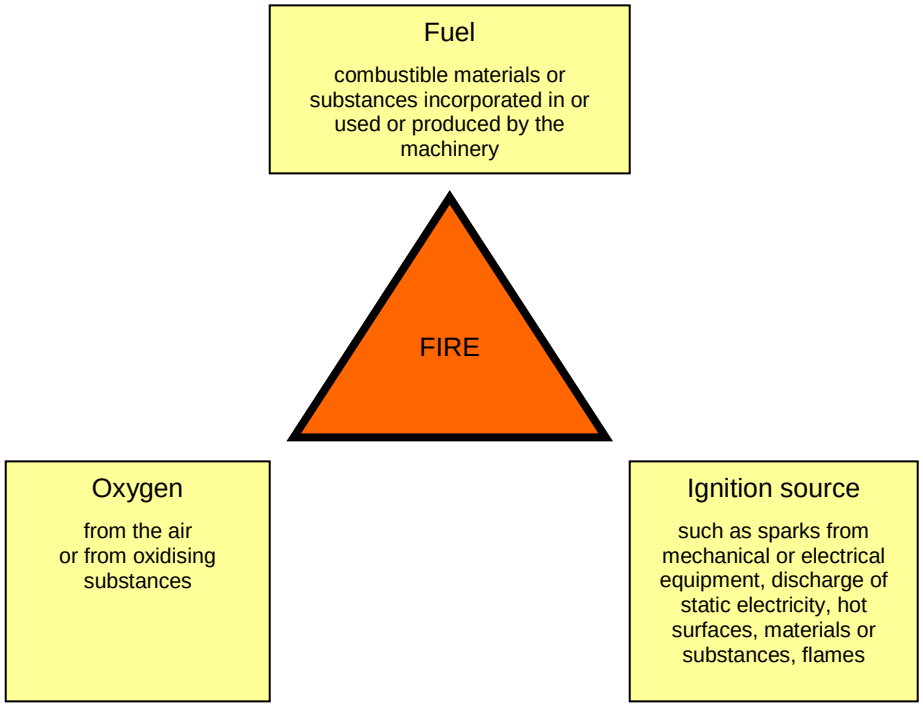
[175] CLC Guide 29: 2007 *Temperatures of hot surfaces likely to be touched - Guidance document for Technical Committees and manufacturers.*

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.

§227 Fire

Fire created by machinery creates a serious risk for persons as well as for property, since fire may damage or destroy the machinery itself and surrounding installations and buildings. Assessment of the fire hazard involves identifying and evaluating the three essential elements needed to start a fire, often presented in the form of a triangle[176]:



Reducing the risk of fire involves taking a combination of measures with respect to the three elements of the triangle:

- Avoiding or reducing the incorporation, the use or the production of combustible materials or substances. Such measures include, for example, the use of fire-resistant materials in the construction of the machinery, the safe containment of flammable liquids, dusts or gases used or produced by the machinery and the safe removal of combustible waste – see §178: comments on section 1.1.3;
- Preventing overheating of the machinery itself or of the materials or substances used or produced by the machinery and, where overheating may occur, detecting it and

[176] The combustion process may also be promoted or inhibited by the presence of other substances (catalysts).

triggering the necessary corrective measures or providing a warning to the operator before it gives rise to a risk of fire;

- Avoiding contact between combustible materials or substances and ignition sources such as, for example, sparks of mechanical or electrical origin or hot surfaces – see §222 and §223: comments on sections 1.5.1 and 1.5.2;
- Reducing the concentration of oxygen (insofar as this does not give rise to an additional risk for persons) or avoiding the presence of oxidising substances.

Where the risk of fire cannot be adequately reduced by such measures, complementary protective measures shall be taken to limit the effects of a fire. Such measures may include, for example, shielding or enclosing the machinery and fitting fire detection, alarm and/or extinction systems. The necessary measures shall be defined on the basis of an assessment of the fire risk.

General specifications for assessing, preventing and protecting against the risk of fire are given in standard EN ISO 19353:2016 [177].

In addition to the general requirements set out in section 1.5.6, supplementary requirements relating to the risk of fire for mobile machinery are set out in section 3.5.2; supplementary requirements relating to the risk of fire for machinery intended for underground work are set out in section 5.5.

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.

§228 Explosion

The requirement set out in the first paragraph of section 1.5.7 applies to the risks of explosion due to the operation of the machinery itself or to materials or substances used or produced by the machinery.

Explosions may occur if the combustion of certain concentrations of flammable substances such as gases, vapours, mists or dust in air is triggered by an ignition source of sufficient energy. Explosions involve a very rapid self-sustaining propagation of the combustion reaction with a build-up of high pressure. The damage caused by explosions to persons and property is due to the violent emission of flames, thermal radiation, pressure waves, flying debris and hazardous substances. The severity of the potential damage depends mainly on the quantity of explosive mixture present and its nature.

[177] EN ISO 19353:2016 *Safety of machinery - Fire prevention and fire protection.*

The principles that apply to the prevention of the risk of explosion are similar to those for the prevention of the risk of fire. Preventing the risk of explosion involves a combination of:

- avoiding the accumulation of explosive mixtures in areas in or around the machinery by avoiding flammable materials and substances or by permanently maintaining their concentration in the air at values outside the lower or upper explosion limits;
- avoiding the presence of ignition sources in hazardous areas;
- reducing the concentration of oxygen in hazardous areas (insofar as this does not give rise to an additional risk for persons).

Where the risk of explosion cannot be completely prevented, complementary protective measures shall be taken to limit the consequences of an explosion. Such measures include, for example, explosion-resistant design, fitting explosion relief devices (vents), fitting automatic explosion detection and suppression systems or devices to prevent the propagation of flame and explosion.

General specifications for assessing, preventing and protecting against the risk of explosion are given in standard EN 1127-1[178].

According to the second paragraph of section 1.5.7, machinery intended for use in or in relation to a potentially explosive atmosphere is subject to the provisions of the ATEX Directive[179] – see §91: comments on Article 3. The concept of a potentially explosive atmosphere is explained in the Guidelines on the application of the ATEX Directive[180].

Machinery subject to the ATEX Directive is subject to specific marking requirements – see §251: comments on the third paragraph of section 1.7.3.

Although the ATEX Directive is not applicable as such to explosion risks generated within the machinery itself, equipment complying with the requirements of the ATEX Directive must be fitted in areas of machinery where there is a risk of accumulation of a potentially explosive atmosphere.

1.5.8 Noise

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

The level of noise emission may be assessed with reference to comparative emission data for similar machinery.

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[178] EN 1127-1:2011 *Explosive atmospheres - Explosion prevention and protection* - Part 1: *Basic concepts and methodology*.

[179] Directive 2014/34/EU of the European Parliament and the Council of 26 February 2014 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (recast). OJ L 96, 29.3.2014, p. 309.

[180] Available on http://ec.europa.eu/growth/sectors/mechanical-engineering/atex/.

§229 Reduction of noise emission

The requirement set out in section 1.5.8 deals with risks associated with the exposure of machinery operators and other persons to noise generated by machinery. Prolonged exposure to noise from machinery is the main cause of occupational noise-induced hearing impairment. Often the risk to health is insidious, since the damage to hearing is cumulative and irreversible but the person concerned is not aware of it at the time of exposure. Exposure to high-energy impulse noise can cause sudden loss of hearing. Exposure to noise is also associated with other hearing disorders such as tinnitus (perception of sound in the absence of an external source). Exposure to noise from machinery is also a factor contributing to fatigue and stress and can contribute to accidents, for example, due to interference with communication – see §181: comments on section 1.1.6.

It is important to distinguish the exposure of persons to noise from the emission of noise by machinery. The emission of noise from machinery, measured under defined conditions, is an intrinsic property of the machinery. The exposure of persons to noise from machinery depends on factors such as the installation of the machinery, the conditions of use of the machinery, the characteristics of the workplace (such as, for example, noise absorption, the scattering of noise, noise reflections), noise emissions from other sources (such as, for example, from other machinery), the position of persons with respect to the sources of noise, the duration of exposure and the use of personal protective equipment (hearing protectors). The machinery manufacturer is responsible for the contribution of his machinery to the risk due to noise.

The exposure of workers to noise is subject to the national provisions implementing Directive 2003/10/EC on the exposure of workers to the risks arising from noise[181]. That Directive sets exposure limit values and exposure action values in respect of the daily noise exposure levels and peak sound pressure levels of workers.

The lower the noise emission from machinery, the easier it is for users to respect the exposure limits set by Directive 2003/10/EC. Users thus have an interest in selecting machinery with as low noise emission as possible for the required performance[182] – see §275: comments on section 1.7.4.3.

The Machinery Directive does not set noise emission limits, but requires manufacturers to reduce risks due to noise emission to the lowest level, taking account of technical progress and the availability of means of reducing noise.

[181] Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (Seventeenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC). OJ L 42, 15.2.2003, p. 38.

[182] See Article 4 (6) of Directive 2003/10/EC.

In addition to the Machinery Directive, certain categories of machinery are subject to the noise emission limits set by Directive 2000/14/EC on equipment for use outdoors[183] – see §92: comments on Article 3, and §273: comments on section 1.7.4.2.(u).

The manufacturer's approach to preventing risks due to noise emission must take account of the principles of safety integration set out in section 1.1.2:

- the first priority must be given to design and construction measures to reduce noise emission at source;
- the second priority must be given to integrated protective measures that complement measures for noise reduction at source, so allowing a further reduction of noise emission;

the third priority must be given to informing the user about the residual noise emission so that he can take the necessary protective measures such as, for example, measures relating to the installation of the machinery, to the design of the workplace and to the provision and use of PPE (hearing protectors) – see §264, §267 and §273: comments on sections 1.7.4.2 (j), (l) (m) and (u).

Reducing noise emission at source is the most effective way to reduce the risks due to noise for both the operators of the machinery concerned and for other persons who may be exposed to noise generated by the machinery. In order to reduce noise emission at source effectively, it is necessary to identify the main sources of the noise generated by the machinery concerned. Measures to reduce the dominant source or sources of noise should be taken as early as possible in the design process.

Integrated protective measures against noise emission include fitting acoustic enclosures around the machinery or around the main sources of noise on the machinery. Where appropriate, guards shall be designed to provide the required noise attenuation as well as providing protection against other hazards – see §169: comments on section 1.1.1 (f), and §216: comments on section 1.4.1.

It is also possible to design enclosures of the work stations or driving positions (cabins or cabs) to provide noise attenuation as well as protection against other hazards – see §182: comments on section 1.1.7 and §294: comments on section 3.2.1. However, it should be noted that such measures do not protect operators while they are outside the enclosures nor other exposed persons.

General specifications for the reduction of noise emissions generated by machinery are given in standard EN ISO 11688-1[184].

§230 Comparative emission data

The second paragraph of section 1.5.8 refers to a means of assessing the adequacy of the measures taken to reduce the risks due to noise emission: comparison of the risk

[183] Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors. OJ L 162, 3.7.2000, p. 1 – see Article 12.

[184] EN ISO 11688-1:2009 *Acoustics - Recommended practice for the design of low-noise machinery and equipment* - Part 1: *Planning* (ISO/TR 11688-1:1995).

level with that of similar machinery. This approach is part of the fourth step of the process of risk assessment set out in General Principle 1: risk evaluation[185] – see §158: comments on General Principle 1 – and is the main means for establishing the state of the art – see §161: comments on General Principle 3.

The approach consists in comparing the noise emission value measured on the machinery concerned with values measured on similar machinery of the same family. Similar machinery is machinery intended to carry out the same function with equivalent performance characteristics. The parameters describing the performance are normally specified in the noise test code for the category of machinery concerned. The noise emission for the machinery to be compared must be measured using the same test code.

If the comparison shows that a significant number of similar machines with comparable parameters have a lower level of noise emission, this indicates that the machinery concerned is not in line with the state of the art, since means of further reducing noise emission are available and should be applied. If the comparison shows that similar machines have a similar or higher level of noise emission, this indicates that the noise reduction measures are adequate, unless it is evident that technical means are available to further reduce noise emission, in which case they should be applied.

Application of this approach must be based on the appropriate noise test code and reliable and representative comparative noise emission data. Only limited data collection has been performed so far. However, it is intended for more and more C-type standards to include comparative emission data for the categories of machinery in their scope.

A method for comparing the noise emission data of machinery is given in standard EN ISO 11689[186].

1.5.9 Vibrations

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

The level of vibration emission may be assessed with reference to comparative emission data for similar machinery.

§231 Vibrations

The requirement set out in section 1.5.9 deals with risks associated with the exposure to vibrations generated by machinery. Vibrations can be generated by the operation of the machinery itself, for example due to rotating or reciprocating masses, gas pulsation or

[185] See clause 8.3 of standard EN ISO 12100:2010 *Safety of machinery - General principals and risk reduction*.

[186] EN ISO 11689:1996 *Acoustics - Procedure for the comparison of noise emission data for machinery and equipment*.

aerodynamic phenomena such as those generated by fans, or by the impact of hand-held machinery on hard materials. Vibrations can also be generated by interaction between the machinery and its environment such as, for example, the movement of mobile machinery over rough ground.

Exposure to vibrations transmitted through the feet or the seat to the whole body can cause or aggravate musculoskeletal disorders such as back pain and damage to the spine. Exposure of the hand/arm system to vibrations can cause damage to blood vessels in fingers and hands (white finger disease) and damage to the peripheral nervous system, tendons, muscles, bones and joints of the hands and arms.

It is important to distinguish the exposure of persons to vibrations from the emission of vibrations by machinery. It should be noted that the exposure of workers to vibrations is subject to the national provisions implementing Directive 2002/44/EC[187]. That Directive sets daily exposure limit values and action values for hand-arm and whole body vibration.

The daily exposure of persons to vibrations cannot be simply deduced from the measurement of vibration emission from machinery, since exposure also depends on the duration and conditions of use of the machinery concerned. However, the lower the level of emission of vibrations from the machinery, the easier it is for users to respect the exposure limits set by Directive 2002/44/EC. Users thus have an interest in selecting machinery with as low vibration emission as possible for the required performance – see §275: comments on section 1.7.4.3.

The manufacturer's approach to preventing risks due to vibration emission must take account of the principles of safety integration set out in section 1.1.2:

- the first priority must be given to design and construction measures to reduce the generation of vibrations at source, for example, by ensuring that the resonance frequencies of machine parts are not close to the vibration excitation frequencies, by choosing materials for the construction of machinery that have high inherent damping characteristics, by including auxiliary mass or by balancing rotating or reciprocating parts;
- the second priority must be given to integrated protective measures: isolating measures can be taken to prevent the transmission of vibrations to the whole body or to the hand-arm system. Isolating measures include the fitting of metal or elastomeric springs, the fitting of friction, liquid or gas dampers or fitting a combination of springs and dampers;
- the third priority must be given to informing the user about the residual vibration emission so that he can take the necessary protective measures such as, for example, measures relating to the installation of the machinery or providing appropriate training – see §264 and §267: comments on sections 1.7.4.2 (j) and (l), §279: comments on section 2.2.1.1, and §325: comments on section 3.6.3.1.

[187] Directive 2002/44/EC of the European Parliament and of the Council of 25 June 2002 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration) (sixteenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC). OJ L 177, 6.7.2002, p. 13.

The second paragraph of section 1.5.9 refers to an approach for assessing the adequacy of the measures taken to reduce the risks due to vibrations: comparison of the risk level with that of similar machinery. This method shall be applied in the same conditions as the equivalent requirement for comparative noise emission data – see §230: comments on section 1.5.8.

General specifications for the isolation of sources of vibration are given in standard EN 1299[188].

In addition to the general requirements set out in section 1.5.9, supplementary requirements relating to seating on machinery subject to vibrations are set out in section 1.1.8.

1.5.10 Radiation

Undesirable radiation emissions from the machinery must be eliminated or be reduced to levels that do not have adverse effects on persons.

Any functional ionising radiation emissions must be limited to the lowest level which is sufficient for the proper functioning of the machinery during setting, operation and cleaning. Where a risk exists, the necessary protective measures must be taken.

Any functional non-ionising radiation emissions during setting, operation and cleaning must be limited to levels that do not have adverse effects on persons.

§232 Ionising and non-ionising radiation from the machinery

The requirements set out in section 1.5.10 concern risks due to emissions of radiation arising from parts of the machinery or from materials or substances used or produced by the machinery. Section 1.5.10 concerns both ionising and non-ionising radiation. Risks due to coherent optical radiation (lasers) are dealt with in section 1.5.11.

Ionising radiation includes radioactive alpha, beta and gamma radiation and X-rays. Exposure to ionising radiation causes damage to cells and can be carcinogenic.

Non-ionising radiation includes magnetic and electromagnetic radiation in the microwave and radio frequency ranges and optical radiation in the infrared, visible and ultraviolet frequency ranges. Exposure to strong magnetic fields can cause vertigo, nausea and magnetophosphenes (visual sensation of flickering lights). Exposure to microwave and radio frequency radiation may lead to heating effects and disturb nerve and muscle responses. Exposure to certain levels of optical radiation can cause burns and other injuries to the eyes and skin. Exposure to ultraviolet radiation can be carcinogenic.

[188] EN 1299:1997+A1:2008 *Mechanical vibration and shock - Vibration isolation of machines - Information for the application of source isolation.*

It should be noted that the exposure of workers to radiation is subject to national provisions implementing the following Directives:

- Ionising radiation: Directive 96/29/Euratom[189]
- Electromagnetic fields: Directive 2013/35/EU[190]
- Artificial optical radiation: Directive 2006/25/EC[191]

These Directives set exposure limit values. While it is important to distinguish the exposure of persons to radiation from the emission of radiation by machinery, the lower the emissions from the machinery, the easier it is for users to respect the exposure limits.

The general requirement set out in the first paragraph of section 1.5.10 applies to undesirable emissions of radiation, that is to say, to emissions that are not essential to the functioning of the machinery. It applies to both ionising and non-ionising radiation. The prevention of risks due to undesirable radiation involves:

- avoiding emissions of radiation or reducing their power to non-harmful levels – it should be noted that there is considered to be no harmless level of exposure to ionising radiation;
- where emissions cannot be eliminated or their power sufficiently reduced, shielding to prevent the exposure of operators and other persons;
- informing users about residual risks due to radiation and on the need to provide and use personal protective equipment – see §267: comments on section 1.7.4.2 (l) and (m).

The second paragraph of section 1.5.10 deals with risks due to functional ionising radiation. It should be recalled that machinery specially designed for the purposes of the nuclear power industry or for the production or processing of radioactive materials is excluded from the scope of the Machinery Directive. However, machinery subject to the Machinery Directive may incorporate sources of ionising radiation, for example, for the purposes of measurement, non-destructive testing or preventing the accumulation of static electric charge – see §50: comments on Article 1 (2) (c).

Such functional ionising radiation must be limited to the lowest level which is sufficient for the proper functioning of the machinery and the necessary protective measures must be taken to ensure that operators and other persons are not exposed to radiation,

[189] Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. OJ L 179, 29.6.2013, p.1-21.

[190] Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC

[191] Directive 2006/25/EC of the Europe and Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation) (19th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC).

whether during normal operation of the machinery or during maintenance operations such as setting and cleaning.

It should be noted that the use of radioactive sources may be subject to authorisation and control according to the national provisions implementing Directive 96/29/Euratom and Directive 2003/122/Euratom[192].

The third paragraph of section 1.5.10 deals with functional non-ionising radiation. Since exposure to low levels of certain types of non-ionising radiation may be harmless, the third paragraph of section 1.5.10 requires that the levels of non-ionising radiation to which persons are exposed must not have adverse effects.

General specifications for the assessment and measurement of and protection against non-ionising radiation are given in standards EN 12198, parts 1 to 3[193].

1.5.11 External radiation

Machinery must be designed and constructed in such a way that external radiation does not interfere with its operation.

§233 External radiation

The requirement set out in section 1.5.11 deals with one aspect of the electromagnetic compatibility of machinery, that is to say the immunity of the machinery to disturbance, due to electromagnetic radiation from external sources that may affect the health and safety of persons. In this respect, particular attention should be paid to the design and construction of safety related parts of the control system – see §184: comments on section 1.2.1.

With respect to the immunity of machinery to electromagnetic radiation that may disturb the functioning of the machinery in general, and with respect to the emissions of electromagnetic radiation from the machinery that may disturb the functioning of other equipment, the Electromagnetic Compatibility (EMC) Directive 2014/30/EU is applicable in addition to the Machinery Directive[194] – see §92: comments on Article 3.

The requirement set out in section 1.5.11 also requires machinery manufacturers to prevent interference from other types of external radiation that can reasonably be

[192] Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources. OJ L 346, 31.12.2003, p. 57 – will be repealed by 2013/59/Euratom on 6 February 2018.

[193] EN 12198-1:2000+A1:2008 *Safety of machinery - Assessment and reduction of risks arising from radiation emitted by machinery* - Part 1: *General principles*; EN 12198-2:2002+A1:2008 *Safety of machinery - Assessment and reduction of risks arising from radiation emitted by machinery* - Part 2: *Radiation emission measurement procedure*; EN 12198-3:2002+A1:2008 *Safety of machinery - Assessment and reduction of risks arising from radiation emitted by machinery* - Part 3: *Reduction of radiation by attenuation or screening.*

[194] Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC. OJ L 390, 31.12.2004, p. 24.

expected in the intended conditions of use. For example, external artificial or natural optical radiation may interfere with the functioning of certain photoelectric devices or wireless remote control devices.

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.*

§234 Laser radiation

Sources of laser radiation are frequently incorporated in machinery for purposes such as, for example, measurement, data processing or presence detection, or in laser processing machinery such as, for example, machinery for heat treatment, marking, cutting, bending or welding of materials or workpieces. The risks due to lasers depend on the wavelength and power of the radiation. Exposure to laser radiation can cause eye or skin injuries and burns.

It should be noted that the exposure of workers to laser radiation is subject to national provisions implementing Directive 2006/25/EC on artificial optical radiation, which sets exposure limit values.

The requirement set out in section 1.5.12 requires machinery manufacturers to integrate laser generators or sources into machinery so that the radiation is only applied where and when it is required. Where necessary, local or peripheral shields or screens must be fitted to protect persons against potentially harmful direct, reflected, diffused or scattered radiation.

As a general rule, on laser processing machinery, access to the process zone must be prevented during normal operation. Where operators are required to observe laser equipment, for example, for setting or adjustment purposes, the manufacturer shall integrate the necessary protective measures to prevent any risk of damage to health. In accordance with section 1.1.2 (b), instructions on the provision and use of PPE (eye protectors) against laser radiation shall only be given for residual risks that cannot be prevented by integrated protective measures.

The third indent of section 1.5.12 entails that optical equipment fitted for the protection of operators during observation or adjustment of laser equipment, such as screens, must have the necessary maximum transmittance, taking account of the wavelength range and the other characteristics of the laser radiation, in order to prevent any risk of damage to health.

General specifications for laser processing machinery are given in standards EN ISO 11553, parts 1 and 2[195].

Specifications for protective screens are given in standard EN 12254[196].

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.

§235 Emissions of hazardous materials and substances

The requirements set out in section 1.5.13 deal with risks to health due to the emission of hazardous materials and substances produced by machinery. Hazardous materials and substances include chemical and biological materials and substances classified as toxic, harmful, corrosive, irritant, sensitising, carcinogenic, mutagenic, teratogenic, pathogenic or asphyxiant. Airborne emissions of hazardous substances are most likely to enter the body by inhalation but may also enter by other routes when deposited on surfaces of the body or ingested. Non-airborne emissions of hazardous substances are most likely to enter the body by ingestion or by contact with the skin, eyes or mucous membranes.

Prevention of risks due to emissions of hazardous materials and substances can be achieved by avoiding the use of hazardous materials and substances or by using less hazardous substances – see §178: comments on section 1.1.3. The production process can also be designed in order to avoid or reduce emissions.

Where emissions of hazardous materials and substances cannot be sufficiently avoided or reduced, the second paragraph of section 1.5.13 requires machinery to be fitted with the equipment necessary to contain, evacuate or precipitate hazardous materials and substances in order to protect persons against exposure. Where the hazardous materials or substances are combustible or may form an explosive mixture with air, precautions must be taken to prevent the risk of fire or explosion during their containment or evacuation – see §227 and §228: comments on sections 1.5.6 and 1.5.7.

[195] EN ISO 11553-1:2008 *Safety of machinery - Laser processing machines* - Part 1: *General safety requirements* (ISO 11553-1:2005); EN ISO 11553-2:2008 *Safety of machinery - Laser processing machines* - Part 2: *Safety requirements for hand-held laser processing devices* (ISO 11553-2:2007).

[196] EN 12254:2010 *Screens for laser working places - Safety requirements and testing*.

The third paragraph of section 1.5.13 deals with cases where the process is not completely enclosed. In such cases, the equipment for the containment or the evacuation of hazardous materials and substances must be designed and located in order to avoid leaks. This can be achieved, for example, by maintaining the containers at negative pressure or by locating extraction hoods or nozzles with an adequate air flow as close as possible to the points of emission.

General specifications for preventing risks due to emissions of hazardous materials and substances are given in standards EN 626, parts 1 and 2[197].

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.

§236 Risk of being trapped

The requirement set out in section 1.5.14 applies in cases where the presence of persons in enclosed areas of the machinery cannot be altogether avoided, for example inside a tunnel kiln or waste compacting machine. The requirement also applies to the carriers of certain types of machinery designed for lifting persons where there is a risk of users being trapped if the carrier is immobilised at a height or between fixed landings. Attention should also be given to the risk of a person being trapped in an operating position at a height, for example, in case of incapacity. For example, the ill person may block the floor access door to a lift running up the ladder in a wind turbine or on a tower crane and so, the ill person cannot be easily reached, or the lift moved where the access to the only operating location is thus blocked.

The requirement set out in section 1.5.14 should be considered in conjunction with the requirements set out in section 1.1.7 relating to exits and emergency exits from operating positions – see §182: comments on section 1.1.7 – and sections 1.6.4 and 1.6.5 relating to operator intervention and the cleaning of internal parts.

1.5.15 Risk of slipping, tripping or falling

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

Where appropriate, these parts must be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.

[197] EN 626-1:1994+A1:2008 *Safety of machinery - Reduction of risks to health from hazardous substances emitted by machinery* - Part 1: *Principles and specifications for machinery manufacturers;* EN 626-2:1996+A1:2008 *Safety of machinery - Reduction of risk to health from hazardous substances emitted by machinery* - Part 2: *Methodology leading to verification procedures*.

§237 Slips, trips and falls

The requirement set out in the first paragraph of section 1.5.15 applies to all parts of the machinery on which persons are liable to move about or stand, whether in order to access operating positions and maintenance points, in order to move from one part of the machinery to another – see §240: comments on section 1.6.2. It also applies to parts of the machinery on which persons move about or stand while using machinery intended for the lifting or moving of persons. The requirement thus applies to parts of machinery such as, for example, footboards, work platforms, gangways, walkways, ramps, steps, stepladders, ladders, floors, the steps of escalators or the band of passenger conveyors.

The requirement set out in section 1.5.15 only applies to parts of the machinery, including means of access to the machinery installed in the user's premises – see §240: comments on section 1.6.2. The employer's obligations with respect to workplace floors are set out in Council Directive 89/654/EEC[198]. Any particular requirements for the floor on which the machinery must be used or installed shall be specified in the manufacturer's instructions – see §264: comments on section 1.7.4.2 (i).

In order to prevent the risk of slipping, the manufacturer must ensure that the surfaces of the machinery on which it is foreseeable that persons will move about or stand have adequate slip resistance, taking account of the conditions of use. Since the accumulation of substances such as water, oil or grease, earth, dirt, snow or ice tends to increase the risk of slipping, the surfaces on which persons are liable to move about and stand must, where possible be designed and located so as to avoid the presence of such substances or be designed so that such substances do not accumulate or can be drained away. Where surfaces may remain wet or damp, smooth surfaces should be avoided.

In order to prevent the risk of tripping, it is important to avoid differences of level between adjacent surfaces. For example, the levelling accuracy of lifting machinery serving fixed landings where persons have access to the carrier must be such as to prevent a difference of level between the floor of the carrier and the landing that could create a tripping risk. Care should be taken when locating and fixing cables and piping to avoid creating obstacles that give rise to a risk of tripping.

Where there is a risk of falling, the areas concerned must be fitted with the necessary enclosures or guard rails and toe plates to prevent falls. Anchorage for attaching PPE against falls from a height shall be fitted where there is a residual risk of falling – see §265: comments on section 1.7.4.2 (m), and §374: comments on section 6.3.2. Appropriate types of anchorage should be chosen, taking account of the need of operators to move. However, in accordance with section 1.1.2 (b), instructions on the provision and use of PPE shall not be a substitute for integrated protective measures against the risk of falling when such measures are practicable.

The second paragraph of section 1.5.15 requires areas of machinery where persons are liable to move about or stand to be fitted, where appropriate, with handholds that are

[198] Council Directive 89/654/EEC of 30 November 1989 concerning the minimum safety and health requirements for the workplace (first individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC) – Annex I, section 9.2.

fixed relative to the users in order to enable them to keep their balance. This is a complementary measure to reduce the risk of slipping, tripping and falling and is particularly important for machinery where users are intended to step on to a moving surface such as escalators and moving walkways.

General specifications to prevent the risks of slipping, tripping and falling are given in the standards of the EN ISO 14122 series – see §240: comments on section 1.6.2.

In addition to the general requirement set out in section 1.5.15, supplementary requirements relating to the risk of falling from the carrier of machinery for lifting persons are set out in section 6.3.2.

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.

§238 Lightning

The requirement set out in section 1.5.16 applies mainly to machinery intended to be used outdoors, whether intended to be installed at one fixed location or to be erected at successive locations. It may also apply to machinery that is connected to the outdoors by conductive parts. Machinery subject to risks due to lightning must be fitted with an appropriate lightning conductor and the means of connecting the conductor to earth. The manufacturer's instructions must specify how the connection to earth is to be made, inspected and maintained so that it remains effective – see §264 and §272: comments on sections 1.7.4.2 (i) and (r).

1.6 MAINTENANCE

1.6.1 Machinery maintenance

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

If one or more of the above conditions cannot be satisfied for technical reasons, measures must be taken to ensure that these operations can be carried out safely (see section 1.2.5).

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

Automated machinery components which have to be changed frequently must be capable of being removed and replaced easily and safely. Access to the components must enable these tasks to be carried out with the necessary technical means in accordance with a specified operating method.

§239 Maintenance

The first paragraph of section 1.6.1 states important general principles for the design of machinery to ensure that maintenance operations can be carried out safely. Locating adjustment and maintenance points outside danger zones avoids the need for maintenance operators to enter danger zones to carry out their tasks and the need to remove fixed guards or open interlocking movable guards for that purpose.

As far as possible, the machinery must be designed so that maintenance operations can be carried out while the machinery is at stop. For example, where tools have to be changed or removed for cleaning purposes, the machinery must be provided with the means of freeing them without starting the machinery. Where special equipment is needed for that purpose, it must be provided with the machinery – see §177: comments on section 1.1.2 (e). In some cases, it may not be necessary to stop the machinery as a whole, provided the parts on which the work is being carried out and the parts which could affect the safety of operators are at a stop.

The second paragraph of section 1.6.1 recognises that it is not possible, in every case, to avoid the need to enter danger zones for maintenance purposes and that it may be necessary to carry out certain setting operations or adjustments with the machinery running. In that case, the control system of the machinery must include an appropriate safe operating mode as referred to in section 1.2.5 – see §204: comments on section 1.2.5.

The requirements set out in the third and fourth paragraphs of section 1.6.1 aim to reduce risks due to operator intervention, particularly for automated machinery. The third paragraph of section 1.6.1 requires machinery to be provided, where appropriate, with the means of connecting the necessary diagnostic fault-finding equipment. The fourth paragraph requires the manufacturer to design automated machinery to facilitate the removal and replacement of components that have to be changed frequently. The safe method to be employed for such maintenance operations must be clearly specified and explained in the instructions – see §272: comments on section 1.7.4.2 (s).

1.6.2 Access to operating positions and servicing points

Machinery must be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment and maintenance of the machinery.

§240 Access to operating positions and servicing points

The requirement set out in section 1.6.2 must be considered when locating operating positions and servicing points. Locating operating positions and servicing points in easily accessible areas, for example, at ground level, can avoid the need to fit special means of access. Where special means of access are required, operating positions and servicing points to which frequent access is required should be located so they can be easily reached from a suitable means of access. Like the adjustment and maintenance points themselves, means of access should also be located outside the danger zones – see §239: comments on section 1.6.1.

The machinery manufacturer is responsible for ensuring that the necessary means of safe access are provided with the machinery. This includes the case of machinery the construction of which is completed at the user's premises. In that case, means of access already existing in the premises can be taken into account by the machinery manufacturer and should be specified in the technical file.

The means of access to servicing points must be designed taking account of the tools and equipment that are needed for the maintenance of the machinery.

Special means for exceptional access, such as, for example, for exceptional repairs, may be described in the manufacturer's instructions – see §272: comments on section 1.7.4.2 (s).

Specifications for the choice and design of permanent means of access to machinery are given in the standards of the EN ISO 14122 series[199].

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.

§241 Isolation of energy sources

The objective of the requirement set out in section 1.6.3 is to keep machinery in a safe condition while maintenance is being carried out. To this end, operators carrying out maintenance operations while the machinery is stopped must be able to isolate the machinery from its sources of energy before intervening in order to prevent dangerous occurrences such as unexpected start-up of the machinery, whether due to machinery faults, to the action of other persons who may ignore the presence of maintenance operators or to inadvertent actions of the maintenance operators themselves.

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[199] EN ISO 14122-1:2001 *Safety of machinery - Permanent means of access to machinery* - Part 1: *Choice of fixed means of access between two levels* (ISO 14122-1:2001); EN ISO 14122-2:2001 *Safety of machinery - Permanent means of access to machinery* - Part 2: *Working platforms and walkways* (ISO 14122-2:2001); EN ISO 14122-3:2001 *Safety of machinery - Permanent means of access to machinery* - Part 3: *Stairs, stepladders and guard-rails* (ISO 14122-3:2001).

For this purpose, means of isolation must be fitted to enable operators to disconnect and separate in a reliable way the machinery from all sources of energy, including the electricity supply and sources of mechanical, hydraulic, pneumatic or thermal energy.

Where the operators carrying out maintenance operations cannot easily check that the means of isolation remain in the isolating position, the isolators must be designed so that they are lockable in this position. When it is foreseeable that several operators may have to carry out maintenance operations simultaneously, the isolator should be designed so that each of the operators concerned can place his or her lock on the isolator for the duration of his or her intervention.

The second paragraph of section 1.6.3 applies mainly to hand-held power tools or transportable machinery, where the operator can check from any of the points to which he has access whether or not the electricity supply is connected. In that case, the removal of the electric plug is sufficient to ensure isolation from the energy source.

The third paragraph of section 1.6.3 requires machinery to be fitted with means to dissipate any stored energy that could put the operators at risk. Such stored energy may include, for example, kinetic energy (inertia of moving parts), electrical energy (capacitors) fluids under pressure, springs or parts of the machinery that may move due to their own weight.

The fourth paragraph of section 1.6.3 admits an exception to the requirements set out in the first three paragraphs, in cases where it is necessary to maintain the energy supply to certain circuits during maintenance operations in order to ensure safe working conditions. For example, it may be necessary to maintain the energy supply for stored information, for lighting, for the operation of tools or for the extraction of hazardous substances. In such cases, the energy supply must only be maintained to the circuits where it is needed and measures must be taken to ensure the safety of operators, such as, for example, preventing access to the circuits concerned or providing appropriate warnings or warning devices.

The manufacturer's instructions on safe adjustment and maintenance must include information on the isolation of energy sources, the locking of the isolator, the dissipation of residual energies and the verification of the safe state of the machinery – see §272: comments to section 1.7.4.2 (s).

General specifications for the means of isolation and locking for different sources of energy are given in standard EN 1037[200]. For the machinery in its scope, standard EN 60204-1[201] gives specifications for the reliable disconnection of the electrical supply.

A specific requirement relating to the disconnection of batteries on mobile machinery is set out in section 3.5.1.

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[200] EN 1037:1995+A1:2008 *Safety of machinery - Prevention of unexpected start-up.*

[201] EN 60204-1:2006+A1:2009 *Safety of machinery - Electrical equipment of machines* - Part 1: *General requirements* (IEC 60204-1:2005 (Modified)).

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.

§242 Operator intervention

The design and construction of the machinery and the fitting of devices and equipment in order to avoid or limit the need for operator intervention in danger zones is an effective way of reducing the associated risks. Where operator intervention cannot be entirely avoided, the machinery must be designed so that it can be carried 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.

§243 Cleaning of internal parts

The requirement set out in section 1.6.5 deals with an example of operator intervention mentioned in the previous section which can be particularly dangerous. Entering parts of machinery such as, for example, silos, tanks, containers or piping, that have contained dangerous substances or preparations can give rise to a risk of intoxication or asphyxia, both for the operators concerned and for persons attempting to rescue them.

The general rule set out in the first sentence of section 1.6.5 is that it must be possible to clean or unblock such parts from the outside so that it is not necessary to enter them. Where it is not possible to avoid entering such parts, the necessary protective measures must be taken, such as, for example, the fitting of an adequate ventilation system, the monitoring of the concentration of hazardous substances or of the lack of oxygen in the air and provisions for the surveillance and safe rescue of operators.

1.7 INFORMATION

§244 Information for users

Since the safe use of machinery depends on a combination of design and construction measures taken by the manufacturer and protective measures taken by the user, providing the necessary information and instructions to users is an essential and integral part of the design of the machinery.

Information, warnings and instructions about residual risks concern the third step of the three-step method set out in section 1.1.2 on the principles of safety integration. The fact

that this third step is the last in the order of priority implies that warnings and instructions must not be a substitute for inherently safe design measures and integrated protective measures when these are possible, taking into account the state of the art - see §174: comments on section 1.1.2 (b).

The requirements set out in sections 1.7.1 to 1.7.4 apply to machinery in the broad sense, that is to say to any of the products listed in Article 1 (1) (a) to (f) – see §33: comments on Article 2. For application of these requirements to partly completed machinery – see §390: comments on Annex VI.

1.7.1 Information and warnings on the machinery

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

§245 Information and warnings on the machinery

The requirements set out in section 1.7.1 concern the form of information and warnings that are part of the machinery. The first sentence of section 1.7.1 advises manufacturers to use readily understood symbols or pictograms for this purpose. Well-designed symbols or pictograms can be understood intuitively and avoid the need for the translation of written or verbal information.

The second sentence of section 1.7.1 applies when information is provided in the form of written words or text on the machinery, on a monitor screen or in the form of oral text provided, for example, by means of voice synthesiser. In such cases the information and warnings must be provided in the official language or languages of the Member States in which the machinery is placed on the market and/or put into service.

The user of machinery may also request the manufacturer to provide the information and warnings on the machinery or on monitor screens accompanied by versions in any other language or languages of the EU that are understood by the operators. This may be for various reasons, for example:

- the persons who are to use the machinery do not understand the official language of the Member State concerned;
- the machinery is to be used in a workplace that has a single working language other than the official language(s) of the Member State concerned;
- the machinery is to be used in one Member State and maintained by technicians from a different Member State;
- remote diagnostics are to be carried out in a Member State different from the Member State where the machinery is to be used.

Providing information or warnings on the machinery in EU languages other than the official language(s) of the Member State in which the machinery is placed on the market and/or put into service or in any other language(s) is a matter to be settled by contract between the manufacturer and the user when the machinery is ordered.

§246 *The official languages of the EU*

There are 24 official EU languages, used in the following Member States:

Austria	–	German	Italy	–	Italian
Belgium	–	Dutch, French and German	Latvia	–	Latvian
Bulgaria	–	Bulgarian	Lithuania	–	Lithuanian
Croatia	–	Croatian	Luxembourg	–	French and German
Cyprus	–	Greek	Malta	–	English and Maltese
Czech Republic	–	Czech	Netherlands	–	Dutch
Denmark	–	Danish	Poland	–	Polish
Estonia	–	Estonian	Portugal	–	Portuguese
Finland	–	Finnish and Swedish	Romania	–	Romanian
France	–	French	Slovakia	–	Slovak
Germany	–	German	Slovenia	–	Slovenian
Greece	–	Greek	Spain	–	Spanish
Hungary	–	Hungarian	Sweden	–	Swedish
Ireland	–	English and Irish (Gaelic)	United Kingdom	–	English

Certain of the Member States with two or more official languages (e.g. Belgium, Finland) accept the use of one language only in areas where only that language is spoken. Manufacturers are advised to check this with the national authorities concerned. Other Member States with two official languages (Malta and Ireland) accept the sole use of English.

In the other countries where the Machinery Directive applies in virtue of the European Economic Area (EEA) Agreement, the Mutual Recognition Agreement (MRA) between Switzerland and the EU-Turkey Customs Union, the national provisions implementing the Machinery Directive require the use of the official language(s) of the country concerned:

Iceland	–	Icelandic	Switzerland	–	French, German and Italian
Liechtenstein	–	German	Turkey	–	Turkish
Norway	–	Norwegian			

1.7.1.1 Information and information devices

The information needed to control machinery must be provided in a form that is unambiguous and easily understood. It must not be excessive to the extent of overloading the operator.

Visual display units or any other interactive means of communication between the operator and the machine must be easily understood and easy to use.

§247 *Information and information devices*

The requirement set out in section 1.7.1.1 applies to all information on the machinery which is needed to help operators to control its operation. In particular, it applies to the indicators and displays provided with control devices – see §194: comments on section 1.2.2. Such information is subject to the requirements set out in section 1.7.1.

Specifications for the design of information, information devices, indicators and displays are given in standards of the EN 894 series[202] and in standards of the EN 61310 series[203].

1.7.1.2 Warning devices

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

Where machinery is equipped with warning devices these must be unambiguous and easily perceived. The operator must have facilities to check the operation of such warning devices at all times.

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

§248 Warning devices

Section 1.7.1.2 deals with risks for persons due to faults in machinery or parts of machinery that are designed to operate without the permanent supervision of operators. The warning devices must be such as to inform the operators or other exposed persons of dangerous faults in order to enable the necessary action to protect persons at risk to be taken. Where appropriate, the warning devices can be fitted to the machinery itself or be activated at a distance.

Standard EN 61310-1 gives specifications for visual and acoustic signals.

The last paragraph of section 1.7.1.2 refers to Directive 92/58/EEC[204], which lays down minimum requirements for signs to be used at the workplace. The national regulations implementing that Directive do not therefore apply directly to machinery manufacturers. However, section 1.7.1.2 requires machinery manufacturers to comply with the technical requirements of that Directive in the interest of uniformity of safety signs in the workplace.

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[202] EN 894-1:1997+A1:2008 *Safety of machinery - Ergonomic requirements for the design of displays and control actuators* - Part 1: *General principles for human interactions with displays and control actuators;* EN 894-2:1997+A1:2008 *Safety of machinery - Ergonomics requirements for the design of displays and control actuators* - Part 2: *Displays*.

[203] EN 61310-1:2008 *Safety of machinery - Indication, marking and actuation* - Part 1: *Requirements for visual, acoustic and tactile signals* (IEC 61310-1:2007); EN 61310-2:2008 *Safety of machinery - Indication, marking and actuation* - Part 2: *Requirements for marking* (IEC 61310-2:2007).

[204] Council Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (ninth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) – see Annex VI: Minimum requirements for illuminated signs, and Annex VII: Minimum requirements for acoustic signs.

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.

§249 Warning of residual risks

The requirement set out in section 1.7.2 refers to residual risks, that is to say, risks that cannot be eliminated or sufficiently reduced by inherently safe design measures and that cannot be completely prevented by integrated protective measures – see §174: comments on section 1.1.2 (b). Warnings about residual risks on the machinery are complementary to the information about the residual risks to be given in the manufacturer's instructions – see §267: comments on section 1.7.4.2 (l). Warnings on the machinery are useful where operators or other exposed persons need to be informed of particular precautions to be taken with respect to residual risks during the use of the machinery such as, for example, the presence of hot surfaces or lasers. They can also be useful to recall the need to use PPE.

The warnings marked on the machinery shall comply with the requirements set out in section 1.7.1. The warnings provided by means of warning devices shall comply with the requirements set out in section 1.7.1.2.

C-type standards may define the form and provide guidance on the content of warnings. Additionally, Directive 92/58/EEC and standard EN 61310-1 include guidance that is relevant for the design of such warnings.

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.

. . .

§250 Marking of machinery

The first paragraph of section 1.7.3 deals with particulars that must be marked on all machinery, in addition to other information or warnings to users. Although the Directive does not specify any marking on partly completed machinery (PCM), it would be a good practice to mark PCMs with sufficient identity information to unambiguously link to their assembly instructions and their Declaration of Incorporation. Where a PCM is subject to other legislation (e.g. ATEX, LVD, etc.), it must be marked in accordance with the requirements of that other legislation. Apart from the CE marking and the ATEX marking, section 1.7.3 does not impose any particular form for the marking on the machinery, providing it is visible, legible and indelible. The marking must therefore be affixed in a place on the machine that is visible from the outside and not hidden behind or beneath parts of the machinery. Taking account of the size of the machinery, the characters used must be large enough to be read easily. The marking technique used must ensure that the marking will not be effaced during the lifetime of the machinery, taking account of the foreseeable conditions of use. If the marking is displayed on a plate, it should be permanently fixed to the machinery, preferably by welding, riveting or bonding.

In the case of products which are too small to bear a legible marking of the particulars required by section 1.7.3, the marking can be displayed on a durable label attached to the product (while ensuring that the correct functioning of the machinery is not affected).

Specific marking requirements for chains, ropes and webbing are set out in section 4.3.1 – see §357: comments on section 4.3.1.

The language requirements set out in section 1.7.1 do not apply to the particulars referred to the in first paragraph of section 1.7.3. However, these particulars should be written in one of the official EU languages.

The following comments refer to the six indents of the first paragraph of section 1.7.3:

- *the business name and full address of the manufacturer and, where applicable, his authorised representative*

The purpose of the requirement set out in the first indent of section 1.7.3 is to enable the user or the market surveillance authorities to contact the manufacturer in case of a problem – see §79 to §81: comments on Article 2 (i). The same information must be given in the EC Declaration of Conformity – see §383: comments on Annex II 1 A.

The term *'business name'* refers to the name under which the company concerned is registered.

The term *'full address'* means a postal address that is sufficient to enable a letter to reach the manufacturer. The name of the country or town alone is not sufficient. There is no obligation to mark the manufacturer's e-mail address or Website, although these can usefully be added.

The business name and full address of the authorised representative of the manufacturer established in the EU must also be marked on the machinery in cases where the manufacturer has mandated such an authorised representative – see §84 and §85: comments on Article 2 (j).

If it is not practicable to include in the marking the full address of the manufacturer or of his authorised representative, for example, in the case of very small machinery, this information be provided in the form of a code, provided that this code is explained and the full address is given in the instructions supplied with the machinery – see §259: comments on section 1.7.4.2 (b) and in the EC Declaration of Conformity of the machinery – see §383: comments on Annex II 1 A.

- *designation of the machinery*

The term *'designation of the machinery'* refers to the usual name of the category of machinery to which the specific model of machinery belongs (the term has a similar meaning to the terms 'generic denomination and function' used in Annex II with respect to the EC Declaration of conformity). Wherever possible, the term used to designate the category of machinery concerned in harmonised standards should be used. The same information must be given in the EC Declaration of conformity – see §383: comments on Annex II 1 A.

If it is not practicable to include in the marking an explicit designation of the machinery, for example, in the case of very small machinery, the designation can be provided in the form of a code, providing that this code is explained and the explicit designation is given in the instructions supplied with the machinery – see §259: comments on section 1.7.4.2 (b) and in the EC Declaration of conformity of the machinery – see §383: comments on Annex II 1 A.

The manufacture's designation of the machinery should not be construed as a basis for determining whether or not certain EHSRs or conformity assessment procedures are applicable, which must be determined independently.

- *the CE Marking (see Annex III)*

The requirements for the CE marking are set out in Article 16 and Annex III. According to Annex III, the CE marking must be affixed in the immediate vicinity of the name of the manufacturer or his authorised representative, using the same technique – see §141: comments on Article 16 and §387: comments on Annex III.

- *designation of series or type*

The designation of the series or type is the name, code or number given by the manufacturer to the model of machinery concerned that has been subject to the relevant conformity assessment procedure. The designation of the series or type often includes a trademark.

- *serial number, if any*

A serial number is a means of identifying an individual item of machinery belonging to a series or type. The Machinery Directive does not require machinery to bear a serial number, but where a serial number has been attributed by the manufacturer, it must be indicated after the designation of the series or type.

– *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.

The year of construction is defined as the year in which the manufacturing process is completed. For machinery that is assembled in the manufacturer's premises, the manufacturing process can be considered to be completed, at the latest, when the machinery leaves the manufacturer's premises to be transferred to an importer, a distributor or to the user.

For machinery that is only finally assembled at the user's premises, the manufacturing process can be considered to be completed when the assembly of the machinery on site has been completed and is ready to be put into service. The same applies for machinery manufactured outside the EU and finished within Europe. For machinery manufactured by the user for his own use, the manufacturing process can be considered to be completed when the machinery is ready to be put into service – see §80: comments on Article 2 (i).

In cases where used machinery, which has never previously been placed on (or put into service in) the EU market and is going to be placed on the EU market, the marking date to be applied is the one when the equipment crosses the border from outside into the EU market (to be put in conformity and sold). Where used machinery has been modified to such an extent it is considered 'new' - see §82: comments on Article 2(i), the marking date to be applied is the one when either the modified machinery is brought back into use or placed on the market for the first time after modification.

In addition to the general requirements on marking set out in section 1.7.3, additional requirements on marking for mobile machinery are set out in section 3.6.2; requirements on marking for chains, ropes and webbing, lifting accessories and lifting machinery are set out in section 4.3; additional requirements on marking for machinery for lifting persons are set out in section 6.5.

It should be noted that, on machinery subject to the Outdoor Equipment Directive 2000/14/EC, the CE marking is accompanied by the marking of the guaranteed sound power level – see §92: comments on Article 3, and §271: comments on section 1.7.4.2 (u).

1.7.3 Marking of machinery (continued)

. . .

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

. . .

§251 Conformity marking for ATEX Machinery

The third paragraph of section 1.7.3 applies to machinery that is subject to the ATEX Directive 2014/34/EU[205] in addition to the Machinery Directive – see §91: comments on Article 3, and §228: comments on section 1.5.7. The CE marking signifies the conformity of the machinery with the applicable EU Directives that provide for its affixing – see §141: comments on Article 16. In addition to the CE marking, the ATEX Directive provides for a specific marking for explosion protection (the "εx", epsilon-x, marking or "the hexagon"):

The ATEX marking is followed by the symbol of the equipment group and category. Note that although this section does not directly apply to Partly Completed Machinery, if the PCM is covered by the ATEX directive it must bear the εx mark and also be CE-marked under the ATEX Directive.

> ***1.7.3 Marking of machinery (continued)***
>
> *. . .*
>
> *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.*
>
> *. . .*

§252 Information essential for safe use

The fourth paragraph of section 1.7.3 requires the machinery to bear the necessary information essential for its safe use. This information is subject to the requirements relating to pictograms and language set out in section 1.7.1. The requirement relating to information and information devices set out in 1.7.1.1 should also be taken into consideration.

The manufacturer is not expected to mark on the machinery all the information for safe use provided in the instructions. However, information concerning essential aspects of safe use must be marked on the machinery, such as, for example, the maximum dimensions of workpieces, the maximum dimensions of the tools to be used, the maximum slope on which the machinery is stable, the maximum wind speed and so on. The information to be marked on the machinery is usually specified in the relevant harmonised standards.

[205] Directive 2014/34/EU of the European Parliament and the Council of 26 February 2014 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (recast). OJ L 96, 29.3.2014, p. 309.

1.7.3 Marking of machinery (continued)

. . .

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

§253 Marking parts of the machinery to be handled with lifting equipment

The requirement set out in the last paragraph of section 1.7.3 is complementary to the requirements relating to the design of machinery to facilitate its handling – see §180: comments on section 1.1.5. It applies to parts of machinery that have to be handled during use, the weight, size or shape of which prevent them from being moved by hand. The requirement is to be applied in the light of an analysis of the different phases of the lifetime of the machinery concerned – see §173: comments on section 1.1.2 (a).

The mass must be marked on such parts in order to enable the user to employ lifting machinery with a sufficient lifting capacity. In order to avoid ambiguity, the mass should be marked in kilograms in a visible place on the part concerned, preferably in the immediate vicinity of the attachments for the lifting machinery.

1.7.4 Instructions

All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service.

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.

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.

The instructions must be drafted in accordance with the principles set out below.

§254 Instructions

Section 1.7.4 deals with one of the obligations to be fulfilled by the manufacturer before machinery is placed on the market and/or put into service – see §103: comments on Article 5 (1).

The first paragraph of section 1.7.4 states that the manufacturer's instructions must accompany the machinery. This entails that the instructions must be drawn up before the machinery is placed on the market and/or put into service and must accompany the machinery until it reaches the user. Importers or distributors of machinery must therefore ensure that the instructions are passed on to the user – see §83: comments on Article 2 (i).

In addition to the general requirements for instructions set out in sections 1.7.4, supplementary requirements for instructions are set out in the following sections:

- sections 2.1.2, 2.2.1.1, 2.2.2.2 and 2.4.8 - foodstuffs machinery and machinery for cosmetics or pharmaceutical products, portable hand-held and hand-guided machinery and portable fixing and other impact machinery; and machinery for pesticide application;
- sections 3.6.3.1 and 3.6.3.2 - mobile machinery and machinery with multiple uses;
- sections 4.4.1 and 4.4.2- lifting accessories and lifting machinery.

§255 The form of the instructions

Section 1.7.4 does not specify the form of the instructions. It is generally agreed that all health and safety related instructions must be supplied in paper form, since it cannot be assumed that the user has access to the means of reading instructions supplied in electronic form or made available on an Internet site. However, it is often useful for the instructions to be made available in electronic form and on the Internet as well as in paper form, since this enables the user to download the electronic file if he so wishes and to recover the instructions if the paper copy has been lost. This practice also facilitates the updating of the instructions when this is necessary.

§256 The language of the instructions

As a general rule, all health and safety related instructions must be supplied in the official EU language or languages of the Member State in which it is placed on the market and/or put into service – see §246: comments on section 1.7.1.

The second paragraph of section 1.7.4 should be understood in light of section 1.7.4.1. Machinery must be accompanied by original instructions, that is to say, instructions verified by the manufacturer or his authorised representative. If original instructions are not available in the language(s) of the Member State in which the machinery is placed on the market and/or put into service, machinery must be accompanied by a translation of the original instructions together with the original instructions. The purpose of the latter requirement is to enable users to check the original instructions in case of doubt about the accuracy of a translation.

The third paragraph of section 1.7.4 foresees this exception to the general requirement set out in the first paragraph relating to the language of instructions. Instructions that are exclusively intended for such specialised personnel do not necessarily have to be supplied in the language(s) of the country of use but can be supplied in a language understood by the specialised personnel.

This derogation does not apply to instructions for maintenance operations that are to be carried out by the user or by maintenance personnel mandated by the user. For the derogation to be applicable, the manufacturer's instructions to the user must therefore specify clearly which maintenance operations are only to be carried out by specialised personnel mandated by the manufacturer or his authorised representative.

1.7.4.1 General principles for the drafting of instructions

(a) The instructions must be drafted in one or more official Community languages. The words 'Original instructions' must appear on the language version(s) verified by the manufacturer or his authorised representative.

(b) Where no 'Original instructions' exist in the official language(s) of the country where the machinery is to be used, a translation into that/those language(s) must be provided by the manufacturer or his authorised representative or by the person bringing the machinery into the language area in question. The translations must bear the words 'Translation of the original instructions'.

. . .

§257 The drafting and translation of instructions

Paragraphs (a) and (b) of section 1.7.4.1 explain in more detail how the language requirements set out in section 1.7.4 must be fulfilled.

Paragraph (a) of section 1.7.4.1 explains that the original instructions are the language versions of the instructions that have been verified by the manufacturer or his authorised representative. These language versions must bear the words *'Original instructions'* (in the language of each version). The manufacturer may provide *"Original Instructions"* in one or more languages.

Paragraph (b) of section 1.7.4.1 deals with the situation where machinery is placed on the market in a Member State for which the manufacturer or his authorised representative has not prepared original instructions. This may occur, for example, if an importer, a distributor or a user takes the initiative to place the machinery on the market or put it into service in a Member State not initially foreseen by the manufacturer. In such cases, a translation of the instructions into the official EU language(s) of the Member State concerned must be provided by the manufacturer or his authorised representative or by the person bringing the machinery into the language area in question.

In practical terms, this requirement entails that the person bringing the machinery into the language area in question must either obtain a translation from the manufacturer or his authorised representative or, failing that, translate the instructions himself or have them translated – see §83: comments on Article 2 (i).

The translations must bear the words *'Translation of the original instructions'* (in the language of each version) and must be accompanied by original instructions – see §254: comments on section 1.7.4.

1.7.4.1 General principles for the drafting of instructions (continued)

. . .

(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.

. . .

§258 Preventing foreseeable misuse

Paragraph (c) of section 1.7.4.1 underlines that the instructions are one of the means for preventing the misuse of machinery. This implies that when drafting instructions on each of the aspects listed in section 1.7.4.2, manufacturers must take account of knowledge about how the machinery is liable to be misused, in the light of experience of past use of similar machinery, accident investigations and knowledge about readily predictable human behaviour – see §172: comments on section 1.1.1 (i), and §175: comments on section 1.1.2 (c).

> ***1.7.4.1 General principles for the drafting of instructions (continued)***
>
> . . .
>
> *(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.*

§259 Instructions for non-professional users

Paragraph (d) of section 1.7.4.1 makes a distinction between machinery intended for non-professional operators and machinery intended for professional use. The wording and layout of the instructions must be adapted to the public to whom they are addressed. Instructions for non-professional users must be written and presented in language that is understandable to laypersons, avoiding specialist technical terminology. This requirement is also relevant for machinery that may be used both by professionals and non-professionals.

Where machinery intended for consumer use is supplied with certain elements dismounted for transport and packaging purposes, particular attention must be given to ensure that the mounting instructions are complete and explicit and include clear, accurate and unambiguous diagrams, drawings or photographs – see §264: comments on section 1.7.4.2 (i).

The C-type standards for particular categories of machinery specify the content of the instructions but generally do not provide guidance on the drafting and layout. General guidance on the drafting of instructions is given in standard EN ISO 12100[206]. Although it is not a harmonised standard under the Machinery Directive, the guidance given in standard EN 62079[207] on the drafting and layout of instructions may also be useful for machinery instructions.

[206] EN ISO 12100:2010 *Safety of machinery - General principles for design. Risk assessment and risk reduction.*.

[207] EN 62079:2001 *Preparation of instructions - Structuring, content and presentation*.

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);

. . .

§260 Contents of the instructions – particulars of the manufacturer and the machinery

Section 1.7.4.2 summarises the main aspects that must be covered in the manufacturer's instructions. The expression *'at least'* indicates that the list is not to be taken as exhaustive. Thus, if any information not mentioned in sections 1.7.4.2 (a) to (v) is needed for the safe use of the machinery, it must be included in the instructions. The expression *'where applicable'* means that the aspects mentioned in sections 1.7.4.2 (a) to (v) only need to be covered in the instructions if they are relevant for the machinery concerned.

The particulars mentioned in section 1.7.4.2 are the same as the particulars to be marked on the machinery – see §250: comments on 1.7.3. However, in the instructions, the designation of the machinery must be written in full in the language of the instructions. The serial number is not required, since the manufacturer's instructions usually cover a model or type of machinery rather than an individual product.

Where a model of machinery has several variants, it must be made clear to the user which specific parts of the instructions apply to each variant. Similarly, if the instructions cover more than one model or type, for example, if they cover several models or types of machinery belonging to the same series, it must be made clear to the user which specific parts of the instructions apply to each model or type.

1.7.4.2 Contents of the instructions (continued)

. . .

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;

. . .

§261 Inclusion of the EC Declaration of Conformity in the instructions

Section 1.7.4.2 (c) concerns the inclusion of the EC Declaration of Conformity in the instructions. Like the instructions, the EC Declaration of Conformity must accompany the machinery – see §103: comments on Article 5 (1). In order to fulfil this obligation, the manufacturer can choose between the two following alternatives:

- the signed EC Declaration of Conformity is included in the instruction handbook. This is appropriate in the case of one-off products or machinery produced in small numbers;
- a document setting out the contents of the EC Declaration of Conformity (not necessarily including the serial number and the signature) is included in the instruction handbook, in which case the signed EC Declaration of Conformity itself must be provided separately – see §382: comments on Annex II 1 A.

1.7.4.2 Contents of the instructions (continued)

. . .

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;

. . .

§262 Descriptions, drawings, diagrams and explanations

The general description of the machinery mentioned in section 1.7.4.2 (d) aims to enable the user to identify the main parts of the machinery and their functions.

Section 1.7.4.2 (e) deals with the information and explanations necessary for safe use, maintenance and repair of the machinery and for checking its correct functioning. (More detailed requirements on the content of the instructions relating to these aspects are set out in the following sections). Clear and simple drawings, diagrams, graphs and tables are usually preferable to long written explanations. However, the necessary written explanations should be placed adjacent to the illustrations to which they refer.

Where the machine or partly completed machinery is also under the ATEX Directive the instructions need to address the precautions in maintenance and replacement of parts so that the integrity with respect to ATEX is not compromised.

Section 1.7.4.2 (f) deals with the workstations foreseen for operators. Aspects to be covered include, for example:

- the location of workstations,
- the adjustment of seats, footrests or other parts of the machinery in order to ensure a good posture and reduce vibrations transmitted to the operator – see §183: comments on section 1.1.8;
- the layout and identification of the control devices and their functions – see §185: comments on section 1.2.2;
- the different operating or control modes and the protective measures and precautions relating to each mode – see §204: comments on section 1.2.5;
- use of the guards and protective devices fitted to the machinery;

– use of equipment fitted to contain or evacuate hazardous substances or to maintain good working conditions.

1.7.4.2 Contents of the instructions (continued)

. . .

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

. . .

§263 Intended use and foreseeable misuse

The description of the intended use of the machinery referred to in section 1.7.4.2 (g) must include a precise indication of the purposes for which the machinery is intended. The description of the intended use of the machinery must specify the limits on the conditions of use taken into account in the manufacturer's risk assessment and in the design and construction the machinery – see §171: comments on section 1.1.1 (h).

The description of the intended use of the machinery must cover all the different operating modes and phases of use of the machinery and specify safe values for the parameters on which the safe use of the machinery depends. Such parameters may include, for example:

– the maximum load for lifting machinery;

– the maximum slope on which mobile machinery can be used without loss of stability;

– the maximum wind-speed in which machinery can be safely used outdoors;

– the maximum dimensions of workpieces;

– the maximum speed for rotating tools where break-up due to overspeed is a hazard;

– the type of materials that can be safely processed by the machinery.

Section 1.7.4.2 (h) requires the manufacturer's instructions to provide warnings against reasonably foreseeable misuse of the machinery – see §172: comments on section 1.1.1 (i), and §175: comments on section 1.1.2 (c). To avoid such misuse, it is helpful to indicate to the user the usual reasons for such misuse and to explain the possible consequences. The warnings against reasonably foreseeable misuse of the machinery should take account of feedback from users and information about accidents or incidents involving similar machinery.

1.7.4.2 Contents of the instructions (continued)

. . .

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;

. . .

§264 Assembly, installation and connection

Section 1.7.4.2 (i) covers operations to be carried out by or on behalf of the user before the machinery is put into service.

Assembly instructions are necessary for machinery that is not supplied to the user ready to use, for example, where elements of the machinery have been disassembled for transport or packaging purposes. Particular attention must be given to assembly instructions where assembly is to be carried out by non-professional users – see §258: comments on section 1.7.4.1 (c).

Assembly instructions for interchangeable equipment must specify the type or types of basic machinery with which the equipment can be safely used and include the necessary instructions for the safe assembly of the interchangeable equipment with the basic machinery by the user – see §41: comments on Article 2 (b).

In the case of machinery supplied without a drive system, the instructions must indicate all the necessary specifications for the drive system to be fitted such as the type, power and means of connection, and include precise fitting instructions for the drive system – see §35: comment on the first indent of Article 2 (a).

Installation instructions are necessary for machinery that has to be installed on and/or fixed to particular supports, structures or buildings, on foundations or on the ground, in order to ensure its safe use and stability. The instructions must specify the requisite dimensions and load bearing characteristics of the supports and the means to be used to fix the machinery to its supports. For machinery intended to be installed on means of transport, the instructions must specify the vehicles or trailers on which the machinery can be safely installed, either by reference to their technical characteristics or, where necessary, by reference to specific models of vehicle – see §37: comments on the third indent of Article 2 (a).

Connection instructions must describe the measures to be used to ensure safe connection of the machinery to energy supplies, supplies of fluids and so on. The relevant characteristics of the supplies, such as, for example, voltage, power, pressure or temperature, must be specified. The safe connection of the machinery to the means of evacuating hazardous substances must also be specified, when these means are not an integral part of the machinery.

Paragraph 1.7.4.2 (j) refers to a specific aspect of the installation and assembly instructions relating to the reduction of noise or vibration emissions.

With respect to noise, the instructions must specify, where appropriate, the correct assembly and installation of equipment supplied by the machinery manufacturer to reduce noise emission.

With respect to vibrations, the instructions may include, for example, specifications for foundations with adequate damping characteristics.

1.7.4.2 Contents of the instructions (continued)

. . .

k) instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators;

. . .

§265 Putting into service and use

Section 1.7.4.2 (k) refers first to instructions relating to the putting into service of the machinery – see §86: comments on Article 2 (k).

The instructions for putting into service shall indicate all of the necessary adjustments, checks, inspections or functional tests to be carried out after the machinery has been assembled and installed and before it is put into service. Any particular procedures to be followed should be described. The same information shall be provided for putting machinery back into service, for example, following transfer to a new site or after major repairs.

The second aspect of the instructions referred to in section 1.7.4.2 (k) relates to the use of the machinery. The instructions must deal with the different phases of the use of the machinery. The instructions shall cover, as appropriate:

- normal operation, setting and adjustment of the machinery;
- the correct use of control devices, guards and protective devices;
- the use of special tools or equipment provided with the machinery – see §117: comments on section 1.1.2 (e);
- the selection and safe use of all operating or control modes – see §204: comments on section 1.2.5;
- particular precautions to be taken in specific conditions of use.

§266 Operator training

The third aspect referred to in section 1.7.4.2 (k) is operator training. The machinery manufacturer must indicate whether specific training is needed to use the machinery safely. Normally, this is only appropriate in the case of machinery intended for professional use.

The manufacturer is not expected to provide a full training program or training manual in the instructions. However, the instructions may indicate important aspects to be covered by the operator training in order to help employers to fulfil their obligations to provide appropriate training to operators. In this respect, it should be noted that, for certain

categories of machinery, operator training and training programmes may be subject to national regulations implementing Directive 2009/104/EC – see §140: comments on Article 15.

In addition to the basic information on training in the instructions, certain machinery manufacturers also offer operator training services to users, however such services are outside the scope of the Machinery Directive.

1.7.4.2 Contents of the instructions (continued)

. . .

l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;

m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;

. . .

§267 Information about residual risks

Sections 1.7.4.2 (l) and (m) deal with an important aspect of third step of the principles of safety integration – see §174: comments on section 1.2.2 (b). According to section 1.7.4.2 (l), the instructions must include clear statements relating to any risks that have not been sufficiently reduced by inherently safe design measures or by integrated technical protective measures.

The purpose of this information is to enable the user to take the necessary protective measures mentioned in section 1.7.4.2 (m). The measures to be specified in the instructions may include, for example:

- the use of additional screens or guards in the workplace;
- the organisation of safe systems of work;
- the restriction of certain tasks to trained and authorised operators;
- the provision and use of appropriate personal protective equipment (PPE).

It should be noted that the selection, provision and use of PPE are under the responsibility of employers and are subject to national provisions implementing Directive 89/656/EEC[208]. However, the machinery manufacturer's instructions may indicate the type of PPE to be used to protect against residual risks arising from the machinery. In particular, if the machinery is fitted with anchorage devices for the attachment of PPE against falls from a height, the compatible PPE must be specified – see §237: comments on section 1.5.15, and §374: comments on section 6.3.2.

[208] Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC). OJ L 393, 30.12.1989, p. 18.

1.7.4.2 Contents of the instructions (continued)

. . .

n) the essential characteristics of tools which may be fitted to the machinery;

. . .

§268 The essential characteristics of tools

Section 1.7.4.2 (n) deals with instructions relating to tools which are items that the machine uses to carry out a task, and are not in themselves machinery or partly completed machinery, such as drill or router bits, simple digging buckets (powered clamshell buckets and attachments are considered part of the machine or interchangeable equipment and not tools), cutting heads, sanding disks, that are not permanently fixed to the machinery and that may be changed by the user. Such tools are not considered as part of the machinery – see §41: comments on Article 2 (b) - however the safe use of the machinery frequently depends on the fitting and use of appropriate tools. The instructions must therefore specify the characteristics of the tools on which safe use depends. This is particularly important for fast moving or fast rotating tools, in order to avoid risks due to the break-up and ejection of fragments of tools or due to the ejection of the tools themselves – see §207 and §208: comments on sections 1.3.2 and 1.3.3.

The essential characteristics to be specified may include, for example:

- the maximum or minimum dimensions and mass of tools;
- the constituent materials and assemblies of tools;
- the requisite shape or other essential design features of tools;
- the compatibility of the tools with the tool-holders on the machinery.

1.7.4.2 Contents of the instructions (continued)

. . .

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;

. . .

§269 Stability conditions

Section 1.7.4.2 (o) is linked to the requirements set out in sections 1.3.1, 2.2.1, 3.4.1, 3.4.3, 4.1.2.1, 4.2.2, 5.1 and 6.1.2 relating to stability. Where the design and construction of the machinery ensures the stability of the machinery under certain defined conditions, these must be specified in the instructions.

In particular, where stability depends on the observance of certain limits on the conditions of use of the machinery such as, for example, the maximum slope, the maximum wind speed, the maximum reach or the position of certain elements of the machinery, these limits must be specified and the necessary explanations must be given

on the use of the corresponding protective and warning devices fitted to the machinery and on how to avoid hazardous situations.

The instructions must also explain how to ensure the stability of the machinery or its parts during other phases of the lifetime of the machinery – see §173: comments on section 1.1.2 (a). Where particular measures, such as orientation during transport, configuration mode for transport or maintenance or use of carrying cradles, are needed to ensure stability during these phases, the measures to be taken and the means to be used must also be specified.

1.7.4.2 Contents of the instructions (continued)

. . .

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;

. . .

§270 Transport, handling and storage

Section 1.7.4.2 (p) is linked to the requirements relating to the handling of the machinery and its parts – see §180: comments on section 1.1.5.

The instructions for safe transport, handling and storage of the machinery and of parts that are to be transported separately shall include, as appropriate:

- instructions for safe manual handling of machinery or parts that are to be moved by hand;
- instructions on the use of attachment points for lifting machinery, the mass of the machinery and of the parts to be transported;
- instructions on how to ensure stability during transport and storage, including the use of any special equipment provided for that purpose;
- a description of the special arrangements for the handling of hazardous tools or parts.

1.7.4.2 Contents of the instructions (continued)

. . .

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;

. . .

§271 Emergency procedures and methods for unblocking

Section 1.7.4.2 (q) requires the machinery manufacturer to anticipate potential malfunctioning of the machinery and to specify the procedures to be followed to deal with emergencies. The measures to be specified, include, for example, the methods to

be used to rescue injured persons, to summon help or to rescue trapped persons – see §236: comments on section 1.5.14.

The instructions must also describe the method to be followed in case of a blockage of moving parts and explain the use of any special protective devices or tools provided for that purpose – see §212: comments on section 1.3.7.

1.7.4.2 Contents of the instructions (continued)

. . .

r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed;

s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;

t) the specifications of the spare parts to be used, when these affect the health and safety of operators;

. . .

§272 Adjustment, maintenance and spare parts

Section 1.7.4.2 (r) requires the manufacturer to describe the adjustment and maintenance operations to be carried out by the user.

In particular, the instructions must specify the adjustment and maintenance operations that must be carried out and indicate their frequency. The instructions must list the elements or parts of the machinery that must be regularly checked in order to detect excessive wear, the periodicity of these checks (in terms of duration of use or number of cycles), the nature of the necessary inspections or tests and the equipment to be used. Criteria must be given for the repair or replacement of worn parts – see §207: comments on section 1.3.2.

Section 1.7.4.2 (s) is linked to the requirements set out in sections 1.6.1 to 1.6.5 relating to maintenance. The instructions must specify the necessary methods and procedures to be followed in order to ensure that adjustment and maintenance operations can be carried out safely. The appropriate protective measures and precautions to be taken during maintenance operations must be indicated. The instructions shall include, as appropriate:

- information on the isolation of energy sources, the locking of the isolator, the dissipation of residual energies and the verification of the safe state of the machinery – see §241: comments on section 1.6.3;
- measures to ensure safety for maintenance operations that must be carried out while the machinery is operating;
- methods to be used to safely remove or replace components – see §239: comments on section 1.6.1;

- precautions to be taken when cleaning internal parts which have contained hazardous substances – see §243: comments on section 1.6.5;
- means of access to be used for exceptional repairs – see §240: comments on section 1.6.2.

Section 1.7.4.2 (t) refers to information about spare parts. In general, the supply of spare parts and the supply of a spare parts list are not covered by the provisions of the Machinery Directive and is thus a matter for contractual agreement between the manufacturer and the user. However, where parts subject to wear and tear need to be replaced in order to protect the health and safety of users, the specifications of the appropriate spare parts must be given in the instructions. Examples of such spare parts include:

- guards for removable mechanical transmission devices – see §319: comments on section 3.4.7;
- flexible guards subject to wear and tear – see §216: comments on section 2.4.1;
- filters for systems to provide clean air to operating positions – see §182: comments on section 1.1.7, and §322: comments on section 3.5.3;
- load bearing components on lifting machinery – see §340 and §341: comments on sections 4.1.2.4 and 4.1.2.5;
- guards and their fixing systems used to retain ejected objects or parts of machinery – see §216: comments on section 1.4.1.

1.7.4.2 Contents of the instructions (continued)

. . .

u) the following information on airborne noise emissions:

- *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).*

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

In the case of 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.

Where the harmonised standards are not applied, sound levels must be measured using the most appropriate method for the machinery. Whenever sound emission values are indicated the uncertainties surrounding these values must be specified. The operating conditions of the machinery during measurement and the measuring methods used must be described.

Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at a height of 1,6 metres from the floor or access platform. The position and value of the maximum sound pressure must be indicated.

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;

. . .

§273 The noise emission declaration

Section 1.7.4.2 (u) sets out the information on airborne noise emission to be stated in what is currently called the noise emission declaration. This declaration has two main purposes:

- to assist users to choose machinery with reduced noise emission;

– to provide information useful for the risk assessment to be carried out by the employer according to the national provisions implementing Article 4 of Directive 2003/10/EC on the exposure of workers to the risks arising from noise[209].

In this respect, it should be recalled that the manufacturer's noise emission declaration only provides information about the contribution of the machinery itself to noise in the workplace. The level of exposure of workers cannot be simply deduced from the machinery manufacturer's noise emission declaration, since the exposure of operators is also influenced by other factors – see §229: comments on section 1.5.8.

The information to be provided in the noise emission declaration includes three different noise emission quantities:

1. The A-weighted emission sound pressure level, L_{pA}, produced by the machinery at its workstation(s). This is the average A-weighted sound pressure level over a specific time, representative of a full work cycle of the machinery. Being an emission value, it excludes contributions from the environment of the machinery such as reflections of noise from walls or noise from other sources at the workplace.

   This quantity must be determined by measurement for all machinery using an appropriate test code, whether or not the machinery is considered noisy. If the measured value does not exceed 70 dB(A), the instructions must state this. If the measured value exceeds 70 dB(A), the measured value must be stated in the instructions.

2. The peak C-weighted instantaneous sound pressure value, also known as the C-weighted peak sound pressure level, L_{pCpeak}. This is the maximum value reached by the C-weighted sound pressure over a specific duration representative of a full work cycle of the machine.

   This value is relevant for machinery that emits strongly impulsive noise. It only has to be stated in the instructions if the measured value exceeds 63 Pa (130 dB in relation to 20 µPa).

3. The A-weighted sound power level, L_{WA}. This quantity represents the airborne sound energy radiated by the machine in space and thus characterises the machine as a noise source. It is the most important noise emission quantity and is independent of the environment in which the machine is placed.

   Since the measurement of the L_{WA} may be complex, this value only has to be measured and stated in the instructions if the L_{pA} at any of the workstations exceeds 80 dB(A).

The second paragraph of section 1.7.4.2 (u) implies that, in the case of series production, testing can be carried out on a representative sample of technically comparable machinery. In the case of one-off production, the manufacturer must determine by measurement the noise emission for each item of machinery supplied.

[209] Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (Seventeenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC). OJ L 42, 15.2.2003, p. 38 – see, in particular, Article 4 (6) (f).

The third paragraph of section 1.7.4.2 (u) deals with the case of very large machinery for which the determination of the sound power level, L_{WA}, can be excessively complex. To determine whether a given category of machinery is to be considered as very large, consideration shall be given both to the distribution and directivity of the sound sources on the machinery and the effort required effort to determine the sound power level, L_{WA}. Whether a given category of machinery is to be considered as very large is to be stated in the relevant noise test code. For such very large machinery, the statement of the L_{WA} can be replaced by a statement of the emission sound pressure levels, L_{pA}, at specified positions around the machinery.

The fourth paragraph of section 1.7.4.2 (u) concerns the methods to be used for measuring noise emission. Operating conditions have a strong influence on noise emission. Measurement of noise emission should therefore be carried out under conditions which are reproducible and representative of the foreseeable conditions of use of the machinery. Where a test code specified in a harmonised standard states the operating conditions under which the measurement is to be made, a reference to the harmonised standard is sufficient to indicate the operating conditions and measurement methods used. Where other test methods are used, the operating conditions and measurement methods used must be indicated in the noise emission declaration.

The fourth paragraph of section 1.7.4.2 (u) also requires the uncertainties surrounding the measured values to be specified in the noise emission declaration. Current technical knowledge does not allow the uncertainty associated with the measurement of L_{pCpeak} values to be determined. Guidance on determining the uncertainty associated with the measurement of the L_{pA} at workstations and the L_{WA} should be given in the relevant test codes.

The fifth paragraph of section 1.7.4.2 (u) explains how to determine by measurement the emission sound pressure level, L_{pA}, at workstations for machinery where the operators do not occupy well-defined workstations. If the method set out in this paragraph is used, the noise emission declaration must indicate where the L_{pA} values have been measured.

The last paragraph of section 1.7.4.2 (u) refers to the Outdoor Noise Directive 2000/14/EC[210]. For the machinery in its scope, the Outdoor Noise Directive applies, in addition to the Machinery Directive, with respect to noise emissions in the environment – see §92: comments on Article 3.

The Outdoor Noise Directive requires the equipment in its scope to bear a marking, accompanying the CE marking, indicating the guaranteed sound power level (which is the value of the sound power level measured according to the method set out in Annex III of the Directive, plus the value of the uncertainties due to production variation and measurement procedures).

The last paragraph of section 1.7.4.2 (u) means that, for machinery in the scope of the Outdoor Noise Directive, the third value to be indicated in the noise emission declaration in the instructions is the guaranteed sound power level rather than the measured sound

[210] Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors. OJ L 162, 3.7.2000, p. 1.

power level, L_{WA}. However, the requirements set out in the first paragraph of section 1.7.4.2 (u) concerning the A-weighted emission sound pressure level, L_{pA}, and the C-weighted peak sound pressure level, L_{pCpeak}, remain applicable to such machinery.

1.7.4.2 Contents of the instructions (continued)

. . .

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.

§274 Implantable medical devices

The requirement set out in section 1.7.4.2 (v) deals with the particular case of residual risk due to non-ionising radiation – see §232: comments on section 1.5.10. Information on the nature of such radiation emission must be provided, particularly if it is likely to affect the functioning of implantable medical devices.

1.7.4.3 Sales literature

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

§275 Sales literature

While the instructions provided with the machinery are primarily intended to ensure safe use of the machinery, sales literature has a principally commercial function. However, section 1.7.4.3 requires that the instructions and commercial documents relating to the machinery be consistent. This is particularly important with respect to the intended use of the machinery referred to in section 1.7.4.2 (g), since users are likely to choose machinery for their purposes on the basis of sales literature.

The second sentence of section 1.7.4.3 is intended to help users to choose machinery with reduced levels of emissions of noise, vibrations, harmful radiation or hazardous substances. In particular, the values included in the noise emission declaration required by section 1.7.4.2 (u) and the information on vibrations required by sections 2.2.1.1 and 3.6.3.1 must be included in commercial documents giving the performance characteristics of the machinery. Many sales brochures or catalogues include a section or table giving the principle performance characteristics of the machinery such as power, speed, capacity, production rate and so on, to enable potential customers to choose machinery appropriate to their needs. This section is the appropriate place to include the required information on emissions.

Sales literature is not intended to be controlled by Notified Bodies during EC-Type certification. However, if the manufacturer introduces that kind of document in the

technical file of the machine (see §391: comments on Annex VII), the Notified Body shall examine it.

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

Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics and machinery for pesticide application must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).

§276 Supplementary requirements for certain categories of machinery

Part 2 of Annex I sets out supplementary EHSRs for a number of specific categories of machinery, laid out in four sub-sections. A section on "machinery for pesticide application" was added by Directive 2009/127/EC[211].

These sections apply to such machinery in addition to the relevant requirements of Part 1 of Annex I and, where applicable, of the other Parts of Annex I – see §163: comments on General Principle 4.

2.1. FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS

2.1.1. General

Machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.

The following requirements must be observed:

(a) materials in contact with, or intended to come into contact with, foodstuffs or cosmetics or pharmaceutical products must satisfy the conditions set down in the relevant Directives. The machinery must be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible disposable parts must be used;

(b) all surfaces in contact with foodstuffs or cosmetics or pharmaceutical products, other than surfaces of disposable parts, must:

- *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*

[211] Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application. OJ L 310, 25.11.2009, p. 29.

thorough cleaning;

(c) it must be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery (if possible, in a 'cleaning' position);

(d) machinery must be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot be cleaned;

(e) machinery must be designed and constructed in such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery must be designed and constructed in such a way that continuing compliance with this requirement can be checked.

2.1.2. Instructions

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.

§277 Hygiene requirements for machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products

The requirements set out in section 2.1 apply to machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products. The requirements apply whether the foodstuffs or products concerned are for human or animal consumption. The machinery concerned includes, for example, machinery for the manufacture, preparation, cooking, processing, cooling, handling, storage, transport, conditioning, packaging and distribution of foodstuffs, cosmetics and pharmaceutical products.

The requirements set out in section 2.1.1 (a) to (e) aim to avoid any hazardous contamination of the foodstuffs, cosmetics or pharmaceutical products from the materials used to constitute the machinery, from the environment of the machinery or from ancillary substances used with the machinery.

These requirements shall be applied in conjunction with the EHSRs set out in section 1.1.3 relating to materials and products, section 1.5.13 relating to emissions of hazardous materials and substances, and section 1.6 relating to maintenance.

Section 2.1.1 (a) deals with the constituent materials of the machinery that are intended to come into contact with the foodstuffs, cosmetics or pharmaceutical products.

The *'relevant Directives'* referred to in section 2.1.1 (a) include:

- Regulation (EC) No 1935/2004[212] on materials and articles intended to come into contact with food;

[212] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and

- Directive 84/500/EEC[213] on ceramic articles to come into contact with foodstuffs;
- Regulation (EC) No 10/2011[214] on plastic materials and articles intended to come into contact with foodstuffs.

It depends on the category of machinery (intended for use with foodstuffs or with cosmetics or pharmaceutical products) and the scope of the legal acts in the list above, whether a legal act is a "relevant legislation" or not. For example, for a machine intended for use with cosmetics, the EU legal act on materials intended to come into contact with foodstuffs is not a "relevant Directive". Since the list above is non-exhaustive, other EU legal acts could be relevant.

Where the materials intended to be in contact with foodstuffs incorporated into machinery are accompanied by a written declaration (such as the Declaration of compliance foreseen by Article 16 of Regulation (EC) No 1935/2004) that declaration must be included in the technical file for the machinery according to the ninth indent of Annex VII A 1 (a). By his signature on the EC Declaration of Conformity, the manufacturer states that all contact materials in the machine are in compliance with the relevant legislation (e.g. Regulation 1935/2004), and that the documentation is kept in the technical file and will be forwarded to the relevant authority on due request.
Such declarations should not be mentioned in the EC Declaration of Conformity of the machinery.

Sections 2.1.1 (b) and (c) require the machinery to be designed and constructed to facilitate complete and thorough cleaning and to enable substances that could contaminate the foodstuffs, cosmetics or pharmaceutical products, such as, for example, waste, cleaning products, disinfectants or rinsing products, to be completely discharged or drained. Where pipes or hoses are used to convey foodstuffs, cosmetics or pharmaceutical products, they may be connected by screw threads, provided the threads are isolated from the product flow, for example, by means of appropriate seals or rings, so they are not in direct contact with the product being processed.

Section 2.1.1 (d) requires the machinery to be designed and constructed to prevent contaminants from the environment of the machinery such as dust or grease, or living creatures such as insects, from entering areas of the machinery that cannot be cleaned, and to prevent any organic matter from accumulating in such parts.

Section 2.1.1 (e) requires the machinery to be designed and constructed to prevent ancillary substances used with the machinery such as, for example, lubricants or hydraulic fluids, from contaminating the foodstuffs, cosmetics or pharmaceutical products.

89/109/EEC. OJ L 338, 13.11.2004, p. 4. According to Article 26 of the Regulation, references to the repealed Directives shall be construed as references to Regulation (EC) No 1935/2004.

[213] Council Directive of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs. OJ L 277, 20.10.1984, p. 12.

[214] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, p. 1.

The requirement set out in section 2.1.2 is complementary to the general requirements relating to the instructions set out in section 1.7.4.

Section 2.1.2 requires the machinery manufacturer to specify the appropriate cleaning methods, including methods for cleaning spaces which are normally inaccessible or to which access could be dangerous. He must also specify the products to be used for cleaning. The machinery manufacturer should not specify particular brands of cleaning products, but must specify the relevant characteristics of the products to be used, in particular, with respect to the chemical and mechanical resistance of the constituent materials of the machinery. If necessary, warnings must be given against the use of unsuitable cleaning products.

General specifications for the hygiene requirements for machinery are given in standard EN ISO 14159[215]. Specifications for hygiene requirements for food processing machinery are given in standard EN 1672-2[216].

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

2.2.1. General

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

- *depending on the type of machinery, have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size, arranged in such a way as to ensure the stability of the machinery under the intended operating conditions,*
- *except where technically impossible, or where there is an independent control device, in the case of handles which cannot be released in complete safety, be fitted with manual start and stop control devices arranged in such a way that the operator can operate them without releasing the handles,*
- *present no risks of accidental starting and/or continued operation after the operator has released the handles. Equivalent steps must be taken if this requirement is not technically feasible,*
- *permit, where necessary, visual observation of the danger zone and of the action of the tool with the material being processed.*

The handles of portable machinery must be designed and constructed in such a way as to make starting and stopping straightforward.

[215] EN ISO 14159:2008 *Safety of machinery - Hygiene requirements for the design of machinery* (ISO 14159: 2002).

[216] EN 1672-2:2005+A1:2009 *Food processing machinery - Basic concepts* - Part 2: *Hygiene requirements*.

§278 Supplementary requirements for portable hand-held and/or hand-guided machinery

The requirements set out in section 2.2.1 apply to portable hand-held machinery and portable hand-guided machinery.

Portable hand-held machinery is machinery which is carried by the operator during use (with or without the aid of a harness).

Portable hand-guided machinery is portable machinery the weight of which is fully or partially supported, for example, on a work bench, on the material or workpiece being worked, on a floor or on the ground, the movement of which is guided by the operator's hands during use.

The categories of machinery concerned include, for example, portable hand-held and portable hand-guided power tools, gardening and forestry machinery. Portable machinery includes machinery driven by a mains or battery-powered electric motor, pneumatically powered machinery and machinery driven by an internal combustion engine.

The requirement set out in the first indent of section 2.2.1 is complementary to the general requirement relating to stability set out in section 1.3.1. The requirement for an adequate supporting surface is applicable, in particular, to portable hand-guided machinery that is in contact with a work bench, the material or the workpiece being worked, a floor or the ground during use.

Where its size permits, portable hand-held and hand-guided machinery must have at least two handles so that the stability of the machinery during use can be ensured by the operator using both hands. The handles shall be located and designed to ensure that the operator’s hands are kept out of the danger zone. The machinery shall be designed, as far as possible, in such a way as to discourage one-hand use. The positioning, dimensions and design of the handles must take account of ergonomic principles – see §181: comments on section 1.1.6.

The requirements set out in the second indent and in the second paragraph of section 2.2.1 are complementary to the general requirements relating to starting and stopping set out in sections 1.2.3 and 1.2.4.1. In general, it must be possible to start and stop the machinery without releasing the handles. These requirements can often be fulfilled, for example, by means of a hold-to-run trigger control device integrated into the handles.

The requirement set out in the third indent of section 2.2.1 is complementary to the general requirement set out in the sixth indent of section 1.2.2 relating to control devices. The requirement has two aims:

- to prevent unintentional start-up of the machinery due to unintended contact with the start control device;
- to ensure that the machinery does not continue to operate when the machinery is put down or if the operator accidentally releases the handles.

In order to fulfil this requirement, the start control device must, as a general rule, be of the hold-to-run type and be designed to avoid undue fatigue during use. It must be located, designed and, if necessary, protected so that it is not liable to be activated

unintentionally when the machinery is grasped, picked up, moved, or put down. Where there remains a risk of the machinery being started unintentionally, additional measures may be necessary such as, for example, fitting an additional enabling device or a start control device requiring two independent actions.

The requirement set out in the last indent of section 2.2.1, relating to the visibility of the danger zone and of the action of the tool with the material being processed, aims to ensure that the operator has the means to ensure full control over the operation of the machinery.

2.2.1.1. Instructions

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

- *the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s2. Where this value does not exceed 2,5 m/s2, this must be mentioned,*
- *the uncertainty of measurement.*

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

If harmonised standards are not applied, the vibration data must be measured using the most appropriate measurement code for the machinery.

The operating conditions during measurement and the methods used for measurement, or the reference of the harmonised standard applied, must be specified.

§279 Declaration of vibrations transmitted by portable hand-held and hand-guided machinery

The requirement set out in section 2.2.1.1 is complementary to the general requirements relating to the instructions set out in section 1.7.4.

The first indent of the first paragraph of section 2.2.1.1 sets out the physical quantity relating to the vibrations transmitted by portable hand-held and hand-guided to the hand-arm system that must be declared in the instructions.

The value measured on the machinery must be declared if it exceeds 2.5 m/s^2. If the value measured on the machinery does not exceed this value, that fact must be declared. The vibrations transmitted by the machinery must therefore be measured by the machinery manufacturer using an appropriate test method, unless it has been established that, for the category of machinery concerned, the measured values never exceed the above limit – this may be stated in the C-type standard for the category of machinery concerned.

The declaration of vibrations transmitted by the machinery has two main purposes:

- to help users to choose machinery with reduced vibration emissions;

– to provide information useful for the risk assessment to be carried out by the employer according to the national provisions implementing Directive 2002/44/EC on the exposure of workers to the risks arising from vibrations[217].

In this respect, it should be recalled that the level of exposure of workers to vibrations cannot be simply deduced from the machinery manufacturer's declaration of vibration emissions, since the exposure of operators is also influenced by other factors – see §231: comments on section 1.5.9.

The second indent of the first paragraph of section 2.2.1.1 requires the uncertainty surrounding the declared value to be specified. Guidance on determining the uncertainty associated with the measurement of vibrations transmitted by the machinery should be given in the relevant test codes.

The second paragraph of section 2.2.1.1 implies that, in the case of series production, measurement can be carried out on a representative sample or samples of technically comparable machinery. In the case of one-off production, the manufacturer must measure the vibrations transmitted by each item of machinery supplied.

The third and last paragraphs of section 2.2.1.1 concern the methods to be used for measuring vibrations. Operating conditions have a strong influence on the vibrations transmitted by machinery. Measurement of vibrations should therefore be carried out under representative operating conditions. Where the test code specified in a harmonised standard states the operating conditions under which the measurement is to be made, a reference to the harmonised standard is sufficient to indicate the operating conditions and measurement methods used. Where other test methods are used, the operating conditions and measurement methods used must be indicated in the declaration of vibrations.

It should be noted that the value declared in the instructions relating to vibrations must also be included in commercial documents relating to the performance characteristics of the machinery – see §273: comments on section 1.7.4.3.

If the residual vibration emissions determined under 2.2.1.1 do not adequately represent the emissions during the intended uses of the machine, additional information and/or warnings should be supplied to enable the potential risks to be assessed and managed.

[217] Directive 2002/44/EC of the European Parliament and of the Council of 25 June 2002 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration) (sixteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) – see Article 4 (4) (e).

2.2.2. Portable fixing and other impact machinery

2.2.2.1. General

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

- *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.*

§280 Portable fixing and other impact machinery

Section 2.2.2 sets out supplementary requirements for portable machinery intended for driving fasteners such as nails, threaded studs, eyelets or similar objects into a base material. They also apply to similar impact machinery intended for other applications such as, for example, machinery for the hard marking of materials by imprinting or captive bolt pistols for the stunning of animals. The requirements apply to machinery operated by explosive cartridges and to machinery using other sources of energy such as pneumatic, spring-operated, electromagnetic or gas combustion-operated machinery.

The main purpose of the requirements set out in section 2.2.2.1 is to prevent the risk of serious injury due to the fasteners or other impacted elements, or splinters from the machinery or the base material, hitting parts of the body of the operator or other persons in the vicinity. They also deal with risks due to incidents during loading and unloading.

The requirement set out in the third indent of section 2.2.2 1 is intended to prevent accidents due to untimely triggering of an impact. It is usually necessary to ensure that both the enabling device and the control device have to be released before another impact can be triggered.

The requirements set out in section 2.2.2.2 are complementary to the general requirements relating to the instructions set out in section 1.7.4.

The first indent of section 2.2.2.2 is relevant to tools, to safeguarding means such as splinter guards and to interchangeable equipment that may be fitted to fixing machinery in order to modify its function, for example, for the hard marking of materials.

The Machinery Directive does not apply to the fasteners or other impacted elements used with fixing and other impact machinery. However, the second indent of section 2.2.2.2 requires the machinery manufacturer to specify the relevant characteristics of fasteners or other impacted elements to be used with the machinery in order to enable the user to choose fasteners and other impacted elements that are compatible with the machinery and do not fracture under the specified conditions of use.

The third indent of section 2.2.2.2 applies to portable fixing machinery and other impact machinery operated by explosive cartridges. The Machinery Directive does not apply to the cartridges used with such machinery, however the machinery manufacturer must specify the relevant characteristics of the cartridges that can safely be used with the machinery[218].

It should be noted that cartridge-operated portable fixing machinery and other cartridge-operated impact machinery are included in the list set out in Annex IV (item 18) of categories of machinery to which one of the procedures referred to in Article 12 (3) and (4) must be applied.

[218] It is expected that, by 4 July 2013, explosive cartridges for cartridge-operated fixing machinery will be subject to Directive 2007/23/EC of the European Parliament and of the Council of 23 May 2007 on the placing on the market of pyrotechnic articles. OJ L 154, 14.6.2007, p. 1.

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;

(b) where the machinery is likely to be used in conditions involving the risk of ejection of workpieces or parts of them, it must be designed, constructed, or equipped in such a way as to prevent such ejection, or, if this is not possible, so that the ejection does not engender risks for the operator and/or exposed persons;

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

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

§281 Machinery for working wood and similar materials

The supplementary requirements set out in section 2.3 apply to machinery for working wood and to machinery that may also be used for working materials with similar physical characteristics such as, for example, cork, bone, rigid rubber or plastic, wood based material (e.g. chipboards, fiberboard, plywood) also when covered with plastic or light alloy laminates/edge. Light alloy is mentioned only as laminate cover and not as a material in total with similar physical characteristics to wood.

Machines dedicated for machining light alloys are not covered by Annex IV, items 1, 4, 5 and 7.

Examples of plastic are thermoplastic materials and thermoplastic resins, thermosetting resins, expanded plastic materials, polyurethane, phenol and polyvinylchloride (PVC).

The requirements set out in section 2.3 (a) aim to ensure that the design and construction of the feeding mechanism, or of the work bench in case of machinery with manual feed, enables the workpiece to be safely placed and guided during the work.

The requirement set out in section 2.3 (b) deals with a particular case of the hazard dealt with in the general requirement relating to ejected objects set out in section 1.3.3. Section 2.3 (b) requires measures to be taken to prevent the ejection of workpieces or parts of them. Such measures include, for example, fitting suitable riving knives on circular saw benches. Where ejections hazards cannot be completely avoided, safeguarding measures must to be taken to prevent ejected objects from injuring

operators or other exposed persons. This requirement must be applied in conjunction with the requirements relating to guards set out in section 1.4.

Section 2.3 (c) deals with the risk of contact with the tool during the run-down time. On machinery with a mechanised or automatic feed, this risk can be prevented by means of an interlocking guard with guard locking if necessary – see §129: comments on section 1.4.2.2. However, in cases where the tool is not completely inaccessible during the work, for example, where an adjustable guard restricting access is fitted according to section 1.4.2.3, it is necessary to prevent excessive run-down time of the tool by means of an automatic braking system (e.g. mechanical or DC injection). Harmonised standards specify the acceptable duration of the run-down time in such cases.

Section 2.3 (d) requires measures to be taken to reduce the risk of injury in case of accidental contact with the moving tool on machinery where access to the danger zone is not completely prevented by an interlocking movable guard. Such measures, include, for example, fitting Limited Cutter Projection Tooling (LCPT), cylindrical (or 'round form') cutter blocks or similar means of restricting the depth of cut.

It should be noted that several categories of woodworking machinery are included in the list set out in Annex IV (items 1 to 7) of categories of machinery to which one of the procedures referred to in Article 12 (3) and (4) must be applied.

2.4. MACHINERY FOR PESTICIDE APPLICATION[219]

2.4.1. Definition

'Machinery for pesticide application' means machinery specifically intended for the application of plant protection products within the meaning of Article 2 (1) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market [(1)].

[(1)] OJ L 309, 24.11.2009, p. 1.

§282 Machinery for pesticide application

The supplementary requirements set out in section 2.4 apply to machinery for pesticide application and concern the protection of the environment. The requirements set out in section 2.4 are the only essential health and safety requirements in Annex I that concern the protection of the environment – see §163: comments on General Principle 4 of Annex I.

The scope of the requirements set out in section 2.4 is determined by the definition of 'machinery for pesticide application' given in section 2.4.1. It is based on the scope of Directive 2009/128/EC[220] on the sustainable use of pesticides. Directive 2009/128/EC

[219] Section 2.4 was introduced by Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application. OJ L 310, 25.11.2009, p. 29.

[220] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides. OJ L 309, 24.11.2009, p. 71.

only applies to the use of pesticides that are plant protection products as defined in the EU Regulation relating to the placing on the market of such products. Plant protection products include products intended for protecting plants against harmful organisms or for preventing the action of such organisms, for influencing the life processes of plants, for preserving plant products, and for destroying, checking or preventing the undesired growth of plants or parts of plants.

Currently, Directive 2009/128/EC does not apply to pesticides that are biocidal products. Consequently, the requirements set out in section 2.4 of Annex I of the Machinery Directive do not apply to machinery specifically designed for the application of biocidal products. However, Recital 2 to Directive 2009/128/EC indicates that it is anticipated that the scope of the Directive will be extended to cover biocidal products. In that case, the Commission will also examine the possible extension of the scope of the requirements set out in section 2.4 of Annex I to the Machinery Directive to machinery for application of biocidal products.

The requirements set out in section 2.4 of Annex I and the guidance given in this text, apply to machinery for the direct application of pesticides primarily in liquid form. However, section 2.4 and this guidance text also applies to dusters and granule spreaders for the application of pesticides in solid form where appropriate. For example, the guidance given (see **§**285 and §288: comments on Annex I sections 2.4.4 and 2.4.6**)** with respect to cleaning using water is not appropriate, and can be unsafe, for machines using dry products. Note that section 2.4 does not apply to machinery used with products containing pesticides such as pesticide-coated seeds.

The machinery subject to the requirements set out in section 2.4 includes self-propelled, towed, vehicle-mounted, semi-mounted and airborne machinery, as well as stationary machinery intended for pesticide application, both for professional and non-professional use. For airborne machinery there are currently no harmonised standards and care must be taken when applying the EHSRs, for example filling is mainly from dedicated ground stations not on the aircraft/sprayer, nozzle positioning is primarily to avoid spray getting into the aircraft wake, and nozzle/boom height adjustment is not relevant. It also includes portable machinery that is carried by the operator, such as knapsack sprayers and mist blowers, and handheld machinery, whether powered or for some manually-operated types that has a pressure chamber that stores the energy for spraying. Very simple manually operated devices without a pressure chamber, such as sprayers for houseplants where the spray is produced by direct application of the trigger, are not concerned since they are not in the scope of the Machinery Directive as they operate by direct manual effort– see §35: comments on Article 2 (a) – first indent.

The European Commission has issued a specific mandate for the development of harmonised standards supporting the requirements set out in section 2.4.[221]. Currently not all types of pesticide equipment in scope of the Machinery Directive are planned to be covered (for example foggers, Controlled Droplet Application (CDA) machines).

[221] Mandate M/471 to CEN for standardisation in the field of machinery for pesticide application, 29th June 2010.

Operators 'protection against the chemical risk when using machinery applying pesticides is addressed in paragraphs 235 (requirement 1.5.13) and 322 (requirement 3.5.3).

2.4.2. General

The manufacturer of machinery for pesticide application or his authorised representative must ensure that an assessment is carried out of the risks of unintended exposure of the environment to pesticides, in accordance with the process of risk assessment and risk reduction referred to in the General Principles, point 1. Machinery for pesticide application must be designed and constructed taking into account the results of the risk assessment referred to in the first paragraph so that the machinery can be operated, adjusted and maintained without unintended exposure of the environment to pesticides.

Leakage must be prevented at all times.

§ 283 Preventing unintended exposure of the environment to pesticides

The first sentence of section 2.4.2 indicates how risks for the environment are to be taken into account in the machinery manufacturer's risk assessment – see §158 and §159: comments on General Principle 1 to Annex I.

Machinery manufacturers are not able to fully assess the risks to the environment caused by pesticide applications as these will differ depending on the situation and circumstances in which the products are used. Factors known only to the pesticide user such as topography, proximity to sensitive areas to the application area and weather conditions, can have a substantial impact on the degree of risk. The pesticide regulatory process manages some aspects of risk by imposing conditions (specifying dose rates, need to confine applications to target areas, etc.) on the way the product must be used. If these are not respected because of, for example, poor machinery design/function, then the degree of risk in use can become unacceptable.

However, the machinery manufacturer is expected to minimise the risks of damage to the environment due to the release of pesticides by the machinery in ways not intended by the user, taking into account specific application in which state of the art machines are used (e.g. machines for open field may have different solutions compared to machines to distribute in urban green areas as parks and gardens). Such risks may result from over application, leakage and spillage or from the contamination of water sources during filling, emptying, cleaning and during application. The risks during use arise from the release of pesticides in unintended quantities or at an unintended rate, and from the unintended release of pesticide to areas other than the target areas during application.

The second paragraph of section 2.4.1 refers to one of the possible sources of losses of pesticide to the environment, namely leakage from parts of the machinery containing the pesticides such as tanks, booms, hoses, lances, nozzles, valves and so on. These parts and their connections must be designed and constructed to prevent the risk leakage under the foreseeable conditions of use. Since the risk of leakage on liquid sprayers is increased by high pressure, the machinery must be provided with appropriate systems

to ensure that the pressure in the parts concerned does not exceed the designed limits. Such systems must be designed to prevent any over pressure venting does not discharge pesticide into the environment.

There are a number of harmonised standards (EN ISO 16119-1 to 3; EN ISO 19932-1 & 2)[222] with others that are being developed that deal with the environmental requirement of various type of sprayers, and these set the "state of the art" that the manufacturer of the machine should meet.

2.4.3. Controls and monitoring

It must be possible to easily and accurately control, monitor and immediately stop the pesticide application from the operating positions.

§ 284 Controls and monitoring

For most power operated machinery where there is an operating station, such as the driving position on the machine itself or the tractor towing the interchangeable equipment, easy access must be provided to a stop control to quickly stop the pesticide application. Also the operator must be able to see visual information devices (dials, display screens etc.) that allows the operator to monitor the application rates and have easy access to the controls to adjust the application rates.

For portable[223] sprayers, the stop function can be provided by the operating trigger on the lance and the monitoring of the application is by direct vision of the spray. On such portable machines the control of the application rate is normally by manual control.

2.4.4. Filling and emptying

The machinery must be designed and constructed to facilitate precise filling with the necessary quantity of pesticide and to ensure easy and complete emptying, while preventing spillage of pesticide and avoiding the contamination of the water source during such operations.

§ 285 Filling and emptying

Filling

This section applies to the need to ensure there is not overfilling and hence spillage of the pesticide and to facilitate complete and safe emptying avoiding spillage.

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[222] EN ISO 16119-1:2013 *Agricultural and forestry machinery - Environmental requirements for sprayers* - Part 1: *General*; EN ISO 16119-2:2013 *Agricultural and forestry machinery - Environmental requirements for sprayers* - Part 2: *Horizontal boom sprayers*; EN ISO 16119-3:2013 *Agricultural and forestry machinery - Environmental requirements for sprayers* - Part 3: *Sprayers for bush and tree crops*; EN ISO 19932-1:2013 *Equipment for crop protection - Knapsack sprayers* - Part 1: *Safety and environmental requirements*; EN ISO 19932-2:2013 *Equipment for crop protection - Knapsack sprayers* - Part 2: *Test methods*.

[223] In section 2.4 "portable sprayers" means those types that are carried by the operator.

Precise filling is required and if it is not easy to see the level in the tank, the use of visible gauges, or other means, must be provided to indicate the level/amount of pesticide in the spray tank(s)/hopper. The gauge or the level in the tank should be clearly visible to the sprayer operator from the normal filing positions. An induction bowl designed with the machinery can be a good solution to facilitate precise filling and to avoid splashing with pesticides

The tank should be clearly and durably marked to show the nominal (manufacturer's recommended) maximum filling level that allows for a reasonable foreseeable error in filling (over fill) without the risk of spillage.

Size and location of filling openings, should be designed to allow easy filling without overflowing or when liquid pesticides are used splashing, for example by providing suction filling from the pesticide container thus eliminating the need to manually decant.

It should be possible for the operator to add the pesticide or water (where the chemical is to be diluted) to the tank either standing on the ground or on a purpose-built platform that gives a stable working area with the filling point at an ergonomically safe and below head height.

Apart from the portable sprayers and machines designed with closed transfer systems or dedicated filling stations, there should be provided means to ensure proper cleaning of the original pesticide containers so that a minimal residual volume of the original contents remain in the container. In all cases the instructions should address the use, cleaning and disposal of the original pesticide containers.

A fail-safe system should be incorporated into sprayers, other than portable types, using liquid pesticides to prevent back-flow by siphoning while the spray tanks are being filled.

Emptying

Spray tanks should incorporate a safe and convenient system to enable the drained liquid to be collected or discharged to a point for safe disposal with minimal risk of splash or spillage.

Machines with large (e.g. > 1000 litres) liquid spray tanks should be equipped with a flushing tank to provide adequate water to clean the sprayer tanks and the plumbing circuits on the sprayer that may contain pesticide solution.

Complete flushing or emptying of the sprayer tanks and plumbing circuits should be provided so there remains only a minimal residual volume of pesticide. It is critical to ensure that drained pesticide and flushing liquid can easily be collected for safe disposal. This should be by means of a discharge point with an operating stop valve positions to allow disposal containers/disposal point to be located to accept the liquid with minimal risk of splash or spillage.

2.4.5. Application of pesticides

2.4.5.1. Application rate

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

2.4.5.2. Distribution, deposition and drift of pesticide

The machinery must be designed and constructed to ensure that pesticide is deposited on target areas, to minimise losses to other areas and to prevent drift of pesticide to the environment. Where appropriate, an even distribution and homogeneous deposition must be ensured.

2.4.5.3. Tests

In order to verify that the relevant parts of the machinery comply with the requirements set out in sections 2.4.5.1 and 2.4.5.2 the manufacturer or his authorised representative must, for each type of machinery concerned, perform appropriate tests, or have such tests performed.

§ 286 Application of pesticides

Application rate

The adjustment of the application rate should be located ergonomically adjacent to the operating position, firmly fixed and under all circumstances a steady reading should be possible.

Distribution, disposition and drift of pesticide

There are three major factors, for sprayer calibration: forward speed, swath width, and liquid flow rate.

Factors of design that can help control sprayer rate and its calibration include positioning, settings/adjustments and maintenance possibilities of nozzles and booms, the use of spray drift reduction technologies, depositional assistance e.g. air support, measurement devices etc.

Tests

Function test on a machine design must be carried out to ensure the calibration system and the distribution of pesticide is according to the design parameters, and quality assurance procedures must be in place to ensure the supplied machines are in compliance – this testing is the responsibility of the manufacturer. Where a machine is built up prior to supply to the end user, some testing may be required to check correct assembly, depending on the machine design and nature and extent of the assembly required. If such testing is required this is the responsibility of the manufacturer/distributor and is in addition to any operational tests that are the responsibility of the user to carry out periodically, including prior to first use.

2.4.5.4. Losses during stoppage

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

§ 287 Losses during stoppage

The primary risk will be with those machines using liquid pesticides. Here the requirement set out in section 2.4.5.4 must be fulfilled by adequate design (e.g. design of the plumbing, anti-drip valves, nozzle shut-off valves, collectors), to ensure a minimum level of spray liquid losses from nozzles once the liquid supply has been turned off.

2.4.6. Maintenance

2.4.6.1. Cleaning

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

2.4.6.2. Servicing

The machinery must be designed and constructed to facilitate the changing of worn parts without contamination of the environment.

2.4.7. Inspections

It must be possible to easily connect the necessary measuring instruments to the machinery to check the correct functioning of the machinery.

§ 288 Maintenance

Cleaning

Rough surfaces and awkward recesses should be avoided.

Sprayers with liquid spray tank capacities above a specific size (e.g. about 300+ litres) must be equipped with a rinsing tank that complies with this module. These tanks are required to provide adequate clean water for internal cleaning of the sprayer and will depend on the volume of the pesticide tank and complexity of the equipment on the machine that needs to be cleaned. Note, water for the operator to use for their cleaning may be required as part of the compliance with EHSR 1.1.3 (see § 178: comments) and should be provided by separate means.

Servicing

Filters and nozzles should be readily accessible for cleaning, replacement and maintenance. Critically the design should allow their replacement in the field as required without spillage and the risk of contamination, by means of isolation valves or other devices. Filters should be able to be cleaned without needing to empty the sprayer tank(s).

Inspections

Readily accessible attachment points for test equipment e.g. calibration of pressure gauge, measurement of flow rate (flowmeter), should be provided.

2.4.8. Marking of nozzles, strainers and filters

Nozzles, strainers and filters must be marked so that their type and size can be clearly identified.

2.4.9. Indication of pesticide in use

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

§ 289 Marking of nozzles, strainers and filters and of pesticide in use

Nozzles – except those of pneumatic mist blowers –, strainers and filters fitted to the pesticide machinery or supplied as spares/consumables must be clearly marked or identified in order to have information about details of their type and size so the operator can ensure the correct type has been fitted. It is preferable to use a marking system that is easily understood, with the use of appropriate codes as required. Nozzles for pneumatic mist blowers that are not expected to need to be replaced or interchanged within the lifetime of the machine need not be so marked.

A “card holder” or similar must be fitted to the machine on which the details (name etc.) of the pesticide being used or contained in the machine can be shown. This will apply to most pesticide mobile machinery, but for smaller machines such as portable sprayers a card holder is not normally required, but it should be possible to record the content on the sprayer, such as a panel that can be written on.

The indication of the pesticide carried in the machine is mainly necessary in case of pesticides that are classified as hazardous substances and that are present in a relevant concentrated form. The transport of hazard substances on public roads is regulated in ADR[224]. For low concentration of pesticides, due to the mixing in the tank, this is not necessary. The reason for this requirement is in the event of a traffic, overturning or other accident with loss of these pesticides. Here, it is important that public services like firefighters can assess the risk for the surrounding environment and population and take the necessary precautions and actions.

[224] European Agreement concerning the International Carriage of Dangerous Goods by Road - http://www.unece.org/trans/danger/publi/adr/adr2013/13contentse.html.

2.4.10. Instructions

The instructions must provide the following information:

(a) precautions to be taken during mixing, loading, application, emptying, cleaning, servicing and transport operations in order to avoid contamination of the environment;

(b) detailed conditions of use for the different operating environments envisaged, including the corresponding preparation and adjustments required to ensure the deposition of pesticide on target areas while minimising losses to other areas, to prevent drift to the environment and, where appropriate, to ensure an even distribution and homogeneous deposition of pesticide;

(c) the range of types and sizes of nozzles, strainers and filters that can be used with the machinery;

(d) the frequency of checks and the criteria and method for the replacement of parts subject to wear that affect the correct functioning of the machinery, such as nozzles, strainers and filters;

(e) specification of calibration, daily maintenance, winter preparation and other checks necessary to ensure the correct functioning of the machinery;

(f) types of pesticides that may cause incorrect functioning of the machinery;

(g) an indication that the operator should keep updated the name of the pesticide in use on the specific mounting referred to in section 2.4.9;

(h) the connexion and use of any special equipment or accessories, and the necessary precautions to be taken;

(i) an indication that the machinery may be subject to national requirements for regular inspection by designated bodies, as provided for in Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides [(1)];

(j) the features of the machinery which must be inspected to ensure its correct functioning;

(k) instructions for connecting the necessary measuring instruments.

[(1)] OJ L 309, 24.11.2009, p. 1.

§ 290 Instructions

(a) The instructions must give comprehensive information on the operation of the machine with respect to loading, use, adjustment and ranges of nozzles, checks, types of pesticides not to be used, features of the machinery, specific instructions. It must also give information on the techniques to be used to avoid spillage, the type of: containers (such as size, materials, design) that should be used; mixing equipment and how these should be cleaned and in particular the means of disposal of wash liquid and waste pesticide. The precautions to be taken in the transport of the equipment such how any

pesticide is isolated so as to minimise the possibility of spillage and how, if relevant, boom sections etc., are to be purged of pesticides.

(b) The detail of the information required will depend on the type of machinery involved. The information should include the limits of wind speed it can be operated in, the size and location of areas it is unsuitable for use and basic information on when the pesticide can be used, with reference to the pesticide information supplied by its manufacture. The manufacturer can make a general reference to national or regional legislation for specific requirements with respect to wind speeds, restricted areas etc., which may vary both between member states and in some cases within them.

Information should also be given on the types of pesticide it is suitable for. Particular attention must be paid to the guidance on the set up of the machine and its adjustments to ensure the designed application control, and how this can be checked and if faulty revised. For a portable sprayer the information will involve the way the lance is operated. It should also give information on maintenance and replacement of the lance nozzle.

(c) Recommended nozzles, nozzle positions, heights and spacing, to give the desired targeting of spray – the range of pressures and flow rates over which the nozzles are designed to operate.

(d) Criteria of procedure for determining when nozzles are worn out to a specific level their original flow rates and operating pressure(s), and should be replaced.

Information on how and when strainers and filters should be checked and when they should be replaced.

(e) Information is required to inform the user about the daily checks needed prior to using the machine and also the special checks for storage or use over winter. These are all to ensure the machine functions are correctly set . There are harmonised standards, for example EN ISO 16122-1 to 4[225] that deal with the inspection of various types of sprayers in use and the instructions may make reference to these.

(f) If any known type of solvent/carrier for pesticides may cause damage to the machine or incorrect application rate, ,then information on these should be given.

(g) The marking of the type of pesticide contained in the machine (see paragraph § 289), other than portable types. It is especially important when the machine is left partly filled and also to give third parties information on what is being sprayed or the emergency services in the case of an accident on the road or elsewhere. A reminder of the need to display this information is required in the instructions.

(h) if accessories or other equipment is envisaged by the manufacturer to be fitted to the machine, whether supplied with the machine or available as an after purchase item, then information on how it is fitted and connected to the spray system (if relevant) and the

[225] EN ISO 16122-1:2015 *Agricultural and forestry machinery - Inspection of sprayers in use* - Part 1: *General*; EN ISO 16122-2:2015 *Agricultural and forestry machinery - Inspection of sprayers in use* - Part 2: *Horizontal boom sprayers*; EN ISO 16122-3:2015 *Agricultural and forestry machinery - Inspection of sprayers in use* - Part 3: *Sprayers for bush and tree crops*; EN ISO 16122-4:2015 *Agricultural and forestry machines - Inspection of sprayers in use* - Part 4: *Fixed and semi-mobile sprayers.*

precautions to take to prevent spillage and the correct delivery of the pesticide is needed.

(i) depending on the national requirements that implemented Directive 2009/128/EC on the use of pesticides there may be a legal requirement for regular inspection of certain types of pesticide machinery by designated bodies. The manufacturer is not expected to give details of these for every member states, but they are expected to inform in the instructions that such measures may exist in a member state and for the operator to check this for where the machine is being used, for example in a member state other than were the machine is based.

(j) to comply with this section a good approach is to provide a “check list” of the items that need to be checked prior to use of the machine to ensure its correct functioning of the delivery system and its correct calibration.

(k) measuring instruments may need to be connected to check calibration depending on the type of machine. Instructions must be given on how this is to be done, for example to avoid spillage, to fit only when the machine is idle and not under pressure etc.

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

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).

§291 Supplementary requirements for hazards due to mobility of machinery

Part 2 of Annex I sets out supplementary EHSRs relating to hazards due to the mobility of machinery. These apply to the machinery concerned in addition to the relevant requirements of Part 1 of Annex I and, where applicable, of the other Parts of Annex I – see §163: comments on General Principle 4.

3.1. GENERAL

3.1.1. Definitions

(a) 'Machinery presenting hazards due to its mobility' means

- *machinery the operation of which requires either mobility while working, or continuous or semicontinuous movement between a succession of fixed working locations, or*
- *machinery which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another.*

. . .

§292 Definition of 'hazards due to mobility'

The definition of 'machinery presenting hazards due to its mobility' set out in section 3.1.1 (a) establishes the scope of the requirements set out in Part 3 of Annex I. According to the definition, the machinery concerned comprises:

- machinery that can travel while fulfilling its main function. Examples of such machinery are dumpers, compactors, lift trucks, gantry cranes, track-mounted mobile cranes and lawnmowers;
- machinery that remains stationary while carrying out its main application but is designed to travel from one working location to another. Examples of such machinery are drill rigs and mobile cranes, loader cranes and self-propelled or trailer-mounted mobile elevating work platforms that are mounted on stabilisers during lifting operations;
- machinery which remains stationary in use but which is equipped with means, such as powered wheels or tracks or towing devices to enable it to travel easily from one place of use to another.

It is clear from the definition that the hazards due to mobility covered in Part 3 of Annex I are those due to the mobility of the machinery itself, not those due to moving parts of the machinery which are dealt with in sections 1.3.7 and 1.3.8.

The machinery concerned by the requirements set out in Part 3 includes, for example:

- mobile construction equipment such as earthmoving machinery,
- mobile road construction machinery,
- mobile machinery for underground mines,
- self-propelled and towed mobile agricultural, forestry and gardening machinery,
- mobile machinery for the transport and lifting of goods or persons such as industrial trucks (including driverless trucks), mobile cranes and mobile elevating work platforms,
- machinery mounted on means of transport such as loader cranes, compressors and tippers,
- refuse collection vehicles,
- mobile machinery for the off-road transport of goods or persons such as quads, buggies, off-road motorcycles and karts,
- mobile winter service machinery,
- mobile aircraft ground support machinery.

3.1.1. Definitions (continued)

. . .

(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.

. . .

§293 Definition of 'driver'

Section 3.1.1 (b) defines 'driver' as an operator responsible for the movement of a machine, in other words, the person who controls the travel movements of the machinery itself. The definition refers to three main driving modes:

- mobile machinery may have a ride-on driver, transported by the machinery, who may be seated or standing;
- mobile machinery may be designed for pedestrian control;
- mobile machinery may be guided from a distance by means of a remote control.

Certain mobile machinery may also be designed with two or more alternative driving modes. For example, mobile machinery may be designed to be controlled either by a ride-on driver or by means of remote control – see §204: comments on section 1.2.5.

The requirements set out in Part 3 address the specific risks associated with the different driving modes and the necessary protective measures to deal with them.

3.2. WORK POSITIONS

3.2.1. Driving position

Visibility from the driving position must be such that the driver can, in complete safety for himself and the exposed persons, operate the machinery and its tools in their foreseeable conditions of use. Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision.

Machinery on which the driver is transported must be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks.

The driving position of ride-on drivers must be designed and constructed in such a way that a driver's cab may be fitted, provided this does not increase the risk and there is room for it. The cab must incorporate a place for the instructions needed for the driver.

§294 Driving position

The requirement set out in section 3.2.1 is complementary to the general requirements relating to operating positions and seating set out in sections 1.1.7 and 1.1.8.

The first paragraph of section 3.2.1 deals with visibility from the driving position. The driver must have permanent control of the movements of the machinery.

- Wherever possible, the machinery must be designed and constructed so that the driver has adequate direct vision of the area around the machinery. In particular, the driver must be able to see whether there are persons near the machinery who may be at risk due to the operation or movement of the machinery – see §195: comments on the fifth paragraph of section 1.2.2. Means that may be used to improve direct visibility include, for example, elevating, tilting or reversible driving positions and cabs or alternative driving positions.
- Where direct visibility is insufficient, in other words, where the driver's view of a person or an obstacle in the danger zone is liable to be obscured by parts of the machinery or by objects or materials carried by the machinery, to the extent that the driver may not be aware of their presence, appropriate devices to provide indirect vision must be fitted. Such devices include appropriate mirrors and closed circuit television (CCTV). The decision to fit devices to provide indirect vision and the choice, design and location of such devices must take account of ergonomic principles and of the constraints to which the driver is subject in the foreseeable conditions of use of the machinery, which will include that pedestrians and other machinery are likely to be in the vicinity at times. Factors to be considered, when choosing the type of device, will include, for example, likely use of the machinery at night or in poor lighting conditions, use on uneven ground, use in areas where pedestrians or other machinery may be at particular risk, such as where children are likely to be present or use involving frequent or prolonged reversing – see §181: comments on section 1.1.6.
- Where there is residual risk of collisions with persons, machinery may be fitted with means to prevent such collisions such as, for example, pressure-sensitive, radar,

infra-red or ultrasonic protective devices, to detect the presence of persons and stop the machinery or warn the driver before a collision occurs. However, such devices do not remove the requirement for direct or when not possible, indirect vision.

The second paragraph of section 3.2.1 concerns machinery where the driving position is close to the wheels or tracks. If the driving position is not completely enclosed and if there is not an adequate safety distance between the driving position and the wheels or tracks, it is necessary to fit guards to prevent inadvertent contact with these parts.

The third paragraph of section 3.2.1 requires machinery with a ride-on driver to be designed and constructed in such a way that a driver's cab may be fitted, unless the machinery is too small to fit a cab or the fitting of a cab would increase the risk or impair the functionality of the machinery. In such cases, other measures must be considered to protect the drivers such as, for example, seats with a protective canopy or remote control.

The requirement set out in the third paragraph of section 3.2.1 must be applied in conjunction with the requirements set out in section 1.1.7 relating to operating positions and section 3.5.3 relating to emissions of hazardous substances - see §182: comments on section 1.1.7 and §322: comments on section 3.5.3.

The second sentence of the third paragraph of section 3.2.1 requires a place to be provided in the driver's cab for the instructions needed for the driver. The instructions concerned are those relating to the safe operation of the machinery and to any inspection or maintenance operations to be carried out by the driver.

3.2.2. Seating

Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the 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.

§295 Seat restraint system

The requirement set out in section 3.2.2 is complementary to the general requirements on seating set out in section 1.1.8.

Section 3.2.2 deals with the risk of crushing due to ejection of operators or other transported persons in case machinery rolls or tips over. The roll-over and tip-over protective structures referred to in section 3.4.3 can only fulfil their role if the persons concerned are maintained within the protected volume. For this purpose, machinery must either:

- be designed to prevent operators from being thrown out if the machinery rolls

or tips over,

- be provided with seats designed to prevent operators from being thrown out, or
- be provided with seats fitted with a seat restraint system with adequate anchorage points.

Seat restraint systems must be easy to open and close and restrict the necessary movements of the operator as little as possible. This is particularly important for machinery such as, for example, industrial trucks, where the driver may have to frequently leave and return to the driving position. Where the safety of the operators depends on the closure of a seat restraint system, the necessary instructions on the use of the restraint system must be given – see §263: comments on section 1.7.4.2 (k).

The last sentence of section 3.2.2 recognises that, in some cases, restraint systems should not be fitted because they may increase the risk. This may be the case, for example, on small mobile machinery that is not fitted with a cab or a protective structure or machinery with a standing ride-on driver It may also be impracticable to fit a restraint system on machinery designed for active riding that demands extensive movement of the driver while travelling. Restraint systems are not usually required on machinery equipped with a falling-object protective structure only.

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.

§296 Positions for persons other than the driver

The requirements set out in section 3.2.3 are complementary to the general requirements relating to operating positions and seating set out in sections 1.1.7 and 1.1.8.

Section 3.2.3 requires safe positions to be provided for persons other than the driver who may be occasionally or regularly transported by the machinery or work on it. Depending on the type of machinery and the tasks of the persons concerned, such positions may be seats or places to stand such as platforms or footboards. Particular protective measures must be taken to deal with risks such as the risk of falling from the machinery or the risk of impacts or crushing where the positions provided for persons other than the driver are outside the normal clearance of the machinery.

The second paragraph of section 3.2.3 states that the requirements set out in section 3.2.1 relating to risks of contact with wheels or tracks and the provision of a cab are applicable to positions for persons other than the driver.

3.3. CONTROL SYSTEMS

If necessary, steps must be taken to prevent unauthorised use of controls.

. . ..

§297 Unauthorised use of controls

The requirements set out in section 3.3 are complementary to the general requirements relating to the safety and reliability of control systems set out in section 1.2.1.

The first sentence of section 3.3 requires measures to be taken to prevent unauthorised use of controls if necessary. These measures are necessary for machinery which is exposed to use by unauthorised persons such as, for example, industrial trucks, or machinery intended to be used or parked in public areas[226]. The measures that can be taken include, for example, fitting locks, electronic access systems or systems requiring the operator to carry an electronic tag to operate the machinery.

3.3. CONTROL SYSTEMS (continued)

. . .

In the case of remote controls, each control unit must clearly identify the machinery to be controlled from that unit.

The remote control system must be designed and constructed in such a way as to affect only:

– the machinery in question,

– the functions in question.

Remote controlled machinery must be designed and constructed in such a way that it will respond only to signals from the intended control units.

§298 Remote controls

The requirements set out in the second, third and last paragraphs of section 3.3 apply to remote control systems for mobile machinery. In the case of machinery intended for control either by a ride-on driver or by means of remote control, these requirements apply to the remote control mode – see §293: comments on section 3.1.1 (b).

These requirements for remote control systems are complementary to the requirement relating to cable-less control systems set out in the last paragraph of section 1.2.1.

The requirement set out in the second paragraph of section 3.3 is a particular application of the general requirement set out in the fourth paragraph of section 1.2.2 relating to indicators. Where the control unit of a remote control system is not located on the machinery it controls, it must be clear to operators which machinery is affected by the use of each control unit.

[226] Such measures may also be required by users of mobile machinery in order to prevent theft, however this aspect is not covered by the Machinery Directive.

The third and last paragraphs of section 3.3 set out requirements for the design and construction of the remote control system itself.

The purpose of the requirement set out in the third paragraph of section 3.3, that the system shall only affect the intended machinery and functions, is to avoid unintended commands being given to other machinery or other functions that may be in the range of the remote control system.

The requirement set out in the last paragraph of section 3.3 aims to prevent signals from any sources other than the appropriate control unit from triggering unintended actions of the remote controlled machinery.

In order to fulfil the requirements, set out in section 3.3, the design and construction of the remote control system must ensure an adequate level of performance – see §184: comments on section 1.2.1.

Supplementary requirements for the remote control of the travelling function are set out in the fourth paragraph of section 3.3.3 and in the third paragraph of section 3.6.1.

3.3.1. Control devices

The driver must be able to actuate all control devices required to operate the machinery from the driving position, except for functions which can be safely actuated only by using control devices located elsewhere. These functions include, in particular, those for which operators other than the driver are responsible or for which the driver has to leave the driving position in order to control them safely.

. . .

§299 Location and positioning of the control devices

The requirements set out in section 3.3.1 are complementary to the general requirements for control devices set out in section 1.2.2.

The requirements set out in the first paragraph of section 3.3.1 concern the location and positioning of the control devices at the driving position – see §187: comments on the second indent of section 1.2.2.

The second paragraph of section 3.3.1 recognises that it may be necessary to provide mobile machinery with control positions other than the driving position in order to control certain functions safely. This may be necessary, for example, to ensure that the operator controlling those functions has adequate visibility of the related danger zones, for example, on mobile cranes or loader cranes - see §195: comments on the fifth paragraph of section 1.2.2, and §343: comments on section 4.1.2.7. In that case, it is important to take account of the requirements set out in the eighth and last paragraphs of section 1.2.2 relating to multiple control and operating positions – see §197 and §198: comments on section 1.2.2.

3.3.1. Control devices (continued)

. . .

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.

. . .

§300 Pedals

Since the operators of ride-on mobile machinery frequently need to have their hands free to steer and control other functions of the machinery, pedals are often used to control, amongst others, the acceleration and braking functions. Since most machinery operators are also drivers of road vehicles, it is important that the pedals for these functions should, as far as possible, have a similar mode of operation and layout to those of road vehicles in order to reduce the risk of incorrect operation – see §190: comments on the sixth indent of section 1.2.2, and §193: comments on the third paragraph of section 1.2.2.

In order to ensure safe operation, the dimensions and layout of the pedals must also take account of the fact that operators may have to wear protective footwear such as, for example, the large boots worn in winter or in refrigerated warehouses – see §176: comments on section 1.1.2 (d). For similar reasons, pedals must have a slip-resistant surface and be easy to clean, taking into account the intended conditions of use.

3.3.1. Control devices (continued)

. . .

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.

. . .

§301 Return to neutral

Control devices for controlling movements of the machinery itself and for controlling other hazardous functions shall, as a general rule, be of the hold-to-run type, returning to the neutral position when released, in order to enable the operator to stop the movement or hazardous function immediately when necessary. Special consideration should be given to situations where the operator may not be able to release the control, for example when being pushed onto the control due to the movement of the machine or part of it. If this is a significant risk, then means to mitigate this by way of the controls' design should be provided.

Control devices with preset positions may be fitted when it is necessary to maintain a parameter, such as, for example, the travel speed of the machinery, at a constant value for a prolonged period. This may be necessary, for example, on certain agricultural machinery or road construction machinery. In that case, the control device should be designed so that it can be easily and quickly returned to the neutral position in an emergency.

Self-propelled machinery with a ride-on driver equipped with a control device with preset positions for the travel movements must be fitted with an enabling device to comply with the requirement set out in the first paragraph of section 3.3.2, since, in that case, it is possible to leave the driving position while the machinery is travelling – see §304: comments on section 3.3.2.

3.3.1. Control devices (continued)

. . .

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

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

. . .

§302 Steering

The requirement set out in the fourth paragraph of section 3.3.1 aims to prevent the risk of loss of control and injury due to kickback of the steering device when the guide wheels hit an obstacle on the ground. In order to meet this requirement, the steering system must have adequate damping between the guide wheels and the steering device.

Some types of mobile machinery are fitted with a locking differential in order to improve traction and prevent wheel spin on soft, slippery or uneven surfaces. The fifth paragraph of section 3.3.1 requires differential locking controls to allow the differential to be opened when the machinery is moving, in order to enable the driver to recover full steering capacity when necessary. Where appropriate, an automatic differential locking system that locks or opens the differential as needed, without action by the driver, can be fitted to comply with this requirement.

3.3.1. Control devices (continued)

. . .

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

§303 Reverse warning signals

The last paragraph of section 3.3.1 refers to the sixth paragraph of section 1.2.2 which requires an acoustic and/or visual warning signal to be given before the starting of machinery if the operator is not able to ensure that no-one is in the danger zone or if it is not possible to design the control system to prevent starting while someone is in the danger zone.

For mobile machinery, an automatic acoustic and/or visual warning signal is only required in the case of the reversing. Since it may be necessary to control reversing movements quickly in case of an emergency, the time interval between the warning

signal and the reversing movement shall usually be reduced. It should be noted that automatic reverse warning signals are not a substitute for measures to ensure direct or indirect visibility of the danger zones – see §294: comments on section 3.2.1.

Warning devices relating to forward movements should usually be actuated by the driver – see §323: comments on section 3.6.1.

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.

. . .

§304 Control of travel movements by a ride-on driver

The requirement set out in the first paragraph of section 3.3.2 stems from the fact that safe travel movement of self-propelled machinery with a ride-on driver requires the driver to be permanently in control. It must not be possible to start travel movements of the machinery if the driver is not at the controls and it must not be possible for the machinery to continue travelling under power if the driver leaves the driving position. In the case of machinery designed for control either by a ride-on driver or by means of a remote control, this requirement only applies to the ride-on control mode – see §293: comments on section 3.1.1 (b).

The requirement set out in the first paragraph of section 3.3.2 can be considered to be fulfilled if:

- the control devices are of the hold-to-run type, returning to neutral when released

  and

- the control devices for controlling travel movements of the machinery are not easily accessible from outside the driver's cab.

If these two conditions are not met, other measures must be taken to prevent travel movements if the driver is not at the controls. Such measures may include, for example, fitting an enabling device such as a sensor on the armrest supporting the control devices, a position sensor in the seat or a seat switch. Such devices shall be chosen and designed to avoid creating other risks and to avoid triggering by vibrations of the machinery or by foreseeable movements of the driver while driving. The devices and their integration into the control system must have an adequate performance level – see §184: comments on section 1.2.1.

3.3.2. Starting/moving (continued)

. . .

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.

. . .

§305 Devices exceeding the normal clearance zone

The requirements set out in the second, third and fourth paragraphs of section 3.3.2 deal with the risk that may be created by devices fitted to the machinery which, for operational purposes, are deployed outside the normal clearance zone.

Such devices include, for example, stabilisers or outriggers which are extended outside the chassis of mobile machinery or of the vehicle on which the machinery is mounted to ensure stability during operation. Stabilisers may be fitted, for example, to lifting machinery such as loader cranes, mobile cranes, mobile elevating work platforms or earth moving equipment. The devices concerned also include, for example, lifting structures such as telescopic or articulated jibs, arms and booms on lifting machinery or on truck-mounted concrete pumps and truck-mounted tipper bodies, which may be extended horizontally or vertically outside the normal clearance zones of the machinery or of the vehicle on which the machinery is mounted.

If these devices are not secured in a safe position before travel movements of the machinery or of the vehicle on which it is mounted, they may hit pedestrians, other machinery, vehicles, bridges, tunnels, overhead electricity lines and so on. Such collisions can cause severe or fatal accidents as well as substantial damage to property.

Where the devices concerned are liable to move from the safe position during travel, due to centrifugal forces for example, it must be possible to lock them in the safe position.

In all such cases, the driver must be able to check that the devices concerned are in a safe travel position, locked in that position if necessary, before starting travel movements. If it is not easy to carry out such a check visually, the necessary indicators or warning devices must be provided at the driving position.

Interlocking systems should be fitted to prevent travel movements of the machinery or prevent starting if the devices concerned are not placed and, where necessary, locked in a safe travel position, provided such devices do not give rise to other risks such as, for example, a risk of unexpected stopping during road circulation.

3.3.2. Starting/moving (continued)

. . .

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

§306 Unintended travel movement

The requirement set out in the last paragraph of section 3.3.2 is a particular application of the general requirement set out in section 1.2.3 relating to starting.

In order to avoid unintended or unexpected movement of mobile machinery, it is necessary to separate the starting of the engine or motor from the starting of movement. It must be possible to start the engine without starting the movement of the machinery and it must not be possible to start the engine or motor if the transmission is engaged, for example the gear shift or travel lever must be in neutral for the starter motor to operate.

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.

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

Where safety so requires, a parking device 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.

. . .

§307 Slowing down, stopping and immobilisation

The first three paragraphs of section 3.3.3 deal with the braking, slowing down, stopping and immobilisation of mobile machinery.

The first paragraph of section 3.3.3 requires mobile machinery to have a braking system that is able to slow down and stop the machinery safely and keep it at a standstill. The braking system must be designed, constructed and verified to ensure that these functions can be ensured under all intended and reasonably foreseeable load, speed, ground and gradient conditions. This requirement applies to self-propelled machinery and to most towed machinery, unless such machinery can be safely slowed down and stopped by the braking system of the towing machinery or vehicle.

The second paragraph of section 3.3.3 requires the braking system of self-propelled mobile machinery to include an emergency braking device that safely slows down and

stops the machinery, or can be used by the driver to do so, in case of the failure of the main braking device or of its energy supply. This requirement applies to all mobile machinery where there is a risk of losing control of the movement of the machinery if the braking system fails. The requirement can be satisfied for example, by a mechanically linked handbrake, spring applied brakes that apply in the event of power failure or a dual braking system that isolates the failed circuit in the event of a failure of the energy supply.

The third paragraph of section 3.3.3 requires mobile machinery to be fitted with a parking brake where there is a risk of the machinery moving unintentionally from a stationary position. The parking brake must be designed so that its effectiveness is not liable to diminish for as long as the machinery is parked. For purely mechanical braking systems, the parking brake can be combined with the main or emergency braking devices.

§308 Regulations for road circulation

The first paragraph of section 3.3.3 states that the requirements of the Machinery Directive in respect to slowing down, stopping and immobilisation apply *'without prejudice to road traffic regulations'*. There is a similar reference to road traffic regulations in the second paragraph of section 3.6.1 on warning devices and light signals.

The rules and procedures governing the circulation of mobile machinery on public roads are not harmonised at EU level. Consequently, in addition to the requirements and procedures of the Machinery Directive, manufacturers seeking approval of mobile machinery for road circulation may have to apply rules and procedures in force at national level. Aspects that may be covered by such national rules include, for example:

- maximum dimensions, mass, axle load and speed,
- suspension and tyres,
- braking and steering systems,
- direct and indirect visibility,
- warning devices, signs and signals, and lights.

3.3.3. Travelling function (continued)

. . .

Remote-controlled machinery must be equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations:

- *if the driver loses control,*
- *if it receives a stop signal,*
- *if a fault is detected in a safety-related part of the system,*
- *if no validation signal is detected within a specified time.*

. . .

§309 Stopping and controlling potentially dangerous operation by remote control

The requirements set out in the fourth paragraph of section 3.3.3 are complementary to the general requirements relating to control systems set out in section 1.2.1 and to the requirements relating to remote control of mobile machinery set out in section 3.3 and in the third paragraph of section 3.6.1.

The remote control device and the control system of the machinery must be designed to bring to a safe stop the machinery itself and, where necessary, to prevent any potentially dangerous operation of the machinery, in all of the situations described in the four indents of this paragraph. These objectives can be achieved by a combination of means, including, for example, hold-to-run control devices, means for detecting and stopping the machinery in the event of hazardous situations such as abnormal acceleration, vibration or tilt, and enabling devices that have to be actuated at regular intervals.

The *'specified time'* referred to in the last indent of the fourth paragraph of section 3.3.3 must be short enough to prevent a dangerous situation arising during the time interval concerned.

In order to fulfil the requirements, set out in section 3.3.2, the remote control system must have an adequate level of performance – see §184: comments on section 1.2.1.

3.3.3. Travelling function (continued)

. . .

Section 1.2.4 does not apply to the travelling function.

§310 Stopping of the travelling function

The last paragraph of section 3.3.3 foresees a derogation to the general requirements for the stopping functions set out in section 1.2.4. In particular, section 1.2.4.1 requires that, once machinery has been stopped, the energy supply to the actuators must be cut off. This does not apply to the travelling function of mobile machinery which may be stopped in neutral with the engine running.

The requirements applicable to the stopping of the travelling function of mobile machinery are those set out in the first three paragraphs of this section – see §307: comments on the first three paragraphs of section 3.3.3.

3.3.4. Movement of pedestrian-controlled machinery

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

The control systems for pedestrian-controlled machinery must be designed in such a way as to minimise the risks arising from inadvertent movement of the machine towards the driver, in particular:

- *crushing,*
- *injury from rotating tools.*

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

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

§311 Movement of pedestrian-controlled machinery

Section 3.3.4 concerns pedestrian-controlled self-propelled mobile machinery, that is to say, machinery with powered travel movements controlled by a driver accompanying the machinery on foot, who usually walks behind or ahead of the machinery and operates the control devices and steering device by hand – see §293: comments on section 3.1.1 (b). Pedestrian-controlled machinery includes pedestrian-controlled pallet trucks, surface cleaning machinery, compactors, cultivators, motor hoes and lawnmowers. Section 3.3.4 does not concern pedestrian-propelled machinery.

The requirements set out in the first paragraph of section 3.3.4 are intended to reduce the risk of uncontrolled movements of the machinery. The control devices for movement must be of the hold-to-run type and the release of the control device must bring the machinery to a safe stop. If the machinery is likely to continue moving after the control device has returned to the neutral position, it may be necessary for the release of the control device to actuate a brake. Since the operator usually has to hold the steering device and the control device for movement with the same hand, it is important for the hold-to-run control device to be designed and located to reduce the constraint for the operator – see §193: comments on the third paragraph of section 1.2.2.

The second sentence of the first paragraph of section 3.3.4 deals with a specific aspect of the requirement set out in the first sentence: the design and construction of the machinery must make it impossible for movement of the machinery to occur during the starting of the engine.

The requirement set out in the second paragraph of section 3.3.4 deals with the risk of the driver being crushed or injured by the moving machinery itself, by moving parts of the machinery or by tools. This risk is particularly important when the driver walks ahead of the machinery or if the machinery is able to reverse towards the driver. In such cases, it may be necessary to fit protective devices that stop the machinery if it approaches or comes into contact with the driver's body.

The requirement, set out in the third paragraph of section 3.3.4, that the speed of travel must be compatible with the pace of the driver on foot, aims to ensure that the driver does not lose control of the machinery while it is moving.

The last paragraph of section 3.3.4 deals with the risk of injury to the pedestrian driver due to contact with a rotary tool such as, for example, the blade of a cultivator or hoe. If the function of the machinery requires a reverse function, the tool must be disengaged during reversing or, where the movement of the machinery results from the movement of the tool, a 'crawl' speed must be foreseen to reduce the risk.

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.

§312 Failure in the power supply to steering

Power-assisted steering is fitted to mobile machinery to reduce the efforts needed to steer the machinery, particularly on large machinery and for tight manoeuvres. However, since the driver must be able to control movement of the machinery at all times, it must be possible to steer the machinery for long enough to bring it to a safe stop in the event of the failure of the power supply. If it is possible steer the machinery manually to a safe stop, this requirement can be fulfilled by reverting to manual steering in the event of failure of the power-supply. Otherwise, a back-up power supply is necessary.

A back-up power supply is always necessary on machinery with a power steering system.

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.

§313 Uncontrolled movements

The requirement set out in section 3.4.1 is complementary to the general requirements relating to stability and the risk of break-up during operation set out in sections 1.3.1 and 1.3.2.

The design and construction of mobile machinery must take account of the dynamic effects due to the movements of the machinery that may affect its stability or the mechanical resistance of its structures. Particular consideration must be given to these risks for self-propelled or towed machinery intended for road circulation, for machinery intended to be mounted on road vehicles and for machinery intended to travel at high speed.

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.

§314 Access to the engine compartment

Section 3.4.2 foresees an exception to the general requirements for preventing access to moving transmission parts set out in section 1.3.8.1. The derogation applies to movable guards preventing access to the moving parts in the engine compartment (engine covers with a guarding function). Such engine covers do not have to be fitted with an interlocking device that stops the engine when the cover is opened. However, measures must be taken to prevent unauthorised access to the engine compartment:

- the engine cover must be designed to require the use of a tool or key to be opened – see §218: comments on section 1.4.2.1,

  or

- the engine cover must be fitted with a lock that can only be released from the driving position by means of a device located in a fully enclosed cab which can itself be locked to prevent unauthorised access.

3.4.3. Roll-over and tip-over

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery must be fitted with an appropriate protective structure, unless this increases the risk.

This structure must be such that in the event of rolling or tipping over it affords the ride-on person(s) an adequate deflection-limiting volume.

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.

§315 Roll-over and tip-over

Section 3.4.3 deals with the residual risk of loss of stability of the machinery if, despite the measures taken according to sections 1.3.1 and 3.4.1 to ensure adequate stability,

there is a residual risk due to the machinery rolling or tipping over. The term *'roll-over'* designates complete overturning involving a rotation of 180°. The term *'tip-over'* designates the situation where the machinery falls over but where its shape or an element such as a mast or a boom prevents it from rotating more than 90°. The machinery may be liable to roll-over or tip-over in a lateral or longitudinal direction or both. Roll-over or tip-over always creates a risk for the driver or other persons transported by the machinery of being ejected or crushed.

The first paragraph of section 3.4.3 requires machinery having such a residual risk to be equipped with an appropriate protective structure, that is to say a roll-over protective structure or a tip-over protective structure. These structures must be designed to protect all persons transported by the machinery who are exposed to the risk concerned.

The assessment of the residual risk due to rolling or tipping over should take account of the following parameters:

- the intended and foreseeable operating conditions of the machinery (such as speed, maximum slope and terrain);
- the mass, dimensions and centre of gravity of the machinery, the different loading conditions, the presence of levelling devices;
- the shape of the machinery and the position of the operator(s).

The necessary protection may be ensured by parts of the machinery itself that ensure the necessary protection of the operator(s) in the event of roll-over or tip-over. When a specific protective structure is required, it may be an integrated into a cab.

For many categories of mobile machinery, harmonised standards state whether a protective structure is necessary and specify the type of protective structure to be fitted.

The only exception to this requirement is where fitting a protective structure would increase the risk related to rolling or tipping over. For example, it is not advisable to fit a protective structure on machinery intended for active riding on which a seat restraint device cannot be used – see §295: comments on section 3.2.2.

The second paragraph of section 3.4.3 sets out the objective to be achieved by roll-over and tip-over protective structures. The protective structure must provide an adequate deflection-limiting volume, in other words, in the event of roll-over or tip-over, it should not deform to the extent that it contacts the operator while he or she is in the operating position. It should be noted that such protective structures can only fulfil their protective functions if the persons concerned are restrained so that they remain inside the protective volume of the self-propelled machinery in the case of roll-over or tip-over. To fulfil this objective, some restraint systems such as: gates, door-bar systems or seat-belts may need to be mounted on the protective structure or on the seat – see §295: comments on section 3.2.2.

The third paragraph of section 3.4.3 requires roll-over and tip-over protective structures to be subject to the necessary type-tests to verify that they fulfil their protective role.

It should be noted that roll-over and tip-over protective structures independently placed on the market are safety components, while ROPS are included in the indicative list of safety components set out in Annex V (item 14). Such ROPS are also included in the

categories of machinery listed in Annex IV (item 22) subject to the conformity assessment procedures referred to in Article 12 (3 and (4).

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.

§316 Falling objects

The requirement set out section 3.4.4 is complementary to the general requirement on risks due to falling or ejected objects set out in section 1.3.3.

The risk for the driver or other persons transported on self-propelled mobile machinery of being injured by falling objects may be due to objects or materials moved or lifted by the machinery, for example, by lift trucks or earthmoving machinery. The risk may also be due to the environment in which the machinery is intended to operate such as, for example, demolition, warehouses with high racking or forestry. Where a risk due to falling objects exists in the intended or foreseeable conditions of use of the machinery, the necessary protective measures must be taken, including, where the size of the machinery allows, the fitting of an appropriate falling object protective structure. The protective structure must be designed to protect all persons transported by the machinery who are exposed to the risk concerned. The design of the protective structure must take account both of the size of potential falling objects (to avoid objects falling through the structure) and the need for adequate visibility from the driving position – see §294: comments on section 3.2.1.

Harmonised standards for most categories of mobile machinery specify the type of protective structure required.

The comments on the second and third paragraphs of section 3.4.3 relating to protection against roll-over and tip-over also apply to the second and third paragraphs of section 3.4.4.

It should be noted that falling object protective structures independently placed on the market are safety components and are included in the indicative list of safety components set out in Annex V (item 15). Such FOPS are also included in the categories of machinery listed in Annex IV (item 23) subject to the conformity assessment procedures referred to in Article 12 (3 and 4).

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.

§317 Steps and handholds for access

Section 3.4.5 deals with the design, construction and location of steps and handholds fitted to enable drivers and other persons to safely reach and leave the driving position and other operating positions and servicing points on the machinery – see §237: comments on section 1.5.15, and §240: comments on section 1.6.2. This requirement should be applied in conjunction with the general requirements on the design of control devices – see §190: comments on the sixth indent of section 1.2.2.

Means of access to driving and other operating positions shall also be designed and located in order to avoid operators using as steps or handholds parts not intended for that purpose, such as, for example, holes in the structure, guards or moving parts. In particular, they should be designed to avoid the risk of a person holding onto the steering wheel when alighting or climbing the access steps, by for example the provision and positioning of easy to access safe hand holds. The access should meet the requirements of section 1.1.6 on ergonomics.

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.

§318 Towing devices

The requirements set out in section 3.4.6 apply to machinery intended to tow other machinery or equipment. Such towing machinery includes, for example, certain industrial trucks, aircraft ground support equipment intended to tow aircraft or other equipment and certain earthmoving machinery. The requirements set out in section 3.4.6 also apply to machinery intended to be towed by other machinery, by a vehicle or a by a tractor. Such towed machinery includes, for example, earthmoving machinery intended to be towed, towed agricultural machinery, trailer-mounted compressors, mobile elevating work platforms and removal lifts.

Towing devices such as tow bars, hooks and hitches, coupling bodies, mounting brackets and base plates, must be easy to connect securely and to disconnect. They must be designed and equipped to prevent accidental disconnection during towing, for example, by means of an automatic latch.

If the towing devices are heavy, a support must be provided such as, for example, a support leg with a surface for bearing on the ground, and the correct use of the support must be described in the instructions.

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

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

On the side of the self-propelled machinery (or tractor), the power take-off to which the removable mechanical transmission device is attached must be protected either by a guard fixed and linked to the self-propelled machinery (or tractor) or by any other device offering equivalent protection.

It must be possible to open this guard for access to the removable transmission device. Once it is in place, there must be enough room to prevent the drive shaft damaging the guard when the machinery (or the tractor) is moving.

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

Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machinery. The removable mechanical transmission device must be marked accordingly.

All recipient machinery, the operation of which requires a removable mechanical transmission device to connect it to self-propelled machinery (or a tractor), must have a system for attaching the removable mechanical transmission device so that, when the machinery is uncoupled, the removable mechanical transmission device and its guard are not damaged by contact with the ground or part of the machinery.

The outside parts of the guard must be so designed, constructed and arranged that they cannot turn with the removable mechanical transmission device. The guard must cover the transmission to the ends of the inner jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in the case of wide-angle universal joints.

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.

§319 Removable mechanical transmission devices

The requirements set out in section 3.4.7 concern the design and construction of removable mechanical transmission devices and their guards – see §45: comments on Article 2 (f). The purpose of these requirements is to prevent persons being caught up in the rotating transmission shaft or in the parts connecting the shaft to the power take-off on the towing machinery or tractor and to the towed machinery. This objective must be

achieved by adequate safeguarding of the transmission shaft and of the connecting parts.

The first, second, third, fourth and seventh paragraphs of section 3.4.7 set out requirements for the guards and their characteristics.

The third, sixth and last paragraphs of section 3.4.7 require measures to be taken to prevent damage to guards for the power take-off and for the removable mechanical transmission device, both during use and while the removable transmission device is uncoupled. The last paragraph of section 3.4.7 is complementary to the general requirement set out in section 1.6.2 relating to access to operating positions and servicing points.

It should be noted that guards for removable mechanical transmission devices independently placed on the market are safety components and are included in the indicative list given in Annex V (item 1). Removable mechanical transmission devices, including their guards, and guards for removable mechanical transmission devices are included among the categories of machinery listed in Annex IV (items 14 and 15) subject to the conformity assessment procedures set out in Article 12 (3) and (4).

3.5. PROTECTION AGAINST OTHER HAZARDS

3.5.1. Batteries

The battery housing must be designed and constructed in such a way as to prevent the electrolyte being ejected on to the operator in the event of rollover or tipover and to avoid the accumulation of vapours in places occupied by operators.

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

§320 Batteries

The requirement set out in section 3.5.1 relates to type of battery and the location, design and construction of the battery housing on mobile machinery. The use of sealed or 'maintenance free' batteries may be one of the means for reducing the risks concerned. Many types of batteries give off hydrogen when being charged and this can present an explosion hazard if allowed to accumulate. The last part of the first paragraph addresses this risk. This can be done by, for example, placing the battery compartment remote and not connected to operator cab and by providing adequate ventilation to the battery compartment.

The requirement set out in the second paragraph relating to the disconnection of the battery is a particular application of the general requirement set out in section 1.6.3 relating to isolation of energy sources. In order to comply with this requirement, the manufacturer may either fit an easily accessible isolator switch or, if the battery terminals are easily accessible, ensure that the battery terminals can be disconnected easily without the use of tools.

3.5.2. Fire

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

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

§321 Fire extinguishers and extinguisher systems

The requirement set out in section 3.5.2 is complementary to the general requirement set out in section 1.5.6 relating to the risk of fire.

Complementary protective measures to limit the effects of a fire on mobile machinery are to be determined in light of the intended conditions of use of the machinery and the assessment of the fire risk, including the possible consequences of a fire for persons and property. Factors to be considered include, for example:

- whether the machinery is intended to be used in an environment where the consequences of a fire may be severe;
- whether the machinery is intended for use indoors or in confined spaces;
- whether the machinery incorporates or is likely to carry significant quantities of combustible or flammable materials or substances;
- whether escape from the driving position or other operating positions could be compromised, for example, on large mobile plant.

If there is a significant residual risk of fire on the machinery and where its size permits, the machinery should be provided with easily accessible places where an appropriate number of adequately dimensioned fire extinguishers can be placed. The machinery manufacturer is not expected to provide the fire extinguishers.

In cases where the machinery presents a high residual risk of fire and/or where the consequences of a fire in the intended conditions of use may be severe, and where its size permits, the machinery manufacturer must fit a built-in fire extinguisher system.

It should be noted that the fitting of a built-in fire extinguisher system is an explicit requirement for certain machinery intended for underground work – see §366: comments on section 5.5.

3.5.3. Emissions of hazardous substances

The second and third paragraphs of section 1.5.13 do not apply where the main function of the machinery is the spraying of products. However, the operator must be protected against the risk of exposure to such hazardous emissions.

§322 Protection of sprayer operators against risks due to exposure to hazardous substances

The first sentence of section 3.5.3 indicates that the requirements set out in the second and third paragraphs of section 1.5.13, relating to the containment, evacuation, precipitation, filtering or treatment of hazardous materials and substances emitted by the machinery, do not apply to machinery the main function of which is the spraying of products that may be hazardous. Such machinery includes, for example, pesticide sprayers and certain surface cleaning and road construction machinery.

It should be noted that the first paragraph of section 1.5.13, relating to the prevention of risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances produced by the machinery, is applicable to machinery intended for spraying products.

The second sentence of section 3.5.3 stresses that, for machinery intended for spraying products, the operator must be protected against the risk of exposure to hazardous emissions by appropriate means that may be different from those mentioned in the second and third paragraphs of section 1.5.13. This requirement must be applied in conjunction with the requirements set out in section 1.1.7 on operating positions and the requirements set out in sections 3.2.1 and 3.2.3 on the driving position and on positions for other persons. Consequently, self-propelled machinery with a ride-on driver must be supplied with a driver's cab designed and constructed to protect against the risk of exposure to the hazardous substances concerned by means such as, for example, an adequate air filtering system with filters suitable and effective for the substance being sprayed and the cab being kept at positive pressure – see §182: comments on section 1.1.7, §235: comments on section 1.5.13, §294: comments on section 3.2.1, §296: comments on section 3.2.3 and §389: comments on Annex V[227].

Complementary requirements for machinery for pesticide application relating to the protection of the environment are set out in section 2.4 of Annex I – see §282 to §290: comments on section 2.4 of Annex I.

[227] European harmonised standards available: EN 15695-1:2009 *Agricultural tractors and self-propelled sprayers - Protection of the operator (driver) against hazardous substances* - Part 1: *Cab classification, requirements and test procedures*; EN 15695-2:2009 *Agricultural tractors and self-propelled sprayers - Protection of the operator (driver) against hazardous substances* - Part 2: *Filters, requirements and test procedures*.

3.6. INFORMATION AND INDICATIONS

3.6.1. Signs, signals and warnings

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

Without prejudice to the provisions of road traffic regulations, machinery with a ride-on driver must have the following equipment:

- *an acoustic warning device to alert persons,*
- *a system of light signals relevant to the intended conditions of use; the latter requirement does not apply to machinery intended solely for underground working and having no electrical power,*
- *where necessary, there must be an appropriate connection between a trailer and the machinery for the operation of signals.*

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

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

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

§323 Signs, signals and warnings

The requirements set out in section 3.6.1 are complementary to the requirements set out in sections 1.7.1 to 1.7.3 on information and information devices, warning devices, warning of residual risks and the marking of information essential for safe use of machinery – see §245 to §250 and §252: comments on sections 1.7.1 to 1.7.3.

The requirements relating to the form and language of information and warnings on the machinery set out in section 1.7.1 apply to the information required in the first paragraph of section 3.6.1. The requirements on warning devices set out in section 1.7.1.2 are applicable to the acoustic and visual warning devices, signals and signs required by the second and third paragraphs of section 3.6.1.

The reference to *'the provisions of road traffic regulations'* in the second paragraph of section 3.6.1 concerns rules for the road circulation of mobile machinery – see §308: comments on section 3.3.3.

The third paragraph of section 3.6.1 deals with risks due to collisions between remote-controlled or driverless mobile machinery and persons. Such machinery must be equipped with appropriate means to signal its movements such as acoustic and/or visual warning devices. Where necessary, protective devices must also be fitted to prevent collisions – see §294: comments on section 3.2.1.

The requirements set out in paragraph 3 of section 3.6.1 also apply to machinery with a ride-on driver intended to execute constant to-and-fro movements, such as, for example, certain road construction machinery or loaders, since the driver of such machinery may not be able to permanently monitor the area to the rear.

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).*

§324 Marking of mobile machinery

The requirements set out in section 3.6.2 for the marking of mobile machinery are complementary to the general requirements for marking set out in section 1.7.3 – see §250: comments on section 1.7.3. The marking of the nominal power, mass and, where appropriate, the maximum drawbar pull and vertical load provided for on the coupling hook should be affixed using the same technique as the other markings. Logically, the marking of power and mass should be affixed in the same place as the other markings, while the marking of the maximum drawbar pull and vertical load should be marked either in the same place or close to the towing device, as appropriate.

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 m/s^2. Where this value does not exceed 2,5 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 m/s^2. Where this value does not exceed 0,5 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.

Where harmonised standards are not applied, the vibration must be measured using the most appropriate measurement code for the machinery concerned.

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

§325 Declaration of vibrations transmitted by mobile machinery

The requirement set out in section 3.6.3.1 is complementary to the general requirements relating to the instructions set out in section 1.7.4. In particular, the requirements relating to the language of the instructions apply – see §257: comments on sections 1.7.4.1 (a) and (b).

The first two indents of the first paragraph of section 3.6.3.1 set out the physical quantities relating to the vibrations transmitted by mobile machinery to the hand-arm system and to the whole body that must be declared in the instructions.

The values measured on the machinery must be declared if they exceed 2.5 m/s^2 for the hand-arm system and 0.5 m/s^2 for the whole body. If the values measured on the machinery do not exceed these values, that fact must be declared. The vibrations transmitted by the machinery must therefore be measured by the machinery manufacturer using an appropriate test method, unless it has been established that, for the category of machinery concerned, the measured values never exceed the above limits – this may be stated in the C-type standard for the category of machinery concerned.

The declaration of vibrations transmitted by the machinery has two main purposes:

- to assist users to choose machinery with reduced vibration emissions;
- to provide information useful for the risk assessment to be carried out by the employer according to the national provisions implementing Directive 2002/44/EC on the exposure of workers to the risks arising from vibrations[228].

In this respect, it should be recalled that the level of exposure of workers to vibrations cannot be simply deduced from the machinery manufacturer's declaration of vibration emissions, since the exposure of operators is also influenced by other factors – see §231: comments on section 1.5.9.

The third indent of the first paragraph of section 3.6.3.1 requires the uncertainties surrounding the declared values to be specified. Guidance on determining the uncertainty associated with the measurement of vibrations transmitted by the machinery should be given in the relevant test codes.

The second paragraph of section 3.6.3.1 implies that, in the case of series production, measurement can be carried out on a representative sample of technically comparable machinery. In the case of one-off production, the manufacturer must measure the vibrations transmitted by each item of machinery supplied.

The third and last paragraphs of section 3.6.3.1 concern the methods to be used for measuring vibrations. Operating conditions have a strong influence on the vibrations transmitted by machinery. Measurement of vibrations should therefore be carried out under representative operating conditions. Vibration test codes for machinery specify the operating conditions or the range of operating conditions under which the measurements shall be made. Where a test code specified in a harmonised standard states the operating conditions under which the measurement is to be made, a reference to the harmonised standard is sufficient to indicate the operating conditions and measurement methods used. Where other test methods are used, the operating conditions and measurement methods used must be indicated in the declaration of vibrations.

General guidance on the determination of the vibration emission value for mobile machinery is given in standard EN 1032[229].

It should be noted that the values declared in the instructions relating to vibrations must also be included in commercial documents relating to the performance characteristics of the machinery – see §273: comments on section 1.7.4.3.

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[228] Directive 2002/44/EC of the European Parliament and of the Council of 25 June 2002 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration) (sixteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). OJ L 177, 6.7.2002, p. 13 – see Article 4 (4) (e).

[229] EN 1032:2003+A1:2008 *Mechanical vibration - Testing of mobile machinery in order to determine the vibration emission value*.

3.6.3.2. Multiple uses

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.

§326 Instructions on multiple uses

Section 3.6.3.2 underlines that instructions for mobile machinery intended to fulfil different functions using interchangeable equipment must include the information necessary for the safe assembly and use of the combination of the basic machinery and the interchangeable equipment.

The manufacturer of the basic machinery must:

– provide detailed information about the interface between the basic machinery and the interchangeable equipment

and

– indicate the essential characteristics of compatible interchangeable equipment or specify the interchangeable equipment that can safely be assembled with the machinery.

This requirement is complementary to the requirement of the manufacturer of interchangeable equipment to specify the basic machinery with which the equipment can be safely used and to provide the necessary assembly instructions – see §41: comments on Article 2 (b), and §262: comments on section 1.7.4.2 (i).

4. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS

Machinery presenting hazards due to lifting operations must meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).

§327 The scope of application of Part 4

Part 4 of Annex I sets out essential health and safety requirements for machinery presenting hazards due to lifting operations. The hazardous situations associated with lifting operations include, in particular, the fall or uncontrolled movement of the load, collisions with the machinery, the carrier or the load and the collapse or overturning of the lifting machinery.

The requirements set out in Part 4 of Annex I apply to all lifting operations as defined in section 4.1.1 (a), whether the lifting operation is the main function of the machinery, a secondary function of the machinery or a function of part of the machinery. In Part 4, the term 'lifting machinery' must therefore be understood as referring to all machinery presenting hazards due to lifting operations.

The requirements set out in Part 4 may be applicable to machinery in the strict sense, to interchangeable equipment intended for lifting operations, to safety components fitted to ensure the safety of lifting operations, to lifting accessories, to chains, ropes and webbing for lifting. Where requirements set out in Part 4 require tests to be carried out in order to check stability and strength, interchangeable equipment for lifting must be tested in the conditions under which it is intended to be used. It may therefore be necessary, for example, to carry out such tests on the interchangeable equipment assembled with a representative item of the basic machinery with which it is intended to be used – see § 41: comments on Article 2 (b).

In the following comments the scope of the different requirements is specified where necessary. It should be noted that any of the requirements set out Part 4 should be applied to partly completed machinery involving lifting operations.

4.1 GENERAL

4.1.1 Definitions

(a) 'Lifting operation' means a movement of unit loads consisting of goods and/or persons necessitating, at a given moment, a change of level.

. . .

§328 Lifting Operation

In the definition of the term *'lifting operation'*, the expression *'unit loads'* refers to groups of one or more persons or objects or quantities of bulk material which are moved as single items.

The expression *'necessitating, at a given moment, a change of level'* implies that the term *'lifting operations'* covers any movement or sequence of movements of unit loads

that includes lifting or lowering or both. Lifting and lowering includes changes of level in an upright vertical direction as well as at an inclined angle. It is important to apply a sensible approach when applying this section to movement along very low angle slopes where if the load came free it would not move, such as on a slight slope on a field. A value of such a slope angles cannot be given as the same slope on a rail system could cause the load to "run away".

The expression *'at a given moment'* indicates that machinery intended to move objects, fluids, materials or persons in a continuous manner, for example, on conveyors, on escalators or through pipes are not considered as carrying out 'lifting operations' in this sense and are not subject to the requirements set out in Part 4.

The expression *'unit loads'* does not cover parts of the machinery itself. Thus an operation where part of a machine is lifted but no external load is lifted is not considered as a lifting operation in this sense.

Normal digging and movement of materials by earth moving machinery such as, for example, excavators and loaders, are not considered as lifting operations, thus earth moving machinery used only for this purpose is not subject to Part 4 of Annex I. However, earth moving machinery that is also designed and equipped for lifting unit loads is subject to the requirements of Part 4 of Annex I, such machinery designed for use in general construction work can be expected to be used for lifting unit loads (e.g. pipes and other equipment), and this should be taken into account.

***4.1.1 Definitions** (continued)*

(b) 'Guided load' means a load where the total movement is made along rigid or flexible guides whose position is determined by fixed points.

. . .

§329 Guided Load

The definition of *'guided load'* covers both loads placed on carriers that follow guide-rails, tracks or ropes and loads lifted by machinery with equipment that moves the carrier along a predetermined trajectory, such as a scissor mechanism – see §336: comments on section 4.1.2.2, §342 to §344: comments on sections 4.1.2.6, 4.1.2.7, and 4.1.2.8, and §356: comments on section 4.2.3. It should be noted that the term *'guided load'* does not apply to machinery, such as, for example, gantry cranes or rail mounted tower cranes, where the movements of the machinery itself are guided but the movements of the load do not follow a predetermined trajectory.

***4.1.1 Definitions** (continued)*

(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.

. . .

§330 Working coefficient

'Working coefficient' is a concept relevant to the strength of load-bearing components of lifting machinery, of lifting accessories or of interchangeable equipment for lifting. Because the strength of such components is critical for the safety of lifting operations, they are to be dimensioned with a safety factor, referred to in part 4 of Annex I as a *'working coefficient'*. The working coefficient of a load bearing component is the ratio between the maximum load to which the component can be subjected without breaking (referred to in the relevant harmonised standards as the *minimum breaking force* of the component), and the specified maximum working load that should not be exceeded during use. Thus, for example, a component with a working coefficient of 5, is a component the minimum breaking force of which is 5 times its maximum working load – see §340 and §341: comments on sections 4.1.2.4 and 4.1.2.5, and §369: comments on section 6.1.1.

***4.1.1 Definitions** (continued)*

(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.

. . .

§331 Test coefficient

'Test coefficient' is a concept relevant to the static and dynamic overload tests carried out to prove that lifting machinery, lifting accessories or interchangeable equipment for lifting will operate correctly and without damage while lifting the maximum loads for which they are designed see §339: comments on section 4.1.2.3, §350 to §352: comments on section 4.1.3, and §360 and §361: comments on sections 4.4.1 and 4.4.2.

***4.1.1 Definitions** (continued)*

(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.

. . .

§332 Static Test

The static test is one of the means used to verify the integrity of machinery for lifting before it is put into service. Static tests are applied to lifting machinery in the strict sense, to lifting accessories and to interchangeable equipment for lifting – see §328: comments on section 4.1.1 (a), §339: comments on section 4.1.2.3, §350 to §352: comments on section 4.1.3, and §361: comments on sections 4.4.1 and 4.4.2.

***4.1.1 Definitions** (continued)*

(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.

. . .

§333 Dynamic Test

The dynamic test is another of the means used to verify the integrity and correct functioning of lifting machinery after it has been assembled. Dynamic tests are applied to lifting machinery in the strict sense and to interchangeable equipment for lifting – see §328: comments on section 4.1.1 (a), §339: comments on section 4.1.2.3, §352: comments on section 4.1.3, and §361: comments on section 4.4.2.

***4.1.1 Definitions** (continued)*

(g) 'Carrier' means a part of the machinery on or in which persons and/or goods are supported in order to be lifted.

§334 Carrier

The term 'carrier' is a generic term to designate parts of the machinery, such as, for example, cars, tables, platforms or chairs on which or in which loads, comprising goods, persons or both goods and persons are supported in order to be lifted – see §343 to §348: comments on sections 4.1.2.7 and 4.1.2.8, §359: comments on section 4.3.3, and §359 to §381: comments on sections 6.1, 6.2, 6.3, 6.4, and 6.5.

4.1.2 Protection against mechanical hazards

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.

§335 Risks due to lack of stability

The requirement set out in section 4.1.2.1 is applicable to lifting machinery in the strict sense, to interchangeable equipment for lifting and, where appropriate, to safety components fitted to ensure the safety of lifting operations.

The requirement set out in section 4.1.2.1 is complementary to the general requirement set out in section 1.3.1 of Annex I, which states that the machinery and its components

and fittings must be stable enough to avoid overturning during transportation, assembly, dismantling, and any other action involving the machinery. Section 4.1.2.1 stresses that the manufacturer must ensure the stability of lifting machinery both in service and out of service, during foreseeable component failures and during the static, dynamic and functional tests to which it may be submitted. The machinery must be designed to remain stable in the intended conditions of use.

The manufacturer must specify in the instructions the conditions under which the machinery meets the stability requirements. These conditions may include factors such as, for example, the maximum slope, the maximum wind speed and the resistance of the surface on which the machinery is used – see §263: comments on section 1.7.4.2 (g), and §269: comments on section 1.7.4.2 (o). Where the stability of the machinery depends on its installation at the place of use, the necessary installation instructions must be given – see §264: comments on sections 1.7.4.2 (i), and §361: comments on section 4.4.2 (a).

The measures to be taken to ensure the stability of the machinery, in accordance with the principles of safety integration set out in section 1.1.2, concern first the intrinsic stability of the machinery. Secondly, where a risk of loss of stability remains, the necessary protective devices and equipment to prevent the machinery tipping or overturning must be fitted. In this respect, the manufacturer must consider foreseeable misuse of the machinery that can give rise to a risk of tipping or overturning. The necessary protective measures may include, for example, fitting stabilisers, speed limiters, position control devices, overload and moment control devices and inclination control devices. Thirdly, for residual risks that cannot be fully prevented by such devices, the necessary indicators such as, for example, speedometers, inclinometers and anemometers, and the necessary information, warnings and instructions must be provided to enable operators to avoid situations that could lead to tipping or overturning of the machinery during the different phases of its lifetime – see §263: comments on section 1.7.4.2 (h).

The verification methods referred to in the last sentence of section 4.1.2.1 may include stability tests, simulations or both. Examples of stability tests include inclined plane tests and dynamic stability tests such as, for example, the ‘kerb test’ used to test mobile elevating work platforms. In the case of one-off production, such tests must be carried out on each machine. For series production, they are type-tests. The appropriate verification methods are usually specified in the relevant harmonised standards for particular categories of machinery.

In general, there is no obligation for such tests or simulations to be carried out by independent or third-party test bodies, although for lifting machinery subject to the EC type-examination or full quality assurance procedures, tests may be carried out by a Notified Body – see §129 and §130: comments on Article 12, §388: comments on Annex IV items 16 and 17, and §406: comments on Annex IX 3.2.

Stability tests carried to verify the conformity of the machinery with the essential requirements of the Machinery Directive should not be confused with tests that may be foreseen in national regulations relating to in-service inspection of lifting machinery – see §140: comments on Article 15.

4.1.2.2 Machinery running on guide rails and rail tracks

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

If, despite such devices, there remains a risk of derailment or of failure of a rail or of a running component, devices must be provided which prevent the equipment, component or load from falling or the machinery from overturning.

§336 Rail tracks and guide rails

The requirement set out in section 4.1.2.2 applies to lifting machinery intended to travel on rails or tracks, such as, for example, lifting machinery operating on rail networks, gantry cranes, container handling cranes, dock cranes, certain tower cranes and certain suspended work platforms.

Derailment can be prevented both by the design of the interface between the guide rails or tracks and the running components of the machinery and also by equipping the machinery with protective devices to prevent derailment, such as, for example, devices that deflect obstacles on the rails from the path of the running components of the machinery.

The requirement set out in the second paragraph of section 4.1.2.2 applies where there is a risk of the machinery overturning or falling away from its support in case of derailment or of the failure of a running component; devices must be fitted to prevent this. Examples of devices to prevent this risk include, for example, mechanical limiters to prevent a rail mounted suspended work platform falling from its support in case the running component leaves the rail.

If the rails on which lifting machinery is to be installed are not supplied by the machinery manufacturer, the manufacturer's instructions for installation must specify the characteristics of the rails and tracks and their foundations on which the machinery can be safely installed – see §361: comments on section 4.4.2 (a). Machinery intended for operation on existing rail networks must be designed to take account of the characteristics of the rails and tracks of the networks on which they are intended to be used – see §264: comments on section 1.7.4.2 (i).

4.1.2.3 Mechanical strength

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

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

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.

. . .

§337 Mechanical strength

The requirement set out in section 4.1.2.3 applies to lifting machinery in the strict sense, to interchangeable equipment intended for lifting, to lifting accessories and, where appropriate, to safety components fitted to ensure the safety of lifting operations. Such machinery is, by its function, subject to repeated mechanical stresses, fatigue and wear which can lead to failures resulting in the fall of the load or the overturning or collapse of the lifting machinery. The requirement set out in section 4.1.2.3 is complementary to the general requirement relating to the risk of break-up during operation – see §207: comments on section 1.3.2 of Annex I.

The first paragraph of section 4.1.2.3 requires the designer to ensure the strength of the components and assemblies of the machinery, taking into account the intended conditions of use during all phases of its lifetime. If certain restrictions on the conditions of use are taken into account in the design, such as, for example, a maximum wind speed, a maximum or minimum temperature or a maximum inclination, measures must be taken, in accordance with the principles of safety integration set out in section 1.1.2, to ensure that the machinery is only used within the prescribed limits.

The second paragraph of this section requires the designer to take account of fatigue and wear. Since fatigue and wear depend on the duration and the intensity of use of machinery, the calculations must be based on hypotheses relating to the lifetime of the machinery, such as, for example, a number of hours of operation or of operational cycles. It should be noted that the hypotheses used for the design of the machinery must be consistent with the instructions given by the manufacturer on the type and frequency of inspections and preventive maintenance of the machinery and on the criteria for the replacement of parts subject to wear – see §207: comments on section 1.3.2, and §272: comments on section 1.7.4.2 (r) of Annex I.

***4.1.2.3 Mechanical strength** (continued)*

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.

. . .

§338 Mechanical Strength – static test coefficients

The fourth paragraph of section 4.1.2.3 is applicable to lifting machinery, lifting accessories and interchangeable equipment for lifting operations that are submitted to a static overload test – see §331 and §332: comments on sections 4.1.1 (d) and (e), and §350 to §352: comments on section 4.1.3.

The design and construction of the machinery, including the strength and stability calculations, must take into account the test coefficient used for the static overload test to which the machinery will be submitted. The purpose of this requirement is to ensure that the machinery will not suffer damage while lifting its maximum working load and to provide a margin of safety in use.

The static test coefficient applies to tests carried out on complete machinery ready use. It should not be confused with the working coefficient that applies to the dimensioning of load-bearing components of machinery – see §330 and §331: comments on sections 4.1.1 (c) and (d).

Section 4.1.2.3 specifies that the static test coefficients used must ensure an adequate level of safety. Consequently, the choice of a test coefficient must be based on the manufacturer's risk assessment. Section 4.1.2.3 also indicates test coefficients to be used "as a general rule". The test coefficients specified in section 4.1.2.3 may not be appropriate for particular categories of lifting machinery or lifting accessories. The test coefficients specified in section 4.1.2.3 should be applied unless more appropriate test coefficients are specified in the relevant harmonised standard or are duly justified in the manufacturer's technical file. Application of a relevant harmonised standard that specifies such an alternative test coefficient gives a presumption of conformity to the requirement set out in section 4.1.2.3 – see §110: comments on Article 7 (2).

As a general rule, for lifting machinery and interchangeable equipment for lifting, the static tests referred to in section 4.1.2.3 are unit tests – see §350 to 352: comments on section 4.1.3.

In general, there is no obligation for these tests to be carried out by independent or third-party test bodies, although for lifting machinery subject to the EC type-examination or full quality assurance procedures, tests may be carried out by a Notified Body – see §129 and §130: comments on Article 12 (3) and (4), §388: comments on Annex IV items 16 and 17, and §398: comments on Annex IX 3.2.

The static overload tests carried to verify the conformity of the machinery with the essential requirements of the Machinery Directive should not be confused with tests that may be foreseen in national regulations relating to in-service inspection of lifting machinery – see §140: comments on Article 15.

***4.1.2.3 Mechanical strength** (continued)*

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.

§339 Mechanical Strength – dynamic test coefficients

The last paragraph of section 4.1.2.3 is applicable to lifting machinery and interchangeable equipment for lifting operations that is submitted to a dynamic test is not applicable to lifting accessories – see §331 and §333: comments on sections 4.1.1 (d) and (f), and §350 to §352: comments on section 4.1.3.

The design and construction of the machinery, including both the strength and stability calculations, must take into account the test coefficient used for the dynamic test to which the machinery will be submitted. The purpose of this requirement is to ensure that that the machinery will function correctly and will not suffer damage during use.

Section 4.1.2.3 specifies that the test coefficient used for the dynamic test must ensure an adequate level of safety. Consequently, the choice of a test coefficient must be based on the manufacturer's risk assessment. Section 4.1.2.3 also indicates the test coefficient to be used "as a general rule". The test coefficient specified in section 4.1.2.3 may not be appropriate for particular categories of lifting machinery or lifting accessories. The test coefficient specified in section 4.1.2.4 should be applied unless a more appropriate test coefficient is specified in the relevant harmonised standard or is duly justified in the manufacturer's technical file. Application of a relevant harmonised standard that specifies such an alternative test coefficient gives a presumption of conformity to the requirement set out in section 4.1.2.4 – see §110: comments on Article 7 (2).

As a general rule, for lifting machinery in the strict sense and interchangeable equipment for lifting, the dynamic tests referred to in section 4.1.2.3 are unit tests – see §350 to §352: comments on section 4.1.3.

In general, there is no obligation for these tests to be carried out by independent or third-party test bodies, although for lifting machinery subject to the EC type-examination or full quality assurance procedures, tests may be carried out by a Notified Body – see §129 and §130: comments on Article 12 (3) and (4), §388: comments on Annex IV items 16 and 17, and §398: comments on Annex IX 3.2.

The dynamic tests carried to verify the conformity of the machinery with the essential requirements of the Machinery Directive should not be confused with tests that may be foreseen in national regulations relating to in-service inspection of lifting machinery – see §140: comments on Article 15.

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.

Ropes used directly for lifting or supporting the load must not include any splicing other than at their ends. Splicings are, however, tolerated in installations which are intended by design to be modified regularly according to needs of use.

Complete ropes and their endings must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 5.

Lifting chains must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 4.

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

§340 Pulleys, drums, wheels, ropes and chains

The requirements set out in section 4.1.2.4 of Annex I are applicable to pulleys, drums, wheels, ropes and chains incorporated into lifting machinery or into interchangeable equipment for lifting. The components of lifting accessories are subject to the specific requirements set out in the following section 4.1.2.5.

The requirements set out in the first and second paragraphs of section 4.1.2.4 relating to the compatibility of pulleys, wheels and drums with the ropes or chains with which they are to be used are intended:

- to ensure that the ropes or chains are not subject to undue wear due to bending round the pulleys, drums or wheels;
- to ensure that the ropes or chains do not come off the pulleys, wheels or drums around which they are wound.

The dimensional ratios and the compatibility of pulleys, drums and wheels on the one hand and chains and ropes on the other hand are usually specified in the relevant harmonised standards.

According to the third paragraph of section 4.1.2.4, as a general rule, splicing of load bearing ropes, other than at their ends, is forbidden. However, the second sentence of this paragraph recognises that splicing may be necessary on certain categories of

machinery, such as, for example, cableways for goods only or mobile yarders for logging, which employ long ropes designed to be modified regularly according to the needs of use or for authorised repair.

Section 4.1.2.4 specifies that the working coefficients for ropes and chains have to ensure an adequate level of safety. Consequently, the dimensioning of ropes and chains must be based on risk assessment carried out by the manufacturer of the lifting machinery or lifting accessory. Section 4.1.2.4 also indicates the working coefficient to be taken into account for the dimensioning of ropes and chains “as a general rule”. The working coefficients set out in section 4.1.2.4 may not be appropriate for particular components or for particular categories of lifting machinery. The working coefficients set out in section 4.1.2.4 should be applied unless more appropriate working coefficients are specified in the relevant harmonised standard or are duly justified in the manufacturer's technical file for the lifting machinery or lifting accessory – see §392: comments on Annex VII A 1 (a). Application of a relevant harmonised standard that specifies such an alternative working coefficient gives a presumption of conformity to the requirement set out in section 4.1.2.4 – see §110: comments on Article 7 (2).

The last paragraph of section 4.1.2.4 requires tests to be carried out in order to verify that the chains or ropes directly used for lifting the load and their endings have an adequate working coefficient. In order to apply a working coefficient, it is necessary to know the minimum breaking force of the chain or rope concerned – see §330: comments on section 4.1.1 (c).

For chains and ropes for lifting purposes, the tests needed to establish the minimum breaking force of the chain or rope itself are normally carried out by the manufacturer of the chain or rope and are specified in the relevant certificate – see §357: comments on section 4.3.1 of Annex I.

However, if the manufacturer of the lifting machinery, the lifting accessory or the interchangeable equipment for lifting manufactures chains or ropes or their endings himself, he must perform the necessary tests or have them performed. The results of the tests must be included in the manufacturer’s technical file for the machinery – see §392: comments on Annex VII A 1 (a).

The tests referred to in section 4.1.2.4 are type-tests intended to experimentally verify the manufacturer’s strength calculations. In general, there is no obligation for such tests to be carried out by independent or third-party test bodies, although for lifting machinery subject to the EC type-examination or full quality assurance procedures, tests may be carried out by a Notified Body – see §129 and §130: comments on Article 12 (3) and (4), and comments on Annex IX. These tests should not be confused with tests that may be foreseen in national regulations relating to in-service inspection of lifting machinery or lifting accessories – see §140: comments on Article 15.

4.1.2.5 Lifting accessories and their components

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

Moreover:

(a) the working coefficient of wire-rope/rope-end combinations must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 5. Ropes must not comprise any splices or loops other than at their ends;

(b) where chains with welded links are used, they must be of the short-link type. The working coefficient of chains must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;

(c) the working coefficient for textile ropes or slings is dependent on the material, method of manufacture, dimensions and use. This coefficient must be chosen in such a way as to guarantee an adequate level of safety; it is, as a general rule, equal to 7, provided the materials used are shown to be of very good quality and the method of manufacture is appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety. Textile ropes and slings must not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling;

(d) all metallic components making up, or used with, a sling must have a working coefficient chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;

(e) the maximum working load of a multilegged sling is determined on the basis of the working coefficient of the weakest leg, the number of legs and a reduction factor which depends on the slinging configuration;

(f) in order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of component referred to in (a), (b), (c) and (d), perform the appropriate tests or have such tests performed.

§341 Lifting accessories and their components

The requirements set out in section 4.1.2.5 apply to lifting accessories and their components – see §43: comments on Article 2 (d). 'Components' in the context of section 4.1.2.5 refers to items to be integrated into lifting accessories and which are relevant to their safety.

The requirement set out in the first paragraph of section 4.1.2.5 is complementary to the requirements set out in the first three paragraphs of section 4.1.2.3 and the general requirements relating to the risk of break-up during operation set out in section 1.3.2. It should be noted that the hypotheses used in the design of lifting accessories and their components with respect to their conditions of use and their foreseeable life-span must be consistent with the instructions given by the manufacturer for their inspection and

maintenance and with the criteria for their replacement – see §207: comments on section 1.3.2 and §272: comments on section 1.7.4.2 (r).

Section 4.1.2.5 specifies that the working coefficients for the components of lifting accessories have to ensure an adequate level of safety. Consequently, the dimensioning of such components must be based on the risk assessment carried out by the manufacturer of the lifting accessory. Paragraphs (a) to (d) of Section 4.1.2.5 indicate the working coefficients to be taken into account for the dimensioning of components of lifting accessories “as a general rule”. The working coefficients set out in section 4.1.2.5 may not be appropriate for particular components or for particular categories of lifting accessories. The working coefficients set out in section 4.1.2.5 should be applied unless more appropriate working coefficients are specified in the relevant harmonised standard or are duly justified in the manufacturer’s technical file. Application of a relevant harmonised standard that specifies such an alternative working coefficient gives a presumption of conformity to the requirement set out in section 4.1.2.5 – see §110: comments on Article 7 (2).

Paragraph (f) of section 4.1.2.5 requires tests to be carried out in order to verify that the components of lifting accessories referred to in paragraphs (a) to (d) have been designed and constructed with an adequate working coefficient. In order to apply a working coefficient, it is necessary to know the minimum breaking force of the component concerned – see §330: comments on section 4.1.1 (c).

For chains, ropes or webbing, the tests needed to establish the minimum breaking force of the chain, rope or webbing itself are normally carried out by the manufacturer of the chain, rope or webbing and are specified in the relevant certificate – see §357: comments on section 4.3.1 of Annex I. For other components, the necessary tests can be carried out by or for the component manufacturer or the manufacturer of the lifting accessory.

If a component of a lifting accessory is manufactured as a single item or in a small series, it may not be practicable to carry out tests that would render the component unusable. In that case, the lifting accessory manufacturer must verify by other appropriate means, such as design calculations, that the component used to make up the lifting accessory has an adequate working coefficient.

The tests referred to in section 4.1.2.5 (f) are type-tests. There is no obligation for the tests to be carried out by an independent or third-party test body. These tests should not be confused with tests that may be foreseen in national regulations relating to in-service inspection of lifting machinery – see §140: comments on Article 15.

The relevant calculations and the reports giving the outcome of the tests referred to in section 4.1.2.5 (f) must be included in the manufacturer's technical file for the lifting accessory - see §392: comments on Annex VII A 1 (a).

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.

(c) Machinery must be designed and constructed in such a way that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine.

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

(e) Holding devices must be designed and constructed in such a way that inadvertent dropping of the loads is avoided.

§342 Control of movements

The requirements set out in section 4.1.2.6 apply to lifting machinery in the strict sense, to interchangeable equipment for lifting and, where appropriate, to safety components fitted to ensure the safety of lifting operations. They may also apply to lifting accessories with controlled moving parts.

The requirement set out in the first sentence of section 4.1.2.6 is a general requirement for all devices controlling movements of the machinery or of the load.

Paragraph (a) of section 4.1.2.6 concerns limits on the amplitude of movements, where this is necessary to ensure safe operation. In some cases, this requirement can be satisfied by the design of the drive and control systems. In other cases, the fitting of limiting devices on the elements subject to movement, such as, for example, mechanical stops, limit switches or buffers may also be necessary to fulfil this requirement.

Paragraph (b) of section 4.1.2.6 deals with the risk of collision between fixed or rail mounted machines. The risk of collision may exist when several machines are used in the same operational area, such as, for example, when two or more tower cranes are installed on one construction site or when two or more gantry cranes are installed in the same building. For lifting machinery intended to be used in situations where this risk may exist, the manufacturer must ensure that the necessary anti-collision devices can be fitted to the machinery, and provide the necessary fitting instructions.

Paragraph (c) of section 4.1.2.6 deals with the risk of uncontrolled movements of the load. Such movements may include uncontrolled upward or downward movement of the load under the effect of its own weight or of a counterweight. Measures to fulfil this

requirement include, for example, the fitting of brakes that apply in absence of energy, check valves on hydraulic cylinders and safety gear on rail guided lifts and hoists.

The requirement does not rule out all creep of the load when slight movement of the load does not create a risk. Harmonised standards may specify the maximum amplitude or speed of movement that is acceptable. For certain types of lifting machinery, such as, for example, vehicles servicing lifts, where no movement of the load from its raised position is acceptable, and locking devices may have to be fitted to comply with this requirement.

Paragraph (d) of section 4.1.2.6 sets out a requirement for the lowering of the load which is applicable to most lifting machinery, since a friction brake does not usually provide a reliable means of controlling the lowering movement.

Paragraph (e) of section 4.1.2.6 applies to the design of load holding devices, whether they are part of lifting machinery or part of a lifting accessory. The most common means used to fulfil this requirement is the safety catch fitted to a hook. For other types of load holding device, the measures necessary to fulfil this requirement include, for example, fitting a reserve vacuum to vacuum lifters or fitting a stand-by battery to electric lifting magnets.

4.1.2.7 Movements of loads during handling

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

Machinery with guided loads must be designed and constructed in such a way as to prevent persons from being injured by movement of the load, the carrier or the counterweights, if any.

§343 Prevention of the risks of collisions

The first paragraph of section 4.1.2.7 applies to lifting machinery or interchangeable equipment for lifting, operations of which are under the constant control of the operator. In that case, the location and design of the operating position must provide the operator with the best possible visibility of the movements of the load. In certain cases, in order to fulfil this requirement, the operating position must itself be moveable. In other cases, a remote control can be provided to enable the operator to control the movements of the load from a position where he has adequate visibility. In the case of mobile lifting machinery, the requirement set out in the first paragraph of section 4.1.2.7 is complementary to the requirement set out in the first paragraph of section 3.2.1 of Annex I.

The second paragraph of section 4.1.2.7 applies to lifting machinery with a guided load, to interchangeable equipment for lifting with a guided load and, where appropriate, to safety components fitted to ensure the safety of such lifting operations – see §329: comments on section 4.1.1 (b). For such machinery, the movements of the carrier, the load and the counterweights if any are usually not under the constant control of the

operator. The measures to be taken to prevent the risk of injury to persons due to contact with the carrier, the load or the counterweight depend on the risk assessment. In some cases, in case of high travel speed for example, the trajectory of the carrier, load or counterweight must be completely inaccessible during normal operation either by location or by guarding. In other cases, in case of low speed for example, it may be possible to prevent the risk of injury by fitting protective devices to the carrier – see §347: comments on section 4.1.2.8.3 of Annex I.

4.1.2.8 Machinery serving fixed landings

§344 Machinery serving fixed landings

Section 4.1.2.8 applies to a variety of lifting appliances that are outside the scope of the Lifts Directive 2014/33/EU, either because they do not correspond to the definition of a lift given in Article 1 of the Lifts Directive, or because they are excluded from the scope of the Lifts Directive by its Article 1 (3) – see §151: comments on Article 24.

Machinery serving fixed landings is machinery intended to move goods, persons or both goods and persons between pre-determined levels or floors of a building, a construction or a structure. Machinery serving fixed landings includes, for example, goods-only lifts, construction site hoists for goods and persons, lifts connected to machinery such as, for example, tower cranes or wind generators, for access to workstations, home lifts, lifting platforms for persons with impaired mobility and stair lifts (if the machine is designed to lift persons then part 6 of this Annex applies in addition to part 4).

Machinery serving fixed landings is to be distinguished from machinery intended to provide access to positions at a height where access to and from the carrier is only foreseen at one level (usually the ground level), such as, for example, mast climbing or suspended work platforms, to which the requirements set out in section 4.1.2.8 are not applicable.

Machinery having both of the above functions, in other words, machinery that serves fixed landings and that can also be used, for example, as a work platform for access to positions in its travel zone, is subject to the requirements set out in section 4.1.2.8 for the hazards associated with the function of serving fixed landings.

4.1.2.8.1 Movements of the carrier

The movement of the carrier of machinery serving fixed landings must be rigidly guided to and at the landings. Scissor systems are also regarded as rigid guidance.

§345 Movements of the carrier

The objective of the requirement set out in section 4.1.2.8.1 is to ensure that the carrier of machinery serving fixed landings is safely guided to the landings, avoiding any risk of collision with the structures and devices at the landings, and reaches a position

permitting the safe transfer of goods, persons or persons and goods between the carrier and the landings – see §329: comments on section 4.1.1 (b).

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.

§346 Access to the carrier

The requirement set out in the first paragraph of section 4.1.2.8.2 deals with the risks due to unintended movement of the carrier while it is being loaded or unloaded or while persons are entering or leaving the carrier at landings. To fulfil this requirement, the lifting mechanism and the control system must be designed so that the carrier remains at the landing while it is accessible.

Application of the requirement set out in the first paragraph of section 4.1.2.8.2 does not rule out levelling movements of the carrier, providing such levelling movements are completed by the time persons are able to access the carrier. Furthermore, if the level of the carrier is liable to change during loading and unloading, re-levelling movements of the carrier may also be necessary.

The requirement set out in the second paragraph of section 4.1.2.8.2 is complementary to the general requirement set out in section 1.5.15 of Annex I. Machinery serving fixed landings with a carrier accessible to persons must have an adequate degree of stopping accuracy to prevent the risk of tripping when persons are entering or leaving the carrier. The requirement is applicable whether access to the carrier is foreseen for the transport of persons or only for the purpose of loading goods.

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.

§347 Contact with the moving carrier

The requirement set out in the first paragraph of section 4.1.2.8.3 is applicable to lifting machinery serving fixed landings in the strict sense and, where appropriate, to safety

components fitted to ensure the safety of lifting operations serving fixed landings. It is complementary to the requirement set out in the second paragraph of section 4.1.2.7.

The requirement set out in the first paragraph of section 4.1.2.8.3 implies that, for machinery serving fixed landings, the general rule is that the travel zone must be inaccessible to persons during normal operation, either by location or by guarding. Exceptions to this general rule are possible for machinery where the travel zone cannot be made inaccessible, such as, for example, stair lifts or certain types of lifting platforms for persons with impaired mobility. In such cases, the risk of contact with persons must be prevented by other means. Usually it is necessary to use a combination of means such as, for example, slow speed, hold-to-run controls and pressure sensitive protective devices.

On the other hand, access to the travel zone may be needed for inspection and maintenance purposes. The requirement set out in the second paragraph of section 4.1.2.8.3 deals with the risk of a person who enters the travel zone for inspection or maintenance purposes being crushed between the carrier and the limits of the travel zone or obstacles situated above or below the carrier, in case of unintended movement of the carrier. This risk can effectively be prevented by ensuring that there is enough permanently available free space above and below the carrier in its highest and lowest positions to enable persons working there to avoid being crushed. If there is not enough room to provide such a permanent free space, mechanical devices must be used to block the carrier in a safe position. It must be possible to deploy such protective devices from a safe position i.e. outside the danger zone.

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.

§348 Loads falling off the carrier

The requirement set out in section 4.1.2.8.4 is expressed in general terms and its practical application depends on the assessment of the risk of the load falling. Factors to be taken into account include, for example, the height to which the load is lifted, the travel speed, the size, shape and weight of the load which the machinery is intended to carry, the possible presence of persons below the carrier and the design of the carrier itself. The normal way to apply this requirement is for the carrier to be equipped with a physical barrier preventing the load falling off.

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.*

§349 Safety at landings

The requirement set out in section 4.1.2.8.5 deals with risks for persons on the landings. It is applicable to lifting machinery serving fixed landings in the strict sense and, where appropriate, to safety components fitted to ensure the safety of such lifting operations. Two risks are considered: risks due to contact with the moving carrier or other moving parts of the machine (such as, for example, the risk of being hit, or crushed by the carrier or entrapped by the moving parts) and the risk of a person at the landing falling from a height into the travel zone when the carrier is not at the landing. Often, the same means can be used to protect against both risks.

The manufacturer of a stair lift must take measures to reduce the risk of falling down the stairs when getting on and off the lift, but he is not expected to fit a guard to prevent the risk of falling down the stairs from the landings, since this risk exists whether or not a stair lift is installed.

The interlocking guards referred to in the second paragraph of section 4.1.2.8.5 may be landing doors that prevent all access to the travel zone in absence of the carrier or barriers that prevent persons from reaching the travel zone. Specifications for such guards are included in harmonised standards for specific categories of machinery. Harmonised standards on safety distances[230], on the design of moveable guards[231], on interlocking devices for guards[232] and on means of preventing falling from platforms or walkways for access to machinery[233] may also be relevant for the design of guards on landings.

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[230] EN ISO 13857:2008 *Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs* (ISO 13857:2008).

[231] EN 953:1997+A1:2009 *Safety of machinery - Guards - General requirements for the design and construction of fixed and movable guards.*

[232] EN 1088:1995+A2:2008 *Safety of machinery - Interlocking devices associated with guards - Principles for design and selection*.

[233] EN ISO 14122-2:2001+A1:2010 *Safety of machinery - Permanent means of access to machinery* - Part 2: *Working platforms and walkways* (ISO 14122-2:2001).

It should be noted that devices for locking landing doors for machinery designed for lifting persons between fixed landings are included in the list of safety components given in Annex V – see §389: comments Annex V item 17.

4.1.3 Fitness for purpose

When lifting machinery or lifting accessories are placed on the market or are first put into service, the manufacturer or his authorised representative must ensure, by taking appropriate measures or having them taken, that the machinery or the lifting accessories which are ready for use — whether manually or power-operated — can fulfil their specified functions safely.

The static and dynamic tests referred to in section 4.1.2.3 must be performed on all lifting machinery ready to be put into service.

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

§350 Checking fitness for purpose

The requirement set out the first paragraph of section 4.1.3 applies to lifting machinery in the strict sense, to interchangeable equipment for lifting and to lifting accessories.

The aim of this requirement is to ensure the integrity and correct functioning (referred to as 'fitness for purpose') of all lifting machinery, interchangeable equipment for lifting or lifting accessories that are placed on the market and put into service. The purpose of the measures required in the first paragraph of section 4.1.3 is not to verify the design of the machinery but to check the integrity of the construction and assembly of the machinery and the correct functioning of the controls and protective devices.

The requirement means that the manufacturer must ensure that the necessary functional tests and inspections are carried out before the machinery is first put into service by the user. There is no obligation for the tests to be carried out by an independent or third-party test body. They can be carried out by the manufacturer himself or entrusted to any competent person or body acting on his behalf.

The measures necessary to check the fitness for purpose of machinery, carried out by or on behalf of the manufacturer after the machinery has been assembled and before the machinery is first put into service should not be confused with tests that may be foreseen in national regulations relating to in-service inspection of lifting machinery – see §140: comments on Article 15.

§351 Static and dynamic tests

The second paragraph of section 4.1.3 specifies that, for all lifting machinery in the strict sense or interchangeable equipment for lifting, the 'measures' required in the first paragraph must include the static and dynamic overload tests referred to in section 4.1.2.3. As a general rule, static and dynamic tests are unit tests to be carried out on

each machine after it has been assembled and before it is first put into service. This is particularly important when manual welding is employed in the production process, since the dynamic and static testing with the required overload contributes to the relief of stresses in the welding.

For some categories of machinery produced in series, where the production techniques employed and the application of a duly documented quality control system make it possible to guarantee that every machine produced will have identical characteristics when fully assembled, static or dynamic tests on adequate samples of the machinery can be considered as fulfilling the requirement set out in the second paragraph of section 4.1.3.

The conditions for carrying out the static and dynamic tests are usually specified in the harmonised standards for the category of machinery concerned. The relevant test reports must be included in the instructions accompanying the machinery – see §361: comments on section 4.4.2 (d). Some harmonised standards propose model formats for such test reports.

§352 Checking fitness for purpose at the place of use

Since the measures necessary to ensure the fitness for purpose required by the first and second paragraphs of section 4.1.3 must be carried out after the machinery has been assembled, the third paragraph of section 4.1.3 specifies that, for lifting machinery that cannot be assembled in the manufacturer's premises but can only be assembled at the place of use, such as, for example, large gantry cranes, the necessary tests and inspections must be carried out at the place of use. For other lifting machinery that can be assembled in the manufacturer's premises, the manufacturer can choose whether the necessary tests and inspections are carried out at his premises or at the place of use.

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

4.2.1 Control of movements

Hold-to-run control devices must be used to control the movements of the machinery or its equipment. However, for partial or complete movements in which there is no risk of the load or the machinery colliding, the said devices may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.

§353 Control of movements of the machinery and the load

The requirement set out in section 4.2.1 applies to lifting machinery in the strict sense, to interchangeable equipment for lifting and to lifting accessories with controlled moving parts. The use of hold-to-run control devices is intended to ensure that the movements of the machinery and the load are kept under the constant control of the operator. The exception to this general rule set out in the second sentence of section 4.2.1 applies to movements of machinery where there is no risk of the load or the machinery colliding with persons, with obstacles or with other machinery. The exception applies, for

example, to the control of movements of a guided load where the travel zone is completely inaccessible during normal operation – see §343: comments on section 4.1.2.7 of Annex I.

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.*

§354 Preventing overloading and overturning

The requirement set out in section 4.2.2 applies to lifting machinery in the strict sense and interchangeable equipment for lifting with a maximum working load of not less than 1000 kg or an overturning moment of not less than 40 000 Nm and to safety components fitted to such machinery to prevent overloading and overturning.

The purpose of the requirement set out in section 4.2.2 is to prevent machinery from being used, intentionally or unintentionally, to lift loads in excess of the maximum working load specified by the manufacturer or in such a way that the overturning moment is exceeded. Overloading of machinery can lead to immediate failure of load-bearing components or to the collapse or overturning of the machinery. Repeated overloading of the machinery may also cause excessive wear of load-bearing components, leading to failure after a certain time.

Section 4.2.2 takes account of the fact that, in the foreseeable conditions of use, the operator may not correctly evaluate the weight of the load to be lifted, he may attempt to lift a load that is too heavy or lift the load to a position that would lead to loss of stability. This requirement thus aims to prevent such foreseeable misuse of the machinery – see §173: comments on section 1.1.2 (a).

The choice of protective devices depends on the category and characteristics of the machinery concerned. For most categories of lifting machinery, the devices to be fitted are specified in the relevant harmonised standards. In general, load and moment control devices must be able to measure or calculate relevant parameters such as, for example, the weight of the load, the position of the load and the overturning moment created by the load. The devices must transmit a warning to the operator before the maximum working load or the overturning moment is reached, in order to enable him to take action to avoid overloading the machinery or moving the load to a position that would lead to overturning. The protective devices must be integrated into the control system in such a way as to prevent dangerous movements of the machinery or the load if the maximum working load or the overturning moment is exceeded. Non-dangerous movements of the machinery can be permitted.

It may be necessary to provide a means of overriding a load or moment control device, for example, in order to carry out overload tests or to bring the load back to a safe position. In that case, the necessary measures must be taken to prevent misuse of the override facility, for example, by means of a mode selector – see §204: comments on section 1.2.5 - or by locating the override control out of the reach of the normal operating position. For machinery intended to be used by emergency services, it may also be necessary to permit trained operators to override a load or moment control device, for example, to deal with a threat of fire or explosion.

Loading control is not required if it does not contribute to the safety of the machinery. For example, for machinery fitted with load holding device, such as a casting ladle, that makes it impossible to lift a load greater than the maximum working load of the machinery, the requirement for loading control may not be applicable.

§355 Loading control on industrial lift trucks

It was recognised, in a statement included in the minutes of the Council meeting of 14 June 1991, that the requirement relating to loading control might be problematic for industrial lift trucks:

> *"The Council and the Commission found that, in the current state of the art, certain machinery, including industrial trucks, might not meet this requirement in its entirety. Any problems in applying this point would be submitted to the Machinery Committee for examination."*

The Machinery Committee set up according to Article 6 (2) of Directive 98/37/EC indicated that the above statement relating to 'industrial trucks' did not apply to variable reach lift trucks with a telescopic boom (telehandlers) but only to industrial mast lifting trucks, since there was no technical difficulty in fitting variable reach trucks with devices to prevent the overturning moment being exceeded as a result of the load being lifted[234].

The statement by the Council and the Commission of 14 June 1991 remains valid for industrial mast lifting trucks with respect to the application of the requirement set out in section 4.2.2 of Annex I to Directive 2006/42/EC. However, it is expected that the state of the art will develop to approach the requirement set out in section 4.2.2. This development will be reflected in the revision of the relevant harmonised standards.

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.

§356 Guide ropes

This requirement applies to lifting machinery with a carrier suspended from carrier ropes and pulled by traction ropes, such as, for example, cableways for the transport of goods. It also applies to machinery with a carrier suspended by the traction ropes, such as, for example, goods only lifts or construction site hoists. Maintaining adequate tension in

[234] Meeting of the Machinery Committee of 9 February 2005.

such ropes is necessary to develop the required friction forces, to ensure that the ropes wind correctly around their drums, pulleys or sheaves and to prevent them from leaving their guides.

4.3 INFORMATION AND MARKINGS

4.3.1 Chains, ropes and webbing

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

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

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

(b) a description of the chain or rope which includes:

- *its nominal size,*
- *its construction,*
- *the material from which it is made, and*
- *any special metallurgical treatment applied to the material;*

(c) the test method used;

(d) the maximum load to which the chain or rope should be subjected in service. A range of values may be given on the basis of the intended applications.

§357 Information and markings for chains, ropes and webbing

The requirements set out in section 4.3.1 applies to the products referred to in Article 1 (1) (e) and defined in Article 2 (e) – see §44: comments on Article 2 (e).

The markings required by section 4.3.1 are complementary to the marking requirements set out in section 1.7.3 – see §250: comments on section 1.7.3.

These marking requirements are applicable to the products placed on the market by the chain, rope or webbing manufacturer. The marking may be affixed to the bulk reels, drums, rolls, coils or bundles of chain, rope or webbing. The plate or ring on which the marking is affixed must be irremovable, in other words, it must not be liable to be unintentionally removed during storage and transport. It is advisable for the CE marking to be affixed in the same place – see §141: comments on Article 16 (2), and §387: comments on Annex III.

The marking requirements do not apply to lengths of chain, rope or webbing cut from the products placed on the market by the chain, rope or webbing manufacturer for incorporation into lifting machinery or lifting accessories. Consequently, the lengths of chain, ropes or webbing that are incorporated into lifting machinery or lifting accessories are not expected to bear these markings.

However, distributors of chains, ropes and webbing must ensure that the relevant EC Declaration of Conformity, the reference of the certificate setting out the characteristics of the chain, rope or webbing and the manufacturer's instructions are passed on with the cut lengths of chain, rope or webbing supplied to manufacturers of lifting machinery or lifting accessories or to users - see §44: comments on Article 2 (e).

The information included in the certificate and the EC Declaration of Conformity of the chain, rope or webbing must be recorded in the manufacturer's technical file for the lifting machinery or lifting accessories into which the chain, rope or webbing is incorporated – see §392: comments on Annex VII A 1 (a).

The certificate referred to in the second paragraph of section 4.3.1 shall set out the technical characteristics of the rope, chain or webbing. The relevant harmonised standards provide model formats for this certificate.

The test method referred to in section 4.3.1 (c) is the method used for the sample test required to establish the minimum breaking force of the chain, rope or webbing – see §340 and §341: comments on sections 4.1.2.4 and 4.1.2.5. Where the appropriate test method set out in a harmonised standard is used, it is sufficient to specify the reference of the standard.

The information required by section 4.3.1 (d) shall enable to manufacturer of lifting machinery or lifting accessory to choose a chain, rope or webbing with an adequate working coefficient, taking account of the intended use of the lifting machinery or lifting accessory and the maximum load to which the chain, rope or webbing is to be subject during use. The chain, rope or webbing manufacturer must therefore indicate the minimum breaking force of the chain, rope or webbing.

Although section 4.3.1 does not specify that the certificate referred to in the second paragraph must accompany the product, the information included in the certificate must be available to manufacturer or user of lifting machinery or lifting accessories to enable him to select ropes, chains or webbing that are appropriate to the intended use and that have the required working coefficient and technical characteristics – see §337 to §341: comments on sections 4.1.2.3, 4.1.2.4 and 4.1.2.5.

It is therefore advisable to include the EC Declaration of Conformity, the information referred to in the second paragraph of section 4.3.1 and the instructions for the chain, rope or webbing in a single document.

4.3.2 Lifting accessories

Lifting accessories must show the following particulars:

- *Identification of the material where this information is needed for safe use,*
- *the maximum working load.*

In the case of lifting accessories on which marking is physically impossible, the particulars referred to in the first paragraph must be displayed on a plate or other equivalent means and securely affixed to the accessory.

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

§358 Marking of lifting accessories

The marking requirements set out in section 4.3.2 apply to lifting accessories – see §43: comments on Article 2 (d). These requirements are complementary to the requirements relating to marking of machinery set out in section 1.7.3.

If a lifting accessory is manufactured from components permanently assembled together, the assembly must be marked as a single lifting accessory. If components for slings or other lifting accessories are placed on the market that can be also be used as separate lifting accessories, such components should bear the markings required by section 4.3.2. On the other hand, components that cannot be used as separate lifting accessories should not bear those markings.

Harmonised standards for steel components for slings specify a code system for marking. It such components can be used as separate lifting accessories; the coded marking can be considered to comply with the requirement set out in section 4.3.2 providing the meaning of the code is made explicit in the manufacturer's instructions – see §360: comments on section 4.4.1 of Annex I.

The CE marking shall be affixed in the same place as the markings required by sections 1.7.3 and 4.3.2 – see §387: comments on Annex III.

4.3.3 Lifting machinery

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

Where the maximum working load depends on the configuration of the machinery, each operating position must be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the working load permitted for each configuration.

Machinery intended for lifting goods only, equipped with a carrier which allows access to persons, must bear a clear and indelible warning prohibiting the lifting of persons. This warning must be visible at each place where access is possible.

§359 Marking of lifting machinery

The requirements set out in section 4.3.3 apply to lifting machinery in the strict sense and to interchangeable equipment for lifting. They are complementary to the requirements relating to the marking of machinery set out in section 1.7.3.

Section 4.3.3 specifies that the maximum working load must be marked 'prominently'. This is a stronger requirement than that applicable to other markings in section 1.7.3, which only have to be 'visible'. This implies that the maximum working load must be marked on the machinery in such a way as to be easily seen by the operators. The maximum working load should be marked in kilograms.

On the other hand, the load plate referred to in the second paragraph of section 4.3.3, indicating the maximum working load for each of the operating positions of the machinery, must be visible from the relevant operating positions.
The third paragraph of section 4.3.3 deals with a foreseeable risk of misuse of certain machinery only intended for lifting goods – see §175: comments on section 1.1.2 (c). Machinery with a carrier that is large enough to allow access to persons, such as, for example, goods-only lifts, must bear an appropriate warning to persons who might be tempted to travel in the carrier. This warning is subject to the requirements set out in section 1.7.1 of Annex I relating to information and warnings on machinery.

4.4 INSTRUCTIONS

4.4.1 Lifting accessories

Each lifting accessory or each commercially indivisible batch of lifting accessories must be accompanied by instructions setting out at least the following particulars:

(a) the intended use;

(b) the limits of use (particularly for lifting accessories such as magnetic or vacuum pads which do not fully comply with section 4.1.2.6 (e));

(c) instructions for assembly, use and maintenance;

(d) the static test coefficient used.

§360 Instructions for lifting accessories

The requirement set out in section 4.4.1 applies to lifting accessories, including slings and components of slings that can be used as separate lifting accessories – see §43: comments on Article 2 (d).

Instructions for lifting accessories may be included in a commercial document such as, for example, a catalogue, but the manufacturer must ensure that a copy of the document is supplied with each lifting accessory or batch of accessories.

Indent (b) relates to accessories such as, for example, magnetic or pneumatic lifters, for which the requirement set out in section 4.1.2.6 (e) cannot always be fully satisfied. The manufacturer must specify these cases and inform the user that the load holding devices concerned must not be used above areas where people are liable to be present.

4.4.2 Lifting machinery

Lifting machinery must be accompanied by instructions containing information on:

(a) the technical characteristics of the machinery, and in particular:

- *the maximum working load and, where appropriate, a copy of the load plate or load table described in the second paragraph of section 4.3.3,*
- *the reactions at the supports or anchors and, where appropriate, characteristics of the tracks,*
- *where appropriate, the definition and the means of installation of the ballast;*

(b) the contents of the logbook, if the latter is not supplied with the machinery;

(c) advice for use, particularly to offset the lack of direct vision of the load by the operator;

(d) where appropriate, a test report detailing the static and dynamic tests carried out by or for the manufacturer or his authorised representative;

(e) for machinery which is not assembled on the premises of the manufacturer in the form in which it is to be used, the necessary instructions for performing the measures referred to in section 4.1.3 before it is first put into service.

§361 Instructions for lifting machinery

The requirement set out in paragraph 4.4.2 applies to lifting machinery in the strict sense and to interchangeable equipment for lifting.

The first indent of paragraph (a) of section 4.4.2 reiterates the importance of informing the user and the operator about the loading limits of the machinery.

The second and third indents of paragraph (a) of section 4.4.2 relate to the installation of lifting machinery in order to ensure its stability. These requirements are complementary to the general requirements relating to instructions for installation and stability set out in sections 1.7.4.2 (i) and (o) of Annex I.

Paragraph (b) of section 4.4.2 refers to the log book. There is no obligation for the manufacturer to supply such a log book. However, supplying a log book in which the preventive maintenance operations to be carried out by the user and their periodicity are indicated can be recommended as a practical way of providing the maintenance instructions required by section 1.7.4.2 (r) of Annex I.

Even if the manufacturer of the lifting machinery does not provide a log book, paragraph (b) of section 4.4.2 requires him to provide advice as to its content. Harmonised standards may specify a standardised form for the content of the log book for particular categories of machinery, which facilitates its use by users and by inspection and maintenance staff.

Paragraph (c) of section 4.4.2 recognises that the despite measures taken by the manufacturer to comply with the requirement set out in the first paragraph of section 4.1.2.7, the operator may nevertheless have inadequate visibility of the load in certain

operating conditions, for example, due to obstacles in the operating zone. The manufacturer must therefore provide guidance to the user on measures that can be taken to compensate such a lack of visibility.

Paragraphs (d) and (e) of section 4.4.2 refer to the measures to be taken by the manufacturer to check the fitness for purpose of lifting machinery according to section 4.1.3 of Annex I.

Paragraph (d) refers to the static and dynamic tests mentioned in the second paragraph of section 4.1.3. The relevant test reports must be included in the instructions. This provides the user with proof that the necessary tests have been carried out by or on behalf of the manufacturer. This requirement applies to all machines equipped for "lifting operations" – see §328: comments on Annex I 4.1.1 (a) – with a lifting mode, such as excavators, pipelines, cable excavator, telescopic loaders equipped with this function, and not only to cranes.

Paragraph (e) is relevant when machinery is not assembled in the manufacturer's premises and its fitness for purpose must therefore be checked by or on behalf of the manufacturer at the place of use – see comments on section 4.1.3. In that case, the instructions for carrying out the necessary measures must be included in the manufacturer's instructions to allow the necessary measures to be carried out at the place of use. It should be noted that this requirement does not imply that manufacturer's obligation to ensure that the fitness for purpose of the machinery is checked before the machinery is first put into service can be transferred to the user.

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).

§362 Supplementary requirements for machinery intended for underground work

Part 5 of Annex I sets out supplementary EHSRs for machinery intended for underground work. These apply to the machinery concerned in addition to the relevant requirements of Part 1 of Annex I and, where applicable, of the other Parts of Annex I – see §163: comments on General Principle 4.

The restricted application of the term *'underground work'* was indicated in the minutes of the Council of 20 June 1991 when these requirements were first introduced into the Machinery Directive:

> *"It is understood that work carried out in underground car parks, underground shopping malls, cellars, mushroom beds and the like is not regarded as underground work."*

Consequently, the EHSRs set out in Part 5 concern machinery intended for use in mines and underground quarries, not in buildings located below ground level.

It should be noted that certain categories of machinery for underground working are included in the list in Annex IV (items 12.1 and 12.2) of categories of machinery to which

one of the conformity assessment procedures referred to in Article 12 (3) and (4) are applicable.

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.

§363 Powered roof supports

The requirements set out in sections 5.1 and 5.2 concern self-advancing hydraulic powered roof supports used to support the roof of the mine face. The requirements set out in section 5.1 are complementary to the general requirement relating to stability set out in section 1.3.1.

Specifications for powered roof supports are given the EN 1804 series of standards.

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.

§364 Control devices

The requirements set out in the first paragraph of section 5.3 concern control devices for machinery running on rails for use in underground mines. They are complementary to the general requirements relating to control devices set out in section 1.2.2 and the requirements relating to control devices on mobile machinery set out in section 3.3.1.

The requirements set out in the second paragraph concern the design and the positioning of control devices for powered roof supports.

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.

§365 Control of travel movements

The requirement set out in section 5.4 is complementary to the requirement relating to control of travel movements set out in the first paragraph of section 3.3.2.

For self-propelled machinery running on rails for use in underground mines and quarries, an enabling device must be fitted not only to ensure that the driver is in the driving position but also to ensure that he or she remains in control of the travel movement.

5.5. FIRE

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

The braking system of machinery intended for use in underground workings must be designed and constructed in such a way that it does not produce sparks or cause fires.

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

§366 The risk of fire on machinery for underground work

The requirement set out in the first paragraph of section 5.5 is complementary to the requirements relating to extinguishing means set out in section 3.5.2. Since the consequences of a fire during underground work are always liable to be severe, the fitting of a built-in fire extinguisher system is an explicit requirement for machinery intended for underground work comprising highly flammable parts.

The requirements set out in the second and third paragraphs of section 5.5 are complementary to the general requirement relating to the risk of fire set out in section 1.5.6. They aim to prevent the braking system or the engine fitted to machinery intended for use in underground mines from igniting or propagating a fire.

It should be noted that internal combustion engines to be used in potentially explosive atmospheres are subject to the ATEX Directive 2014/34/EU – see §91: comments on Article 3, and §228: comments on section 1.5.7.

5.6. EXHAUST EMISSIONS

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

§367 Exhaust emissions

The main reason for the requirement set out in section 5.6 relating to the discharge of exhaust emissions from internal combustion engines fitted to machinery intended for underground work is to prevent the roof of the mine or quarry form being exposed to thermal stresses.

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

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).

§368 Scope of Part 6

Part 6 of Annex I sets out essential health and safety requirements for machinery presenting hazards due to the lifting of persons and applies in addition to the requirements in part 4. The particular hazardous situations associated with lifting persons include, in particular, the fall or the uncontrolled movement of the carrier, the fall of persons from the carrier, collisions between the carrier or the persons in or on the carrier and obstacles in the environment of the machinery and the collapse or overturning of the lifting machinery.

The risks related to lifting persons are generally higher than risks related to lifting goods in terms of the greater severity of possible harm due to failure leading to accidents, greater exposure to the hazards, since persons being lifted by machinery are continuously exposed to hazards such as, for example, the carrier falling, and a reduced possibility of avoiding the hazards or their consequences.

The requirements set out in Part 6 apply to all machinery carrying out operations involving the lifting of persons, whether lifting persons is the main function of the machinery, a secondary function of the machinery or a function of part of the machinery.

The term ‘lifting’ covers any movement or sequence of movements that includes lifting or lowering or both. Lifting and lowering includes changes of level in an upright vertical direction as well as at an inclined angle – see §328: comments on section 4.1.1 (a).

The requirements of Part 6 do not apply to hazards due to the movement of persons in a continuous manner, for example, on machinery such as escalators and moving walkways – see §328: comments on section 4.1.1 (a).

The requirements set out in Part 6 are applicable to machinery in the strict sense, to interchangeable equipment for lifting persons, to safety components fitted to ensure the safety of operations involving the lifting of persons, to lifting accessories or to chains, ropes and webbing for lifting persons.

It should be noted that any of the requirements set out Part 6 may be applied to partly completed machinery involving the lifting of persons.

6.1 GENERAL

6.1.1 Mechanical strength

The carrier, including any trapdoors, must be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load.

The working coefficients for components set out in sections 4.1.2.4 and 4.1.2.5 are inadequate for machinery intended for the lifting of persons and must, as a general rule, be doubled. Machinery intended for lifting persons or persons and goods must be fitted with a suspension or supporting system for the carrier designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk of the carrier falling.

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

§369 Mechanical strength

The requirements set out in section 6.1.1 are complementary to the general requirements set out in section 1.3.2 on the risk of break up during operation and to the requirements set out in section 4.1.2.3 on mechanical strength to offset hazards due to lifting operations.

The first paragraph of section 6.1.1 requires the design and construction of the carrier to take account both of the maximum working load to be carried and of the maximum number of persons permitted on the carrier. The maximum working load is calculated taking account of both the maximum number of persons intended to be lifted by the machinery and their weight and also the weight of objects or materials, such as, for example, work equipment or tools, that the machinery is intended to lift. The space provided for the persons must be adequate to enable them to be carried comfortably and safely and, in the case of work platforms, to enable them to carry out their tasks safely. In certain cases, the space provided may be limited to discourage overloading of the carrier.

The requirement set out in the second paragraph of section 6.1.1 takes account of the fact that, when lifting persons, the fall or uncontrolled movement of carrier or the load will nearly always result in a serious or fatal accident. Consequently, a more stringent working coefficient is to be used when calculating the strength of load bearing components than that used for machinery for lifting goods only – see §330: comments on section 4.1.1 (c).

The third paragraph of section 6.1.1 sets out a specific requirement for machinery with a suspended carrier. The objective of this requirement is to prevent the risks of the fall or the uncontrolled upward movement of the carrier in case of the rupture of a suspension rope or cable. The general rule for such machinery is to employ two or more separate suspension ropes or chains, each with its own anchorage.

Deviations from this general rule are possible in case it is not practicable to provide two suspension ropes, provided at least an equivalent level of safety can be achieved. An example of such a deviation is to use one suspension rope in combination with a safety rope and safety gear that is automatically triggered in case of overspeed of the carrier.

Any such deviations should be justified by the risk assessment and based on the state of the art. Technical solutions may be given in the relevant harmonised standards – see §162: comments on General Principle 3.

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.

§370 Loading control

The requirement set out in section 6.1.2 is complementary to the requirement set out in section 4.2.2 on loading control. Machinery intended for lifting persons must be fitted with the devices to prevent overloading and overturning required by section 4.2.2, including machinery with a maximum working load of less than 1000 kg or an overturning moment of less than 40 000 Nm.

It should be noted that loading control devices cannot prevent certain risks due to overloading such as, for example, the overloading of a work platform while working at a height. However, such devices can prevent an overloaded carrier being raised from its access position and they can provide a warning to the operator and prevent dangerous movements if the carrier is overloaded. Specifications for loading control are given in the harmonised standards for the particular categories of machinery for lifting persons.

Section 6.1.2 admits derogations to the requirement for loading control where the manufacturer can demonstrate that there is no risk of overloading or overturning. This might be the case either if the risk assessment shows that either these hazards are not present or if they have been sufficiently reduced by other means. A derogation might be acceptable, for example, on machinery where the size of the carrier provides only limited space and where the carrier and lifting structures have been calculated to withstand any overload the limited size of the carrier might permit. The conditions for such derogations are given in the harmonised standards for the particular categories of machinery concerned.

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.

§371 Control Devices

The requirements set out in section 6.2 are complementary to the general requirements set out in section 1.2.2 on control devices and to the requirements set out in sections 4.1.2.6 and 4.2.1 on control of movements to offset hazards due to lifting operations. The requirements set out in section 3.3.1 on control devices are also applicable to machinery for lifting persons presenting hazards due to its mobility.

The requirement set out in the first paragraph of section 6.2 takes account of the fact that, in general, the person being lifted in or on the carrier has the best appreciation of the hazards to which he might be exposed due, for example, to obstacles in the environment of the machinery. It is therefore essential for him to be able to control the movements of the carrier. Exceptions to this general rule can be admitted, for example, where the person or persons being lifted are protected against any hazards due to the movement of the carrier by other means such as, for example, a completely enclosed carrier, or if control of certain movements from outside of the carrier is necessary to reduce the risks.

The requirement set out in the second paragraph of section 6.2 means that the control devices in the carrier for the upward and downward movement must have priority over the control devices at landings or in other places for upward and downward movement and any other movement of the carrier.

According to the third paragraph of section 6.2, hold-to-run control devices are required for all movements of the carrier, whether or not the control devices are in the carrier, unless the carrier is completely enclosed. Completely enclosed carriers are carriers with full-length walls, fitted floors and ceilings included (with the exception of ventilation apertures) and full-length doors.

Use of hold-to-run control devices prompts the operator to pay attention to the movements he is controlling and facilitates an immediate halt in case a hazardous situation arises. In accordance with section 1.2.2, it is particularly important to ensure that hold-to-run control devices for machinery for lifting persons are located and designed to prevent them from being blocked in the 'run' position if the carrier comes into contact with an obstacle.

6.3 RISKS TO PERSONS IN OR ON THE CARRIER

6.3.1 Risks due to movements of the carrier

Machinery for lifting persons must be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for persons.

§372 Movement of the carrier

Excessive acceleration or deceleration of the carrier can cause the persons being lifted to lose their balance, to be injured by contact with parts of the carrier or even to be thrown out of the carrier. Persons may also be injured when safety devices are triggered. The requirement set out in section 6.3.1 requires the positive and negative acceleration values to be limited by the design and construction of the drive,

transmission and braking systems and of the safety devices. In the case of machinery that is not designed to travel while persons are in or on the carrier, the requirement only applies to movements of the carrier. In the case of machinery that is designed to travel while persons are in or on the carrier, the requirement applies both to the movements of the carrier and to the travel movements of the machinery itself.

6.3.2 Risk of persons falling from the carrier

The carrier must not tilt to an extent which creates a risk of the occupants falling, including when the machinery and carrier are moving.

. . .

§373 Tilt of the carrier

The requirements set out in section 6.3.2 are complementary to the requirement set out in section 1.5.15 on the risk of slipping, tripping or falling.

Tilting of the carrier may occur as a result of the position or the movement of the lifting machinery itself or as a result of movements of the carrier on its suspension system or supporting structure. Examples of hazardous situations involving tilting include, for example, an imbalance of hoist operation on suspended work platforms with more than one hoist, or the excessive tilt of a mobile elevating work platform due to movements of the supporting structure or due to internal leakage in hydraulic systems.

The first paragraph of section 6.3.2 does not rule out all tilting of the carrier, but requires the machinery to be designed and constructed to limit tilt to values that do not create a risk of persons falling in, on or from the carrier. The acceptable values depend on the manufacturer's risk assessment. Values are indicated in relevant harmonized standards.

Where excessive tilt cannot be prevented by inherently safe design measures, it may be necessary to fit devices to detect and correct excessive tilt automatically or, failing that, to stop movement of the carrier and warn the operator so that he can take the necessary corrective action before a hazardous situation is created.

6.3.2 Risk of persons falling from the carrier (continued)

. . .

Where the carrier is designed as a work station, provision must be made to ensure stability and to prevent hazardous movements.

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.

. . .

§374 Use of the carrier as a workstation

If the carrier is intended to be used as a workstation, the second paragraph of section 6.3.2 requires the carrier itself, its suspension system or supporting structure and the systems driving and controlling movements of the carrier to be designed and constructed to allow the work in question to be carried out safely by operators standing or sitting in or on the carrier. Account must therefore be taken of factors such as, for example, the kind of work for which the machinery is intended to be used, the related postures of the operators, the forces that may be exerted on the carrier during the work, including wind forces and manual forces, and the kind of equipment or tools that may be employed to carry out the work. The manufacturer's instructions must specify the limits on the forces that can safely be exerted on the carrier.

Because the possible consequences of a person or persons falling from the carrier are so serious, if there is even a slight residual risk of this happening, the third paragraph of section 6.3.2 requires the machinery manufacturer to provide the carrier with the necessary anchorage point or points to enable the operator or operators to attach the necessary personal protective equipment (PPE) to prevent falls. It should be noted that providing an anchorage point for attaching PPE is a complementary protective measure and in no case a substitute for integrated means of protection against falls from the carrier.

The appropriate PPE is usually a work restraint system that maintains the operator on the work station and prevents the operator from falling from the carrier. The manufacturer's strength and stability calculations must take account of the forces that can be created by use of the PPE. Appropriate information and warnings must be provided in the carrier – see §245 and §249: comments on sections 1.7.1 and 1.7.2. The manufacturer's instructions must also inform users about the residual risk of falling from the carrier and specify the type of personal protective equipment to be provided and used (for example a work restraint system with a rope length adapted to the surface of the work station). In particular, the instructions must warn against the use of a fall arrest system if the anchorage point has not been designed for such a system and if a fall of the operator from the carrier could cause a loss of stability of the machine – see §267: comments on sections 1.7.4.2 (l) and (m).

6.3.2 Risk of persons falling from the carrier (continued)

. . .

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.

§375 Doors on the carrier

The requirement set out in the fourth paragraph of section 6.3.2 seeks to reduce the risk of persons falling from the carrier through the openings needed for access, egress or escape purposes. Inadvertent opening must be prevented by the design of the doors and trapdoors themselves and by the location and the design of the means used to open them. For example, door handles must be located and designed to prevent inadvertent

opening due to contact with parts of the body. Care must also be taken to ensure that doors and trapdoors are not easy to jam in the open position.

In order to fulfil the requirement, set out in section 6.3.2, side doors must, as a general rule, be designed so that they open towards the inside of the carrier – they should not open with an outward movement or under the effect of their own weight. Trapdoors in the floor or ceiling of the carrier should usually open upwards. However, exceptions to these general rules may be necessary, for example, on platforms used by fire fighters, since they may restrict movement and thereby reduce the possibility of saving life.

The requirement set out in the fourth paragraph of section 6.3.2 is not relevant to the doors or gates used for access and for loading and unloading at landings on machinery serving fixed landings. However, such doors must be fitted with interlocking and guard locking devices – see §378: comments on section 6.4.1.

6.3.3 Risk due to objects falling on the carrier

Where there is a risk of objects falling on the carrier and endangering persons, the carrier must be equipped with a protective roof.

§376 Protective roof

The requirement set out in section 6.3.3 applies to machinery intended to be used in situations where there is a risk due to falling objects such as, for example, stones or debris. In that case, the protective roof, the carrier and the machinery itself must have sufficient mechanical strength and stability to resist the forces that may be exerted by such falling objects.

If, however, the intended use of the machinery makes it impracticable to equip the carrier with a protective roof, such as, for example, for work platforms intended to provide access to places situated above the carrier, the manufacturer's instructions must include warnings against the use of the machinery in situations where there is a risk due to falling objects – see §263: comments on sections 1.7.4.2 (g) and (h).

6.4. MACHINERY SERVING FIXED LANDINGS

§377 Machinery for lifting persons serving fixed landings

The requirements set out in section 6.4 are complementary to the requirements set out in section 4.1.2.8 on lifting machinery serving fixed landings.

The requirements set out in section 6.4 apply to machinery such as, for example, construction site hoists for persons or persons and goods, lifts connected to machinery such as, for example, tower cranes or wind generators, for access to workstations, home lifts, lifting platforms and stair lifts intended for persons with impaired mobility.

6.4.1 Risks to persons in or on the carrier

The carrier must be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfil this requirement, the carrier itself must be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless the doors are closed. The doors must remain closed if the carrier stops between landings where there is a risk of falling from the carrier.

The machinery must be designed, constructed and, where necessary, equipped with devices in such a way as to prevent uncontrolled upward or downward movement of the carrier. These devices must be able to stop the carrier at its maximum working load and at the foreseeable maximum speed. The stopping action must not cause deceleration harmful to the occupants, whatever the load conditions.

§378 Risk to persons in or on the carrier

The first sentence of section 6.4.1 means that, in all cases, the necessary protective measures must be taken to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. The second sentence of section 6.4.1 refers to cases where full enclosure of the carrier (or car) is necessary to achieve that objective. Full enclosure is necessary, for example, in the case of machinery with a fast moving carrier, such as, for example, certain construction site hoists. For such machinery, the doors must be fitted with interlocking devices to prevent movements of the carrier until the doors are closed. Where there is a risk of falling from the carrier if it stops between landings, the interlocking devices must be associated with guard locking devices to prevent opening of the doors until the carrier reaches a landing.

However, the Machinery Directive also applies to lifts with a travel speed of no more than 0.15 m/s – see §151: comments on Article 24. For such low-speed lifts, it may be possible to sufficiently reduce the risks due to contact between persons and/or objects in or on the carrier with fixed or moving elements by a combination of other means such as, for example, hold-to-run control devices to control movements of the carrier and partial enclosure of the carrier.

The second paragraph of section 6.4.1 deals with the risk of uncontrolled movements of the carrier, whether downward movement due to the weight of the carrier and the load or upward movement due to the counterweight. Where necessary to prevent these risks, the lift must be equipped with devices to detect such uncontrolled movements and to stop the carrier safely if such movements are detected.

6.4.2 Controls at landings

Controls, other than those for emergency use, at landings must not initiate movements of the carrier when:

- *the control devices in the carrier are being operated,*
- *the carrier is not at a landing.*

§379 Controls at landings

The requirement set out in section 6.4.2 aims to ensure that, when a person in or on the carrier has initiated a movement of the carrier, another person at a landing shall not be able to take control of the movement of the carrier using the “call" control until the person on the carrier has reached the intended landing. This means the call control must not take control either when a hold-to-run device has been released between landings or a safety device has been tripped.

On the other hand, means must be provided to bring the carrier safely to a landing in case of an emergency.

6.4.3 Access to the carrier

The guards at the landings and on the carrier must be designed and constructed in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons to be lifted.

§380 Access to the carrier

The requirement set out in section 6.4.3 is complementary to the requirement set out in section 1.5.15 on risks of slipping, tripping and falling and the requirement set out in section 4.1.2.8.2 on access to the carrier for lifting machinery serving fixed landings. The guards or doors on the carrier and at the landings must be designed taking into account the intended use of the machinery such as, for example, use by persons carrying or handling goods, use by children, use by persons with impaired mobility or wheelchair users.

Any gaps between the carrier and the landing must be sufficiently reduced, bridged or guarded to prevent risks to persons entering and leaving the carrier.

6.5 MARKINGS

The carrier must bear the information necessary to ensure safety including:

- *the number of persons permitted on the carrier,*
- *the maximum working load.*

§381 Markings in the carrier

The requirement set out in section 6.5 is complementary to the requirements set out in section 1.2.2 on the identification of control devices, section 1.7.1.1 on information and information devices, section 1.7.3 on marking of machinery and the first two paragraphs of section 4.3.3 on information and markings on lifting machinery.

Section 6.5 refers to information that must be easily and permanently available to the person or persons in or on the carrier of the machinery in order to ensure safe use of the machinery.

The maximum working load must be marked in the carrier (as well as on the machinery as required by section 4.3.3). The number of persons permitted in or on the carrier must also be marked in the carrier.

Other necessary information to be marked in the carrier may include action to be taken in emergencies and the correct use of emergency communication equipment.

ANNEX II

Declarations

1. CONTENT

A. EC DECLARATION OF CONFORMITY OF THE MACHINERY

This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex I, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.

This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.

. . .

§382 The EC Declaration of Conformity of machinery

Annex II 1 A concerns the EC Declaration of Conformity that must be drawn up by the manufacturer of machinery or his authorised representative in the EU and that must accompany the machinery until it reaches the user – see §103: comments on Article 5 (1), and §109: comments on Article 7 (1). The EC Declaration of Conformity is a legal statement by the manufacturer or his authorised representative attesting that the machinery concerned complies with all of the relevant provisions of the Machinery Directive.

The requirement set out in the first paragraph of Annex II 1 A, that the declaration and translations thereof must be drawn up under the same conditions as the instructions, entails that the EC Declaration of conformity must be drafted in one or more official EU languages. These language versions must bear the words *'Declaration of conformity'* (in the language of each version). The manufacturer may provide *"Declarations of conformity'"* in one or more languages. Where no original EC Declaration of conformity exists in the official language(s) of the country where the machinery is to be used, a translation into that or those languages 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 Declaration of Conformity'* (in the language of each version) and must be accompanied by original Declaration of Conformity. – see §246: comments on section 1.7.1, §255: comments on section 1.7.4, and §257: comments on sections 1.7.4.1 (a) and (b) of Annex I.

The EC Declaration of Conformity must be typewritten (printed) or handwritten in capital letters. It must either be included in the instruction manual or provided separately, in which case a document setting out the contents of the EC Declaration of Conformity must be included in the instruction manual – see §261: comments on section 1.7.4.2 (c) of Annex I.

The second paragraph of Annex II 1 A underlines that the EC Declaration of Conformity relates only to the machinery as it has been designed, constructed and placed on the market by the manufacturer. If the manufacturer authorises another economic operator

such as an importer or a distributor to modify machinery before it is supplied to the final user, the manufacturer remains legally responsible for the machinery as supplied. However, the manufacturer is not legally responsible for any additions or modifications made to the machinery without his authorisation by other economic operators or by the final user. This must be taken into account when machinery in use is examined by the market surveillance authorities – see §94: comments on Article 4 (1).

Annex II 1 A (continued)

. . .

The EC declaration of conformity must contain the following particulars:

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.*

. . .

§383 The content of the EC Declaration of Conformity

The following comments refer to the numbered paragraphs in Annex II 1 A:

1. The manufacturer's business name and full address must be the same as those marked on the machinery – see §250: comments on section 1.7.3 of Annex I. Where the manufacturer has chosen to mandate an authorised representative in the EU to carry out all or part of his obligations set out in Article 5 – see §84 and

§85: comments on Article 2 (j) – the particulars of the authorised representative must also be indicated in the EC Declaration of Conformity.

2. All machinery manufacturers must indicate the name and address of the person authorised to compile the technical file. That person is a natural or legal person established in the EU who has been entrusted by the manufacturer with the task of assembling and making available the relevant elements of the technical file in response to a duly reasoned request from the market surveillance authorities of one of the Member States – see §98: comments on Articles 4 (3) and (4), and §393: comments on Annex VII A 2 and 3. Essentially there must be a contact point in the EU for non-EU manufacturers. It is also required by other EU legislation like the Outdoor Noise Directive 2000/14/EC.

   The person authorised to compile the technical file is not, as such, responsible for the design, construction or conformity assessment of the machinery, for drawing up the documents included in the technical file, for affixing the CE marking or for drawing up and signing the EC Declaration of Conformity. Those roles remain with the manufacturer.

   For manufacturers established in the EU, the person authorised to compile the technical file may be the manufacturer himself, his authorised representative, a contact person belonging to the manufacturer's staff (who can be the same as the signatory of the EC Declaration of Conformity) or another natural or legal person established in the EU to whom the manufacturer entrusts this task. There is no need to create new functions such as “CE managers” within companies as there is no requirement as to the status of this person, provided they have access to and the means to compile the information. However, the responsibility to make available the technical file stays with the company and not with the person compiling the technical file.

   For manufacturers established outside the EU, the person authorised to compile the technical file may be any natural or legal person established in the EU who is entrusted with the task of assembling and making available the technical file in response to a duly reasoned request. If a manufacturer established outside the EU has chosen to mandate an authorised representative in the EU to carry out all or part of the obligations set out in Article 5 – see §84 and §85: comments on Article 2 (j) – the authorised representative in the EU can also be the person authorised to compile the technical file[235].

3. The particulars required for the description and identification of the machinery are essentially the same as those to be marked on the machinery – see §250: comments on section 1.7.3 of Annex I. The generic designation of the machine

[235] - EEA Agreement:
http://ec.europa.eu/world/agreements/prepareCreateTreatiesWorkspace/treatiesGeneralData.do?redirect=true&treatyId=1
- EU-Turkey Custom Union :
http://www.avrupa.info.tr/fileadmin/Content/Downloads/PDF/Custom_Union_des_ENG.pdf
- MRA Switzerland: http://ec.europa.eu/growth/single-market/goods/international-aspects/mutual-recognition-agreements/index_en.htm.

may be in the same language as on the marking, but not necessarily in the same language of the declaration of conformity. However, in the EC Declaration of Conformity the particulars of the machinery must be given in full. The purpose of this information is to enable both the user and the market surveillance authorities to identify the machinery covered by the declaration without ambiguity.

As a general rule, the serial number of the machinery covered by the EC Declaration of Conformity shall be indicated. In the case of machinery produced in large series, it is possible to draw up a single EC Declaration of Conformity covering a range of produced machines. To do this it must be possible to identify that an individual machine is covered by the Declaration of Conformity, for example by reference to a specific identification number or code or product batch, reference which is marked on the machine, in which case the range covered by the declaration must be specified and a new EC Declaration of Conformity must be issued for each new range. In any case, the necessary identification must be provided to ensure the link between each item of machinery and the EC Declaration of Conformity that applies to it.

4. The sentence declaring that the machinery fulfils all the relevant provisions of the Machinery Directive is the key element of the EC Declaration of Conformity. In this sentence, the manufacturer or his authorised representative attests that the machinery concerned complies with all of the applicable EHSRs of Annex I to the Machinery Directive and that the appropriate conformity assessment procedure has been carried out.

   Where the machinery concerned is subject to other EU legislation in addition to the Machinery Directive, the conformity with the other Directives or Regulations concerned must also be declared – see §91 and §92: comments on Article 3. The manufacturer may draw up a single EC Declaration of Conformity for these other Directives or Regulations, provided that the declaration contains all the information required by each Directive. This may not be possible in all cases since certain Directives specify a particular format for the Declaration of Conformity – see §89: comments on Article 3.

5. For machinery belonging to one of the categories listed in Annex IV, where the manufacturer has chosen to follow the EC type-examination procedure, the particulars of the Notified Body which carried out the EC type-examination and the number of the EC type-examination certificate are to be indicated – see §129 and §130: comments on Articles 12 (3) and (4). The name, address and four-figure identification number of the Notified Body to be indicated can be checked in the NANDO database – see §133: comments on Article 14.

6. For machinery belonging to one of the categories listed in Annex IV, where the manufacturer has chosen to follow the full quality assurance procedure, the particulars of the Notified Body which approved the manufacturer's full quality assurance system are to be indicated - see §129 and §130: comments on Articles 12 (3) and (4). The name, address and four-figure identification number of the Notified Body to be indicated can be checked in the NANDO database – see §133: comments on Article 14.

7. In order to inform about the presumption of conformity conferred by the application of harmonised standards that cover all the relevant essential health and safety requirements, manufacturers may indicate the references of the harmonised standard(s) applied in the EC Declaration of Conformity – see §110 and §111: comments on Articles 7 (2), and §114: comments on Article 7 (3). However, it should be recalled that the application of harmonised standards remains voluntary – see §110: comments on Article 7 (2).

   In the case of machinery belonging to one of the categories listed in Annex IV where the manufacturer has followed the procedure for assessment of conformity with internal checks on the manufacture of machinery according to Annex VIII, the manufacturer must indicate the reference(s) of the harmonised standard(s) applied in the EC Declaration of Conformity, since the application of harmonised standards that cover all of the EHSRs applicable to the machinery is a condition for using that conformity assessment procedure – see §129: comments on Article 12 (3).

   Where the reference of a harmonised standard is indicated in the EC Declaration of Conformity, the market surveillance authorities are entitled to consider that the manufacturer has applied the specifications of the standard in full. If the manufacturer has not applied all of the specifications of a harmonised standard, he may still indicate the reference of the standard in the EC Declaration of Conformity, but, in that case, he must indicate which specifications of the standard he has or has not applied.

8. Where harmonised standards have not been used, the manufacturer may indicate the references of other technical documents used to design and construct the machinery. It should be borne in mind that the application of such documents does not confer a presumption of conformity – see §162: comments on General Principle 3 of Annex I.

9. The indication of the place and date of the declaration are customary requirements for a signed legal document. The place to be indicated is usually the town where the premises of the manufacturer or his authorised representative are established. Since the EC Declaration of Conformity must be drawn up before the machinery is placed on the market or put into service – see §103: comments on Article 5 (1) - the date indicated in the EC Declaration of Conformity must be no later than the placing on the market of the machinery, or in the case of machinery for the manufacturer's own use, no later than the putting into service of the machinery.

10. The identity of the person empowered by the manufacturer or his authorised representative to draw up the EC Declaration of Conformity must be indicated adjacent to his or her signature. The identity of the person is understood as comprising his or her name and position.

    The EC Declaration of Conformity can be signed by the Managing Director of the Company concerned or by another representative of the Company to whom this responsibility has been delegated. The EC Declaration of Conformity shall be signed and kept by the manufacturer or his authorised representative – see §386:

comments on Annex II 2. Signature can be a hand written signature or a printed digital one. The signature can be reproduced on the copies of the Declaration of Conformity that accompany the machinery.

ANNEX II

1. CONTENT (continued)

. . .

B. DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY

This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex 1, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.

. . .

§384 The Declaration of Incorporation of partly completed machinery

Annex II 1 B concerns the Declaration of Incorporation that must be drawn up by the manufacturer of partly completed machinery or his authorised representative in the EU and that must accompany the partly completed machinery until it reaches the manufacturer of the final machinery into which it is to be incorporated - see §104: comments on Article 5 (2), and §131: comments on Article 13. The Declaration of Incorporation shall then form part of the Technical file for the final machinery – see §392: comments on Annex VII A 1 (a).

The Declaration of Incorporation is a legal statement by the manufacturer of the partly completed machinery or his authorised representative with the following main purposes:

- to inform the manufacturer of the final machinery which of the applicable EHSRs of Annex I to the Machinery have been applied and fulfilled;
- where appropriate, to refer to a declaration of conformity for the partly completed machinery which is also covered by the provisions of other applicable EU legislation;
- to undertake to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery;
- to indicate 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 relevant provisions of the Machinery Directive.

The comments relating to the first paragraph of Annex II 1 A also apply to the first paragraph of Annex II 1 B.

Annex II 1 B (continued)

. . .

The declaration of incorporation must contain the following particulars:

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.*

. . .

§385 The content of the Declaration of Incorporation

The following comments refer to the numbered paragraphs in Annex II 1 B:

1. The comments on paragraph 1 of Annex II 1 A apply.
2. With respect to the person authorised to compile the technical documentation, the comments on paragraph 2 of Annex II 1 A relating to the person authorised to compile the technical file apply.
3. The comments on paragraph 3 of Annex II 1 A apply.
4. The Machinery Directive does not determine which of the applicable EHSRs must be applied and fulfilled by the manufacturer of partly completed machinery. The following considerations may be taken into account when deciding whether or not to apply and fulfil certain EHSRs:
   - it may not be possible for the manufacturer of the partly completed machinery to fully assess certain risks which depend on the way the partly completed machinery is incorporated into the final machinery;

– the manufacturer of the partly completed machinery may agree with a manufacturer of final machinery on a 'division of tasks' whereby the application and fulfilment of certain EHSRs is left to the manufacturer of the final machinery.

In the sentence required by paragraph 4 of Annex II 1 B, the manufacturer of partly completed machinery must indicate in the Declaration of Incorporation precisely which of the applicable EHSRs have been applied and fulfilled. If a given EHSR has been fulfilled for certain parts or aspects of the partly completed machinery and not for others, this shall be indicated. The Assembly instructions for the partly completed machinery must indicate the need to deal with the EHSRs that are not fulfilled or only partly fulfilled – see §390: comments on Annex VI. The manufacturer of the partly completed machinery must also state that he has compiled the Relevant Technical Documentation showing how those EHSRs have been applied – see §394: comments on Annex VII B.

Where the partly completed machinery (or part of it) is subject to other EU legislation in addition to the Machinery Directive, the conformity with the other Directives or Regulations concerned must also be declared – see §91 and §92: comments on Article 3. Where those Directives or Regulations foresee an EC Declaration of Conformity, an EC Declaration of Conformity according to those texts must be drawn up for the partly completed machinery. Such Declarations of Conformity are to be included in the Technical file for the final machinery – see §392: comments on Annex VII A 1 (a).

5. The undertaking required by paragraph 5 of Annex II 1 B concerns the obligation of the manufacturer of partly completed machinery to present any information relevant to health and safety and, in particular, the relevant technical documentation, in response to a duly reasoned request from the market surveillance authorities of one of the Member States – see §394: comments on Annex VII B.

   Since the Declaration of Incorporation of the partly completed machinery is to form part of the Technical file for the final machinery – see §392: comments on Annex VII A 1 (a) – the manufacturer of the final machinery thereby has in his possession an undertaking by his supplier to transmit the relevant technical documentation to the market surveillance authorities in response to a duly reasoned request.

   The intellectual property rights of the manufacturer of the partly completed machinery are protected by the fact that the market surveillance authorities are bound to treat as confidential information obtained in the execution of their tasks – see §143: comments on Article 18 (1).

6. The statement required by paragraph 6 takes account of the fact that partly completed machinery cannot be considered safe until:

   - any EHSRs applicable to the partly completed machinery, not fulfilled by the manufacturer of the partly completed machinery, have been fulfilled;

- any risks arising from the incorporation of the partly completed machinery into the final machinery have been assessed and the necessary protective measures have been taken to deal with them.

7. The comments on paragraph 9 of Annex II 1 A apply.
8. The comments on paragraph 10 of Annex II 1 A apply.

Annex II (continued)

. . .

2. CUSTODY

The manufacturer of machinery or his authorised representative shall keep the original EC declaration of conformity for a period of at least 10 years from the last date of manufacture of the machinery.

The manufacturer of partly completed machinery or his authorised representative shall keep the original declaration of incorporation for a period of at least 10 years from the last date of manufacture of the partly completed machinery.

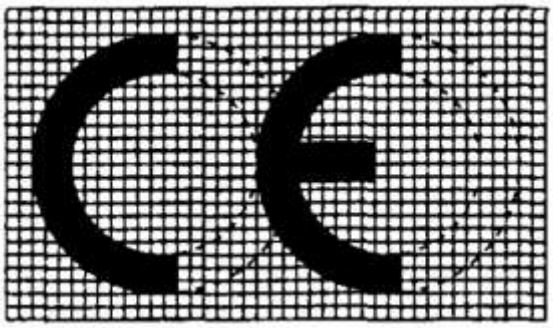
§386 Custody of the EC Declaration of Conformity and the Declaration of Incorporation

The period of custody of ten years from the last date of manufacture set out in Annex II 2 for the EC Declaration of Conformity and the Declaration of Incorporation is to enable the market surveillance authorities to verify these documents if necessary – see §98: comments on Article 4 (3) and (4).

ANNEX III

CE marking

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



If the CE marking is reduced or enlarged the proportions shown in the above drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. 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.

§387 The form of the CE marking

The provisions relating to the CE marking set out in Article 16 apply together with the provisions of Regulation (EC) 765/2008 – see §141: comments on Article 16. Annex III sets out the mandatory graphic form of the CE marking. The CE marking consists only of the letters "CE" with the graphic form shown in the diagram – the grid and dotted lines are only included in the diagram to help to define the shape of the letters and must not be reproduced in the CE marking.

The fourth paragraph of Annex III relating to the location and technique of the CE marking must be applied in conjunction with the general requirements on marking of machinery – see §250: comments on section 1.7.3 of Annex I.

The last paragraph of Annex III applies only to machinery belonging to one of the categories listed in Annex IV for which the full quality assurance procedure has been applied – see §129, §130 and §132: comments on Article 12 (3) and (4). In that case, the CE marking must be followed by the four-digit identification number of the Notified Body that has approved the manufacturer's full quality assurance system – see §133: comments on Article 14. For such machinery, the CE marking and the identification number of the Notified Body may only be affixed once the manufacturer has been notified of the approval of his full quality assurance system by the Notified Body – see

§404: comments on section 2.3 of Annex X. These markings can no longer be affixed if the approval of the full quality assurance system has been suspended or withdrawn by the Notified Body - see §406: comments on section 3 of Annex X.

The identification number of the Notified Body must not be marked on machinery for which the EC type-examination procedure has been followed.

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.*
13. *Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.*
14. *Removable mechanical transmission devices including their guards.*
15. *Guards for removable mechanical transmission devices.*
16. *Vehicle servicing lifts.*
17. *Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres.*
18. *Portable cartridge-operated fixing and other impact machinery.*
19. *Protective devices designed to detect the presence of persons.*
20. *Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11.*
21. *Logic units to ensure safety functions.*
22. *Roll-over protective structures (ROPS).*
23. *Falling-object protective structures (FOPS).*

§388 Categories of machinery that may be subject to one of the conformity assessment procedures involving a Notified Body

Annex IV sets out the list of categories of machinery that may be subject to one of the two conformity assessment procedures involving a Notified Body: EC type-examination or Full quality assurance. These categories include machinery in the broad sense – see §33: comments on Article 2. Machinery belonging to one of the categories listed in Annex IV may also be subject to the procedure for assessment of conformity with internal checks when it is manufactured in accordance with harmonised standards that cover all of the applicable EHSRs – see §129 and §130: comments on Article 12 (3) and (4).

The list set out in Annex IV is exhaustive, in other words, only the machinery belonging to the categories listed is subject to the conformity assessment procedures set out in Article 12 (3) and (4). Machinery belonging to categories not listed in Annex IV, even if it is similar or presents similar hazards to the categories listed, is subject only to the procedure for assessment of conformity with internal checks – see §128: comments on Article 12 (2).

Items 1 to 8

Item 1 covers only circular saws for working with wood and analogous materials or for working with meat or analogous materials belonging to the categories referred to in items 1.1 to 1.4.

It should also be noted that not all circular saws for working wood are concerned; for example, sawing machinery with a blade moved by hand during cutting (such as some mitre saws) are not referred to in Annex IV.

Materials analogous to wood include, for example, chipboard, fibreboard, plywood (and also these materials when they are covered with plastic or light alloy laminates/edges), cork, bone, rigid rubber or plastic. On the other hand, stone, concrete and similar materials requiring an abrasive type of cutting tool are not considered as materials analogous to wood.

Materials analogous to meat include fish and frozen or deep-frozen food.

Items 1.3, 1.4, 3 and 4 refer to manual loading and/or unloading. Manual loading and/or unloading occurs when the operator places workpieces directly in the feed device or workpiece support device and removes them directly from that device, so that it is possible for the operator to have direct contact with the workpiece while it is in contact with the tool. Machinery is not considered to have manual loading or unloading if it is equipped with a feed device or a device for loading and unloading workpieces (such as, for example, a conveyor) such that the tools are out of reach of the user while the device is being used and the machinery cannot be operated without the device.

Items 1.1, 2, 6 and 7 refer to manual feed or hand fed machinery. Manual feed or hand feed occurs when either the workpiece or the tool is manually moved during machining so that it is possible for the operator to come into contact with the tool. The same applies to the machinery with a manually operated reciprocating saw-bench or carriage referred to in item 1.2.

The combined woodworking machinery referred to in item 5 is machinery designed to carry out any combination of the functions referred to in items 1 to 4 and 7, with manual removal of the workpiece between each operation - see §210: comments on section 1.3.5 of Annex I. Only combined machinery carrying out functions referred to in items 1 to 4 and 7 is subject to item 5 of Annex IV, however such machinery may also carry out other additional functions. Since the necessary protective measures are often common to several or all of the combined functions, the EC type-examination or the assessment of the full quality assurance system for such combined woodworking machinery shall always concern the entire machinery.

The vertical spindle moulding machines referred to in item 7 have one spindle passing through the table and one drive motor situated beneath the table. Routing machinery with a spindle located completely above the table is not covered by item 7.

Item 9

The presses for cold working of metals referred to in item 9 are presses the intended or foreseeable use of which includes the possibility of the operator placing or removing workpieces between the tools with his hands without the use of integrated ancillary handling devices. The term 'cold working' refers to the shaping of metal without heating, usually at room temperature. The term 'metal' refers to material in sheet, rolled or forged form.

Item 9 only applies to presses with movable working parts having both of the two following characteristics:

- a travel greater than 6 mm, and
- a closing speed greater than 30 mm/s.

When establishing the closing speed of mechanical presses, the highest instantaneous speed reached by the slide (in general, at about the mid-point of its travel) should be taken into consideration.

Item 9 does not cover other kinds of machinery for cold working of metals such as, for example:

- sintering presses,
- alligator or guillotine shears,
- riveting, stapling or stitching machines,
- assembly presses,
- bending machines,
- straightening presses,
- turret punch presses,
- extruder presses,
- drop forging or drop stamping presses,
- blow forging presses,
- isostatic presses.

Items 10 and 11

The plastics and rubber moulding machinery referred to in items 10 and 11 is machinery designed for working polymers, such as thermoplastics and thermosets, or rubber, by injection or compression. Loading and unloading refers only to placing and removal of material or parts in and out of the mould. Loading and unloading is not considered as manual if:

- the machinery is designed to operate only with robot or manipulator equipment,

or

- the machinery is fitted with loading and unloading devices such that it is not possible to operate the machinery without those devices.

In all other cases, loading and unloading shall be considered as manual.

Item 12

Locomotives for underground working referred to in item 12.1 are self-powered vehicles running on a track of one or two rails situated above or under the vehicle for use in mines or other underground workings, designed for hauling or transporting persons, materials or mineral. Brake vans are railway vehicles for underground working equipped with a brake which can be applied by the operator.

Hydraulic-powered roof supports referred to in item 12.2 are usually self-advancing supports used to support the roof at a mine face. They include:

- one support unit under adjacent control;
- several support units under group control;
- entire mine face support systems under central control.

Tunnelling machines are not covered by item 12.

Item 13

An explanation of the term 'manual loading' with respect to manually loaded trucks for the collection of household refuse incorporating a compression mechanism referred to in item 13 is given in specific guidance that can be found in section §415. It also shows examples of machinery that is within the scope of item 13 and machinery that is outside the scope of item 13.

In general, the vehicle itself is excluded from the scope of the Machinery Directive, so the machinery referred to in item 13 is the refuse collection and compression equipment mounted on the chassis – see §37: comments on the third indent of Article 2 (a), and §54: comments on Article 1 (2) (e).

Items 14 and 15

The removable mechanical transmission devices referred to in item 14, commonly known as “power take-off (PTO) shafts", are removable components for the transmission of power between self-propelled machinery or a tractor and recipient machinery such as towed agricultural machinery – see § 45: comments on Article 2 (f). Removable mechanical transmission devices must always be placed on the market together with an appropriate guard. Guards for removable mechanical transmission devices may also be placed on the market independently as safety components – such guards are covered by item 15.

Item 16

The vehicle servicing lifts referred to in item 16 are stationary, mobile or movable lifts designed to raise whole vehicles off the ground for the purpose of examining and working on or under the vehicles whilst they are in a raised position. Short stroke vehicle servicing lifts not intended for working under the vehicles are not covered by Item 16.

They include machinery intended for the servicing of vehicles such as, for example, cars, motorcycles, snowmobiles, lorries, buses, trams, rail vehicles, and industrial trucks. They also include assemblies of lifting devices operating in a synchronised system for lifting whole aircraft for inspection or maintenance purposes.

Item 16 does not cover:

- jacks that are not designed to raise the whole vehicle off the ground,
- lifts intended for the parking of vehicles,
- lifts incorporated into vehicle assembly lines.

Item 17

The devices for the lifting of persons or persons and goods referred to in item 17 include the following:

a) machinery with the main function of lifting persons or persons and goods such as, for example:

- mobile, mast-climbing or suspended elevating work platforms;
- construction site hoists for persons or persons and goods;
- lifting devices intended to be connected to machinery such as cranes or wind generators, for access to workstations;
- machinery serving fixed landings subject to the Machinery Directive such as home lifts and lifting platforms intended for persons with impaired mobility – see §151: comments on Article 24;

b) devices for lifting persons or persons and goods fitted to machinery with main functions other than lifting persons. Such devices include, for example, elevating operating, driving or control positions on industrial trucks, on rail dependent storage and retrieval equipment, on cranes or on earth-moving machinery.

For such devices, the EC type-examination or the assessment of the full quality assurance system concern the conformity of the devices for lifting persons and not the other functions of the machinery;

c) lifting machinery with main functions other than lifting persons with on-board control positions such as, for example, aircraft ground support equipment, passenger boarding bridges for aircraft, bridge spans for access to ships and climbing frames for the erection of tower cranes;

d) interchangeable equipment for the lifting of persons such as work platforms to be assembled with, for example, variable reach lift trucks, loader cranes or mobile cranes. The conformity assessment must ensure that the assembly of the interchangeable equipment and all the types of basic machinery with which it is intended to be assembled complies with all the relevant EHSRs – see §41: comments on Article 2 (b).

Such interchangeable equipment must be distinguished from equipment that is not assembled with lifting machinery but used exceptionally for lifting persons with machinery designed for lifting goods (according to section 3.1.2 of Annex II to Directive 2009/104/EC) that is not subject to the Machinery Directive – see §10: comments on Recital 7. This distinction is explained in specific guidance that can be found in §416.

The above devices are covered by item 17 when they involve a hazard of falling from a vertical height of more than three metres. The vertical height is to be understood as the vertical distance between the surface of the carrier on which persons or persons and goods are supported in order to be lifted – see §334: comments on section 4.1.1 (g) of Annex I - and the level to which the persons or the carrier itself could fall. That level is usually the ground level or the level of the floor or surface on which the

machinery is intended to be installed or used, but could be a lower floor or ground level if the machinery is intended by the manufacturer to be installed next to a drop.

Item 18

The portable cartridge-operated fixing machinery referred to in item 18 is portable machinery operated by explosive cartridges intended for driving fasteners such as nails, threaded studs, eyelets or similar objects into a base material. Item 18 also covers cartridge-operated impact machinery intended for other applications such as, for example, machinery for the hard marking of materials by imprinting or captive bolt pistols for the stunning of animals.

Item 18 does not cover portable fixing or other impact machinery using other sources of energy, such as pneumatic, spring, electromagnetic or gas cartridge-operated machinery.

Item 19

Item 19 covers safety components that detect the presence of persons or parts of persons and that generate an appropriate signal to the control system to reduce risks to the persons detected. The signal may be generated when a person or part of a person goes beyond a predetermined limit (tripping), or when a person is detected in a predetermined zone (presence sensing), or both. Such protective devices include, for example:

- pressure sensitive protective devices such as, for example, pressure sensitive mats, floors, edges, bars, bumpers, plates and wires;
- active opto-electronic protective devices such as, for example, light curtains, scanning heads, light beam and laser devices;
- radar, infrared, ultrasonic and camera-based protective devices.

Item 19 does not cover indirect vision devices such as mirrors or closed circuit television (CCTV).

Item 20

Item 20 covers power-operated moveable guards that correspond to the definition of safety components – see §42: comments on Article 2 (c) – intended to be fitted to presses for the cold working of metal referred to in item 9 or to injection or compression plastics-moulding machinery or rubber moulding machinery with manual loading and/or unloading referred to in items 10 and 11.

Item 21

The logic units to ensure safety functions referred to in item 21 are complex components which:

- correspond to the definition of safety components – see §42: comments on Article 2 (c) and
- analyse one or several input signals and generate, by a given algorithm, one or more output signals and

- are intended to operate in connection with, or as part of, the control system of machinery in order to perform one or more safety functions.

The control system as a whole is not to be considered as a logic unit, although the assessment and design of the control system must fulfil EHSR 1.2.1. such that it can, to the state of the art for the product:

- withstand the intended operating stresses and external influences,
- faults in the hardware or the software of the control system do not lead to hazardous situations,
- errors in the control system logic do not lead to hazardous situations, etc.
  - see §184 comments on safety and reliability of control systems.

Protective devices designed to detect the presence of persons (item 2, Annex V, which are taken to include detecting the presence of domestic animals – see §88: comments on Article 4), are not to be considered as a logic unit as they are already covered by item 19 of Annex IV.

To be considered a logic unit to ensure a safety function, the component delivering its logic shall be complex. However, the way the logic is processed is independent of the technology, and can include mechanical, electronic and other systems that may be developed in the future.

Where the logic is delivered by simple devices like electromechanical sensors or switching devices, which just transform an input signal into an output signal, they are not to be considered as logic units.

But where an input signal (or signals) is transformed into an output signal by a complex component, e.g. an electronic chip or complex mechanical component that processes the signal(s), it will be considered a logic unit to ensure a safety function. Such complex components may also simultaneously monitor themselves or other components, but a monitoring function is not essential for the component to be considered a logic unit.

The table in section §418 indicates which safety components are considered to be logic units to ensure safety functions (LUTESF), and devices which are not considered LUTESF.

Items 22 and 23

Items 22 and 23 cover roll-over protective structures (ROPS) and falling-object protective structures (FOPS) that correspond to the definition of safety components - see §42: comments on Article 2 (c).

ROPS and FOPS manufactured by a machinery manufacturer to be fitted to his own machinery are not covered by items 22 and 23.

The same goes for ROPS or FOPS intended to be used as spare parts to replace identical ROPS or FOPS supplied by the manufacturer of the original machinery – see §48: comments on Article 1 (2) (a) – since they are not subject to the Machinery Directive as such.

However, all ROPS and FOPS, whether placed on the market as safety components or manufactured by a machinery manufacturer for his own machinery, must be

submitted to appropriate tests – see §315 and §316: comments on sections 3.4.3 and 3.4.4 of Annex I - and the corresponding test reports must be included in the technical file for the machinery to which they are fitted – see §392: comments on Annex VII A 1.

Appropriate tests are also required for tip-over protective structures (TOPS) according to section 3.4.3 of Annex I, but these structures are not covered by item 22 of Annex IV and the related conformity assessment procedures.

It should be noted that FOPS are sometimes referred to in harmonised standards by other terms such as, for example, 'overhead guards' or 'front guards'. All structures intended to be fitted to mobile machinery to protect the operator from falling objects are to be considered as FOPS, regardless of the term used in the standards for the machinery concerned.

ANNEX V

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

1. *Guards for removable mechanical transmission devices.*
2. *Protective devices designed to detect the presence of persons.*
3. *Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in items 9, 10 and 11 of Annex IV.*
4. *Logic units to ensure safety functions.*
5. *Valves with additional means for failure detection intended for the control of dangerous movements on machinery.*
6. *Extraction systems for machinery emissions.*
7. *Guards and protective devices designed to protect persons against moving parts involved in the process on the machinery.*
8. *Monitoring devices for loading and movement control in lifting machinery.*
9. *Restraint systems to keep persons on their seats.*
10. *Emergency stop devices.*
11. *Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.*
12. *Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex 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:*
    - *(a) devices for locking landing doors;*
    - *(b) devices to prevent the load-carrying unit from falling or unchecked upwards movement;*
    - *(c) overspeed limitation devices;*
    - *(d) energy-accumulating shock absorbers,*
      - *non-linear, or*
      - *with damping of the return movement;*
    - *(e) energy-dissipating shock absorbers;*
    - *(f) safety devices fitted to jacks of hydraulic power circuits where these are used*

as devices to prevent falls;

(g) electric safety devices in the form of safety switches containing electronic components.

§389 Indicative list of safety components

Annex V provides an indicative list of 17 safety components as defined in Article 2 (c) of the Machinery Directive – see §42: comments on Articles 1 (c) & 2 (c).

The list given in Annex V is not exclusive and other components that comply with the definition set out in Article 2 (c) – see §117: comments on Article 8 (2) – are to be considered as a safety component subject to the Machinery Directive. Such components are filtration systems, intended to be integrated into machinery cabins in order to protect operators or other persons against hazardous materials and substances, and filters for these filtration systems[236].

The indicative list of safety components given in Annex V can be updated by the Commission after consulting the Machinery Committee – see §116: comments on Article 8 (1) (a), and §147: comments on Article 22 (3).

It should be noted that the following safety components included in the indicative list given in Annex V are also included among the categories of machinery listed in Annex IV to which one of the conformity assessment procedures referred to in Article 12 (3) and (4) must be applied:

Annex V		**Annex IV**
Item 1	Guards for removable mechanical transmission devices	= Item 15
Item 2	Protective devices designed to detect the presence of persons	= Item 19
Item 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	= Item 20
Item 4	Logic units to ensure safety functions	= Item 21
Item 14	Roll-over protective structures (ROPS)	= Item 22
Item 15	Falling-object protective structures (FOPS)	= Item 23

For explanations on the above items – see §388: comments on Annex IV.

The other categories of safety components listed in Annex V (and any safety components not listed in Annex V) are subject to the procedure for assessment of conformity with internal checks on the manufacture – see §128: comments on Article 12 (2) and §391: comments on Annex VII.

[236] As agreed by the Machinery Working Group 14-15 February 2012.

Item 5

The valves referred to in item 5 are components fitted to hydraulic or pneumatic systems to prevent dangerous movements of machinery in case of failure – see §205: comments on section 1.2.6, and §342: comments on section 4.1.2.6 (c) of Annex I.

Item 6

The extraction systems referred to in item 6 are systems fitted to evacuate hazardous materials and substances produced by machinery or by materials processed by machinery, in order to protect the health and safety of exposed persons – see §235, comments on section 1.5.13, and §322: comments on section 3.5.3 of Annex I. Such systems may be designed to be fitted to individual machines or to be installed in the same workplace so that several machines can be connected.

Item 6 does not cover systems fitted specifically for the purposes of environmental protection.

Item 7

Item 7 covers guards and protective devices designed to be fitted to machinery to protect persons against moving parts involved in the process – see §214: comments on section 1.3.8.2.

Item 8

Item 8 covers monitoring devices for loading and movement control to be fitted to lifting machinery – see §342: comments on section 4.1.2.6, §354: comments on section 4.2.2, and §370: comments on section 6.1.2 of Annex I.

Monitoring of loading and movement in lifting machinery is usually carried out by a system consisting of several components including an Electronic Control Unit (ECU), sensors, and hydraulic actuators and so on.

The component that is essential to the safety function is the ECU embedded with appropriate software. An ECU embedded with appropriate software is therefore to be considered as a safety component, whether it is supplied separately or as part of a monitoring system. A complete monitoring system shall also be considered as a safety component.

Item 9

Item 9 covers restraint systems to keep persons on their seats intended to be fitted to mobile machinery, for example, 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 – see §295: comments on section 3.2.2 of Annex I.

Item 10

Item 10 covers emergency stop control devices – see §202: comments on section 1.2.4.3 of Annex I.

Item 11

Item 11 covers discharging systems to prevent the build-up of potentially dangerous electrostatic charges – see §223: comments on section 1.5.2 of Annex I.

Item 12

Item 12 covers safety components intended to be fitted in order comply with the requirements set out in sections 1.5.7 (*Explosion*), 3.4.7 (*Transmission of power between self-propelled machinery or tractor and recipient machinery*) and 4.1.2.6 (*Control of movements*) of Annex I.

Item 13

Item 13 covers systems and devices intended to be fitted to machinery to reduce the emission of noise and vibrations. Systems and devices for reducing noise emission include acoustic enclosures, mufflers and active noise reduction devices – see §229: comments on section 1.5.8 of Annex I. Systems and devices for reducing vibration emissions include systems using springs, dampers or a combination of both - see §231: comments on section 1.5.9 of Annex I.

Item 16

Two-hand control devices are a kind of protective device – see §221: comments on section 1.4.3 of Annex I.

Item 17

The safety components listed in item 17 (a) to (g) are intended to be fitted to machinery for lifting persons or persons and goods between fixed landings – see §344 to §349: comments on section 4.1.2.8, and §377 to §380: comments on sections 6.4.1 to 6.4.3 of Annex I. The list is identical to the list of safety components set out in Annex IV of the Lifts Directive 95/16/EC[237]. This reflects the fact that similar safety components may be fitted to construction site hoists, lifts whose travel speed is not greater than 0.15 m/s and other lifts excluded from the scope of the Lifts directive that are subject to the Machinery Directive – see §151: comments on Article 24.

It should be noted that according to the Lifts Directive, the safety components listed in item 17 (a) to (g) are subject to a conformity assessment procedure involving a Notified Body. Safety components bearing the CE marking and accompanied by a Declaration of Conformity according to the Lifts Directive may be used to fulfil similar functions in machinery serving fixed landings subject to the Machinery Directive. On the other hand, safety components designed for such machinery subject to the Machinery Directive may not be used in lifts subject to the Lifts Directive unless they have been subject to one of the conformity assessment procedures foreseen by that Directive.

[237] See the Guide to application of the Lifts Directive, available on http://ec.europa.eu/growth/sectors/mechanical-engineering/lifts/.

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.

§390 Assembly instructions for partly completed machinery

The provisions of Annex VI apply to partly completed machinery referred to in Article 1 (g) and defined in Article 2 (g) – see §46: comments on Article 2 (g).

The assembly instructions for partly completed machinery must be drawn up by the manufacturer of the partly completed machinery or his authorised representative and supplied to the manufacturer of the final machinery – see §131: comments on Article 13. The assembly instructions shall then form part of the technical file for the final machinery - see §392: comments on Annex VII A 1 (a).

The assembly instructions shall deal with all safety-related aspects of the partly completed machinery and of the interface between the partly completed machinery and the final machinery which have to be considered by the assembler when incorporating the partly completed machinery into the final machinery.

The assembly instructions shall indicate the need to take the necessary measures to deal with the EHSRs applicable to the partly completed machinery that have not been applied and fulfilled or that have only been partly fulfilled by the manufacturer of the partly completed machinery – see §385: comments on Annex II 1 B.

In some cases, the manufacturer of the partly completed machinery may apply and fulfil the EHSRs relating to instructions set out in Annex I ESHR 1.7.4 and state this in his Declaration of Incorporation. For example, the manufacturer of a drive systems with its engine to be incorporated into mobile machinery may provide the manual for the engine. In other cases, the assembly instructions for partly completed machinery shall provide the necessary information relating to the partly completed machinery to enable the manufacturer of the final machinery to draft the parts of the instructions relating to the partly completed machinery. If the manufacturer of the PCM does not declare to have fulfilled ESHR 1.7.4., then only assembly instructions need to be provided. However, the information needed by the manufacturer of the final machine to allow them to compile the user instructions to meet ESHR 1.7.4 must be contained in the assembly instructions.

The assembly instructions are addressed to the manufacturer of the final machinery and must therefore be understandable to him. According to the second paragraph of Annex VI, the assembly instructions must be written in one of the official EU languages acceptable to the manufacturer of the final machinery - see §246: comments on section 1.7.1 of Annex I.

This means that, where the manufacturer of the final machinery is known to the manufacturer of the partly completed machinery, the language of the assembly instructions provided with the partly completed machinery can be agreed between the two parties, for example, in the contract of sale. Where there is no such agreement, the assembly instructions must be provided in the official EU language(s) of the Member State in which manufacturer of the final machinery is established since that manufacturer cannot be presumed to understand another language.

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.

. . .

§391 Technical file for machinery

The obligation to compile a technical file as described in Annex VII A applies to the manufacturer of any of the products listed in Article 1 (1) (a) to (f) or his authorised representative – see §103: comments on Article 5 (1).

The purpose of the technical file is to enable manufacturers to demonstrate the conformity of the machinery with the relevant EHSRs. It also helps the market surveillance authorities to check the conformity of the machinery, particularly for aspects that cannot be checked by visual inspection. The first paragraph of Annex VII A states that the technical file must cover the design, manufacture and operation of the machinery, to the extent necessary for this assessment. It is not necessary to include in the technical file all the details of the design and construction of the machinery that are not specific to the machinery concerned and can be justified on the basis of good engineering practice. However, the manufacturer must ensure that the technical file includes all the information needed to demonstrate clearly that adequate measures have been taken to deal with all significant risks associated with the machinery in order to comply with the relevant EHSRs - see §98: comments on Article 4.

The first paragraph of Annex VII A also states that the technical file must be compiled in one or more official Community language(s) – see §246: comments on section 1.7.1 of Annex I.

Manufacturers established in the EU usually compile most of the elements of the technical file in the official language of the Member State in which they are established, although another official EU language may be preferred. Manufacturers may also include in the technical file documents provided by suppliers of components or sub-assemblies or reports from test bodies written in other official EU languages. Such documents do not need to be translated. However documents written in non-EU languages must be translated into one of the official EU languages. Manufacturers established outside the EU must compile the technical file in one or more official EU languages.

There is one exception to the general rule, since, according to the 7th indent of Annex VII A 1, the technical file must include a copy of the instructions which are subject to specific language requirements – see §256 and §257: comments on sections 1.7.4 and 1.7.4.1 (a) and (b) of Annex I.

ANNEX VII A (continued)

. . .

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,*
- *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:*
  - *(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;*

(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.

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.

. . .

§392 The content of the technical file

Sections 1 (a) and 1 (b) of Annex VII A set out the content of the technical file. Section 1 (a) concerns the design and construction of the machinery; section 1 (b) concerns the production of the machinery.

The first three indents of section 1 (a) concern the description of the machinery which must be sufficiently detailed to enable the market surveillance authorities to understand the operation of the machinery and check the conformity of the machinery with the relevant EHSRs. These indents should be read in light of the third paragraph of section 2 of Annex VII A which limits the level of detail required in the technical file with respect to sub-assemblies.

A technical file is required for each model or type of machinery. The terms 'model' or 'type' designate machinery with a given design, technical characteristics and application. A type of machinery may be produced in series or as a single unit. One type of machinery may have variants; however, to be considered as belonging to the same type, variants must have the same basic design, present similar hazards and require similar protective measures. The description of the machinery in the technical file must specify any variants of the model or type concerned.

The fourth indent of section 1 (a) concerns the risk assessment carried out by the manufacturer. The outcome of the risk assessment must be documented to enable the authorities to check that the applicable EHSRs have been correctly identified and that the necessary protective measures have been taken, in accordance with the principles of safety integration – see §173 to §177: comments on section 1.1.2 of Annex I. The information required in (i) and (ii) of the fourth indent of section 1 (a) can be drawn up in the form of a checklist indicating the EHSRs that are applicable to the machinery and the corresponding protective measures. The documentation of the risk assessment is facilitated by the application of harmonised standards, although the application of such standards does not dispense the manufacturer from the obligation to carry out a risk assessment – see §158 and §159: comments on General Principle 1 of Annex I.

The fifth indent of section 1 (a) requires the manufacturer to document the standards or other technical specifications used, indicating the EHSRs covered. Reference to the specifications of the relevant harmonised standards facilitates the demonstration of the conformity of the machinery, since their application confers a presumption of conformity with the EHSRs they cover – see §110: comments on Article 7 (2).

The sixth indent of section 1 (a) concerns reports on the results of any tests carried out by or on behalf of the manufacturer. The verification methods needed to ensure the conformity of machinery, including the necessary inspections, type-tests, sample tests or unit tests, are usually specified in the relevant harmonized standards.

Furthermore, certain tests are required by EHSRs of Annex I:

- tests on ROPS, TOPS and FOPS for mobile machinery – see §315 and §316: comments on sections 3.4.3 and 3.4.4 of Annex I;
- tests relating to the mechanical strength of machinery for lifting – see §339 to §341: comments on sections 4.1.2.3, 4.1.2.4 and 4.1.2.5 of Annex I;

- tests relating to the fitness for purpose of lifting machinery and lifting accessories – see §356: comments on section 4.1.3 of Annex I.

The seventh indent of section 1 (a) concerns the instructions for the machinery – see §254 to §274: comments on section 1.7.4, and, as appropriate §277: comments on section 2.1.2, §279: comments on section 2.2.1.1, §280: comments on section 2.2.2.2, §325: comments on section 3.6.3, and §360 and §361: comments on section 4.4 of Annex I.

The eighth indent of section 1 (a) refers to the Declaration of Incorporation for any partly completed machinery that is incorporated – see §384 and §385: comments on Annex II 1 B - and the relevant assembly instructions – see §390: comments on Annex VI. These documents shall not accompany the final machinery but must be included in the technical file for the final machinery.

The ninth indent of section 1 (a) refers to the EC Declaration of Conformity of machinery or other products incorporated into the machinery. The following products may be concerned:

a) safety components or chains, ropes or webbing incorporated into the machinery;

b) equipment incorporated into the machinery subject to a specific Directive requiring the provision of an EC Declaration of conformity such as, for example, ATEX equipment or pressure equipment – see §91: comments on Article 3;

c) complete machinery that is incorporated into an assembly of machinery – see §38: comments on the fourth indent of Article 2 (a).

The EC Declaration(s) of conformity for the above products do not have to accompany the machinery into which they are incorporated but must be included in the technical file for that machinery.

The tenth indent of section 1 (a) requires a copy of the EC Declaration of conformity of the machinery to be included in the technical file for that machinery – see §382 and §383: comments on Annex II 1 A.

Section 1 (b) of Annex VII A requires the technical file for machinery produced in series to document the measures to be taken to ensure that the machinery produced remains in conformity with the relevant EHSRs. These measures may include, for example:

- monitoring of supplies of materials, components and sub-systems;
- inspections and tests to be carried out at various stages of production and on finished products;
- measures to ensure that the manufacturer's specifications are correctly executed by subcontractors.

These measures can be implemented by applying a quality management system such as, for example, a system according to standard EN ISO 9001[238].

[238] EN ISO 9001:2015 *Quality management systems - Requirements* (ISO 9001:2015).

The last paragraph of section 1 of Annex VII A requires the manufacturer to carry out the necessary research and tests on components and fittings. The necessary verification methods, including the necessary inspections, type-tests, sample tests or unit tests, are usually specified in the relevant harmonised standards.

All of the documents referred to in section 1 of Annex VII A must be regularly reviewed and updated when changes are made to the design or manufacture of the machinery concerned.

ANNEX VII A (continued)

. . .

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.*

   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.

   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.

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.*

. . .

§393 Communication of the technical file

Section 2 and 3 of Annex VII A set out the conditions under which the technical file must be made available to the market surveillance authorities of the Member States – see §98: comments on Article 4 (3) and (4). The relevant elements of the technical file must be made available in response to a reasoned request from the competent authorities, whether of the Member State where the manufacturer is established or of any other Member State.

The second paragraph of section 2 indicates that the technical file does not have to be located in the territory of the EU. The technical file for machinery manufactured outside the EU can therefore remain at the manufacturer's premises.

The second paragraph of section 2 also indicates that the technical file does not have to be permanently available in material form. The term 'technical file' thus refers to a body of information which can be stored on paper or in electronic form in one or several places. In particular, there is no need to duplicate documents that are common to different types of machinery. However, the information must be organised, classified and stored so that the manufacturer can, without delay, communicate the relevant elements

of the technical file in response to a duly reasoned request addressed by the market surveillance authorities of any of the Member States to the person designated in the EC Declaration of Conformity for that purpose – see §383: comments on Annex II 1 A.

Requests for communication of the technical file may be made for the purposes of market surveillance and should indicate the nature of the doubt about the conformity of the machinery concerned and be limited to the elements that are necessary for the investigation – see §98 and §99: comments on Article 4 (3) and (4).

The technical file may contain commercially sensitive or confidential information. The market surveillance authorities are bound to respect the confidentiality of such information – see §143: comments on Article 18. There is no obligation to communicate elements of the technical file to anybody other than the competent authorities of the Member States. For example, the manufacturer is not obliged to communicate elements of the technical file to his customers or to any in the distribution chain.

The third paragraph of section 2 of Annex VII A limits the level of detail required in the technical file with respect to sub-assemblies – see §392: comments on section 1 of Annex VII A.

Section 3 of Annex VII A states that failure to present the technical file in response to a duly reasoned request may constitute sufficient grounds for doubting the conformity of the machinery in question. Failure to present the technical file is not proof of the non-conformity of the machinery but, if the manufacturer does not communicate the relevant elements of the technical file, the market surveillance authorities are entitled to decide what action to take on the basis of whatever other evidence is available to them.

ANNEX VII (continued)

. . .

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.

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.

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.

§394 Relevant technical documentation for partly completed machinery

The obligation to compile the relevant technical documentation described in Annex VII B applies to the manufacturer of partly completed machinery referred to in Article 1 (1) (g) – see §131: comments on Article 13 (1) .

The purpose of the relevant technical documentation is to enable manufacturers to demonstrate the conformity of partly completed machinery with the EHSRs they have applied and fulfilled, as indicated in the Declaration of Incorporation – see §95: comments on Article 4 (2), and §98: comments on Article 4 (3) and (4). It also helps the market surveillance authorities to check the conformity of the partly completed machinery with those EHSRs, particularly for aspects that cannot be checked by visual inspection. The scope of the relevant technical documentation is thus limited to those EHSRs that have been applied and fulfilled by the manufacturer of the partly completed machinery and to his assembly instructions – see §385: comments on Annex II B (4).

Otherwise, the comments on the provisions relating to the technical file for machinery set out in Annex VII A are valid for the equivalent provisions relating to the relevant technical documentation for partly completed machinery set out in Annex VII B – see §391 to §393: comments on Annex VII A.

ANNEX VIII

Assessment of conformity with internal checks on the manufacture of machinery

1. *This Annex describes the procedure by which the manufacturer or his authorised representative, who carries out the obligations laid down in points 2 and 3, ensures and declares that the machinery concerned satisfies the relevant requirements of this Directive.*
2. *For each representative type of the series in question, the manufacturer or his authorised representative shall draw up the technical file referred to in Annex VII, part A.*
3. *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.*

§395 Assessment of conformity with internal checks on the manufacturer of the machinery

Annex VIII describes the conformity assessment procedure to be followed for all categories of machinery not listed in Annex IV – see §128: comments on Article 12 (2). This procedure is also one of the three conformity assessment procedures that may be chosen for machinery belonging to the categories listed in Annex IV when the manufacturer has applied harmonised standards the references of which are listed in the OJEU that cover all of the relevant essential health and safety requirements – see §129: comments on Article 12 (3).

Section 2 of Annex VIII recalls the obligation of the manufacturer or his authorised representative to draw up a technical file according to Annex VII A 1 for each type of machinery – see §103: comments on Article 5 (1) (b). The technical file must identify the EHSRs applicable to the machinery and describe how they have been fulfilled. The term 'representative type' is equivalent to the terms 'type' or model – see §392: comments on Annex VII A 1.

It should be noted that a technical file is required both for machinery manufactured in series and for machinery manufactured as a single unit. If changes are made to the design of machinery manufactured in series, for example where materials or components from different suppliers are incorporated or where improvements are made to the design, the conformity of the aspects of the design that have been modified must be reassessed and the technical file must be updated accordingly.

Section 3 of Annex VIII requires the manufacturer to take the measures necessary to ensure that the manufacturing process ensures compliance of the manufactured machinery with the technical file and with the applicable EHSRs – see §392: comments on Annex VII A 1 (b). These are the 'internal checks on manufacture' referred to in the title of Annex VIII.

ANNEX IX

EC type-examination

EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative model of machinery referred to in Annex IV (hereafter named the type) satisfies the provisions of this Directive.

1. The manufacturer or his authorised representative must, for each type, draw up the technical file referred to in Annex VII, part A.

. . .

§396 EC type-examination

Annex IX sets out one of the conformity assessment procedures that can be followed for machinery belonging to one of the categories listed in Annex IV - see §129 and §130: comments on Article 12 (3) and (4), and §388: comments on Annex IV.

When the EC type-examination procedure is chosen, each model or type of machinery belonging to one of the categories listed in Annex IV must be examined by a Notified Body. The Notified Body checks the documentation and carries out the necessary inspections and tests on a sample or samples of the machinery to ensure that the model or type is designed and constructed in conformity with the applicable EHSRs.

The terms 'model' or 'type' designate one or more machines representative of a given design, technical characteristics and application. A type of machinery may be produced in series or as a single unit.

One type of machinery may have variants; however, to be considered as belonging to the same type, variants must have the same basic design, present similar hazards and have similar protective measures. It is the responsibility of the Notified Body to judge, in each specific case, whether variants can be considered as belonging to the same type or must be treated as distinct types. The variants of a given type of machinery must be described in the technical file and the conformity of all variants must be assessed. The EC type-examination certificate must identify any variants of the type of machinery it covers – see §399: comments on section 4 of Annex IX.

Paragraph 1 of Annex IX recalls the manufacturer's obligation to draw up a technical file according to Annex VII A for each type of machinery – see §103: comments on Article 5 (1) (b).

ANNEX IX (continued)

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2. For each type, the application for an EC type-examination shall be submitted by the manufacturer or his authorised representative to a notified body of his choice.

The application shall include:

- *the 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.*

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.

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§397 The application for an EC type-examination

Section 2 of Annex IX sets out the content of the application for an EC type-examination. Such an application can be made to any Notified Body in the EU that is notified for the EC-type examination procedure and for the category of machinery concerned.

The application can be written in any official EU language acceptable to the Notified Body - see §399: comments on section 8 of Annex IX.

The application can be made by the manufacturer himself or be entrusted to an authorised representative – see §84 and §85: comments on Article 2 (j). The first indent of section 2 states that the application must include the name and address of the manufacturer and, where appropriate, of his authorised representative – see §250: comments on section 1.7.3 of Annex I.

The second indent of section 2 implies that the application for an EC type examination can only be addressed to one Notified Body. It is not the intention of this provision to prevent the manufacturer from obtaining several quotations before choosing a Notified Body for an EC type-examination, but simply to prevent him going from one Notified Body that has refused his design to another, until one of them approves the type concerned.

Once the manufacturer has chosen a Notified Body to carry out the EC type-examination for a given type of machinery, he must declare that he has not made an application to any other Notified Body for the same type of machinery, that is to say for machinery with the same design, technical characteristics and application. However, the manufacturer is free to choose another Notified Body for the EC type-examination of a different type of machinery.

The third indent of section 2 requires the application for an EC type-examination to include the technical file for the type of machinery concerned – see §392: comments on Annex VII A 1. The technical file covers the whole of the machinery and not only the

aspects of the machinery presenting the risks for which the category of machinery is listed in Annex IV.

For the purposes of the EC type-examination procedure, the technical file must therefore be made available to the Notified Body at an earlier stage than is generally prescribed in Article 5 (1) (b) which requires the technical file to be available before the machinery is placed on the market or put into service – see §103: comments on Article 5 (1). The technical file can be made available in a form agreed between the applicant and the Notified Body.

The last paragraph of section 2 requires the applicant to place one or more samples of the type at the disposal of the Notified Body for the purposes of inspection, measurement and testing. The number of samples required must be reasonable, and justified by the nature of the examinations and tests to be carried out. Where destructive tests are required, more than one sample may be needed. For large machinery, one sample is usually sufficient. By agreement, the necessary sample(s) can be sent to the Notified Body or placed at the disposal of the Notified Body at a place agreed between the Notified Body and the manufacturer – see §398: comments on section 3.4 of Annex IX.

ANNEX IX (continued)

. . .

3. The notified body shall:

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;

3.2. carry out or have carried out appropriate inspections, measurements and tests to ascertain whether the solutions adopted satisfy the essential health and safety requirements of this Directive, where the standards referred to in Article 7 (2) were not applied;

3.3. 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;

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.

. . .

§398 The content of the EC type-examination

Section 3 of Annex IX sets out the objectives and content of the EC type-examination.

Section 3.1 requires the Notified Body to:

– examine the technical file;

- check that the type was manufactured in accordance with the technical file;
- establish which parts or aspects of the machinery have been:
  a) designed in accordance with the relevant provisions of harmonised standards;
  b) designed in accordance with other technical specifications.

This enables the Notified Body to verify that the manufacturer has carried out an adequate risk assessment, that the EHSRs applicable to the machinery have been correctly identified and that adequate protective measures have been implemented. The examination of the technical file also enables the Notified Body to determine the appropriate inspections, measurements and tests to be carried out on the sample(s) of machinery placed at its disposal.

Sections 3.2 and 3.3 distinguish the approach to be taken for machinery designed according to harmonised standards and machinery not designed according to those standards. The approaches set out in paragraphs 3.2 and 3.3 may be combined in cases where the harmonised standards applied do not cover all the EHSRs applicable to the machinery, where harmonised standards have not been fully applied or where they have only been applied for certain parts or aspects of the machinery.

According to section 3.2, in the case of machinery (or parts or aspects of machinery) for which harmonised standards have not been applied, the Notified Body must determine the appropriate inspections, measurements and tests to verify the conformity of the machinery with the applicable EHSRs. Even in such cases, harmonised standards may provide an important indication of the state of the art to be taken into account when verifying conformity with the EHSRs – see §161 and §162: comments on General Principle 3 of Annex I. The verification methods set out in harmonised standards can often be used or adapted for machinery not designed according to those standards. Otherwise, verification methods set out in other appropriate technical specifications may be used. Failing that, the Notified Body must rely on the knowledge and experience of its inspection staff to use an appropriate verification method that ensures a level of risk reduction at least equivalent to that set out in the harmonised standards – see §408: comments on section 4 of Annex XI. Guidance may also be available in the Recommendations for Use issued by the coordination of Notified Bodies for Machinery (NB-M) – see §137: comments on Article 14 (7).

According to section 3.3, in the case of machinery (or aspects of machinery) for which harmonised standards have been used, the Notified Body must carry out the necessary inspections, measurements and tests to verify that the design and construction requirements of the standard(s) have been applied correctly.

As a general rule, the inspections, measurements and tests needed to verify the conformity of the machinery are to be carried out by the Notified Body itself – see §408: comments on section 3 of Annex XI. However, the Notified Body may subcontract exceptional checks such as, for example, the non-destructive inspection of welding. In order to avoid the duplication of testing, the Notified Body may also take into account reports on inspections or tests carried out by other competent bodies or by the manufacturer himself. Nonetheless, a Notified Body that accepts reports from other

sources remains fully responsible for the decision on the conformity of the machinery subject to the EC type-examination.

In accordance with section 3.4, the Notified Body and the applicant must agree on the place where the examination of the machinery is to take place. Practical criteria for deciding on the appropriate place include the size of the machinery and the nature of the inspections, measurements and tests to be carried out. In some cases, in particular for large machinery, it may be appropriate for the machinery as a whole to be examined at the manufacturer's premises, while some components or sub-assemblies are brought to the Notified Body's premises for examination. In the case of EC type-examination of machinery assembled at the user's premises or of purpose-built machinery, it is often necessary to perform the inspection, measurement and testing at the site of installation.

ANNEX IX (continued)

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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.

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.

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.

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.

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.

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.

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§399 The EC type-examination certificate

According to section 4 of Annex IX, when the outcome of the EC type-examination is positive, the Notified Body issues an EC type-examination certificate. The certificate must clearly identify the type of machinery it covers. The data necessary for identifying the approved type includes the designation of the machinery and the reference of the series or type as marked on the machinery – see §250: comments on section 1.7.3 of Annex I. If the certificate covers a type with variants, the certificate must identify these variants, indicating their distinguishing features.

It is possible to issue an EC type-examination certificate to one manufacturer for a type of machinery to be placed on the market under more than one reference or trademark. In that case, the different references and trademarks concerned shall be specified in the EC type examination certificate with an indication that they refer to the same type of machinery. If it is decided to place the machinery on the market with a different reference or trademark after the issue of the original EC type-examination certificate, the Notified Body must be informed and the certificate must be revised accordingly.

The manufacturer and the Notified Body must keep a copy of the EC type-examination certificate, the technical file for the machinery and related documents for 15 years after the issue of the certificate. This is in order to enable the Commission, the Member States or the other Notified Bodies to consult the documents according to section 7. This period of 15 years starts again each time the certificate is renewed – see §400: comments on section 9.3 of Annex IX. The duration of 15 years ensures that the documents concerned are available for the period of 10 years after the manufacture of the last unit of a series during which the manufacturer must keep the technical file for machinery available to the competent authorities – see §393: comments on Annex VII A 2. Since the Notified Body does not usually know when the last unit of the type covered by the certificate is manufactured and the certificate is valid for a period of five years, the period of custody for the EC type-examination certificate is five years longer but is counted from the date of issue of the certificate.

According to section 5 of Annex IX, if the outcome of the EC type-examination is negative, the Notified Body shall inform the applicant of its refusal to issue an EC type-examination certificate, giving the detailed reasons and indicating the procedure for appealing against the decision – see §135: comments on Article 14 (6). The other Notified Bodies and the Member State which notified the Notified Body concerned must be informed of each refusal to issue an EC type-examination certificate.

Section 6 of Annex IX requires the applicant to inform the Notified Body of any modifications he intends to make to the approved type. The Notified Body then has to decide whether or not the modification affects the validity of the EC type-examination certificate.

If the modifications are minor, the Notified Body may issue a new version or an extension of the original certificate. If the changes are liable to affect the conformity of the machinery with the relevant EHSRs, further verifications may be necessary before the new version or extension of the certificate is issued. The technical file held by the manufacturer and the Notified Body must be updated accordingly.

If the modification involves such major changes that the conformity of the machinery with the applicable EHSRs requires a new assessment, the Notified Body shall inform the applicant that the initial certificate is no longer valid for the modified type. If the manufacturer intends to continue with the modifications, he must make an application for a new EC type-examination. In general, this examination can be limited to the aspects of the machinery affected by the modifications.

According to section 7 of Annex IX, the Commission, the Member States and the other Notified Bodies may, on request, obtain from a Notified Body a copy of the certificates it has issued. 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. Notified Bodies must respond to such requests whether they are addressed by the authorities of the Member State that notified them or by the authorities of any of the other Member States. Requests for such documents may be made for the purposes of market surveillance. Such requests should indicate the nature of the doubt about the conformity of the machinery concerned and be limited to the elements that are necessary for the investigation – see §98 and §99: comments on Article 4 (3) and (4).

EC type-examination certificates do not have to accompany the machinery when it is placed on the market, but the EC Declaration of Conformity must indicate the particulars of the Notified Body which carried out the EC type-examination and the number of the EC type-examination certificate – see §383: Comments on Annex II 1 A.

Section 8 of Annex IX deals with the language of files and correspondence referring to the EC type-examination procedure other than the technical file – see §391: comments on Annex VII A. The choice of official EU language for this purpose is a matter to be agreed between the applicant and the Notified Body concerned.

ANNEX IX (continued)

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9. Validity of the EC type-examination certificate

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.

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.

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.

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.

§400 Validity and review of the EC type-examination certificate

Section 9 of Annex IX deals with validity of EC type-examination certificates and their periodic review.

Section 9.1 makes the Notified Body responsible for ensuring that the EC type-examination certificates that it has issued remain valid. This responsibility is exercised within the limits of the information at the disposal of the Notified Body. The Notified Body must inform the certificate holder of major changes to the legal requirements or to the state of the art of which it is aware that might affect the validity of the certificate.

For example, since the Notified Bodies must follow the situation of standards relevant to their areas of activity – see §408: comments on section 8 of Annex XI – they shall inform their certificate holders of any new or revised harmonised standards which reflect significant changes in the state of the art for the machinery concerned – see §162: comments on General Principle 3 of Annex I.

Notified Bodies shall also inform their certificate holders of Commission Decisions relating to measures to deal with categories of potentially hazardous machinery – see §118: comments on Article 9 – relating to formal objections to harmonised standards – see §121: comments on Article 10 - or relating to the safeguard procedure – see §123: comments on Article 11 – when these Decisions have implications for the conformity of the machinery concerned.

For the withdrawal of EC type-examination certificates – see §135: comments on Article 14 (6).

Section 9.2 is complementary to section 6 – see §397: comments on Annex IX - and to section 9.1. It recalls the obligation of the manufacturer to take account of any significant evolution of the state of the art which may entail that the machinery subject to an EC type-examination certificate can no longer be considered to fulfil certain EHSRs. This may occur, for example, when new or more effective means of protection become available or when a new or revised harmonised standard is published – see §161 and §162: comments on General Principle 3 of Annex I.

Section 9.3 sets out the obligation for the holder of an EC type-examination certificate to request a periodic review of the validity of the certificate every five years. This implies that the certificate issued by the Notified Body should indicate the date at which its validity ceases. The manufacturer is responsible for requesting the review in due time, however it is useful for the Notified Bodies to send a reminder to their certificate holders.

When reviewing an EC type-examination certificate, the Notified Body shall examine the technical file for the machinery in the light of any significant evolution of the state of the art over the elapsed five-year period. Where necessary for its assessment, the Notified Body shall carry out verifications on a sample of the machinery. In light of the review, the Notified Body shall take a decision on whether or not the certificate is to be renewed for a further five years.

The renewed certificate, the updated technical file and all other relevant documents are subject to the same custody requirements as the initial certificate – see §399: comments on section 4 of Annex IX.

Section 9.4 states that if the EC-type examination certificate is not renewed, the manufacturer shall cease the placing on the market of the type of machinery concerned, since it can no longer be considered to comply with the requirements of the Machinery Directive.

ANNEX X

Full quality assurance

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.

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.*

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§401 Full quality assurance

Annex X sets out one of the conformity assessment procedures that can be followed for the categories of machinery listed in Annex IV – see §129 and §130: comments on Article 12 (3) and (4), and §388: comments on Annex IV. When the full quality assurance procedure is followed, the manufacturer is not obliged to have each type of machinery examined by a Notified Body. Instead, a Notified Body assesses and monitors the application of the manufacturer's full quality assurance system. The system must be set up and operated to ensure that the Annex IV machinery concerned is designed and manufactured in conformity with the applicable EHSRs and is subject to the necessary inspections and tests to ensure that the conformity of the machinery is constantly maintained.

Section 1 sets out, in general terms, the obligation of the manufacturer or his authorised representative who chooses to use the procedure set out in Annex X.

ANNEX X (continued)

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2. Quality system

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.

The application shall contain:

- *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.*

§402 The application for assessment of a full quality assurance system

Section 2.1 of Annex X sets out the content of the application to be made by the manufacturer or his authorised representative for the assessment of a full quality assurance system. Such an application can be made to any Notified Body in the EU that is notified for the full quality assurance procedure and for the category or categories of machinery covered by the manufacturer's full quality assurance system.

Although Annex X does not include a requirement relating to the language to be used in the correspondence between the manufacturer and the Notified Body, it can be assumed that, as for the EC type-examination procedure, such correspondence can be written in any official EU language acceptable to the Notified Body – see §399 comments on section 8 of Annex IX.

The second indent of section 2.1 requires the application to indicate the places of design, manufacture, inspection, testing and storage of the machinery. The purpose of this information is to enable the Notified Body to carry out the on-site inspections referred to in sections 2.3 and 3.2.

Where the manufacturer subcontracts or outsources all or a significant part of the design, manufacture, inspection, testing or storage of the machinery, the application must specify the identity of the subcontractors concerned and the places where the subcontracted tasks are carried out. The machinery manufacturer is responsible for obtaining from his subcontractors the information and documentation required for the assessment of the aspects of the full quality assurance system that apply to the subcontracted tasks. This does not concern the purchase of complete components, safety components or partly completed machinery, but the full quality assurance system

must include the measures necessary to ensure the suitability of such supplies to ensure the conformity of the final machinery.

The third indent of section 2.1 requires the manufacturer to include, as part of his application for assessment of the full quality system, a technical file for one model of each category of machinery covered by the full quality assurance system. The term 'category' refers to the title of Annex IV: *"Categories of machinery to which one of the procedures referred to in Article 12 (3) and (4) must be applied".* Each of the 23 items of Annex IV is therefore to be considered as a category of machinery; in this context the sub-categories of items 1, 4 and 12 of Annex IV are not to be considered as distinct categories.

The manufacturer must provide one technical file for each category of machinery to be manufactured. Thus, for example, if the full quality assurance system covers the manufacturer of vehicle servicing lifts (item 16 of Annex IV) and of devices for the lifting of persons (item 17 of Annex IV), the manufacturer must provide a technical file for one model of vehicle servicing lift and a technical file for one model of device for lifting persons.

Since the purpose of this requirement is to enable the Notified Body to review the technical files concerned to ensure their conformity with the applicable EHSRs, the technical file must be representative of the manufacturer's product range and display all the main hazards associated with the category of machinery concerned. The Notified Body shall therefore make sure that the technical file provided is for a model that represents the most complex machinery in each category covered by the full quality assurance system.

The technical file shall be made available to the Notified Body before the inspection at the manufacturer's premises is carried out, since the review of the technical file is an important tool for checking the full quality assurance system.

As a general rule, the complete technical file must be communicated to the Notified Body. For very complex machinery, it might be impractical to communicate the complete technical file before the inspection of the manufacturer's premises. In such cases, the content of the documentation to be sent before the audit can be reduced, in agreement with the Notified Body. However, during the audit, all the elements of the technical file must be made available.

The fourth indent of section 2.1 refers to the documentation on the quality system required by section 2.2.

The last indent of section 2.1 implies that the application for the assessment of a full quality system can only be addressed to one Notified Body. It is not the intention of this requirement to prevent the manufacturer from obtaining several quotations before choosing a Notified Body for the assessment of his full quality assurance system but simply to prevent him going from one Notified Body to another until one of them approves his system.

Once the manufacturer has chosen a Notified Body to carry out the assessment of his full quality assurance system, he must declare that he has not made an application relating to the same full quality assurance system to any other Notified Body.

ANNEX X (continued)

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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.*

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§403 The objectives and content of the full quality assurance system

Section 2.2 of Annex X sets out the objectives and summarises the content of the full quality assurance system. The basic objectives of the full quality assurance system are to ensure that the machinery concerned is designed and constructed in conformity with the relevant EHSRs of the Machinery Directive and that the conformity of the machinery produced is checked and maintained.

The first paragraph of section 2.2 requires the full quality system to be fully documented. The seven indents of the second paragraph of section 2.2 summarise the main elements of the documentation of the full quality assurance system.

The first indent of the second paragraph of section 2.2 deals with the objectives and organisational aspects of the system. The organisational structure and the definition of

management responsibilities must ensure that the objectives of the full quality assurance system are effectively fulfilled. Where all or significant parts of the design, manufacture, inspection, testing or storage of the machinery are carried out by subcontractors or outsourced, the description of the organisational aspects of the full quality assurance system must cover the relations between the manufacturer and his subcontractors.

The second indent of the second paragraph of section 2.2 refers to the technical design specifications used. Where harmonised standards are applied, their references must be documented, indicating the EHSRs they cover. Where harmonised standards are not applied or not applied in full, the alternative technical specifications used to fulfil the EHSRs applicable to the machinery must be documented.

The third indent of the second paragraph of section 2.2 refers to inspections, verification techniques, processes and systematic actions carried out to ensure the conformity of the design of the machinery. The responsibilities and competency of the persons in charge of these actions must be defined and their actions must be traceable. The design inspection and review shall be carried out under controlled conditions (with clear instructions, checklists etc.). It is good practice to have the design inspection and verification performed by persons not directly involved in the design process itself.

The fourth indent of the second paragraph of section 2.2 refers to quality control and quality assurance techniques, processes and systematic actions to be carried out to ensure that the manufacturing process produces machinery that complies with the design specifications. These measures must include the means to ensure that basic components, safety components or partly completed machinery procured complete from suppliers are controlled to ensure that they are appropriate to ensure the conformity of the final machinery.

The fifth indent of the second paragraph of section 2.2 refers to inspections and tests to be carried out before, during and after manufacture. These may include inspections and tests to be carried out on materials, components or sub-assemblies before or during production, as well as inspections and tests to be carried out at the end of the manufacturing process on complete machinery to ensure the conformity of the production with the design specifications. The nature of the inspections and tests, their frequency and acceptance criteria must be documented. The actions to be taken in case of negative results must be defined.

Where the manufacturer subcontracts (or outsources) all or significant parts of the design and/or manufacturing of the machinery concerned, the objectives and obligations set out in the third, fourth and fifth indents of the second paragraph of section 2.2 must cover the subcontracted design and/or manufacturing activities and the premises where they are carried out.

The sixth indent of the second paragraph of section 2.2 refers to the quality records. The documentary output of the full quality assurance system must be classified and stored so that the information is available both for the needs of management of the system and for auditing purposes.

The last indent of the second paragraph of section 2.2 requires the manufacturer to define the means to be used to monitor the output of the full quality assurance system to

ensure that it is effectively operated according to the documentation set out in the six previous indents of section 2.2. These means must ensure that anomalies are detected, that appropriate remedial action is taken and that, where necessary, the content of the full quality system is updated or improved.

ANNEX X (continued)

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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.

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§404 Assessment of the full quality assurance system

Section 2.3 of Annex X summarises the tasks of the Notified Body with respect to the assessment of the full quality assurance system.

The second paragraph of section 2.3 refers to *'the relevant harmonised standard'*. The relevant harmonised standard for a full quality assurance system is standard EN ISO 9001[239]. Application of that standard therefore confers a presumption of conformity with the requirements of Annex X, provided that the full quality system ensures the conformity of the products concerned with all the specific requirements of the Machinery Directive (referred to in the standard as *'statutory and regulatory requirements applicable to the product'*). However, application of standard EN ISO 9001 and certification against this standard by a certification body are not mandatory.

The Notified Body carrying out the assessment of a full quality assurance system according to Annex X cannot fully rely on an existing certification of the system

[239] EN ISO 9001:2015 *Quality management systems - Requirements* (ISO 9001: 2015). The reference of this standard is published in the OJEU in the framework of the Decision setting out the conformity assessment modules – see: Commission communication in the framework of the implementation of the Regulation (EC) No 765/2008 of the European Parliament and of the Council, Decision 768/2008/EC of the European Parliament and of the Council, Regulation (EC) No 761/2001 of the European Parliament and of the Council (Publication of titles and references of harmonised standards). OJ C 136, 16.6.2009, p. 8.

according to EN ISO 9001, but it is up to the Notified Body to determine the extent of the further assessment required.

The third and fourth paragraphs of section 2.3 refer to the audit of the full quality system. The audit team must include at least one auditor who is an expert in the assessment of the technology of the categories of machinery concerned by the full quality assurance system. The number of auditors needed depends on the scope and complexity of the design and manufacturing process covered by the full quality assurance system. For example, if the system covers several categories of machinery with different technology or machinery incorporating complex electronic control systems, more than one technical expert may be needed.

The third paragraph of section 2.3 states that the audit shall include an inspection to be carried out at the manufacturer's premises. Where the design, manufacture, inspection and testing of the machinery are carried out at more than one site, the necessary inspections must be carried out by or under the responsibility of the Notified Body at all sites relevant for ensuring the conformity of the product with the applicable EHSRs, including the sites of subsidiaries of the manufacturer or of significant sub-contractors – see §395: comments on section 2.1 of Annex X. In this respect, manufacturers established within the EU and outside the EU must receive the same treatment.

The duration of the audit shall be determined by the Notified Body taking into account of factors such as, for example, the number of manufacturing sites, the complexity of the manufacturing process, how much work is sub-contracted, the number, variety and complexity of the types of machinery produced and the volume of production. Guidance drawn up by the International Accreditation Forum may be used as a basis for determining a minimum duration for the audit[240].

The third sentence of the third paragraph of section 2.3 also refers to the review of the technical file(s) submitted with the application for assessment of the full quality assurance system according to the third indent of section 2.1.

The review of the sample technical file(s) is one of the checks to be carried out by the Notified Body to ensure that the manufacturer's full quality assurance system is adequate. The review of technical file(s) to be carried out in the framework of the assessment of a full quality assurance system is similar to that required for EC type-examination, but without a detailed inspection of the machinery – see §398: comments on section 3.1 of Annex IX.

Where harmonised standards are applied for the design of the machinery, the Notified Body shall check that the appropriate standards have been chosen, that the most recent versions are available and that the manufacturer monitors the development of the relevant standards. Where other technical design specifications are applied, the Notified Body shall check that they are justified by the risk assessment and fulfil the applicable EHSRs, taking account of the state of the art.

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[240] IAF *Guidance on the Application of ISO/IEC Guide 62:1996 - General Requirements for Bodies Operating Assessment and Certification/registration of Quality Systems*, Issue 3 (IAF GD 2: 2003) - Annex 2: *Auditor Time*: http://elsmar.com/pdf_files/IAF-GD2-2003_Guide_62_Issue_3_Pub.pdf.

The review of the technical file also helps the Notified Body to identify the other aspects of the full quality assurance system that should be inspected. During the audit, the Notified Body shall check that the technical files for other models of machinery are compiled using the same approach as that used for the sample technical file(s) submitted with the application.

The fourth paragraph of section 2.3 refers to the notification of the decision of approval of a full quality assurance system. The approval decision that shall be notified to the applicant following the audit shall be accompanied by or refer to a written audit report. The approval decision shall clearly specify the scope of the approval, indicating the categories of Annex IV machinery covered and the addresses of the manufacturing sites that have been inspected. Any particular limitations to which the approval is subject shall be mentioned. The decision shall indicate its date of issue and date of expiry.

If the Notified Body decides not to approve the full quality assurance system, it shall inform the applicant of its decision, giving the detailed reasons and indicating the procedure for appealing against the decision – see §135: comments on Article 14 (6). In that case, the audit report shall contain sufficient information and explanation to enable the manufacturer to identify the shortcomings of his system and take the appropriate corrective measures prior to requesting a further assessment visit.

ANNEX X (continued)

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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.

The notified body shall evaluate the proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in point 2.2, or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

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§405 Implementation and modification of the full quality assurance system

The first paragraph of section 2.4 of Annex X underlines the manufacturer's obligation to implement the approved full quality assurance system, to monitor its implementation and to update and improve the system as necessary.

The second paragraph of section 2.4 requires the manufacturer or his authorised representative to inform the Notified Body of any planned change to the full quality assurance system. Since the purpose of the system is to ensure that the manufacturer is able to design and manufacture new models of machinery without recourse to a Notified Body each time, the Notified Body does not have to be informed of changes to the design of the machinery covered by the system or the introduction of new models,

provided these changes do not involve modifications of the full quality assurance system itself. Changes of which the Notified Body must be informed include, for example:

- the addition of new manufacturing facilities or sites;
- new subcontracting or outsourcing of manufacturing activities or the taking back of manufacturing activities previously subcontracted or outsourced;
- extensions of the system to cover new categories of Annex IV machinery;
- extensions of the system to cover machinery belonging to the same category of Annex IV but using different technology;
- the introduction of new manufacturing techniques;
- changes to the quality control methods;
- reorganisation of the quality management.

According to the third paragraph of section 2.4, it is for the Notified Body to determine whether audits are necessary to assess the adequacy of the parts or aspects of the full quality assurance system to be modified.

Following the necessary audits carried out in accordance with the fourth paragraph of section 2.4, the decision of the Notified Body is notified to the applicant in the same conditions as the initial decision, indicating, where appropriate, the procedure for appealing against the decision – see §404: comments on section 2.3 of Annex X.

ANNEX X (continued)

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3. Surveillance under the responsibility of the notified body

3.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

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:

— 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.

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.

3.4. Moreover, the notified body may pay the manufacturer unannounced visits. The need for these additional visits and their frequency will be determined on the basis of a visit monitoring system managed by the notified body. In particular, the following factors will be taken into account in the visits monitoring system:

- *the results of previous surveillance visits,*
- *the need to monitor remedial measures,*
- *where appropriate, special conditions attaching to approval of the system,*
- *significant modifications in the organisation of the manufacturing process, measures or techniques.*

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.

§406 Surveillance of the full quality assurance system

Section 3 of Annex X deals with the surveillance of the ongoing implementation of an approved full quality assurance system under the responsibility of the Notified Body that issued the initial approval decision.

This surveillance is exercised by means of the periodic audits referred to in section 3.3 and the unannounced visits referred to in section 3.4.

For the purpose of these audits and visits, section 3.2 requires the manufacturer to allow the Notified Body access to all the relevant design and manufacturing sites and to the relevant documentation.

The duration and frequency of the periodic audits referred to in section 3.3 shall be determined by the Notified Body, taking account of factors such as, for example, the number of manufacturing sites, the complexity of the manufacturing process, how much work is sub-contracted, the number, variety and complexity of the types of machinery produced and the volume of production. According to the Recommendation for Use CNB/M/13.021 of NB-M – see §137: comments on Article 14 (7) – the period between audits should not be longer than 12 months. The Notified Body shall also take account of the experience of previous audits when determining the frequency of periodic audits. If certain periodic audits are limited to parts of the full quality assurance system, the Notified Body shall ensure that all elements of the system are reassessed at least every three years.

Following a periodic audit, the Notified Body shall communicate to the manufacturer an audit report and inform him whether the approval of his full quality assurance system is renewed, in the same conditions as the initial decision, indicating, where appropriate, the procedure for appealing against the decision – see §404: comments on section 2.3 of Annex X.

Section 3.4 indicates some of the reasons which might induce the need for unannounced visits. The need for and frequency of these visits is a matter for the Notified Body to determine. A duly motivated complaint made to the Notified Body by the Commission, a Member State, a manufacturer, another Notified Body or any other interested party is one of the factors which could trigger an unexpected visit. Another factor may be the awareness of the Notified Body of modifications in the manufacturer's organisation, manufacturing process, measures or techniques. Such a visit may also be needed if a market surveillance authority detects the non-conformity of machinery covered by the full quality assurance system or if such machinery is subject to a Commission Decision in the framework of the safeguard procedure. According to a Recommendation of NB-M, the contractual agreement between the Notified Body and the manufacturer should foresee the possibility of such visits.

The Notified Body may carry out tests (or have them carried out) on the product where it is necessary to verify the correct functioning of the full quality assurance system. Such tests should generally be confined to instances where there is reasonable doubt about the effectiveness of the system.

Following an unannounced visit, a visit report and, where appropriate, a test report, shall be communicated to the manufacturer in the same conditions as the audit reports.

If, during a periodic audit or an unannounced visit, the Notified Body identifies either:

- a failure of the full quality assurance system to comply with the requirements set out in section 2.2 of Annex X, or
- a non-conformity of the machinery manufactured under the system,

the Notified Body shall suspend the approval of the full quality assurance system and require the manufacturer to resolve the non-conformities within a specified time. If the

non-conformities are not corrected appropriately or within the specified time, the Notified Body must withdraw its approval of the quality system – see §135: comments on Article 14 (6).

Placing on the market of Annex IV machinery subject to the full quality assurance procedure must cease if the approval of the manufacturer's full quality assurance system is suspended or withdrawn by the Notified Body.

ANNEX X (continued)

. . .

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:

- *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.*

§407 Custody of the documentation, decisions and reports relating to the full quality assurance system

Section 4 of Annex X requires the manufacturer having an approved full quality assurance system or his authorised representative to keep the documentation, decisions and reports relating to the system available to the national authorities for 10 years from the last date of manufacture. This is the date on which the manufacture of the last unit of Annex IV machinery covered by the full quality assurance system is completed. These documents may be required in the course of market surveillance – see §99: comments on Article 4 (3) and (4).

This obligation is complementary to the general obligation of the manufacturer relating to the custody of the technical file for each type of machinery manufactured – see §393: comments on Annex VII A 2.

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.*

§408 Minimum criteria for the assessment of Notified Bodies

Notified Bodies to carry out the EC type-examination conformity assessment procedure set out in Annex IX and the full quality assurance procedure set out in Annex X for machinery belonging to the categories listed in Annex IV are assessed, appointed and notified to the Commission by the Member States – see §133: comments on Article 14 (1) to (5).

Annex XI sets out the criteria to be applied by the Member States when assessing candidate Notified Bodies prior to their appointment according to Article 14 (1) and when monitoring their activity according to Article 14 (2). They are minimum criteria, in other words, the Member States are entitled to have further requirements for the bodies they appoint, provided the nine criteria set out in Annex XI are satisfied.

The assessment and monitoring of Notified Bodies can be carried out by means of accreditation based on the relevant harmonised standards – see §134: comments on Article 14 (2), (3) and (5).

Section 1 of Annex XI sets out the criterion of independence of the body, its director and staff. Notified Bodies for machinery are third-party conformity assessment bodies that must be organisationally and economically independent of parties involved in the design, manufacture, supply, marketing, installation or maintenance of machinery.

Sections 2 and 5 deal with the professional integrity, technical competence and impartiality of the body and its staff.

Sections 3 and 4 require the body to have staff with the necessary knowledge, training and experience to carry out the technical and administrative aspects of conformity assessment. The assessment of these aspects must take account of both the category or categories of Annex IV machinery and the procedure(s) for which the body wishes to be notified.

Section 3 also requires the body to have the means necessary to complete the technical and administrative tasks involved in the conformity assessment procedure for which it wishes to be notified and to have access to the equipment necessary for the exceptional checks. Thus, as a general rule, the Notified Body must itself have the necessary facilities and equipment to carry out the inspections, measurements and tests required by the conformity assessment procedure concerned. However, subcontracting of exceptional checks can be foreseen – see §398: comments on section 3.1 of Annex IX.

Section 6 requires the body to have liability insurance unless its liability is assumed by the state.

Section 7 requires the staff of the Notified Body to be bound to observe professional secrecy with regard to confidential information obtained during conformity assessment activity. This does not affect the obligations of the Notified Body to provide information to the notifying authority, since the authorities of the Member States are themselves bound to respect the confidentiality of such information – see §143: comments on Article 18.

Section 8 requires the Notified Bodies to participate in coordination activities. This criterion can be fulfilled if the Notified body takes part directly in the work of the European Coordination of Notified Bodies for machinery (NB-M) or takes part in a coordination structure at national level which is represented in NB-M – see §137: comments on Article 14 (7).

Section 8 also requires the Notified Bodies to take part directly or be represented in European standardisation, or ensure that they know the situation in respect of the relevant standards. The participation of Notified Bodies in the development of standards for the categories of machinery for which they are notified is important to ensure that the standards take account of experience of the inspection and testing of the machinery concerned. It is also important for the Notified Bodies not only to have adequate knowledge of published harmonised standards but also to monitor the development of new and revised standards. For this purpose, they can be directly involved in standardisation at European level or, at least, be affiliated to the national standardisation group(s) that follow the development of the standards relevant to their activity – see §112: comments on Article 7 (2).

Section 9 aims to ensure that, in the event of cessation of activities of a Notified Body either because the body ceases to exist or because its notification is withdrawn, the necessary arrangements are made to ensure that the relevant files can still be made available to the market surveillance authorities if necessary – see §399: comments on Annex IX 7, and §407: comments on Annex X 4. This can be achieved either by the transfer of the files to another Notified Body, in agreement with the manufacturer concerned, or by making the files available to the notifying authority.

(§409 - §410 Reserved)

SPECIFIC GUIDANCE DOCUMENTS

The following sections on specific issues have been approved as guidance documents by the Machinery Working Group.

§411 Safety fences as safety component under the Machinery Directive 2006/42/EC

Safety fences are one element in the tool box of safety components to fulfil the requirements of the Machinery Directive 2006/42/EC in order to provide compliant and safe machinery on the market. The intention of this section is therefore to give guidance on safety fences in terms of their classification as Safety Components within the meaning of the Machinery Directive 2006/42/EC. The document focuses on the conditions under which a safety fence (Fig. 1) can be regarded as independently placed on the market. Three scenarios for placing safety fences on the market are considered and clarified in this section.

It is emphasised that the question under which conditions safety fences can be regarded as independently placed on the market does not change the fundamental principle of the Machinery Directive that all machinery must be supplied with all protective devices when first placed on the market. Furthermore, it is always the machinery manufacturer's responsible for placing on the market only machinery in conformity which the relevant requirements of the Machinery Directive 2006/42/EC and to provide the EC Declaration of Conformity and to affix the CE-marking on the machine.

Fig. 1: Safety fence (Hans Georg Brühl GmbH)

Background

Safety components referred to in Article 1 (1) (c) of the Machinery Directive 2006/42/EC are defined as follows:

Safety component means a component:

– which serves to fulfil a safety function,

– which is independently placed on the market,

– the failure and/or malfunction of which endangers the safety of persons, and

– which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.

As defined in Article 1 (1) (c) of Directive 2006/42/EC, safety components are components intended by the component manufacturer to be fitted to machinery in order to fulfil a protective role, that is, a safety function. Safety fences are regarded as guards. They can be used as one of the means to prevent access to danger zones in or around machinery. In many cases, the safety fence acts as a barrier in both directions in order to protect against two or more risks simultaneously. For example, a safety fence may be fitted both to prevent persons entering a danger zone or to initiate the shutdown of the machinery in case of a person entering the danger zone, and also to prevent ejected objects from reaching persons in the environment of the machinery.

Taking into account the nature of a safety fence regarding its function as a safety component, the fence can in principle fulfil its protective role only as an integral whole. Regarding the meaning of the “safety function”, to be fulfilled by a safety fence, it is the manner and intention when a safety fence is placed on the market. In most cases individual “fence elements” (see Scenario 3) are not intended in themselves to provide a safety function, they only do so when they are collected together for a specific purpose. This is different to other listed (Annex V) safety components such as safety interlocks which are a discrete item, but are intended to provide a safety function in themselves. However, even single parts such as a door or a single element can be regarded as a safety component, depending on its specific application (e.g. to prevent access to a danger zone).

Scenario 1: Safety fences for whose design and construction the machinery manufacturer has planning responsibility

If a safety fence is constructed precisely in accordance with specifications from a machinery manufacturer for a particular machine, either by a third party or by the manufacturer itself, for example from individual safety fence components, and placed on the market together with said machine, it is not a safety component within the meaning of the Machinery Directive. The safety fence must be deemed a component or part of the machine, and is placed on the market together with the machine as a single unit.

Explanation:

If, in a case falling within Scenario 1, a third party (fence manufacturer) is commissioned to supply the safety fence for a particular machine, and the machinery manufacturer itself is solely responsible for its design (that is the machinery manufacturer has specified the geometry of the fence, the materials to be used, the mesh dimensions etc.), the fence manufacturer will be wholly or partly unable to satisfy the obligations of Art. 5 of the Machinery Directive 2006/42/EC regarding the placing on the market of a safety component. The machinery manufacturer is in charge of planning and thus, as it is understood legally to be the "manufacturer" of the machine, and is also responsible for the safety fence forming part of the machine.

The fence manufacturer, here only performing a specific order, itself bears no responsibility for the planning of the safety fence. The fence manufacturer in such cases is accordingly dependent on others for planning instructions and acts solely as the machinery manufacturer's "extended workbench" (as a sub-contractor).

Given the above, the passing on of the safety fence to the machinery manufacturer by the fence manufacturer cannot be assumed to constitute any independent and/or separate placing on the market within the meaning of the relevant machinery legislation; on the contrary, it is a purely dependent action carried out in the course of manufacture of the machine/assembly under the control of the machinery manufacturer. It is precisely because there is no such separate placing on the market that such safety fences, for whose planning the machinery manufacturer bears the principal responsibility, that they do not satisfy the definition contained in Art. 2 c) of the Machinery Directive 2006/42/EC and so are not safety components in the legal sense, even if they are intended to perform safety functions.

The allocation of responsibility as described above will not change in other respects even if the machinery manufacturer makes use of the fence configuration software for example provided by one of several fence manufacturers during the planning of the safety fence. Such planning tools constitute merely "workmanlike" assistance in the planning of safety fences, and do not result in any shift in planning control or responsibility.

Scenario 2: Safety fences for whose design and construction the fence manufacturer has planning responsibility

Safety fences which are designed, constructed and placed on the market separately as complete items by fence manufacturers shall be regarded as safety components within the meaning of the Machinery Directive and must therefore bear the CE marking, and an EC Declaration of Conformity (DoC) and user instructions (in the appropriate language) must be issued and enclosed with them. This also applies to those safety fences placed on the market by a manufacturer independently of any particular machine, split up into their individual parts but as complete items in the manner of a construction kit (system components, modular protective fences) and only assembled at their intended destination.

Explanation:

In contrast to those cases covered by Scenario 1, it is not the machinery manufacturer but instead the fence manufacturer (who may, or may not be commissioned by the former) who designs the safety fence for a machine/assembly. The fence manufacturer concerned shall be responsible for the planning of the safety fence.

It logically follows as an essential condition that before the fence manufacturer is able to design the safety fence:

a) either the machinery manufacturer confers upon the fence manufacturer full design/planning control in such a way as to ensure that the latter is provided by the machinery manufacturer with all planning-relevant information about the dangers/risks presented by the machine which have not already been sufficiently minimised by incorporating appropriate safety measures into the machine, that is,

adequate information is provided about the risks which the protective fence is intended to eliminate, or

b) the fence manufacturer itself obtains planning-relevant information for particular types of machine and designs on its own initiative suitable safety fences for those machine types and places them on the market (ready to install).

In such cases, the fence manufacturer no longer acts as the machinery manufacturer's extended workbench (sub-contractor), but instead on its own initiative and responsibility.

The fence manufacturer is here not only *de facto*, but also *de jure*, the "manufacturer" of the safety fence. The passing on of the safety fence to the machinery manufacturer must be deemed as a separate placing on the market, and the safety fence as such as a safety component within the meaning of the definition in Art. 2 c) of the Machinery Directive 2006/42/EC. The fence manufacturer must conduct the EC conformity assessment procedure and affix the CE marking, providing the DoC and instructions.

The approach does not differ even if the safety fence designed by the fence manufacturer is supplied to the machinery manufacturer as a complete unit, though broken down into its constituent parts, which the machinery manufacturer only has to assemble (according to comprehensive instructions which must be provided by the manufacturer of the safety fence). The mere assembly of the construction kit does not involve any act of planning or design which could result in a shift of the design/planning responsibility for the entire safety fence from the fence manufacturer to the machinery manufacturer.

Scenario 3: Individual components of safety fences and combinations of individual components without any safety function

Individual components/elements of safety fences which are supplied separately are simple components, but not safety components, because they cannot as such (that is, on their own) ensure any safety function. No CE marking shall be affixed to such components.

Individual fence elements which are either as such or in combination with each other neither capable nor intended to perform any safety function within the meaning of the Machinery Directive 2006/42/EC are also simple components. They shall not be classified as safety components and no CE shall be affixed to them. Their assembly shall not result in the creation of any safety barrier, nor any safety fence.

Explanation:

Ensuring a safety function within the meaning of Art. 2 c) of the Machinery Directive 2006/42/EC can in the case of safety fences only be achieved by the safety fence as a whole integrated with the machinery. Only the complete item can for example prevent access to a danger zone. Accordingly, it is only the safety fence in its entirety which can be used as the basis for deciding in an individual case whether a safety fence constitutes a safety component as defined by relevant machinery legislation.

As a general rule, individual components and elements of safety fences (for example, fence posts, grille elements) are incapable in themselves of performing any safety function and do not constitute safety components within the meaning of the Machinery

Directive as long as they are supplied as separate individual items. An exception of the rule applies, if single parts such as a door on an access route to the machine or a single element with regard to its specific application, can for instance prevent the access to a danger zone, in this sense these single components fulfil a safety function.

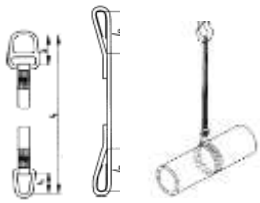
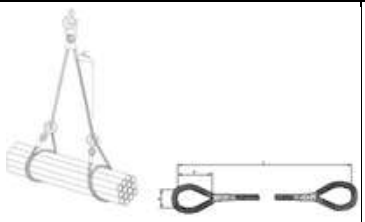
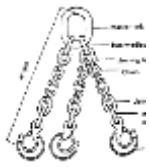
§412 Classification of equipment used for lifting loads with lifting machinery

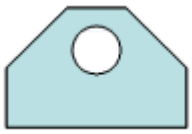
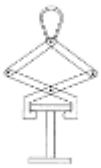
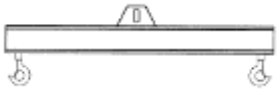
Machinery Working Group approved in June 2012 a guidance document on equipment used in the lifting of loads with machinery: when it is a “lifting accessory” and when it is not. This guidance gives examples of equipment that are considered as lifting accessories and other examples of equipment used for lifting loads that are not considered as lifting accessories.

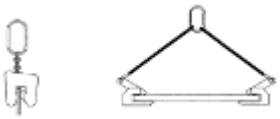
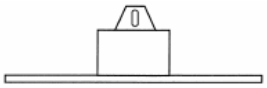
Note that the following apply to some items as indicated:

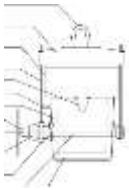
* Such equipment is considered as a lifting accessory when it is independently placed on the market, see items 4 to 9 and 27.

* * Such equipment is considered as a lifting accessory when it is not permanently attached or fixed to the lifting machinery, in other words, when the machinery can be used to lift loads without the equipment or with other lifting accessories, see items 10 to 18.

N°	Picture / examples	Designation	Description	Standard / Reference	Lifting accessory covered by Directive 2006/42/EC	Work equipment not covered by Directive 2006/42/EC
1		Textile slings and their components	Assembly of one or more sewn webbing components for attaching loads to the hook of a crane or other lifting machine	EN 1492 parts 1, 2 & 4	X	
2		Steel wire rope slings and their components	Assembly of one or more steel wire rope legs or an endless sling for attaching loads to the hook of a crane or other lifting machine	EN 13414 parts 1, 2 & 3	X	
3		Chain slings and their components	Assembly of one or more chains for attaching loads to the hook of a crane or other lifting machine	EN 818 parts 1 to 8	X	
4		Lifting eyelets	Eyelets intended to be placed on the load by threading for lifting it *		X	

N°	Picture / examples	Designation	Description	Standard / Reference	Lifting accessory covered by Directive 2006/42/EC	Work equipment not covered by Directive 2006/42/EC
5		Lifting eyelets	Eyelets intended to be placed on the load by welding for lifting it *		**X**	
6		Lifting ear	Steel plate with a hole intended to be welded to a load for lifting it *		**X**	
7		Lifting anchor	A device intended to be integrated into a structure (e.g. a concrete units, concrete panel) in order to provide an anchorage for lifting the structure *	Machinery Working Group Doc. 2000.21rev1, item 4	**X**	
8		Rope eyelets	Rope eyelets intended to be attached to prefabricated building elements for lifting them *		**X**	
9		Corner fittings	Corner fittings intended to be integrated in ISO containers by welding for lifting them *		**X**	
10		C-hook	Equipment in the form of a 'C' used for lifting hollow loads e.g. coils, pipes etc. * *	EN 13155	**X**	
11		Clamp	Equipment used to handle loads by clamping on a specific part of the load – also known as tongs * *	EN 13155	**X**	
12		Lifting beam	Equipment consisting of one or more members equipped with attachment points to facilitate the handling of loads which require support at several points * *	EN 13155	**X**	

N°	Picture / examples	Designation	Description	Standard / Reference	Lifting accessory covered by Directive 2006/42/EC	Work equipment not covered by Directive 2006/42/EC
13		Container spreader beams	Container spreader beams placed between lifting machinery and the load in order to attach it * *	98/37/EC Committee Doc. 2003.13rev.1	**X**	
15		Lifting forks	Equipment consisting of two or more arms fixed to an upright with an upper arm, essentially to lift palletised or similar loads* *	EN 13155	**X**	
15a		Forks attached to a lift truck	Forks attached to a masted or variable reach industrial truck for holding the load			Such forks are part of the machine subject to Directive 2006/42/EC
16		Plate clamps	Non powered equipment used to handle steel plates by clamping them between jaws * *	EN 13155	**X**	
17		Lifting magnet	Equipment with a magnetic field creating sufficient force for gripping, holding and handling loads with ferro-magnetic properties * *	EN 13155	**X**	
18		Vacuum lifter	Equipment which includes one or several suction pads operating by vacuum * *	EN 13155	**X**	
19		Cargo/liftnet				**X**
20		Reusable big bag	Big bag specifically intended for lifting bulk material or debris and not used for packaging, storage or transport			**X**

N°	Picture / examples	Designation	Description	Standard / Reference	Lifting accessory covered by Directive 2006/42/EC	Work equipment not covered by Directive 2006/42/EC
21		Single use big bag	Big bag used for packaging bulk material for transport and storage that can be lifted in order to unpack the material, for single use (one trip)			**X**
22		Foundry crane ladle	Tiltable vessel with a manual or motorised tilting mechanism intended for containing, transporting and discharging molten material with lifting machinery	EN 1247		Powered foundry crane ladles are subject to the Machinery Directive.
23		Concrete bucket	Bucket that is hung from a crane to transport and distribute concrete on a construction site			Powered concrete buckets are subject to the Machinery Directive.
24		Lifting wheel barrow	Wheel barrow with lifting eyelets intended for transport and application of concrete and mortar within a building site			**X**
25		Debris bucket	Bucket specifically intended for transporting debris on a construction site with a crane and to unload debris without detaching it from the crane			**X**
26		Container	Container provided with eyelets for lifting operation, used for transport and storage of goods	98/37/EC Committee Doc. WG 2005.41		**X**
27		Eyelet for container	The lifting eyelets for the above container *		**X**	

N°	Picture / examples	Designation	Description	Standard / Reference	Lifting accessory covered by Directive 2006/42/EC	Work equipment not covered by Directive 2006/42/EC
28		Bulk container	Container used for collecting e.g. waste products in one place and then lifted on to a vehicle and transported to another location where it is unloaded (The chain sling in the picture is not part of the container)			**X**
29		ISO-container				**X**
30		Load pallet for forklift trucks				**X**
31		Stacking system for wind turbine blades	Stacking system for the storage, transport and lifting of wind turbine blades (The chain sling in the picture is not part of the system)	Machinery Working Group 14/15 February 2012 item 14		**X**
32		Stillage	Frame used for the storage, transport and lifting of flat glass	Machinery Working Group 14/15 February 2012 item 14		**X**
33		Dynamometer for lifting (crane scale)	Dynamometer placed between lifting machinery and the load to indicate the weight of the load	Machinery Working Group 27 June 2011 item 3.30	**X**	

§413 Emergency stop devices

With reference to the third paragraph of section 1.2.4.3, which sets out requirements for the design of emergency stop devices, such device must have clearly identifiable, clearly visible and quickly accessible control devices. The requirement of the quick accessibility has consequences for both the choice of the type of control device and the number and location of control devices to be fitted. A typical such device is shown in Fig. 1.

Fig. 1: Emergency stop device

Harmonised standards, applicable to emergency stop devices

The following harmonised standards substantiate the design and functioning of the emergency stop device.

EN ISO 13850:2006 *Safety of machinery - Emergency stop - Principles for design* specifies functional requirements and design principles for the emergency stop function on machinery, independent of the type of energy used to control the function. It is applicable to all machinery except for machines, in which the provision of emergency stop would not lessen the risk, and hand-held portable machines and hand-guided machines. It does not deal with functions such as reversal or limitation of motion, deflection, shielding, braking or disconnecting, which can be part of the emergency stop function.

Concerning the colour scheme of the red push button against a yellow background standardized in EN ISO 13850:2006 section 4.4.5, also standard EN 60073 *Basic and safety principles for man-machine interface, marking and identification - Coding principles for indicators and actuators (IEC 60073:2002)* can be used. This standard establishes general rules for assigning particular meanings to certain visual, acoustic and tactile indications.

The standard EN 60947-5-5 1997 + A1:2005 *Low-voltage switchgear and control gear* - Part 5-5: *Control circuit devices and switching elements - Electrical emergency stop device with mechanical latching function* is applicable to electrical control circuit devices and switching elements which are used to provide an emergency stop signal. Where electrical switches are used, they should have direct opening action in accordance with EN 60947-5-1:2004+A1:2009, Annex K. Such devices may be either provided with their

own enclosure, or installed according to the manufacturer's instructions.

Emergency stop devices

An emergency stop device as shown in Figure 1 comprises a specific control device linked to the control system that gives a stop command and the components or systems necessary to stop the hazardous functions of machinery as quickly as possible, without creating any further risks.

Fig. 2: Emergency stop device with protection against unintended activation or damage

The device fulfils the design requirement of clearly identifiable regarding the colour scheme of the red push button against a yellow background, as well as the requirement of clearly visible and quickly accessible.

Emergency stop devices with protection measures to prevent unintended activation or damage

At a certain type of machinery, mainly mobile machinery or machinery in the construction sector, emergency stop devices are used with protective measures, such as collars or shrouding as sown in Fig. 2, in order to assure its proper function also under demanding conditions. Those measures are sometimes provided to prevent unintentional activation, debris or process materials accumulating on the device and preventing its operation.

A protective collar must not have any sharp corners or edges or rough surfaces which could lead to injury. Corners and edges should be rounded and surfaces smooth to the touch.

Fig. 3: Disconnecting device as emergency stop

The protection collar must not impair the accessibility of the emergency stop device. A full protection collar is in principle not acceptable with regard to Annex I section 1.2.4.3 of the Machinery Directive 2006/42/EC. However, its particular suitability could be demonstrated by testing. Requirements concerning the acceptable design of protective collars of emergency stop devices are not yet available in the relevant standards. However, it should be noted that the proposed amendment to EN ISO 13850 includes a test method to ensure that the collar does not impair accessibility.

Disconnecting device as emergency stop

According to market observations, also the disconnecting device as shown in Fig. 3 is

used as emergency stop device.

The supply disconnecting device is sometimes being locally operated to serve the function of emergency stop with regard to EN 60204-1 *Safety of machinery - Electrical equipment of machines* - Part 1: *General requirements* in which it is stated under section 10.7.4 “Local operation of the supply disconnecting device to effect emergency stop”:

The supply disconnecting device may be locally operated to serve the function of emergency stop when:

– it is readily accessible to the operator; and

– it is of the type:

a) switch-disconnector, with or without fuses, in accordance with IEC 60947-3, utilization category AC-23B or DC-23B;

b) disconnector, with or without fuses, in accordance with IEC 60947-3, that has an auxiliary contact that in all cases causes switching devices to break the load circuit before the opening of the main contacts of the disconnector;

c) a circuit-breaker suitable for isolation in accordance with IEC 60947-2;

d) any other switching device in accordance with an IEC product standard for that device and which meets the isolation requirements of IEC 60947-1 as well as a utilization category defined in the product standard as appropriate for on-load switching of motors or other inductive loads.

When also intended for such use, the supply disconnecting device shall be coloured red. If a background exists immediately around the actuator, then this background shall be coloured yellow. See also ISO 13850.

This allows supply disconnecting devices that meet these requirements to provide the emergency stop function. Nevertheless, it should be noted, that the supply disconnecting device is regarded as an exception and the normal emergency stop device should be used whenever possible.

Stop devices covering the start and the stop-contact

Stop devices covering the start and the stop-contact such as the flap stop (Fig. 4), is a special kind of ”stop device” produced normally outside the EU, and used as a normal emergency stop for different machinery, in particular for smaller machines, such as bench drilling machines.

Fig. 4: Flap stop device (taken from the original Danish document MD AdCo 2005-19)

The flap-stop is a start and stop contact, which is equipped with a yellow flap and a red mushroom-type push button (Fig. 4), covering both the start and the stop contacts. When the mushroom push button is activated, the flap will press the stop button into a stop command position. The flap can be kept in an open position which cannot assure the availability at all times. The flap stop can therefore not provide the emergency stop function as required in Annex I section 1.2.4.3 of the Machinery Directive 2006/427EC.

Other stop devices

Sometimes, Emergency stop device are designed as padlock able stop devices to make the isolation secure. More typically padlocks will be used with devices that can directly isolate equipment from the supply of electricity, such as disconnectors, switch disconnectors, circuit-breakers etc. Other devices to interrupt the machine movement, such as mats, light curtains, laser scanners etc.) cannot be considered to be an emergency stop device. Those devices are protective devices (as required by EHSR 1.3.7 with 1.4.3 specifying their characteristics). They are part of the safety system for the machine operation and are not an emergency stop device that should be provided in addition.

§414 Guards for drilling machines

As result of discussion on the conformity of bench drilling machines with the requirements of the Machinery Directive 2006/42/EC, it was agreed that only standard EN 12717:2001+A1:2009 can provide presumption of conformity for bench drilling machines. It was agreed as well that interlocking movable guards are not appropriate as a safety device for small bench drilling machines.

As a consequence of the agreement mentioned above, at least larger bench drill machines have to be fitted with interlocking movable guards as referred to in section 1.4.2.2 of Annex I of the MD in order to avoid hazards from the drill chuck.

Tests showed that it is possible to distinguish large and small bench drilling machines by the calculated torque at the drilling bit. As a result it was agreed that bench drilling machines can be regarded as small if with a torque value less than 6 Nm. Consequently, bench drilling machines with a torque at the drilling bit higher than 6 Nm can be regarded as large and would require an interlocking movable guard to fulfil the requirements of the Machinery Directive. For small bench drilling machines with a torque at the drilling bit less than 6 Nm, an adjustable guard as referred to in section 1.4.2.3 of Annex I of the Machinery Directive would be sufficient.

§415 Manually loaded trucks for the collection of household refuse incorporating a compression mechanism

Guidance is given on manually loaded trucks for the collection of household refuse incorporating a compression mechanism, as interpretation of the term "manually loaded" in relation to the scope of Annex IV 13, agreed by the Machinery Working Group and also accepted by the European coordination of Notified Bodies for machinery.

For refuse collection vehicles, the term “*manually loaded*” specifies the situation when an operator directly deposits the refuse into the machine without the use of

any intermediate lifting or loading device.

Annex IV 13 includes the following types of machinery:

a) Machinery only intended to be manually loaded;

b) Machinery with different ways of operating or operation modes of which at least one is intended for manual loading;

c) Machinery not intended for manual loading but with a design such that manual loading can reasonably be expected.

   Manual loading can reasonably be expected when:

   i. the vertical distance between the in-feed and any platform, ladder or similar standing areas on the vehicle within reach from the in-feed is less than 1.9 m

   or

   ii. the vertical distance between the in-feed and the driving level of the vehicle (ground level) is less than 2.1 m.

These values are derived from the assumption that manual loading cannot reasonably be expected if the in-feed is positioned above the operator's head. The relevant operator height is approximately 1.9 m according to EN 547-3 (Body height P95 = 1881 mm). The value of 2.1 m compensates for conventional kerb height (= 200 mm – see EN 1501-2, figure A.2).

Examples of machinery <u>within</u> the scope of Annex IV - 13[1]	
	Side loader. Machinery intended only for manual loading.
	Back loader. Machinery intended both for manual loading and loading with the help of a lifting device.
	Back loader. Machinery intended both for manual loading and loading with the help of a lifting device.
	Side loader. Machinery intended both for manual loading and loading with the help of a lifting device.
	Back loader. Machinery with two different modes of operation, one for manual loading and one for non-manual loading with the help of a lifting device.

Examples of machinery <u>outside</u> the scope of Annex IV – 13	
	Front loader. Machinery not intended for manual loading and with the in-feed more than 2.1 m above driving level.
	Side loader. Machinery not intended for manual loading and with the in-feed more than 2.1 m above driving level.
	Front-side loader. Machinery not intended for manual loading and with the in-feed more than 2.1 m above driving level.
	Back loader. Machinery not intended for manual loading and with the in-feed more than 2.1 m above driving level.
	Crane loader. Machinery not intended for manual loading and with the in-feed more than 2.1 m above driving level.

§416 Interchangeable equipment for lifting persons and equipment used with machinery designed for lifting goods for the purpose of lifting persons

This section distinguishes two categories of equipment:

1) interchangeable equipment assembled with lifting machinery for the purpose of lifting persons;
2) equipment used the purpose of lifting persons with machinery designed for lifting goods.

1) <u>Interchangeable equipment assembled with lifting machinery for the purpose of lifting persons</u>

Equipment assembled with lifting machinery in order to modify its function for the purpose of lifting persons is <u>interchangeable equipment</u> according to Article 2 (b) of the Machinery Directive:

> *'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, in so far as this equipment is not a tool.*

'*...is assembled with...*' means that the equipment is fitted to the lifting machinery by the user so that the assembly functions as an integral whole.

The resulting assembly of the interchangeable equipment and the lifting machinery must comply with all the relevant essential health and safety requirements of Annex I of the Machinery Directive, including those of part 6 of Annex I. The interchangeable equipment must bear the CE-marking and be accompanied by an EC Declaration of conformity according to Annex II 1 A to Directive 2006/42/EC, specifying the type or types of lifting machinery with which the equipment is intended to be assembled.

Such interchangeable equipment is subject to one of the conformity assessment procedures applicable to a device for the lifting of persons according to Annex IV, item 17. The conformity assessment must ensure, by means of the necessary examination, inspection and tests, that the assembly of the interchangeable equipment and the type or types of lifting machinery with which it is intended to be assembled complies with all the relevant essential health and safety requirements of Annex I.

The requisite information relating to the conformity assessment of the assembly of the interchangeable equipment and the lifting machinery shall be mentioned in the EC Declaration of conformity for the interchangeable equipment (where appropriate, the number of the EC type-examination certificate, the name and address of the Notified Body, where appropriate, the reference of the harmonised standard applied). The instructions for the interchangeable equipment must specify the type or types of lifting machinery with which the equipment is intended to be assembled and include the necessary assembly instructions.

The use of interchangeable equipment assembled with lifting machinery for the purpose of lifting persons is not concerned by the provisions of the second and third paragraphs

of section 3.1.2 of Annex II of Directive 2009/104/EC[241], since the assembly of the interchangeable equipment and the lifting machinery constitutes work equipment designed for the purpose of lifting persons.

Examples of interchangeable equipment assembled with lifting machinery

Work platforms assembled with loader cranes

Work platform assembled with a variable reach lift truck

2) <u>Equipment not assembled with the lifting machinery</u>

Equipment (such as platforms, cages, baskets etc.) used to lift persons with machinery designed for lifting goods that is not assembled with the lifting machinery but simply lifted by the machinery (e.g. suspended from the hook of a crane or placed on the forks

[241] Directive 2009/104/EC of the European Parliament and of the Council of 16 September 2009 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). OJ L 260, 3.10.2009, p. 5. Directive 2009/104/EC is a codified version of Directive 89/655/EEC and the amending Directives 95/63/EEC, 2001/45/EC and 2007/30/EC.

of a lift truck) is not interchangeable equipment. (Equipment placed on the forks of a lift truck or the hook of a crane is not considered interchangeable equipment even if it is provided with means to prevent it slipping or falling from the forks or the hook).

Such equipment is not used to attach the load to the machinery: therefore it is not a lifting accessory[242] (although such equipment may be attached to the machinery by means of a lifting accessory such as a sling). Such equipment is to be considered as a part of the load. It is thus not in the scope of the Machinery Directive and shall not bear the CE-marking in relation to that Directive[243].

The use of machinery for a function for which it was not designed is, as a general rule, forbidden by the legislation on the use of work equipment. However, lifting persons with machinery designed for lifting goods is permitted exceptionally by section 3.1.2 of Annex II of Directive 2009/104/EC, subject to national legislation and/or practice[244].

The national legislation and/or practice, referred to in the second paragraph of section 3.1.2, may set out the conditions under which such exceptional use is permitted, the measures that must be taken to ensure the safe use of the equipment and the necessary technical requirements for the equipment concerned.

Such obligations apply to the user, but they also have implications for persons placing the equipment used for this purpose on the market in the Member State concerned, since they must take account of the relevant national legislation.

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[242] Article 2 (d) of Directive 2006/42/EC defines 'lifting accessory' as: "*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*".

[243] See Recital 7 to Directive 2006/42/EC: *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)*. Directive 89/655/EEC has been replaced by Directive 2009/104/EC - see footnote 239.

[244] "*3.1.2. Persons may be lifted only by means of work equipment and accessories provided for this purpose. Without prejudice to Article 5 of Directive 89/391/EEC, exceptionally, work equipment which is not specifically designed for the purpose of lifting persons may be used to this effect, provided appropriate action has been taken to ensure safety in accordance with national legislation and/or practice laying down appropriate supervision. While workers are on work equipment designed for lifting loads the control position must be manned at all times. Persons being lifted must have reliable means of communication. In the event of danger, there must be reliable means of evacuating them*".

Examples of equipment not assembled with the lifting machinery

Work platform lifted by a crane using a sling (lifting accessory)

Work platform lifted on the forks of an industrial truck

ANNEX I (to the Guide)

§417 Status of machinery control units under the Machinery Directive

Machinery rely on their control units for their function, which often includes ensuring safety, where failure could result in serious injury or even death. Control units/circuit boards may be placed on the market in a number of ways which affect their status under the Machinery Directive, and the extent to which conformity assessment, the preparation of a technical file and supporting information is required. A number of compliance scenarios are presented here in this table covering the range of situations commonly found so that the legal status of machinery control units/boards when placed on the market either on their own or as part of another product is clear.

Compliance scenarios for machinery control units (circuit boards) under the Machinery Directive 2006/42/EC

Example	Control unit delivering safety functions within a complete machine when placed on market	Control unit delivering safety functions with actuator/motor placed on market as single product *(need not be in same enclosure, just marketed as a single product)*	Control unit delivering safety functions, independently placed on market so meet definition of 'Safety Component'	Control unit delivering safety functions that meet the definition of 'Safety Component' but supplied by OEM as a spare part	Control unit placed independently on the market but not delivering any safety functions
Definition	Component, part of a '**Machine**'	Component, part of a '**Partly Completed Machinery**' (PCM)	A '**Safety Component**' (SC) as defined	An OEM **spare part**	A **component** part
Applicable Directive (Note: EMC, LVD, &/or RED may also apply)	**MD: as machinery** **Art. 2a** see Guide §103/5	**MD: as PCM** see Art 13 NB: a Declaration of Conformity may be required for all other applicable Directives **Art. 2g** see Guide §46 & §131	**MD: Safety Component** **Art. 2c** see Guide §42	***NOT MD***: Exempted Safety Component (LVD & EMC may apply instead) **Art. 1(2)a** see Guide §48	***NOT MD*** "purely operational components are not considered as safety components" see 'Guide' *§ 42*
Which EHSRS must be	**All relevant to machinery** including EHSR 1.2	**No EHSRs are mandatory** (but the Declaration of	**Relevant parts of EHSR 1.2 CONTROL**	EHSR 1.2 has already been covered by the full conformity assessment	***NONE*** *MD not applicable*

met?	CONTROL SYSTEMS: through full conformity assessment of the whole machine, as shown by the technical file for the complete machine	Incorporation (DoI) must declare which EHSRs have been applied and fulfilled by the PCM, and the PCM technical file must show how any EHSRs declared on the DoI are met (Annex VII B)	**SYSTEMS:** through full conformity assessment of the 'Safety Component' as shown by the technical file (NB: may also be Annex IV device if a 'Logic Unit to Ensure Safety Functions')	of the original machine for which it is a spare part	
Declaration	of **Conformity** required	of **Incorporation** required	of **Conformity** required	*None required under MD*	*None required under MD*
Instructions to be provided? (and on what basis)	**Complete machine instructions** must meet EHSR 1.7.4 (and also the issues EHSR 1.2 covers, in so far as necessary for use, etc, such as: starting, stopping, mode selection, inspection, maintenance)	**Assembly instructions according to Annex VI** to permit safe incorporation, Guide §46 & §390 (for PCMs delivering safety these should include information on functional safety that the PCM can deliver when used as specified by the assembly instructions, eg category &/or safety level)	**Safety Component** (SC) **instructions** must meet relevant parts of EHSR 1.7.4, including relevant functional safety data, including category & safety performance level, the SC can deliver)	**None required by MD** as exempted SC, however **'assembly/connection' instructions are required** to ensure LVD and EMC obligations are met	**None required by MD** as out of scope component, ***but if LVD and/or EMC apply, instructions are required*** *to ensure their obligations are met*

ANNEX II (to the Guide)

§418 Table of safety components which are considered to be logic units

The following non-exhaustive list with accompanying explanatory notes indicate which safety components are considered to be logic units to ensure safety functions in the scope of Annex VI, Item 21, and which are NOT considered to be logic units to ensure safety functions (see also the comments at §388 item 21 on categories of machinery that may be subject to one of the conformity assessment procedures involving a Notified Body).

It must be remembered that Logic Units to Ensure Safety Functions must be a Safety Component as defined by Art 2 (c) (see §42), that is a component:

- which serves to fulfil a safety function,
- which is independently placed on the market,
- the failure and/or malfunction of which endangers the safety of persons, and
- which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.

	Type of safety component (Note: must meet the definition of Art 2 (c) when placed on market)	**Logic Unit to Ensure Safety Function (Item 21 Annex IV)** *(see also the notes at end of the table)*
1	**Proximity devices for safety functions** which include the control unit processing the signal (for example PDF-X according to EN 60947-5-3) which operate without mechanical contact with the moving part	**YES** (If an Annex IV item 19 'protective device to detect the presence of persons' then not a LUTESF).
2	**Position switches for safety related applications** with direct opening action according to EN 60947-5-1, Annex K (eg convert the position of a guard to an output signal)	**NO**
3	**Interlocking devices incorporating guard locking by means of Electromagnetic force alone where the device itself internal monitors the magnetic force maintaining the lock** for safety functions according to EN ISO 14119 (for protection of persons);	**YES**
4	**Interlocking devices with mechanical guard locking** (eg a bolt) according to EN 1088 (for the protection of persons)	**NO**

	Type of safety component (Note: must meet the definition of Art 2 (c) when placed on market)	**Logic Unit to Ensure Safety Function (Item 21 Annex IV)** *(see also the notes at end of the table)*
5	**Protective devices for indirect detection** of the presence of persons, eg by the use of radio frequency identification (RFID) technology	**YES** (not considered item 19 Annex IV device, as does not directly detect the presence of a person)
6	**Protective devices for the detection and deactivation of possible hazards** (not just a warning system), such as tower crane anti-interfernce/collision avoidance devices, or the detection and turning off laser radiation	**YES**
7	**Safety control units** for: • the monitoring of speed, vibration, torque, temperature, pressure, force, or other physical property • devices such as guards, and emergency stop, two-hand control, enabling and similar devices • the control of machinery which receive signals from external devices such as electro or pressure sensitive devices	**YES** (the associated sensing components and/or physical devices need not be LUTESF)
8	**Rotary encoders, length measuring devices, speed measuring devices and braking control units** with integrated logic intended to be used in safety functions	**YES**
9	**Safety PLCs** Programmable Logic Controllers for the implementation of safety related parts of control systems	**YES** (the associated physical and/or sensing devices need not be LUTESF)
10	**Wireless remote controls** providing at least one safety function, eg Emergency Stop	**YES**
11	**Power Drive Systems** (for example PDS(SR) according to EN 61800-5-2) with one or more integrated safety functions (e.g. STO, SS1, SS2, SLS, SBC), e.g. frequency inverters, servo converters	**YES**
12	**Components/devices for the logical processing of safety-related signals of safety bus systems**, excluding devices/components to be applied in "black channels" according to EN 61784-3 (black channel: communication channel without available evidence of design or validation according to IEC 61508);	**YES** (failures in so-called 'black channel' devices are detected by the devices for the logical processing of safety-related signals of safety bus systems, so the black channel devices are in themselves not considered as a LUTESF)

	Type of safety component (Note: must meet the definition of Art 2 (c) when placed on market)	**Logic Unit to Ensure Safety Function (Item 21 Annex IV)** *(see also the notes at end of the table)*
13	**Banks of valves with self-contained logic combination of safety relevant signals**, that have internal monitoring, for example a safety valve block for presses	**YES**
14	Manually activated **Emergency Stop** devices (simple mechanical switches)	**NO**
15	**Emergency stop systems** comprising a long sensing/actuating device the state of which is continuously monitored by an electronic sensing system	**YES**
16	**Emergency stop systems** comprising a simple long trip wire system with purely electromechanical switching on ‘pull-wire‘ or ‘broken-wire‘ states	**NO**
17	Manually operated **Enabling devices intended for delivering a safety function** (e.g. a three-position enabling switch) requiring continuous actuation for safety	**NO**
18	**Brake assemblies** used to stop hazardous movements	**NO** (unless the brake system itself incorporates internal monitoring of the braking function)
19	**Equipment for stopping movement** (e.g. resettable check valves);	**NO**
20	**Valves with additional means for failure detection** intended for the control of dangerous movements where fault detection and related functions are ensured by external means	**NO**
21	**Equipment for protection against overpressure**, e.g. pressure valves;	**NO**
22	**Safety clamps** for piston rods of hydraulic or pneumatic cylinders used to stop hazardous movements of piston rods	**NO**
23	**Time delay interlocking devices using a manually screwed bolt for the delay**	**NO**
24	**Time delay** interlocking devices employing a clock as the means for delaying operation, eg mechanical or microprocessor controlled clock	**YES**
25	**Trapped-key interlocking systems with integrated complex logic features** such as electromagnetic guard locking or internal time delay with internal monitoring of the lock or time delay	**YES**

	Type of safety component (Note: must meet the definition of Art 2 (c) when placed on market)	**Logic Unit to Ensure Safety Function (Item 21 Annex IV)** *(see also the notes at end of the table)*
26	**Purely mechanical trapped-key interlocking systems** for safety functions, which work together through the transfer of multiple keys, provided there are no additional integrated safety monitoring systems	**NO**, even if there is external monitoring of the device by additional switch contacts
27	**Mechanical single key operated interlock intended for safety applications** eg to lock a guard door (the key may be trapped within the device when the guard door is open)	**NO**, even if there is external monitoring of the device by additional switch contacts

Notes:

1. *The definition of a safety component covers both the intended function and manner in which the product is placed on the market.*
2. *Even if a device delivers a safety function, where it is part of a product –so not placed independently on the market, or only intended to be used as a spare part to replace identical components and supplied by the manufacturer of the original machinery (the limited exclusion of Art 1(2)a), it is not a safety component as defined, and cannot be a logic unit in the scope of Annex IV & V.*
3. *The control system as a whole, which must fulfil EHSR 1.2.1, is not to be considered as a logic unit.*
4. *A partly completed machine (PCM) is not a safety component by definition, and so not a logic unit (although a PCM may incorporate a safety component, which may be a logic unit).*
5. *Safety-related application software is in itself not considered to be a logic unit, as it is not a safety component, and in any case will always be dependent on a physical component to perform its function (see §42: safety components).*
6. *Simple devices like electromechanical sensors or switching devices which just transform an input signal into an output signal are not to be considered as logic units.*
7. *Certain devices such as contactors, contact expansion modules used to enhance safety switchgear, and devices for under-voltage release for supply disconnecting devices are not considered to be safety components (unless they meet the definition of a safety component as defined by Art 2c and are marketed as such), even though they are components specially constructed (eg with high reliability levels) specifically for use in safety related applications.*
8. *Protective devices designed to detect the presence of persons, including domestic animals (item 2, Annex V) are already covered by Annex IV (item 19), and so are not considered as logic units (item 21).*

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