CEN GUIDE 414

Safety of machinery – Rules for the drafting and presentation of safety standards

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European foreword

This document (CEN Guide 414:2017) has been prepared by Technical Committee CEN/TC 114 "Safety of machinery", the secretariat of which is held by DIN.

This document is intended for use by Technical Committees writing type B and type C standards in the field of Safety of Machinery (as defined in 3.2 and 3.3).

It gives the rules for the presentation of standards requested by CEN/BT in the programme mandated from the European Commission in support of the "Machinery Directive" (Directive 2006/42/EU).

This document supersedes CEN Guide 414:2014.

The revision of CEN Guide 414 takes into account ISO Guide 78:2012, relevant ISO/IEC Directives, CEN/CENELEC Internal Regulations, resolutions and guidance of CEN/BT, and the CEN Business Operations Support System. It is also the result of feedback from TCs and WGs using the first edition of CEN Guide 414:2014 when revising type B and type C standards.

The main changes with respect to the second edition (CEN Guide 414:2014) are as follows:

a) The introductory wording to Clause 2 and Clause 3 has been updated in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017.

b) 5.2, item b) has been deleted.

c) 6.10 has been updated and re-numbered.

d) Annex B has been updated by introducing the generic template for Annex Z… amended in accordance with decision CEN/BT 23/2016.

e) In Table D.1 the reference to EN ISO 12100 has been stated more precisely.

f) All cross references to the CEN/CENELEC Internal Regulations, Part 3 have been updated with regard to the edition of February 2017.

Introduction

As a response to the increased global trade in machinery, the relevant CEN/CENELEC Technical Committees have undertaken publication of a series of related machinery safety standards. It has thus been necessary to develop rules for the preparation, drafting and presentation of such safety standards, supplementing the CEN/CENELEC Internal Regulations, Part 3, which sets out general principles and requirements for all European Standards.

This document provides those rules. It is intended for use by Technical Committees writing type-B and type-C standards in the field of safety of machinery (as defined in 3.2 and 3.3). It both makes use of, and refers to, the principles and concepts established in EN ISO 12100, and also takes into account, as far as possible, ISO/IEC Guide 51.

European Standards prepared according to this Guide are intended as a means for supporting European regulations, in particular, the "Machinery Directive" (Directive 2006/42/EC).

1 Scope

This document presents rules for the drafting and presentation of European Standards dealing with machinery safety and their revisions, primarily to achieve consistency and acceptable quality of the various standards to be prepared.

It also gives requirements on the criteria for the selection of new work items and for procedures to prepare, produce or revise standards in an efficient and effective way.

This document gives requirements that are additional to the CEN/CENELEC Internal Regulations, Part 3, when this is necessary owing to the special requirements of machinery safety standards.

This document is primarily intended for the drafting of type-C standards. It is also applicable to the drafting of type-B standards; however, the foreseeable variation in the format of these standards prevents general application. When its requirements are specific to type-B standards, this is indicated.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction (ISO 12100:2010)*

CEN/CENELEC Internal Regulations, Part 3:2017*, Principles and rules for the structure and drafting of CEN and CENELEC documents (ISO/IEC Directives, Part 2:2016, modified)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in the CEN/CENELEC Internal Regulations, Part 3 and EN ISO 12100, and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
type-A standard
basic safety standard
standard giving basic concepts, principles for design and general aspects that can be applied to machinery

Note 1 to entry: See EN ISO 12100:2010, Introduction.

3.2
type-B standard
generic safety standard
standard dealing with one safety aspect or one type of safeguard that can be used across a wide range of machinery

Note 1 to entry: See EN ISO 12100:2010, Introduction.

3.2.1
type-B1 standard
type-B standard on particular safety aspects (for example, safety distances, surface temperature, noise)

Note 1 to entry: See EN ISO 12100:2010, Introduction.

3.2.2
type-B2 standard
type-B standard on safeguards (for example, two-hand control devices, interlocking devices, pressure-sensitive devices, guards)

Note 1 to entry: See EN ISO 12100:2010, Introduction.

3.3
type-C standard
machine safety standard
standard dealing with detailed safety requirements for a particular machine or group of machines

Note 1 to entry: See EN ISO 12100:2010, Introduction.

Note 2 to entry: The term "group of machines" means machines having a similar intended use and similar hazards, hazardous situations or hazardous events.

3.4
relevant hazard
hazard which is identified as being present at or associated with the machine

Note 1 to entry: A relevant hazard is identified as the result of one step of the process described in EN ISO 12100:2010, Clause 5.

Note 2 to entry: This term is included as basic terminology for type B- and type C-standards.

[SOURCE: EN ISO 12100:2010, 3.7]

3.5
significant hazard
hazard which has been identified as relevant and which requires specific action by the designer to eliminate or to reduce the risk according to the risk assessment

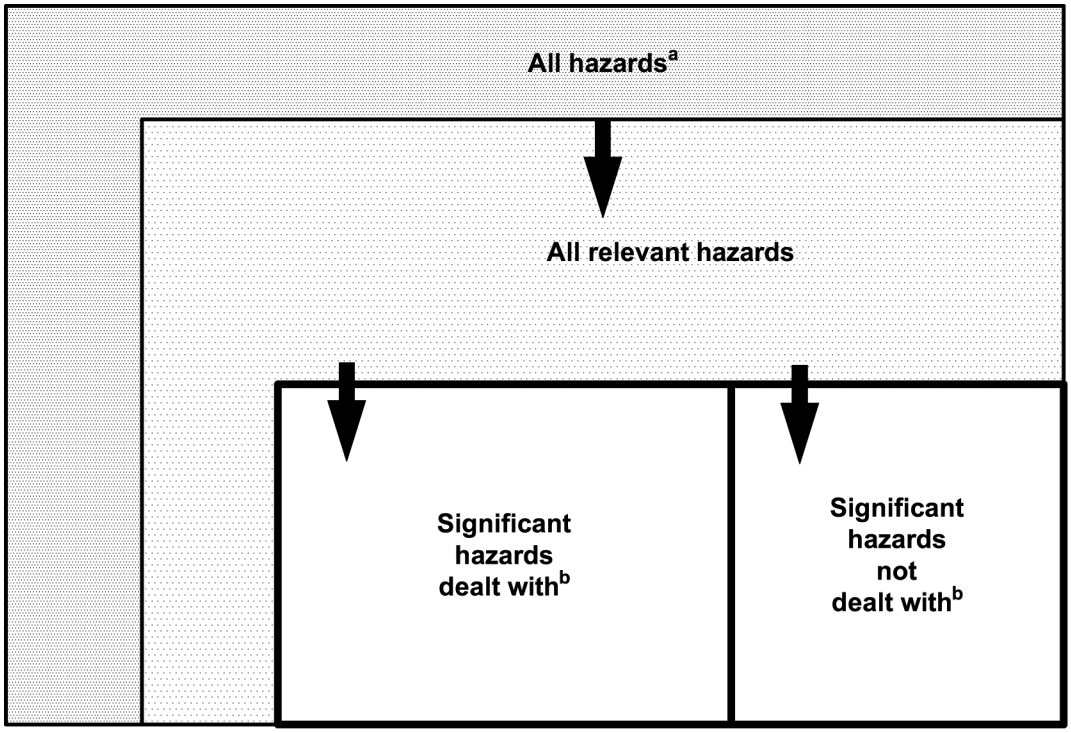
Note 1 to entry: This term is included as basic terminology for type B- and type C-standards.

[SOURCE: EN ISO 12100:2010, 3.8]

3.6
added value
more detailed description or specification of a requirement than in existing, less specific, documents, according to the structure prescribed in EN ISO 12100

Note 1 to entry: A type-B standard gives added value to the requirements of type-A standards, while a type-C standard gives added value to the requirements of type-A and type-B standards.

Note 2 to entry: The added value results from the design requirements applied to the product, by consensus of the interested parties, when the standard was prepared.



Key

[a] These hazards are listed in EN ISO 12100:2010, Annex B.

[b] See 6.10.3.1.

Figure 1 — Dealing with hazards of a particular machine or group of machines

4 General principles

4.1 All safety standards

The CEN/CENELEC Internal Regulations, Part 3 and EN ISO 12100 shall be used in conjunction with this document when preparing a new safety standard or revising an existing one.

A safety standard shall not contradict the basic concepts and general principles for design stated in a type-A standard, but can deviate from specific requirements. The overall purpose of the type-A standard is to provide manufacturers, designers, etc. with the strategy or framework necessary to achieve adequate risk reduction.[1)]

In general, the standards should not repeat or paraphrase the text of other reference standards; however, for better understanding of safety standards, it is acceptable to repeat a basic definition or concept, the scope of the standard, and/or a basic requirement given in EN ISO 12100.

NOTE For the purposes of this document, the terms "protective measure" (see EN ISO 12100:2010, 3.19) and "risk reduction measure" are synonymous and defined as any action or means used to eliminate hazards and/or reduce risks.

1) A definition of adequate risk reduction is given in EN ISO 12100:2010, 3.18.

4.2 Type-B standards

They shall

a) deal either with one safety aspect (type-B1 standard) or a safeguard (type-B2 standard),

b) for type-B1 standards, define the basic principles of the safety topic and define by data and/or methodology how these can be applied to type-C standards, including, where relevant, the means of verification,

c) for type-B2 standards, give the performance requirements for the design and construction of the safeguard together with the means of verification, and

d) establish, as necessary and practicable, performance requirements (for example, types or performance levels) based on the application.

NOTE Possible reasons for establishing different performance requirements are:

— the severity of the possible harm from the considered hazard,

— the frequency and duration of the hazardous situation,

— the probability of occurrence of a hazardous event, and

— the possibility to avoid or limit the harm.

4.3 Type-C standards

4.3.1 General

Type-C standards should deal with all the significant hazards concerning one type of machine or one group of machines in one standard, as follows.

a) By reference to relevant and applicable type-B standards (see 6.7.4).

   1) Any type-B standard available as a draft standard (stage 40.20) may be used as a reference standard on the condition that the reference is dated.

   2) When type-B standards offer a choice between various solutions (for example, EN ISO 13857:2008 offers the alternative of Table 1 for low risks and Table 2 for high risks, for reaching over protective structures), the type-C standard shall state which solution(s) shall be used.

b) By reference to other standards (such as another type-C standard) where such significant hazards are adequately dealt with (see 4.4).

c) By specifying safety requirements in the standard, when reference to other standards is not possible or not sufficient and where risk assessment and priorities show this is required (see 5.4 to 5.6).

d) By dealing as far as possible with objectives rather than design details to minimize restrictions on design.

4.3.2 Mandatory provisions

Type-C standards shall clearly establish the following:

— the scope (see 5.3 and 6.4);

— the significant hazard(s) (see 6.10.3.1);

— the requirements prescribing protective/risk reduction measures that add value to relevant subclauses of EN ISO 12100:2010, Clause 6, originating from the significant hazard(s) (see 4.3.3, 5.7 and 6.7);

— the means of verifying the protective/risk reduction measures (see 5.8 and 6.8);

— information for use (see 6.9).

This means that, wherever possible, a type-C standard should deal with all significant hazards, hazardous situations or hazardous events identified as arising from the use of the machine. The justifiable exception to this comprehensive treatment of significant hazards, hazardous situations or hazardous events is where a type-C standard deals with one or more hazard(s) that are sufficiently important to require special treatment. Where a type-C standard deals with specific hazard(s), this should be indicated clearly in the title and scope (for example, *Safety of textile machines — Measurement of noise*). These standards may be produced as a series of parts forming a complete standard or as several discrete standards that could be combined at a subsequent revision.

Where it is decided not to deal with all significant hazards, hazardous situations or hazardous events (for example, by lack of knowledge or because this will cause an unacceptable delay in the drafting of the standard) this shall be clearly indicated in the scope (see 6.4.2).

A special case requiring careful consideration are those type-C standards dealing with "common requirements". Common requirements are defined as those requirements adding value to existing type-A or type-B standards that can be used to minimize or eliminate a risk occurring across the range of defined machines and that can be applied to all or most of these machines. Any machines not covered by a particular aspect of a common requirement should be identified as an exclusion. Too many exclusions from any common requirement would indicate that it is not common. The standard dealing with "common requirements" should not contain unspecific general principles.

4.3.3 Provisions with added value

It is a basic principle that type-C standards shall contain sufficient added value to the requirements of existing type-A and type-B standards. Added value will normally consist of a description of specific protective/risk reduction measure(s) dealing with the significant hazard, hazardous situation or hazardous event. However, this may also include reference to type-B standards or to other reference standards (see 6.7).

In the absence of a published type-B standard, common requirement standard or other reference standard, the following options are available:

— repeat in full the relevant sections of the draft type-B standard, draft common requirement standard, or any other suitable technical document;

— refer to the relevant section of a draft standard identified by number and date of issue;

— refer to a technical specification produced by a professional organization - this can be done following the specific policy on normative references;

— seek help from the TC/WG (technical committee/working group) preparing the relevant type-B standard;

— provide self-drafted data/specification.

Dealing with a significant hazard by direct reference to the relevant subclauses of EN ISO 12100:2010, Clause 6 is only acceptable

a) where this reference gives sufficient requirements (particularly the *Information for use* clause, see 6.9), and

b) if the drafting of requirements would cause an unacceptable delay in the preparation of the standard.

However, in the case of b):

— it shall be stated in the scope that the hazard concerned is not dealt with in the current version of the standard;

— the TC shall make every effort to complete as soon as possible the drafting of the needed requirements.

4.4 Need for a type-B standard

The creation of a type-B standard (see 6.10.2) shall be considered when requirements appropriate to more than one type of machine or one group of machines have been identified.

4.5 Deviations in a type-C standard

When a type-C standard deviates from one of several aspects or requirements dealt with by a type-A or type-B standard, then the existing type-C standard shall take precedence over the type-A or type-B standard (see 6.3.2).

The reason for any deviation shall be carefully justified and kept by the responsible body in the standardization file or, in case of comments at draft stage (40.20), in the CRM (comments resolution meeting) file.

5 Principles to be considered before and during drafting process

5.1 General

Whereas the Machinery Directive 2006/42/EC states in its Annex I Essential Requirements, the general methodology for safety of machinery specified in EN ISO 12100 is based on the consideration of significant hazards basically without any specific reference to the Essential Requirements of Directive 2006/42/EC. Annex D gives as far as possible examples of significant hazards, hazardous situations, hazardous events and their relation to this Essential Requirements.

Before a standard is drafted, the need for it shall have been established, using the criteria given in 5.2.

NOTE The result of the procedure can provide information which can be used in the scope (see 5.3).

During the drafting process and the revision of a standard, the procedure given in 5.3 to 5.8 shall be carried out in the order indicated, in order to provide information that will allow an appropriate standard to be drafted.

5.2 Determination of necessity for standardization and/or revision

The need for standardization and/or for the revision of an existing standard and the respective priorities shall be determined from the answers to the questions posed in 5.2 a) to 5.2 k), as applicable.

a) Is there a demand for European Standards arising from interested bodies (relevant market players such as regulatory bodies, manufacturers' associations, employees' or employers' associations, trade unions, accident prevention organizations or consumer organizations)?

b) Is there a need for a standard (for example, terminology) to support other safety standards?

c) Are there significant hazards, hazardous situations or hazardous events generating risk to the safety or health of persons? See EN ISO 12100:2010, 5.4.

d) If a new technology is to be standardized, is it sufficiently stable and established in the market and can it be therefore considered as state-of-the-art?

e) Is there, or will there be in the foreseeable future, a sufficient number of related machines or safeguards to justify the production of a standard?

f) Are there national standards/specifications giving specific requirements, either directly or by reference to another document, which can be barriers to international trade?

g) Are there proven professional, national or international documents or other documents available to give a reasonable expectation of positive and rapid results?

h) Is there sufficient expertise, collective knowledge and experience for standardization?

i) Is there sufficient availability of experts (in principle from at least five members), project leader and support (secretariat, financial resources)?

j) Is there sufficient feedback on the use of the existing safety standard?

k) Has the state of the art changed such that the existing safety standard has become at least partly obsolete?

5.3 Definition of scope

The precise limits of the machine or group of machines to be standardized shall be established and shall include the following (see EN ISO 12100:2010, 5.3):

a) definition of the machine or group of similar machines;

b) determination of the intended use of the machine (see EN ISO 12100:2010, 3.23);

c) determination of the space limits (see EN ISO 12100:2010, 5.3.3);

d) determination of the foreseeable "life limit", when applicable;

e) definition of the field of application.

Any machines and/or hazards not covered by the standard shall be clearly stated in the scope.

The various phases in the life of the machine to be dealt with in the standard shall be established. See EN ISO 12100:2010, 5.4.

5.4 Identification of hazards, hazardous situations or hazardous events

Considering EN ISO 12100:2010, especially its Annex B, as guidance:

a) identify the hazards that the machine is likely to generate;

b) identify the various hazardous situations for each hazard, taking into account the different operating modes of the machine and the different intervention procedures for the operators as well as the reasonably foreseeable misuse;

c) identify the hazardous events which can lead to harm.

Particular attention should be paid to the fact that the list given in EN ISO 12100:2010, Annex B, is not exhaustive, especially in as far as it concerns the hazardous situations.

5.5 Estimation and evaluation of risk(s) generated by hazard(s)

5.5.1 Risk estimation

The risk shall be estimated by combining the following steps.

a) Estimate the severity of the possible harm for the hazard under consideration.

b) Estimate the probability of occurrence of that harm which is a function of

   1) the exposure of persons to the hazard (for example, frequency, duration),

   2) the probability of occurrence of a hazardous event,

   3) the technical and human possibilities to avoid or limit the harm.

5.5.2 Risk evaluation

After the risk estimation, a risk evaluation shall be carried out to determine:

— if risk reduction is required;

— whether the risk reduction objectives have been achieved.

5.6 Identification of risk reduction objectives

The following steps shall be carried out using the result of the procedures according to 5.4 and 5.5:

a) define risk reduction objectives in terms of reduction of the severity of the harm and/or the probability of that harm;

b) identify the relevant clauses of EN ISO 12100 applicable for each significant hazard, hazardous situation or hazardous event;

c) determine for each significant hazard whether it is sufficient to refer to other standards for safety requirements and/or protective/risk reduction measures, or whether there is a need for specific safety requirements and/or protective/risk reduction measures.

The entire above process should preferably be recorded and kept by the responsible body in the standardization file, for example, in a table.

5.7 Determination of safety requirements and/or protective/risk reduction measures for eliminating hazards and/or limiting risks

The risk reduction process according to 5.6 shall be carried out in the following order (three-step method as described in EN ISO 12100:2010, Figure 1):

a) by inherently safe design (see EN ISO 12100:2010, 6.2);

b) by safeguarding (see EN ISO 12100:2010, 6.3);

c) by information for use (see EN ISO 12100:2010, 6.4).

The principle — for the various phases of the "life" of the machine — is to eliminate the hazard or reduce the risk as much as possible by inherently safe design without relying on guards or other methods of safeguarding. If this is not practicable, other means should be defined to ensure safety.

NOTE For the drafting of safety requirements and for protective/risk reduction measures for eliminating hazards and/or limiting risks, see 6.7.3.

5.8 Verification of compliance with safety requirements and/or protective/risk reduction measures

For each safety requirement and/or protective/risk reduction measure identified and determined in accordance with 5.6 and 5.7 (except if it is self-evident), a method of verification shall be established

a) by testing (for example, functional test of a two-hand control, strength test of a guard, stability test),

b) by measurement (for example, measurement of noise emission),

c) by calculation (for example, position of the centre of gravity), or

d) by any other method of verification, if testing and calculation are not adequate (for example, by visual inspection).

It shall be determined

— whether adequate testing/calculating methods (or other methods of verification) are available in another standard, or

— whether it is necessary to draft such methods.

NOTE For the drafting of requirements for verification, see 6.8.

6 Format of a safety standard

6.1 General

The format of a safety standard shall comply with the CEN/CENELEC Internal Regulations, Part 3 (see model format given in Annex B of this document) and the specific requirements for safety standards on machinery given in 6.2 to 6.10.

The model format given in Annex B is intended to help standards developers and to provide for a consistent presentation for all type-C standards according to Clause 6.

6.2 Foreword

The Foreword is an unnumbered mandatory element. It shall be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 12.

If relevant, the significant technical changes in relation to the previous edition shall be stated.

As a minimum requirement, the following statement[2)] shall be inserted in each mandated standard:

"This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex Z [appropriate letter(s)], which is (are) an integral part of this document".

In case of revision or amendment of a standard, the standard makers shall consider the transition period of application of the previous and the revised standard or amendment. The transition period shall be defined in the enquiry document (prEN – stage 40.20). See Annex C for additional guidance on consideration of the transition period.

6.3 Introduction

6.3.1 Although the Introduction is an optional element according to the CEN/CENELEC Internal Regulations, Part 3, it is an unnumbered mandatory element in machinery safety standards. It shall be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 13.

When a subject of a type-B standard is covered by EN ISO 12100, reference shall be made to the relevant clause of EN ISO 12100.

6.3.2 At least the following statement shall be inserted in each type-C standard:

"This document is a type-C standard as stated in EN ISO 12100.

This document is of relevance, in particular, for the following stakeholder groups representing the market players with regard to machinery safety:

— *machine manufacturers (small, medium and large enterprises);*

— *health and safety bodies (regulators, accident prevention organizations, market surveillance etc.).*

Others can be affected by the level of machinery safety achieved with the means of the document by the above-mentioned stakeholder groups:

— *machine users/employers (small, medium and large enterprises);*

— *machine users/employees (e.g. trade unions, organizations for people with special needs);*

— *service providers, e.g. for maintenance (small, medium and large enterprises);*

— *consumers (in case of machinery intended for use by consumers).*

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2) These sentences are taken from CEN BOSS. In case of modification of the guidance given by CEN BOSS, the current version of that guidance should take precedence over this document.

The above-mentioned stakeholder groups have been given the possibility to participate at the drafting process of this document.

The machinery concerned and the extent to which hazards, hazardous situations or hazardous events are covered are indicated in the Scope of this document.

When requirements of this type-C standard are different from those which are stated in type-A or type-B standards, the requirements of this type-C standard take precedence over the requirements of the other standards for machines that have been designed and built according to the requirements of this type-C standard."

6.3.3 At least the following statement shall be inserted in each type-B standard:

"This document is a type-B standard as stated in EN ISO 12100.

This document is of relevance, in particular, for the following stakeholder groups representing the market players with regard to machinery safety:

— *machine manufacturers (small, medium and large enterprises);*

— *health and safety bodies (regulators, accident prevention organizations, market surveillance etc.);*

Others can be affected by the level of machinery safety achieved with the means of the document by the above-mentioned stakeholder groups:

— *machine users/employers (small, medium and large enterprises);*

— *machine users/employees (e.g. trade unions, organizations for people with special needs);*

— *service providers, e.g. for maintenance (small, medium and large enterprises);*

— *consumers (in case of machinery intended for use by consumers).*

The above-mentioned stakeholder groups have been given the possibility to participate at the drafting process of this document.

In addition, this document is intended for standardization bodies elaborating type-C standards.

The requirements of this document can be supplemented or modified by a type-C standard.

For machines that are covered by the scope of a type-C standard and have been designed and built according to the requirements of that standard, the requirements of that type-C standard take precedence."

6.4 Scope

6.4.1 The Scope is a mandatory element. It shall be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 14, and shall be drafted using the result of the procedure according to 5.3 of this document. It shall be numbered as Clause 1.

6.4.2 The Scope shall indicate, when applicable, the following:

a) the limits of the machine, preferably by physical characteristics and taking into account aspects such as intended use as well as reasonably foreseeable misuse (see EN ISO 12100:2010, 3.23, 3.24 and 5.3);

b) whether protective/risk reduction measures dealt with in the standard account for all or only some of the significant hazards.

   This applies to hazards arising during the various phases of the "life" of the machine as described in EN ISO 12100:2010, 5.4. The significant hazards dealt with in the standard (see 3.5 and Figure 1) shall be mentioned, as appropriate,

   1) by listing them in the Scope, when they are few, or

   2) by a statement in the Scope that they are dealt with in the standard (see 6.10.3.1).

   In the case of 2), above, those significant hazards not dealt with shall also be mentioned in the Scope.

c) whether additional designed-in protective/risk reduction measures are taken into consideration for certain types of machines (e.g. hygiene requirements for food-processing machinery).

The scope shall indicate that the standard is not applicable to machinery or machinery components which are manufactured before the date of publication of the standard. As a minimum requirement, the following statement shall be inserted in Scope:

"This document is not applicable to [<precisely state the machinery or machinery components here>] manufactured before the date of its publication."

6.5 Normative references

This clause is a mandatory element. It shall be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 15, and shall be numbered as Clause 2.

a) Only documents (standards) to which normative reference is made in the text of the safety standard shall be listed in this clause. Therefore, at least the following shall always be referenced:

   EN ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

   Normative references in the text of a standard need to be made using the verbal form "shall", signifying a requirement.

   EXAMPLE "This shall be in accordance with EN 12345-201x, Clause 6."

   When a reference is made only for information, it shall be introduced by the phrase "see EN ..." and the standard referenced shall be listed, not in this clause, but in a bibliography (see 6.10.4).

   This document, even though applicable to the drafting and presentation of the safety standard, shall not be given as a normative reference.

b) References to standardization documents shall be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 10, and should be dated in accordance with 10.5 of those Internal Regulations.

When a normative reference, e.g. to an ISO/IEC International Standard, is required, the safety standard shall

— either reproduce the text of the normatively referenced document, in the main body of the safety standard or in a normative annex, clearly indicating its origin by "(extract from ISO/IEC ...)", or

— make dated reference to a specific clause(s) or subclause(s) of the referenced document (without reproducing it), or

— make dated (preferably) or undated reference to the whole of the normatively referenced document, if applicable — for example, in cases where the subject of the normatively referenced document is an applicable test method.

In principle, the referenced documents shall be documents published either by CEN, CENELEC, ISO or IEC. Documents published by other bodies may be referred to in a normative manner provided that the criteria listed in the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 15, are met (see 4.3.3).

6.6 Terms and definitions [symbols and abbreviated terms]

6.6.1 This clause is a mandatory element. It shall be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clauses 16 and 17, and shall be numbered as Clause 3.

6.6.2 The terms and definitions given in EN ISO 12100 shall be used. Therefore, at least the following statement shall be given as the first, introductory, paragraph to the terms and definitions clause in each type-B and type-C standard:

"For the purposes of this document, the terms and definitions given in EN ISO 12100 apply."

6.6.3 The terms and definitions given in relevant type-B and type-C standards should be used as far as applicable. For new terms and definitions, the association of the word "safety" with the name of a component or a device should be avoided. A recommended approach is to replace, where possible, the word "safety" by an indication of the objective or characteristic.

EXAMPLE "Active optoelectronic protective device" instead of "safety light curtain".

6.6.4 When there is need to define symbols or abbreviations (especially for test methods), this conditional element shall be included in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 17.

6.7 Safety requirements and/or protective/risk reduction measures

6.7.1 This clause is a mandatory element. It shall be in accordance with CEN/CENELEC Internal Regulations, Part 3:2017, Clause 4 and 5.4 to 5.8.

As a minimum requirement, the following statement shall appear in this clause in each type-C standard:

"Machinery shall comply with the safety requirements and/or protective/risk reduction measures of this clause. In addition, the machine shall be designed according to the principles of EN ISO 12100:2010 for relevant but not significant hazards which are not dealt with by this document."

This clause should be structured based on the result from 5.6, except for *Information for use*-related issues, which shall be dealt with in a specific clause (see 6.9).

6.7.2 All safety standards shall contain such a clause, stating the safety requirements and/or protective/risk reduction measures to be met to reduce the effect of all hazards determined in accordance with 5.6 b) and c), and which are to be mentioned in the standard. The safety requirements and protective/risk reduction measures shall be defined in accordance with 5.7.

Protective/risk reduction measures to avoid or minimize harm shall be defined, directly or by reference to another standard and/or to the *Information for use* clause, for all the significant hazards dealt with.

6.7.3 The safety requirements and/or protective/risk reduction measures specified shall be expressed in terms of verifiable performance with regard to safety, using performance characteristics (parameters), together with their values, rather than merely descriptive characteristics.

To minimize restraint on design, safety standards should specify requirements in terms of the objective to be met and then define the means for achieving it, such as by giving examples or defining test specifications. The safety requirements and/or protective/risk reduction measures shall be sufficiently precise to allow verifications.

NOTE In many type-C standards, it can be necessary to define acceptable means of achieving the objective, such as particular types of protective/risk reduction measures, in order to ensure that the safety requirements and/or protective/risk reduction measures will be adequate, or to give examples of well-known and proven solutions for reaching and maintaining the level of safety.

More than one solution for reducing the risk may be given if allowing the same objective of risk reduction to be reached.

Measures in terms of objectives, and measures defined by data, limits, results and requirements giving the practical means for achieving the objectives, may be given together or in separate subclauses.

6.7.4 Where requirements contained in relevant type-A or type-B standards are used, reference shall be made to them in accordance with 4.3.

Where type-B standards are not yet available and general requirements (valid for several types of machines) are included in the type-C standard, these requirements shall preferably be included in normative annexes of the type-C standard (see Annex A).

When measures given in another standard are used, specific reference shall be made to that standard.

6.7.5 Type-B standards shall give added value (more specific and/or more detailed requirements) to the requirements of type-A standards and type-C standards shall give added value to the requirements of type-A and type-B standards. See 4.3.3 for more details on *added value*.

6.7.6 Protective/risk reduction measures shall be laid down in precise and clearly understandable terms such that they

a) ensure that the objective is met,

b) are technically correct and precise,

c) are unequivocal as to whether a measure is optional or mandatory, using verbal forms in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 7, and

d) can be verified in accordance with 5.8 and 6.8.

Subjective terms or words should not be used unless they are defined in the standard or are consistent with the method of verification.

6.8 Verification of the safety requirements and/or protective/risk reduction measures

6.8.1 Each safety standard shall contain, either in a separate clause or together with the relevant measures, the method to be used to verify conformity with the measures given in accordance with 6.7, unless the methods for verification are self-evident.

The standard shall not contain any instruction on *who* shall carry out the verification (see CEN/CENELEC Internal Regulations, Part 3: 2017, Clause 33).

The method of verification shall be related to the nature of the safety requirements and/or protective/risk reduction measures, and shall follow the procedure according to 5.8.

If the methods of verification are to be put in a separate clause, the order of presentation should be the same as that of the safety requirements and/or protective/risk reduction measures and there shall be a link between the two.

Priority should be given to the use of existing and standardized methods of verification (as defined in standardization documents) by reference.

When drafting a new method of verification which is not specific to the machine itself (e.g. measurement of dust suction efficiency in a standard on belt sanding machines), this method shall appear either in a normative annex (see 6.10.2), or in a separate part of the standard, or even in a separate standard, so that reference can be made to it in another safety standard.

6.8.2 The wording of methods of verification shall be sufficiently precise to ensure reproducible results. The structure relating to measurement and test methods given in the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 18 shall be followed. If there are several test methods for one safety requirement and/or protective/risk reduction measure, the test method(s) to be used shall be indicated.

Calculation methods, for example, could be appropriate when only destructive testing is possible and for special types of safety requirements and/or protective/risk reduction measures, such as those concerning stability.

Where testing and calculation methods are not practicable for technical reasons or would cause excessive costs compared to the risk reduction that would be achieved, other methods can be more appropriate. Verification may be by inspection, or by examination when sufficiently precise (e.g. inspection to check the colour of warning signs and marking).

6.9 Information for use

6.9.1 General

This clause is a mandatory element and shall be numbered. The safety standard shall make reference to EN ISO 12100:2010, 6.4, and shall contain additional requirements about the information for use for machines within the scope of the standard.

NOTE As these safety standards deal with machinery design, the *Information for use* clause is the only one in which the standards developer can provide instructions on installation and use of the machinery in relation to residual risks.

6.9.2 Signals and warning devices

Where safety signals or pictograms are fitted to the machine, they shall be described in this clause. The safety signals or pictograms already defined in relevant standardization documents should be used (e.g. EN 61310).

6.9.3 Accompanying documents (in particular: instruction handbook)

6.9.3.1 General

As the instructions are a mandatory part of the machine, each type-C standard shall contain the requirement that the manufacturer provide an instruction handbook. The type-C standard shall make reference to EN ISO 12100:2010, 6.4.5, and shall give specific information (e.g. intended use, reasonably foreseeable misuse, training, systems of work and personal protective equipment) to be included in the handbook, compiled from the results of the procedures according to 5.2 to 5.7 of this document.

NOTE The instructions are normally the only means available to the user providing information on the use of the machine including maintenance interventions.

6.9.3.2 Noise

If noise is applicable, the requirements concerning both noise emission measurement and declaration shall be specified in a normative annex or by reference to a specific standard (Noise Test Code) or at least by reproducing the corresponding requirements of 1.7.4.2 u) in Annex I of the Machinery Directive 2006/42/EC.

Further guidance on the drafting of noise clauses is given in EN 1746.

6.9.3.3 Vibration

If vibration is applicable, the requirements concerning both vibration emission measurement and declaration shall be specified in a normative annex or by reference to a specific standard (Vibration Test Code) or at least by reproducing the corresponding requirements of 2.2.1.1 and 3.6.3.1 in Annex I of the Machinery Directive 2006/42/EC.

Further guidance on the drafting of vibration clauses is given in EN 12786.

6.9.4 Marking

All safety standards shall require at least the marking as specified in EN ISO 12100:2010, 6.4.4.

6.10 Annexes

6.10.1 General

Annexes shall be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 20.

6.10.2 Normative annexes

When it is foreseeable that certain parts of the safety standard could be applicable to other documents (e.g. test methods), these parts shall be included as normative annexes.

NOTE This form of presentation can assist referencing by other documents and allows easier conversion of those parts into a type-B standard at a later date (see 4.4).

6.10.3 Informative annexes

6.10.3.1 List of significant hazards

When 6.4.2 b) 2) applies, the list of significant hazards shall be given in an informative annex, titled *List of significant hazards*.

This annex shall present, for defined danger zones, all the significant hazards, significant hazardous situations (circumstances that lead to exposure of a person to these hazards) and significant hazardous events identified during the risk assessment and covered by this standard. It should also refer to the particular subclause of the *Safety requirements and/or protective/risk reduction measures* clause (see 6.7) and, if appropriate, that of the *Information for use* clause (see 6.9) in which the hazard, hazardous situation or hazardous event is dealt with.

The list of significant hazards, hazardous situations or hazardous events should preferably follow the order given in EN ISO 12100:2010, Annex B, but not reproduce it. It is not appropriate to list all possible hazards, hazardous situations or hazardous events as described in EN ISO 12100, indicating those dealt with and those not dealt with.

6.10.3.2 Significant technical changes between this standard and the previous edition

This annex shall be drafted only in cases where the significant technical changes from one edition to the next are not stated in the Foreword of the revised standard. See 6.2.

6.10.3.3 Annex Z [appropriate letter]

6.10.3.3.1 General

Each mandated standard shall contain for each EU New Approach Directive dealt with an Annex Z **[**followed by a letter to be precised**]** (informative) about the relationship between the standard and the essential requirements of the relevant EU Directive (see 6.2).

NOTE This annex being always located as last annex of the standard, it will normally be called "ZA". However, if one or more European annexes exist after an adopted International standard, the letter A will be replaced by the letter following the previous European annexes (e.g. if there is an Annex ZD, the annex about the relationship to an EU Directive becomes Annex ZE).

Annex Z shall be drafted in accordance with the format given in 6.10.3.3.2.

The table format shown in Table Z...1 should be used and its content can be accommodated to one of the possible cases as prescribed in the following options.

Option A.1 = standard covering all relevant ERs (significant hazards) by applying all clauses of the standard;

Option A.2 = standard covering all relevant ERs (significant hazards) by applying all clauses of the standard except some clauses;

Option B.1 = standard covering all relevant ERs (significant hazards) except one/or a few by applying all clauses of the standard;

Option B.2 = standard covering all relevant ERs (significant hazards) except one/or a few by applying all clauses of the standard except some clauses;

Option C = to declare a more detailed correspondence between the ERs covered and the relevant clauses in the standard; in this case, the table would contain as many rows as needed. Where it is possible that in certain cases, only a limited set of ERs is covered by the standard, this option can then be used to identify this limited set of ERs is covered.

6.10.3.3.2 Format

Annex Z...
(informative)

Relationship between this European Standard and the essential requirements of Directive 2006/42/EC aimed to be covered

This European Standard has been prepared under a Commission's standardization request "M/396 Mandate to CEN and CENELEC for Standardisation in the field of machinery" to provide one voluntary means of conforming to essential requirements of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast).

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table Z....1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

Table Z....1 – Correspondence between this European Standard and Annex I of Directive 2006/42/EC

Essential Requirements of Directive	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
Option A.1: *Within the limits of the scope <u>all relevant</u> essential requirements are covered*	*All normative clauses*	*For relation of normative clauses of this standard to significant hazards/relevant essential requirements of 2006/42/EC see informative annex XX „List of significant hazards" of this standard in combination with annex D "Examples of significant hazards, hazardous situations, hazardous events and their relation to the Essential Requirements of the Machinery Directive 2006/42/EC" of CEN Guide 414 (https://boss.cen.eu/ref/CEN_414.pdf).*

Option A.2: *Within the limits of the scope <u>all relevant</u> essential requirements are covered*	*All normative clauses except clause(s) yyy*[3)]	*For relation of normative clauses (except clause(s) yyy*[3)]*) of this standard to significant hazards/relevant essential requirements of 2006/42/EC see informative annex XX „List of significant hazards" of this standard in combination with annex D "Examples of significant hazards, hazardous situations, hazardous events and their relation to the Essential Requirements of the Machinery Directive 2006/42/EC" of CEN Guide 414 (https://boss.cen.eu/ref/CEN_414.pdf).*
Option B.1: *Within the limits of the scope <u>all relevant</u> essential requirements <u>with the exception of essential requirement(s) xxx</u> are covered*	*All normative clauses*	*For relation of normative clauses of this standard to significant hazards/relevant essential requirements of 2006/42/EC see informative annex XX „List of significant hazards" of this standard in combination with annex D "Examples of significant hazards, hazardous situations, hazardous events and their relation to the Essential Requirements of the Machinery Directive 2006/42/EC" of CEN Guide 414 (https://boss.cen.eu/ref/CEN_414.pdf).*
Option B.2: *Within the limits of the scope <u>all relevant</u> essential requirements <u>with the exception of essential requirement(s) xxx</u> are covered*	*All normative clauses except clause(s) yyy*[3)]	*For relation of normative clauses (except clause(s) yyy1)) of this standard to significant hazards/relevant essential requirements of 2006/42/EC see informative annex XX „List of significant hazards" of this standard in combination with annex D "Examples of significant hazards, hazardous situations, hazardous events and their relation to the Essential Requirements of the Machinery Directive 2006/42/EC" of CEN Guide 414 (https://boss.cen.eu/ref/CEN_414.pdf).*
Option C *[Per row: an essential requirement]*	*[The relevant normative clauses linked to the individual essential requirement]*	

3) In cases where certain normative clauses of the standard do cover other aspects than those providing presumption of conformity

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) */ [service(s)] / [...]* falling within the scope of this standard.

6.10.4 Bibliography

Standards or documents that give only information, or which have served as references in the preparation of the standard, shall appear in a Bibliography in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 21, and not in the Normative references clause.

Documents that are not publicly available shall not be referenced.

Annex A
(normative)

Procedure to be followed if type-B standards do not exist

Where possible, type-B standards should be prepared first, so that reference can be made to them when preparing type-C standards for specific machines. When a type-C standard needs to use type-B requirements and such standards do not exist, the type-C standard shall give those requirements in annexes. Where this method is adopted, the annexes can be withdrawn when revising the standard and the references in the standard changed to the relevant type-B standard.

In order to facilitate this approach, the following procedure shall be used.

a) All type-C working groups shall be able to obtain information about the on-going work in type-A and type-B working groups and of all existing type-A and type-B standards including drafts.

b) If type-C working groups need to formulate type-B requirements, due to a lack of existing type-B standards, the relevant type-B working groups and/or relevant technical committees on safety of machinery shall be involved.

c) Where applicable, type-C working-group experts should participate in relevant type-B working groups and should influence the creation and content of type-B standards.

d) Type-B requirements in type-C standards shall be placed in annexes.

Annex B
(informative)

Model format of a type-C European draft standard

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Foreword

[See CEN/CENELEC Internal Regulations, Part 3:2017, Clause 12]

This document (EN ...: < *year* >) has been prepared by CEN/TC.../WG..

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by [*date of availability*] and conflicting national standards shall be withdrawn at the latest by [*date of withdrawal*[4)] .

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex Z [*appropriate letter(s)*], which is (are) an integral part of this document.

Introduction

This document is a type-C standard as stated in EN ISO 12100.

This document is of relevance, in particular, for the following stakeholder groups representing the market players with regard to machinery safety:

— machine manufacturers (small, medium and large enterprises);
— health and safety bodies (regulators, accident prevention organizations, market surveillance, etc.).

Avant-propos

[Voir le Règlement Intérieur du CEN/CENELEC, Partie 3:2017, Article 12]

Le présent document (EN ...: < *année* >) a été élaboré par le Comité Technique CEN/TC.../WG...

La présente Norme européenne devra recevoir le statut de norme nationale, soit par publication d'un texte identique, soit par entérinement, au plus tard en [*date de disponibilité*], et toutes les normes nationales en contradiction devront être retirées au plus tard en [*date de retrait*].

Le présent document a été élaboré dans le cadre d'un mandat donné au CEN par la Commission Européenne et l'Association Européenne de Libre Échange et vient à l'appui des exigences essentielles de la (des) Directive(s) UE.

Pour les relations avec la (les) directive(s) UE, voir l'Annexe Z [*lettre appropriée*] informative, qui fait partie intégrante du présent document.

Introduction

Le présent document est une norme de type C tel que mentionné dans l'EN ISO 12100.

Le présent document concerne, en particulier, les groupes de parties prenantes suivants, représentant les acteurs du marché dans le domaine de la sécurité des machines:

— fabricants de machines (petites, moyennes et grandes entreprises);
— organismes de santé et de sécurité (autorités réglementaires, organismes de prévention des risques professionnels, surveillance du marché, etc.).

Vorwort

[Siehe CEN/CENELEC Geschäftsordnung, Teil 3:2017,Abschnitt 12]

Dieses Dokument (EN ...: < *Jahr* >) wurde vom Technischen Komitee CEN/TC .../WG ... erarbeitet.

Diese Europäische Norm muss den Status einer nationalen Norm erhalten, entweder durch Veröffentlichung eines identischen Textes oder durch Anerkennung bis [*Datum der Verfügbarkeit*], und etwaige entgegenstehende nationale Normen müssen bis [*Datum der Zurückziehung*] zurückgezogen werden.

Dieses Dokument wurde unter einem Mandat erarbeitet, das die Europäische Kommission und die Europäischen Freihandelszone dem CEN erteilt haben, und unterstützt grundlegende Anforderungen der EU-Richtlinien.

Zum Zusammenhang mit EU-Richtlinien siehe informativen Anhang Z[*entsprechende Buchstabe(n)*], welche(r) Bestandteil(e) dieses Dokuments ist/sind.

Einleitung

Diese Norm ist eine Typ C-Norm wie in EN ISO 12100 angegeben.

Dieses Dokument ist insbesondere für die folgenden Interessentengruppen von Relevanz, die die Marktakteure im Hinblick auf die Sicherheit von Maschinen repräsentieren:

— Maschinenhersteller (kleine, mittlere und große Unternehmen);
— Organisationen des Arbeits- und Gesundheitsschutzes (Gesetzgeber, Unfallversicherungen, Marktaufsicht usw.).

4) The European Commission will generally use the "date of withdrawal" of the new edition as the "date of cessation of presumption of conformity of the superseded standard" (transition period).

Others can be affected by the level of machinery safety achieved with the means of the document by the above-mentioned stakeholder groups:

— machine users/employers (small, medium and large enterprises);
— machine users/employees (e.g. trade unions, organizations for people with special needs);
— service providers, e.g. for maintenance (small, medium and large enterprises);
— consumers (in the case of machinery intended for use by consumers)

The above-mentioned stakeholder groups have been given the possibility to participate at the drafting process of this document.
The machinery concerned and the extent to which hazards, hazardous situations or hazardous events are covered are indicated in the Scope of this document.

When requirements of this type-C standard are different from those which are stated in type-A or type-B standards, the requirements of this type-C standard take precedence over the requirements of the other standards for machines that have been designed and built according to the requirements of this type-C standard.

D'autres partenaires peuvent être concernées par le niveau de sécurité des machines atteint à l'aide du document par les groupes de parties prenantes mentionnés ci dessus:

— utilisateurs de machines/employeurs (petites, moyennes et grandes entreprises);
— utilisateurs de machines/salariés (par exemple syndicats de salariés, organisations représentant des personnes ayant des besoins particuliers);
— prestataires de services, par exemple sociétés de maintenance (petites, moyennes et grandes entreprises);
— consommateurs (dans le cas de machines destinées à être utilisées par des consommateurs).

Les groupes de parties prenantes mentionnés ci-dessus ont eu la possibilité de participer à l'élaboration du présent document.
Les machines concernées et l'étendue des phénomènes dangereux, situations dangereuses ou événements dangereux couverts sont indiqués dans le domaine d'application du présent document.
Lorsque des prescriptions de la présente norme de type C sont différentes de celles énoncées dans les normes de type A ou de type B, les prescriptions de la présente norme de type C ont priorité sur celles des autres normes pour les machines ayant été conçues et fabriquées suivant les prescriptions de la présente norme de type C.

Andere interessierte Kreise können durch das in diesem Dokument (durch die oben genannten interessierten Kreise) festgeschriebene Sicherheitsniveau betroffen sein. Es handelt sich dabei um:
— Maschinenanwender/Arbeitgeber (kleine, mittlere und große Unter-nehmen);
— Maschinenanwender/Arbeitnehmer (z B. Gewerkschaften, Organisationen für Personen mit spezifischen Bedürfnissen);
— Dienstleistungsanbieter (kleine, mittlere und große Unternehmen);
— Verbraucher (falls die behandelten Maschinen für die Nutzung durch Verbraucher bestimmt sind).

Den oben genannten interessierten Kreisen wurde die Möglichkeit eingeräumt, sich an der Erarbeitung dieses Dokuments zu beteiligen.
Auf die betreffenden Maschinen und die behandelten Gefährdungen, Gefährdungs-situationen und Gefährdungsereignisse wird im Anwendungsbereich dieses Dokumentes hingewiesen.
Für Maschinen, die nach den Festlegungen dieser Typ C-Norm konzipiert und gebaut worden sind, gilt: Wenn die Festlegungen in dieser Typ C-Norm von den Festlegungen in Typ A- oder Typ B-Normen abweichen, haben die Festlegungen dieser Typ C-Norm Vorrang gegenüber den Festlegungen der anderen Normen.

1 Scope

This document specifies…
It is applicable to…
and/or
It is not applicable to…
This document deals with all significant hazards, hazardous situations or hazardous events relevant to… machinery, when it is used as intended and under conditions of misuse which are reasonably foreseeable by the manufacturer.

[or]
This document deals with all significant hazards, hazardous situations or hazardous events with the exception of … relevant to … machinery, when it is used as intended and under conditions of misuse which are reasonably foreseeable by the manufacturer.

[or]
This document deals with the following significant hazards, hazardous situations or hazardous events relevant to.... machinery, when it is used as intended and under conditions of misuse which are reasonably foreseeable by the manufacturer:
— [*details*]
—
— .

This document is not applicable to …precise the machinery or machinery components here … manufactured before the date of its publication.

1 Domaine d'application

Le présent document spécifie…
Il s'applique aux ....
et/ou
Il ne s'applique pas aux ....
Le présent document traite tous les phénomènes dangereux, situations dangereuses ou événements dangereux significatifs qui sont pertinents pour les machines ..., lorsqu'elles sont utilisées normalement et dans les conditions de mauvais usage raisonnablement prévisible par le fabricant.
[ou]
Le présent document traite tous les phénomènes dangereux, situations dangereuses ou événements dangereux significatifs, à l'exception de ..., qui sont pertinents pour les machines ..., lorsqu'elles sont utilisées normalement et dans les conditions de mauvais usage raisonnablement prévisible par le fabricant.

[ou]
Le présent document traite les phénomènes dangereux, situations dangereuses ou événements dangereux significatifs suivants qui sont pertinents pour les machines ...., lorsqu'elles sont utilisées normalement et dans les conditions de mauvais usage raisonnablement prévisible par le fabricant:
— [*préciser*]
—
— .
Ce document ne s'applique pas aux ...préciser les machines ou composants de machine ... fabriqués avant sa date de publication.

1 Anwendungsbereich

Diese Norm legt ….fest.
Diese Norm gilt für ….
und/oder
Diese Norm gilt nicht für ….
Diese Norm behandelt alle signifikanten Gefährdungen, Gefährdungssituationen oder Gefährdungsereignisse, die auf die ... Maschinen, Geräte, Anlagen zutreffen, wenn sie bestimmungsgemäß und unter Bedingungen, die vom Hersteller als Fehlanwendung vernünftigerweise vorhersehbar sind, verwendet werden.
[oder]
Diese Norm behandelt alle signifikanten Gefährdungen, Gefährdungssituationen oder Gefährdungsereignisse, mit Ausnahme derjenigen, die auf die ... Maschinen, Geräte, Anlagen zutreffen, wenn sie bestimmungsgemäß und unter Bedingungen, die vom Hersteller als Fehlanwendung vernünftigerweise vorhersehbar sind, verwendet werden.
[oder]
Diese Norm behandelt die folgenden signifikanten Gefährdungen, Gefährdungssituationen oder Gefährdungsereignisse, die auf die ... Maschinen, Geräte, Anlagen zutreffen, wenn sie bestimmungsgemäß und unter Bedingungen, die vom Hersteller als Fehlanwendung vernünftigerweise vorhersehbar sind, verwendet werden:
— [*genau*]
—
— .
Diese Norm gilt nicht für ...., die vor Veröffentlichung dieser EN hergestellt wurden.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 12100:2010 [and ...] [and the following] apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

4 Safety requirements and/or protective/risk reduction measures

Machinery shall comply with the safety requirements and/or protective/risk reduction measures of this clause.
In addition, the machine shall be designed according to the principles of EN ISO 12100:2010 for relevant but not significant hazards which are not dealt with by this document.

5 Verification of safety requirements and/or protective/risk reduction measures

2 Références normatives

Les documents suivants cités dans le texte constituent, pour tout ou partie de leur contenu, des exigences du présent document. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document de référence (y compris les éventuels amendements) s'applique.

EN ISO 12100:2010, *Sécurité des machines — Principes généraux de conception — Appréciation du risque et réduction du risque*

3 Termes et définitions

Pour les besoins du présent document, les termes et définitions donnés dans l'EN ISO 12100:2010 [et...] [ainsi que les suivants] s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

— IEC Electropedia: disponible à l'adresse http://www.electropedia.org/

— ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

4 Prescriptions de sécurité et/ou mesures de prévention/réduction des risques

Les machines doivent être conformes aux exigences de sécurité et/ou aux mesures de prévention/ réduction des risques du présent article.
De plus, les machines doivent être conçues selon les principes de l'EN ISO 12100:2010 pour les phénomènes dangereux pertinents mais non significatifs qui ne sont pas traités dans le présent document.

5 Vérification des prescriptions et/ou mesures de prévention/ réduction des risques

2 Normative Verweisungen

Die folgenden Dokumente werden im Text in solcher Weise in Bezug genommen, dass einige Teile davon oder ihr gesamter Inhalt Anforderungen des vorliegenden Dokuments darstellen. Bei datierten Verweisungen gilt nur die in Bezug genommene Ausgabe. Bei undatierten Verweisungen gilt die letzte Ausgabe des in Bezug genommenen Dokuments (einschließlich aller Änderungen).
EN ISO 12100:2010, *Sicherheit von Maschinen – Allgemeine Gestaltungsleitsätze – Risikobeurteilung und Risikominderung*

3 Begriffe

Für die Anwendung dieses Dokuments gelten die Begriffe nach EN ISO 12100:2010 [und...] [sowie die Folgenden].
ISO und IEC stellen terminologische Datenbanken für die Verwendung in der Normung unter den folgenden Adressen bereit:

— IEC Electropedia: unter http://www.electropedia.org/

— ISO Online Browsing Platform: unter http://www.iso.org/obp

4 Sicherheitsanforderungen und/oder Schutz-/Risikominderungs-maßnahmen

Maschinen müssen den Sicherheitsanforderungen und/oder Schutz-/Risikominderungsmaßnahmen dieses Abschnittes entsprechen.
Außerdem muss die Maschine im Hinblick auf relevante aber nicht signifikante Gefährdungen, die nicht in diesem Dokument behandelt werden, entsprechend den Leitsätzen der EN ISO 12100:2010 konstruiert werden.

5 Feststellung der Übereinstimmung mit den Sicherheits-anforderungen und/oder

6 Information for use

Additional clauses, if needed

Annex A
(normative)
Annex B
(informativ)
Annex C
(informative)
List of significant hazards
Annex D
(informative)
Significant technical changes between this standard and the previous edition

[Only in cases where the significant technical changes are not stated in the Foreword.]

6 Informations pour l'utilisation

Articles supplémentaires, s'il y a lieu.

Annexe A
(normative)
Annexe B
(informative)
Annexe C
(informative)
Liste des phénomènes dangereux significatifs
Annexe D
(informative)
Modifications techniques significatives entre la présente norme et l'édition précédente

[Uniquement dans le cas où ces modifications techniques significatives ne sont pas signalées dans l'avant-propos.]

Schutz-/Risikominderungsmaßnahmen
6 Benutzerinformation

Zusätzliche Abschnitte, falls erforderlich

Anhang A
(normativ)
Anhang B
(informativ)
Anhang C
(informativ)
Liste der signifikanten Gefährdungen
Anhang D
(informativ)
Signifikante technische Änderungen dieser Europäischen Norm gegenüber der Vorgängerausgabe

[Nur in den Fällen, in denen signifikante technische Änderungen nicht im Vorwort angegeben sind.]

Annex ZA
(informative)
Relationship between this European Standard and the essential requirements of Directive 2006/42/EC aimed to be covered

This European Standard has been prepared under a Commission's standardization request „M/396 Mandate to CEN and CENELEC for Standardisation in the field of machinery" to provide one voluntary means of conforming to essential requirements of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast).

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

Annexe ZA
(informative)
Relation entre la présente Norme européenne et les exigences essentielles concernées de la Directive 2006/42/CE visant à être couvert

La présente Norme européenne a été élaborée en réponse à la demande de normalisation "M/396 Mandat adressé au CEN et au CENELEC concernant des travaux de normalisation dans le domaine des machines" de la Commission européenne afin d'offrir un moyen volontaire de se conformer aux exigences essentielles de la Directive 2006/42/CE du Parlement Européen et du Conseil du 17 mai 2006 relative aux machines et modifiant la directive 95/16/CE (refonte).

Une fois la présente norme citée au Journal officiel de l'Union européenne au titre de ladite Directive, la conformité aux articles de cette norme indiqués dans le Tableau ZA.1 confère, dans les limites du domaine d'application de la norme, présomption de conformité aux exigences essentielles de ladite Directive et de la réglementation AELE associée.

Anhang ZA
(informativ)
Zusammenhang zwischen dieser Europäischen Norm und den grundlegenden Anforderungen der abzudeckenden Richtlinie 2006/42/EG

Diese Europäische Norm wurde im Rahmen eines von der Europäischen Kommission erteilten Normungsauftrages „M/396 Auftrag an CEN und CENELEC betreffend die Normung im Bereich Maschinen" erarbeitet, um ein freiwilliges Mittel zur Erfüllung der grundlegenden Anforderungen der Richtlinie 2006/42/EG des Europäischen Parlaments und des Rates vom 17. Mai 2006 über Maschinen und zur Änderung der Richtlinie 95/16/EG (Neufassung) bereitzustellen.

Sobald diese Norm im Amtsblatt der Europäischen Union im Sinne dieser Richtlinie in Bezug genommen worden ist, berechtigt die Übereinstimmung mit den in Tabelle ZA.1 aufgeführten normativen Abschnitten dieser Norm innerhalb der Grenzen des Anwendungsbereiches dieser Norm zur Vermutung der Konformität mit den entsprechenden grundlegenden Anforderungen der Richtlinie und den zugehörigen EFTA Vorschriften.

Table ZA.1 –Correspondence between this European Standard and Annex I of Directive 2006/42/EC

Essential Requirement of Directive	Clause(s)/ subclause(s) of this EN	Remarks/ Notes
*Option A.1: Within the limits of the scope **all relevant** essential requirements are covered*	*All normative clauses*	*For relation of normative clauses of this standard to significant hazards/relevant essential requirements of 2006/42/EC see informative annex XX „List of significant hazards" of this standard in combination with annex D "Examples of significant hazards, hazardous situations, hazardous events and their relation to the Essential Requirements of the Machinery Directive 2006/42/EC" of CEN Guide 414 (https://boss.cen.eu/ref/CEN_414.pdf).*

Tableau ZA.1 – Correspondance entre la présente Norme Européenne et l'Annexe I de la Directive 2006/42/CE

Exigence Essentielle de la Directive	Article(s)/ paragraph(es) de la présente EN	Remarques/ Notes
*Option A.1: Dans les limites du domaine d'application **toutes** les exigences essentielles **applicables** sont indiquées*	*Tous les articles normatifs*	*Pour les relations entre des clauses normatives de la présente norme et des phénomènes dangereux /exigences essentielles applicables de 2006/42/CE voir annexe informative XX "Liste des phénomènes dangereux" de cette norme en combinaison avec l'annexe D " Exemples de phénomènes dangereux, de situations dangereuses, d'événements dangereux significatifs et leur relation avec les Exigences Essentielles de la Directive 2006/42/CE relative aux machines" du Guide 414 CEN (https://boss.cen.eu/ref/CEN_414.pdf)*

Tabelle ZA.1 – Zusammenhang zwischen dieser Europäischen Norm und Anhang I der Richtlinie 2006/42/EG

Grundlegende Anforderung der Richtlinie	Abschnitt(e)/ Unter-abschnitt(e) dieser EN	Erläuterungen/ Anmerkungen
*Option A.1: Innerhalb der Grenzen des Anwendungsbereiches sind **alle relevanten** grundlegenden Anforderungen behandelt*	*Alle normativen Abschnitte*	*Hinsichtlich des Zusammenhangs der normativen Abschnitte dieser Norm zu signifikanten Gefährdungen/rele-vanten grundlegenden Anforderungen der 2006/42/EG siehe Anhang XX „Liste der signifikanten Gefährdungen" dieser Norm in Verbindung mit Anhang D „Beispiele für signifikante Gefährdungen, Gefährdungs-situationen, Gefährdungs-ereignisse und deren Zusammenhang mit den Grundlegenden Anforderungen der Maschinenrichtlinie 2006/42/EG„ von CEN Guide 414 (https://boss.cen.eu/ref/CEN_414.pdf).*

*Option A.2: Within the limits of the scope **all relevant** essential requirements are covered*	*All normative clauses except clause(s) yyy*)*	*For relation of normative clauses **(except clause(s) yyy*))** of this standard to significant hazards/relevant essential requirements of 2006/42/EC see informative annex XX „List of significant hazards“ of this standard in combination with annex D “Examples of significant hazards, hazardous situations, hazardous events and their relation to the Essential Requirements of the Machinery Directive 2006/42/EC” of CEN Guide 414 (https://boss.cen.eu/ref/CEN_414.pdf).*

*Option A.2: Dans les limites du domaine d’application **toutes** les exigences essentielles **applicables** sont indiquées*	*Tous les articles normatifs à l’exception des articles yyy*)*	*Pour les relations entre des clauses normatives **(à l’exception des articles yyy*))** de la présente norme et des phénomènes dangereux /exigences essentielles applicables de 2006/42/CE voir annexe informative XX "Liste des phénomènes dangereux" de cette norme en combinaison avec l'annexe D " Exemples de phénomènes dangereux, de situations dangereuses, d’événements dangereux significatifs et leur relation avec les Exigences Essentielles de la Directive 2006/42/CE relative aux machines" du Guide 414 CEN (https://boss.cen.eu/ref/CEN_414.pdf)*

*Option A.2: Innerhalb der Grenzen des Anwendungsbereiches sind **alle relevanten** grundlegenden Anforderungen behandelt*	*Alle normativen Abschnitte mit Ausnahme von yyy*)*	*Hinsichtlich des Zusammenhangs der normativen Abschnitte dieser Norm **(mit Ausnahme von yyy*))** zu signifikanten Gefährdungen/relevanten grundlegenden Anforderungen der 2006/42/EG siehe Anhang XX „Liste der signifikanten Gefährdungen“ dieser Norm in Verbindung mit Anhang D „Beispiele für signifikante Gefährdungen, Gefährdungssituationen, Gefährdungs-ereignisse und deren Zusammenhang mit den Grundlegenden Anforderungen der Maschinenrichtlinie 2006/42/EG„ von CEN Guide 414 (https://boss.cen.eu/ref/CEN_414.pdf).*

*Option B.1: Within the limits of the scope **all relevant** essential requirements **with the exception of essential requirement(s) xxx** are covered*	*All normative clause*	*For relation of normative clauses of this standard to significant hazards/relevant essential requirements of 2006/42/EC see informative annex XX „List of significant hazards" of this standard in combination with annex D "Examples of significant hazards, hazardous situations, hazardous events and their relation to the Essential Requirements of the Machinery Directive 2006/42/EC" of CEN Guide 414 (https://boss.cen.eu/ref/CEN_414.pdf).*

*Option B.1: Dans les limites du domaine d'application **toutes** les exigences essentielles **applicables** sont indiquées **à l'exception des exigences essentielles xxx***	*Tous les articles normatifs*	*Pour les relations entre des clauses normatives de la présente norme et des phénomènes dangereux /exigences essentielles applicables de 2006/42/CE voir annexe informative XX "Liste des phénomènes dangereux" de cette norme en combinaison avec l'annexe D " Exemples de phénomènes dangereux, de situations dangereuses, d'événements dangereux signify-catifs et leur relation avec les Exigences Essentielles de la Directive 2006/42/CE relative aux machines" du Guide 414 CEN (https://boss.cen.eu/ref/CEN_414.pdf)*

*Option B.1: Innerhalb der Grenzen des Anwendungsbereiches sind **alle relevanten** grundlegenden Anforderungen **mit Ausnahme der grundlegenden Anforderung(en) xxx** behandelt*	*Alle normativen Abschnitte*	*Hinsichtlich des Zusammenhangs der normativen Abschnitte dieser Norm zu signifikanten Gefährdungen/relevanten grundlegenden Anforderungen der 2006/42/EG siehe Anhang XX „Liste der signifikanten Gefährdungen" dieser Norm in Verbindung mit Anhang D „Beispiele für signifikante Gefährdungen, Gefährdungssituationen, Gefährdungsereignisse und deren Zusammenhang mit den Grundlegenden Anforderungen der Maschinenrichtlinie 2006/42/EG„ von CEN Guide 414 (https://boss.cen.eu/ref/CEN_414.pdf).*

Option B.2: *Within the limits of the scope* ***all relevant*** *essential requirements* ***with the exception of essential requirement(s) xxx*** *are covered*	*All normative clauses except clause(s) yyy*)*	*For relation of normative clauses* ***(except clause(s) yyy*))*** *of this standard to significant hazards/relevant essential requirements of 2006/42/EC see informative annex XX „List of significant hazards" of this standard in combination with annex D "Examples of significant hazards, hazardous situations, hazardous events and their relation to the Essential Requirements of the Machinery Directive 2006/42/EC" of CEN Guide 414 (https://boss.cen.eu/ref/CEN_414.pdf).*

Option B.2: *Dans les limites du domaine d'application* ***toutes*** *les exigences essentielles* ***applicables*** *sont indiquées* ***à l'exception des exigences essentielles xxx***	*Tous les articles normatifs à l'exception des articles yyy*)*	*Pour les relations entre des clauses normatives* ***(à l'exception des articles yyy*))*** *de la présente norme et des phénomènes dangereux /exigences essentielles applicables de 2006/42/CE voir annexe informative XX "Liste des phénomènes dangereux" de cette norme en combinaison avec l'annexe D " Exemples de phénomènes dangereux, de situations dangereuses, d'événements dangereux significatifs et leur relation avec les Exigences Essentielles de la Directive 2006/42/CE relative aux machines" du Guide 414 CEN (https://boss.cen.eu/ref/CEN_414.pdf)*

Option B.2: *Innerhalb der Grenzen des Anwendungs-bereiches sind* ***alle relevanten*** *grundlegenden Anforderungen* ***mit Ausnahme der grund-legenden Anforde-rung(en) xxx*** *behandelt*	*Alle normativen Abschnitte mit Ausnahme von yyy*)*	*Hinsichtlich des Zusammenhangs der normativen Abschnitte dieser Norm* ***(mit Ausnahme von yyy*))*** *zu signifikanten Gefährdungen/relevanten grundlegenden Anforderungen der 2006/42/EG siehe Anhang XX „Liste der signifikanten Gefährdungen" dieser Norm in Verbindung mit Anhang D „Beispiele für signifikante Gefährdungen, Gefährdungssituationen, Gefährdungsereignisse und deren Zusammenhang mit den Grundlegenden Anforderungen der Maschinenrichtlinie 2006/42/EG„ von CEN Guide 414 (https://boss.cen.eu/ref/CEN_414.pdf).*

Option C: *[Per row: an essential requirement]*	*The relevant normative clauses linked to the individual essential requirement]*	

**) In cases where certain normative clauses of the standard do cover other aspects than those providing presumption of conformity.*

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) */ [service(s)] / […]* falling within the scope of this standard.

Bibliography

Option C: *[Une exigence essentielle par ligne]*	*[L'article normatif pertinent en lien avec l'exigence essentielle particulière]*	

**) Dans les cas où certains articles normatifs traitent d'autres aspects que ceux donnant présomption de conformité*

AVERTISSEMENT 1 — La présomption de conformité demeure valable tant que la référence de la présente Norme européenne figure dans la liste publiée au Journal officiel de l'Union européenne. Il est recommandé aux utilisateurs de la présente norme de consulter régulièrement la dernière liste publiée au Journal officiel de l'Union européenne.

AVERTISSEMENT 2 — D'autres dispositions de la législation de l'Union européenne peuvent être applicables aux produits */ [services] / […]* relevant du domaine d'application de la présente norme.

Bibliographie

Option C: *[Je Zeile: eine grundlegende Anforderung.]*	*[Die relevanten normativen Abschnitte, die sich auf die jeweilige grundlegende Anforderung beziehen]*	

**) In Fällen, bei denen sich bestimmte normative Abschnitte der Norm mit Aspekten beschäftigen, die keine Vermutungswirkung auslösen.*

WARNHINWEIS 1 — Die Konformitäts-vermutung bleibt nur bestehen, so lange die Fundstelle dieser Europäischen Norm in der im Amtsblatt der Europäischen Union veröffent-lichten Liste erhalten bleibt. Anwender dieser Norm sollten regelmäßig die im Amtsblatt der Europäischen Union zuletzt veröffentlichte Liste einsehen.

WARNHINWEIS 2 — Für Produkte */ [Dienstleistungen] / […]*, die in den Anwendungsbereich dieser Norm fallen, können weitere Rechtsvorschriften der EU anwendbar sein.

Literaturhinweise

Annex C
(informative)

Guidance on extension of transition period

C.1 General

When a European Standard (EN) is approved, implementation is compulsory for all CEN National Members from EEA countries.

European Standards (EN) will be implemented by the CEN National Members within a period expressed in months from the date of availability (dav) of the EN. This is normally three months for the date of announcement (doa), six months for the date of publication (dop) and six months for the date of withdrawal (dow).

The date of withdrawal (dow) is by definition the latest date by which any national standard conflicting with an EN shall be withdrawn. It is a date common to all CEN National Members.

C.2 Exceptional extension of the date of withdrawal

To allow the industry (manufacturers) to make an ordered conversion to the new EN it should be considered by the responsible TC if an extension of the transition period *(dow later than dav + 6 months)*, is justified and should be therefore requested.

As a first step a transition period, if necessary, should be proposed by the standardization body (e.g. WG) in charge of elaborating the draft standard and be included in the document intended for CEN Enquiry using the following wording:

"A transition period of *X* months *(dav + 6 months + **X extra months**)* is proposed."

After the CEN Enquiry the responsible TC should decide on an extended transition period *(dow later than dav + 6 months up to maximum of dav + 36 months)* in accordance with the CEN BOSS Guidance document “Date of withdrawal.

C.3 Consequences for European Standards to be cited in the Official Journal of the European Union

European Standards can be listed in the 'Official Journal of the European Union' (OJEU) under one or more New Approach directives. In practice, this means that a product manufactured according to a European Standard, the reference of which is cited in the OJEU under a New Approach directive, is presumed to comply with the essential requirements of that directive (this is called 'presumption of conformity').

When a European Standard that is cited in the OJEU is replaced by a new version (also to be cited in the OJEU under the same directive), the European Commission (EC) will generally use the dow of that new version as the 'Date of cessation of presumption of conformity of the superseded standard'. This date marks the end of the period during which both the old and the new version of the standard can be used to claim 'presumption of conformity' to the essential requirements of the relevant directive. After that date, 'presumption of conformity' can no longer be claimed for a product manufactured according to the old version of the standard.

It should be noted that extending the dow does not lead to an automatic extension of the 'Date of cessation of presumption of conformity of the superseded standard', for standards that have already been sent to the EC for citation in the OJEU. When it is deemed necessary to extend the 'Date of cessation of presumption of conformity of the superseded standard' for such standards, CCMC should be contacted for guidance.[5)] For the process for requesting and deciding on a dow later than dav + 6 months see CEN BOSS.

5) This Annex is based on the guidance document "Date of withdrawal" from CEN BOSS. In case of modification of the guidance given by CEN BOSS, the current version of that guidance takes precedence over this Annex.

Annex D
(informative)

Examples of significant hazards, hazardous situations, hazardous events and their relation to the Essential Requirements of the Machinery Directive 2006/42/EC

Whereas the Machinery Directive 2006/42/EC states in its Annex I Essential Requirements, the general methodology for safety of machinery specified in EN ISO 12100 is based on the consideration of significant hazards basically without any specific reference to the Essential Requirements of Directive 2006/42/EC. As there is not always an obvious linkage from the Essential Requirements to the significant hazards, hazardous situations, hazardous events they are based on, Table D.1 provides as far as possible examples of significant hazards, hazardous situations, hazardous events and their relation to this Essential Requirements.

Table 1 — Examples of significant hazards, hazardous situations, hazardous events and their relation to the Essential Requirements of the Machinery Directive 2006/42/EC

Group	Significant hazard in accordance with EN ISO 12100:2010, Table B.1	Directive 2006/42/EC, Annex I
General, for many machines relevant		
1	**Mechanical hazards**	
1.1	Due to machine parts or workpieces, e.g. — by potential energy (falling objects, height from the ground, gravity)	1.3.3 Risks due to falling or ejected objects
	— by kinetic energy (acceleration, deceleration, moving/rotating elements)	1.3.7 Risks related to moving parts
	— by mechanical strength (break-up)	1.1.3 Materials and products 1.3.2 Risk of break-up during operation
1.2	by stored energy, e.g.: — elastic elements (springs)	1.3.9 Risks of uncontrolled movements 1.5.3 Energy supply other than electricity 1.6.3 Isolation of energy sources
1.3	Crushing	1.3 Protection against mechanical hazards
1.4	Shearing	1.3 Protection against mechanical hazards
1.5	Cutting or severing	1.3.4 Risks due to surfaces, edges or angles
1.6	Entanglement	1.3 Protection against mechanical hazards
1.7	Drawing-in or trapping	1.3 Protection against mechanical hazards
1.8	Impact	1.3 Protection against mechanical hazards
1.9	Stabbing or puncture	1.3 Protection against mechanical hazards
1.10	Friction or abrasion	1.3.4 Risks due to surfaces, edges or angles
1.11	Injection	1.3.2 Risk of break-up during operation
1.12	Slipping, tripping and falling	1.5.15 Risk of slipping, tripping or falling
1.13	Instability	1.1.5 Design of machinery to facilitate its handling 1.3.1 Risk of loss of stability

Group	Significant hazard in accordance with EN ISO 12100:2010, Table B.1	Directive 2006/42/EC, Annex I
2	**Electrical hazards**	
2.1	Touching live parts	1.5.1 Electricity supply 1.6.3 Isolation of energy sources
2.2	Parts which have become live under fault conditions	1.5.1 Electricity supply
2.3	Not enough distance to live parts under high voltage	1.5.1 Electricity supply 1.6.3 Isolation of energy sources
2.4	Electrostatic phenomena	1.5.2 Static electricity
2.5	Electromagnetic phenomena	1.2.1 Safety and reliability of control systems
2.6	Projection of molten particles	1.5.5 Extreme temperatures
2.7	Short-circuit	1.5.1 Electricity supply
2.8	Overload	1.5.1 Electricity supply
2.9	Thermal radiation	1.5.1 Electricity supply
3	**Thermal hazards**	
3.1	Burn, scald	1.5.5 Extreme temperatures 1.5.6 Fire 1.5.7 Explosion
3.2	Frostbite	1.5.5 Extreme temperatures
3.3	Radiation of heat sources	1.5.5 Extreme temperatures
3.4	Dehydration	1.5.5 Extreme temperatures
4	**Noise hazards**	
4.1	Permanent hearing loss, tinnitus	1.5.8 Noise
4.2	As a consequence of an interference with speech communication or with acoustic signals.	1.5.8 Noise
4.3	Physiological impairment (e.g. loss of balance, loss of awareness)	1.5.8 Noise
5	**Vibration hazards**	
5.1	Vibrations transmitted to the operator when sitting during operation	1.1.8 Seating
5.2	Portable hand-held and/or hand-guided machinery (e.g. vascular disorder, neurological disorder)	1.5.9 Vibrations
5.3	In conjunction with a rigid position (e.g. trauma of the spine, osteo-articular disorder, low-back morbidity)	1.5.9 Vibrations
6	**Radiation hazards**	
6.1	Low frequency electromagnetic radiation	1.5.10 Radiation
6.2	Radio frequency electromagnetic radiation	1.5.10 Radiation 1.5.11 External radiation
6.3	Optical radiation (infrared, visible and ultraviolet)	1.5.10 Radiation
6.4	Laser	1.5.12 Laser radiation
6.5	Ionizing radiation source	1.5.10 Radiation 1.5.11 External radiation

Group	Significant hazard in accordance with EN ISO 12100:2010, Table B.1	Directive 2006/42/EC, Annex I
7	**Material/ substance hazards**	
7.1	Hazards from contact with inhalation of harmful fluids, gases, mists, fumes and dusts	1.1.3 Materials and products 1.5.13 Emissions of hazardous materials and substances 1.6.5 Cleaning of internal parts
7.2	Fire	1.5.6 Fire
7.3	Explosion	1.5.7 Explosion
7.4	Biological and microbiological (viral or bacterial) agent	1.1.3 Materials and products 1.6.5 Cleaning of internal parts 2.1 Foodstuff Machinery and Machinery for cosmetics or pharmaceutical products
7.5	Use/application of pesticides	2.4 Machinery for pesticide application
8	**Ergonomic hazards**	
8.1	Unhealthy postures or excessive effort	1.1.5 Design of machinery to facilitate its handling 1.1.6 Ergonomics
8.2	Inadequate consideration of anatomy	1.1.6 Ergonomics 1.6.2 Access to operating positions and servicing points 2.2 Portable hand-held and/or hand-guided machinery
8.3	Insufficient means for evacuation/emergency exit	1.1.7 Operating positions
8.4	Inadequate local lighting	1.1.4 Lighting
8.5	Design or location of indicators and visual displays units	1.7.1 Information and warnings on the machinery
8.6	Design, location or identification of control devices	1.2.2 Control devices
8.7	Flicker, dazzling, shadow, stroboscopic effect	1.1.4 Lighting
8.8	Mental overload/underload	1.1.6 Ergonomics 1.6.4 Operator intervention
8.9	Human error during operation	1.1.6 Ergonomics 1.2.1 Safety and reliability of control systems 1.2.2 Control devices 1.2.5 Selection of control or operating modes 1.5.4 Errors of fitting 1.7 Information
8.10	Repetitive activity	1.1.6 Ergonomics
9	**Hazards associated with the environment in which the machine is used**	
9.1	Lightning	1.5.16 Lightning
9.2	Moisture	1.1.3 Material and products 1.2.1 Safety and reliability of control systems 1.1.7 Operating positions

Group	Significant hazard in accordance with EN ISO 12100:2010, Table B.1	Directive 2006/42/EC, Annex I
9.3	Pollution	1.1.3 Material and products 1.2.1 Safety and reliability of control systems 1.1.7 Operating positions
9.4	Snow, water, wind, temperature	1.1.3 Material and products 1.2.1 Safety and reliability of control systems 1.1.7 Operating positions
9.5	Exhaust gas/ lack of oxygen at workplace	1.1.7 Operating positions
9.6	Dust and fog	1.1.7 Operating positions
10		
10.1	Failure/disorder of the control system and control circuits	1.2.1 Safety and reliability of control systems 1.2.3 Starting 1.2.4 Stopping 1.2.5 Selection of control or operating modes 1.6.3 Isolation of energy sources
10.2	Restoration of energy supply after an interruption	1.2.3 Starting 1.2.6 Failure of the power supply
10.3	Software error	1.2.1 Safety and reliability of control systems
10.4	Failure of the power supply	1.2.6 Failure of the power supply
11	**Combination of hazards**	
11.1	— for example, repetitive activity + effort + high environmental temperature	1.1.5 Design of machinery to facilitate its handling 1.1.6 Ergonomics 1.6.2 Access to operating positions and servicing point 1.6.4 Operator intervention 1.5.5 Extreme temperatures
11.2	— for example, dismantling of heavy guards + painful effort	1.3 Protection against mechanical hazards 1.1.6 Ergonomics
12	**Hazards due to:** — assembly and installation — setting — cleaning — fault-finding — maintenance	
12.1	Maintenance	1.6.1 Machinery maintenance
12.2	Insufficient means of access during use, setting and maintenance	1.6.2 Access to operating positions and servicing points
12.3	Cleaning inside the machine	1.6.4 Operator intervention
12.4	Being trapped in a machine	1.5.14 Risk of being trapped in a machine

Group	Significant hazard in accordance with EN ISO 12100:2010, Table B.1	Directive 2006/42/EC, Annex I
Supplementary, for certain categories of machinery		
13	**Hazards due to contamination of: foodstuffs, cosmetics or pharmaceutical products**	
13.1	Unsuitable material	2.1 Foodstuffs machinery and machinery cosmetics or pharmaceutical products
14	**Hazards due to portable machinery — hand-held and/or hand-guided machinery**	
14.1	Instability	2.2 Portable hand-held and/or hand-guided machinery
14.2	Accidental starting/or continued operation	2.2 Portable hand-held and/or hand-guided machinery
14.3	Accidental start	2.2 Portable hand-held and/or hand-guided machinery
15	**Hazards due to working with wood and material with similar physical characters**	
15.1	Ejection of workpieces	1.3 Protection against mechanical hazards 2.3 Machinery for working wood and material with similar physical characters
Supplementary, due to the mobility of machinery		
16	**Hazards related to travelling function**	
16.1	Movement when starting the engine	3.3.2 Starting/moving 3.3.4 Movement of pedestrian-controlled machinery
16.2	Movement without a driver at the driving position	3.3.2 Starting/moving
16.3	Movement without all parts in safe position	3.3.2 Starting/moving
16.4	Excessive speed of pedestrian controlled machinery	3.3.4 Movement of pedestrian-controlled machinery
16.5	Insufficient ability of machinery to be slowed down, stopped and immobilized	3.3.3 Travelling function 3.3.5 Control circuit failure
17	**Hazards linked to work position (including driving station) on the machine**	
17.1	Fall of persons during access to or at/from the work position	3.4.5 Means of access 3.4.7 Transmission of power between self-propelled machinery (or tractor) and recipient machinery
17.2	Fire (lack of extinguishing means)	3.5.2 Fire
17.3	Mechanical hazards at the work position, such as: — contact with the wheels — rollover and overturning — slipping during access — fall of objects, penetration by objects — contact of persons with machine parts or tools (pedestrian controlled machines	3.2.1 Driving position 3.4.3 Roll-over and tip-over 3.4.5 Means of access 3.4.4 Falling objects 3.3.4 Movement of pedestrian-controlled machinery
17.4	Insufficient visibility from the work position	3.2.1 Driving position
17.5	Inadequate seating	3.2.2 Seating
18	**Hazards due to the control system**	
18.1	Inadequate location of manual controls	3.3.1 Control devices 3.4.5 Means of access

Group	Significant hazard in accordance with EN ISO 12100:2010, Table B.1	Directive 2006/42/EC, Annex I
18.2	Inadequate design of manual controls and their mode of operation	3.3.1 Control devices 3.3.3 Travelling function
19	**Hazards due to the power source and the transmission of power**	
19.1	Engine and batteries	3.4.2 Moving transmission parts 3.5.1 Batteries
19.2	Transmission of power between machines	3.4.7 Transmission of power between self-propelled machinery (or tractor) and recipient machinery
19.3	Couplings and towings	3.4.6 Towing devices
20	**Hazards from/to third persons**	
20.1	Unauthorized start-up/use	3.3.2 Starting/moving
20.2	Drift of a part away from its stopping position	3.3.3 Travelling function
20.3	Lack or inadequacy of visual or acoustic warning means	3.6.1 Signs, signals and warnings
21	**Hazards due to insufficient instruction for the driver/operator**	
21.1	Insufficient instruction for the driver/operator	3.6 Information and Indications
Supplementary, due to lifting operations		
22	**Mechanical hazards caused by load falls, collisions, machine tipping**	
22.1	Lack of stability	4.1.2.1 Risks due to lack of stability
22.2	Uncontrolled loading, overloading, overturning moments exceeded	4.2.2 Loading control 4.3.3 Lifting machinery 4.4.2 Lifting machinery
22.3	Uncontrolled amplitude of movements	4.1.2.6a) Control of movements 4.2.1 Control of movements
22.4	Unexpected/unintended movement of loads	4.1.2.6c) Control of movements
22.5	Inadequate holding devices/accessories	4.1.2.6e) Control of movements 4.4.1 Lifting accessories
22.6	Collision of more than one machine	4.1.2.6b) Control of movements
22.7	Access of persons to load support	4.3.3 Lifting machinery
22.8	Derailment	4.1.2.2 Machinery running on guide rails and rail tracks
22.9	Insufficient mechanical strength of parts	4.1.2.3 Mechanical strength
22.10	Inadequate design of pulleys and drums	4.1.2.4 Pulleys, drums, wheels, ropes and chains
22.11	Inadequate selection of chains, ropes, lifting and accessories and their inadequate integration into the machine	4.1.2.4 Pulleys, drums, wheels, ropes and chains 4.1.2.5 Lifting accessories and their components 4.3.1 Chains, ropes and webbing 4.3.2 Lifting accessories
22.12	Lowering of the load under the control of friction brake	4.1.2.6d) Control of movements

Group	Significant hazard in accordance with EN ISO 12100:2010, Table B.1	Directive 2006/42/EC, Annex I
22.13	Abnormal conditions of assembly/use/maintenance	4.4.1 Lifting accessories 4.4.2d) Lifting machinery 4.4.2e) Lifting machinery
22.14	Effect of load on persons (impact by load or counterweight)	4.1.2.6b) Control of movements 4.1.2.7 Movements of loads during handling 4.1.2.8 Machinery serving fixed landings
23	**Hazards linked to driver/operator position**	
23.1	Insufficient visibility from driver position	4.1.2.7 Movements of loads during handling 4.4.2c) Lifting machinery
Supplementary, for machinery intended for underground work		
24	**Mechanical hazards**	
24.1	Lack of stability of powered roof supports	5.1 Risks due to lack of stability
24.2	Failing accelerator or brake control of machinery running on rails	5.3 Control devices
24.3	Failing or lack of deadman`s control of machinery running on rails	5.3 Control devices 5.4 Stopping
25	**Ergonomic hazards**	
25.1	Restricted movements of persons	5.2 Movement
26	**Hazards associated with the environment in which the machine is used**	
26.1	Fire and explosion	5.5 Fire
26.2	Emission of dust, gases, etc.	5.6 Exhaust emissions
Supplementary, for machinery presenting particular hazards due to the lifting of persons		
27	**Mechanical hazards**	
27.1	Due to: — inadequate mechanical strength — inadequate working coefficients — failing of loading control	6.1.1 Mechanical strength 6.1.2 Loading control for machinery moved by power other than human strength
27.2	Failing of controls in person carrier (function, priority)	6.2 Control devices
27.3	Overspeed of person carrier	6.3.1 Risks due to movements of the carrier 6.4.1 Risks to persons in or on the carrier
27.4	Falling of persons from person carrier	6.3.2 Risk of persons falling from the carrier 6.4.1 Risks to persons in or on the carrier
Hazards not be by eliminated or reduced by inherently safe design measures or safeguarding and/or complementary protective measures		
—	—	1.7 Information

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