

Instruction on informative Annex ZA (in CEN) and ZZ (in CENELEC) in harmonised standards under the Machinery Directive 2006/42/EC

- Apply the new template that foresees the indication of the Essential Health and Safety Requirements (EHSRs) being relevant for the product addressed in the standard and if applicable the indication of this (these) ESHR(s) which is (are) relevant but is (are) not covered by the standard
 - the template for standards under CEN responsibility is available on the <u>CEN BOSS</u> (Forms & templates – Annex ZA)
 - the template for standards under CENELEC responsibility is available on the <u>CENELEC BOSS</u> (*Forms & templates Annex ZZ*).

For the purpose of efficiency and simplicity of the standardization work - one template of an informative Annex ZA (in CEN) / ZZ (in CENELEC) (with the same headings in the first column of the table stating now "Relevant Essential Requirements...") should be used in all harmonised standards under the Machinery Directive (type A, type B- and type-C standards). See figure below. However, in line with the European Commission's request, the obligation to indicate the relevant EHSR(s) being not covered by the standard is applicable <u>only to type-C</u> standards.

"The relevant" shall be indicated in the heading of the 1st column of an informative Annex Z of type-B and type-C standards

Table 71 - (crespondence between this F	uropean Standard and Annex I of Directive
Tuble Linit ,	2006/4	
	2000/4	2/10

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
[Per row: an essential requirement]	[The relevant normative clauses linked to the individual essential requirement]	
[Per row: an essential requirement]		not covered
[Example] 1.7.4.2 u)		not covered

Non-covered elements shall only be indicated in an informative Annex Z of type-C standards



2. Do not indicate in an informative Annex ZA (in CEN) / ZZ (in CENELEC) references of other standards or other standardization deliverables (Technical Reports, Technical Specifications) or legal acts (apart from the Machinery Directive). The European Commission informed in their letter:

"Any reference in Annex ZA/ZZ to other standards or documents (which are not the standards) including to other legal acts than the one which should be supported are not acceptable. Annex ZA/ZZ cannot be used to establish relationship between the 'legal requirements' and other documents. In consequence, all harmonised standards failing to comply with this, will not be published in the OJEU".

The examples of incorrect references:

1.7	4.5, 4.6, 4.7, 4.8.10, 4.9	1
1.5.1	4.8.4	With exclusion of the reference to the national differences in the fore- word of IEC 60204-1:2016.
1 5 9	240	not accound bacauca not availing for

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

Essential Requirements of Directive 2006/42/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes
		Compliance with the requirements of EN 13001-1, EN 13001-2, EN 13001-3-1 and EN 13557 this specific part is necessary to achieve presumption of conformity.
1. ESSENTIAL HEALTH AND		

- 3. Apply the following instructions on the level of detail of an informative Annex ZA (in CEN) / ZZ (in CENELEC) which was agreed by the CEN-CENELEC sector forum on machinery with the European Commission:
 - All Essential Health and Safety Requirements (EHSRs) having a number (except 1.1.1; 3.1.1 and 4.1.1 containing definitions) should be referenced (as far as applicable), assuming that all the sub-parts under these EHSRs are covered in so far as they are relevant;
 - In relation to the first indent, reference to subparts of a numbered EHSR (subclauses starting with a letter, indent or without any marking) is not required
 - It is acceptable to cover <u>all</u> numbered sub-EHSRs of a main EHSRs by making reference to the main EHSR, only (e. g. covering subEHSRs 1.2.1, 1.2.2 and 1.2.3 by reference to EHSR 1.2 "Control



systems"); but, not accepted to make reference to the entire section of EHSR 1, EHSR 2, EHSR 3, EHSR 4, EHSR 5 and EHSR 6.

- <u>Type C- standards</u> should reference the particular normative clauses/annexes which address an individual EHSRs (it is acceptable to cover <u>all</u> sub-clauses of a main clause by making reference to the main clause, only)
- For <u>type B-standards</u> (normally addressing one or very few EHSRs) it is acceptable to reference to particular normative clauses/annexes at the highest clause numbering level only.
- Use the wording <u>strictly</u> as indicated in the templates for Annex ZA (in CEN) / ZZ (in CENELEC). Do not modify the texts above and below the table. Do not add any text below or above the table.
- 5. Do not change the order of the columns of the table.
- 6. Do not refer to "not relevant" Essential Health and Safety Requirements as an informative Annex ZA (in CEN) / ZZ (in CENELEC) under the Machinery Directive shall list only the <u>relevant</u> Essential Health and Safety Requirements as indicated in the heading of the first column of the table.
- 7. Do not indicate in the second column of the table that a given Essential Health and Safety Requirement is addressed by "all clauses". Instead in the 2nd column of the table always provide <u>the numbers</u> of clauses and Annexes addressing a given Essential Health and Safety Requirement.
- 8. Do not refer to the Essential Health and Safety Requirement 1.1.1, 3.1.1 and 4.1.1. because they deal with definitions.
- 9. The Essential Health and Safety Requirement 1.1.2 'Principles of safety integration'

As EHRS 1.1.2 **indent (b)** covers "procedural aspects" it should not be covered at all in Annex ZA (in CEN) / ZZ (in CENELEC).

Essential Requirement(s) of 2006/42/EC	Clause(s), subclause(s) of this standard
1.1.2 (a)	4, 5, 6 ¹⁾
1.1.2 (c)	4, 5, 6 ¹⁾
1.1.2 (d) ²⁾	4, 5, 6 ¹⁾
1.1.2 (e) ²⁾	4, 5, 6 ¹⁾

EHRS 1.1.2 indents (a); (c); (d) and (e) should be covered as follows:

¹) Clauses according to CEN Guide 414:

⁴ Safety requirements and/or protective/risk reduction measures 5 Verification of safety requirements and/or protective/risk reduction measures



If the respective clauses dealing with these aspects have different numbers, then these different numbers should be provided.

²⁾ To be integrated only in case aspect stated in indent is relevant for machinery covered by hEN and to the extent these product requirements are dealt with in the concerned standard

- 10. Do only refer to the parts of the standard which are normative, deal with significant hazards and contain verifiable requirements. According to CEN Guide 414, the sentence "In addition, the machine shall be designed according to the principles of EN ISO 12100:2010 for hazards relevant but not significant which are not dealt with by this document" ¹ appears in each type -C standard under clause 4 "Safety requirements and/or protective measures" as first subclause "General". As this sentence does not contain a verifiable requirement, no link to any of the Essential Health and Safety Requirements can be made. Consequently, this subclause shall not appear in an informative Annex ZA (in CEN) / ZZ (in CENELEC). As a consequence, the important general requirements which are linked to specific EHSRs should be made separate from the above-mentioned sentence on not significant hazards and put in a different subclause that will be referred to in an informative Annex ZA (in CENELEC).
- 11. Where relevant, apply the instruction on <u>multi-part series standards</u> which explains on how to ensure that there are sufficient links between the Part 1 dealing with common requirements and the specific Parts of the series in the main body of the standard as well as includes the guidance regarding an informative Annex ZA (in CEN) / ZZ (in CENELEC) of such standards. This instruction applies to these multi-part standards which are organized as a series of several parts, where one part (usually Part 1) of the standard provides general specifications that are applicable to a family of machinery and other parts of the standard provide specifications for specific categories of machinery belonging to the family, supplementing or modifying the general specifications of Part 1. This instruction was agreed by the CEN-CENELEC Sector Forum on Machinery with the European Commission. The instruction is enclosed below.
- 12.Where relevant, apply the instruction on standards series developed in line with <u>Global relevance</u> principles. Relevant for EN ISO standards providing global requirements and their corresponding homegrown CEN standards providing European regional requirements. This instruction was agreed by the CEN-CENELEC Sector Forum on Machinery with the European Commission. The instruction is enclosed below.

¹ CEN-Guide 414 will be modified accordingly at its next revision

Instruction for multi-part standard series including the presentation of detailed informative Annex ZA/ZZ

This instruction was developed in order to provide guidance to CEN and CENELEC Technical Bodies which develop harmonized standards under Machinery Directive¹. It concerns harmonized standards under Machinery Directive which are organized in multi-part series. Another objective of the document is to ensure a consistent approach in the machinery sector with regard to multi-part series.²

1. Structure of a multi-part standard series (interrelation between Part 1 and Part X)

This document applies to multi-part standards organized as a series of several parts, where one part (usually Part 1) of the standard provides general specifications that are applicable to a family of machinery and other parts of the standard provide specifications for specific categories of machinery belonging to the family, supplementing or modifying the general specifications of Part 1 (see GUIDE TO THE APPLICATION OF MACHINERY DIRECTIVE 2006/42/EC, §111).

Part 1 provides general/common requirements which are applicable for the whole machine family and shall not contain any specific normative reference to one of the Parts X.

Part X (Part 2, Part 3, ... Part N) shall provide specific requirements for a particular category of machinery within this family, by supplementing or modifying the general/common requirements specified in Part 1 via specific normative references.

In particular, each specific Part X dealing with a specific category of machines contains a statement in the European Foreword as well as in the normative clause specifying requirements that this part is intended to be applied in conjunction with Part 1 of the series (see examples of the sentences below):

- 1. In the Foreword: "This document is intended to be used in conjunction with Part 1 of the series";
- 2. In the normative part dealing with requirements:" [Name of a given category machine] complies with the requirements of [title of the Part 1], as far as not modified or replaced by the requirements of this part."

Therefore, in case of specified requirements from Part 1 being applicable without any additions/modifications for the specific category of machines covered by Part X, then Part X does not need to systematically refer back to the respective clauses of Part 1

¹ Full compliance with 'Internal Regulations Part 3 - Principles and rules for the structure and drafting of CEN and CENELEC documents' shall be ensured.

² The first version of the instruction was developed by CEN-CENELEC Sector Forum on machinery in 2019 and was approved by the EC in January 2020. Since then, the requests for clarification of an additional aspect. This reviewed version clarifies the case where a requirement of Part 1 applies to Part X without any modification. It also brings editorial and linguistic improvements. This second edition of the instruction was approved by the EC and endorsed by the <u>CEN-CENELEC Sector Forum on Machinery in October 2021. It was approved by CEN and CENELEC BTs on XXXXXXXXX</u>

In case when the specifications from Part 1 are not sufficient/not relevant – Part X will additionally indicate one or more of the following:

- a) Which general/common requirements of Part 1 are being supplemented or modified by the technical measures contained in the present Part X, because the general/common requirements are not sufficient for the specific category of machines;
- b) Which general/common requirements of Part 1³ are not applicable because the risk assessment [carried out by the Technical Committee] has shown that for the specific category of machines [covered by the scope of the concerned Part X]:
 - i. The corresponding hazard does not exist and/or
 - ii. No technical solution exists according to the generally acknowledged state of the art and/or
 - iii. There is no need to reduce the risk
- c) Which <u>additional</u> technical measures (not covered by Part 1) are necessary because, the corresponding hazards only exist for the specific category of machines.

2. Presentation of a detailed Annex ZA/ZZ in combination with the corresponding clauses of the standard

From the structure of a multi-part standard series as explained above the following have to be concluded:

Part 1 (a general/common requirement standard) alone cannot provide a presumption of conformity, therefore, the following note shall be inserted at the bottom of the table in Annex ZA/ZZ of Part 1 :

Part 1 (general/common requirements standard)

Table ZA.1 — Correspondence between this European Standard	
and Directive 2006/42/EC	

The relevant Essential Requirements of Directive 2006/42/EC*	Clause(s)/subclause(s) of this EN	Remarks/Notes
1.1.3 Materials and products	4.3.2.2, 4.3.2.5, 4.18, 4.19	

The last row of the table:

*To cover all the relevant Essential requirements for the products(s) in its scope, this standard (providing general/common requirements for a whole machine family) is intended to be applied together with one of those standards as specified in the foreword (providing specific requirements for a particular category of machinery within this family).

The note should appear only once and should not be repeated in all rows.

³ Common requirements are those common to two or more categories of machinery within the whole machinery family dealt with, and therefore they may be not applicable to a certain range of machines belonging to the family.

Annexes ZA/ZZ of Part 1 and Part X have to be applied in the same way in conjunction (together) as corresponding clauses/subclauses of the main body of the Part 1 and the Part X. The commonly specified relevant Essential Requirement (EHSR) in the 1st column of the table ZA/ZZ.1 is functioning as a "bracket" between the corresponding clauses/subclauses specified in relation to this EHSR in the Annexes ZA/ZZ of Part 1 and Part X.

In case when a given requirement of Part 1 covers a corresponding requirement for a particular machine category without additions/modifications/restrictions by Part X, the Annex ZA/ZZ of the Part X shall not refer to the clause of Part 1 covering the respective requirement.

See examples below in relation to the possible constellations as explained under 1. A) to c).⁴

Example for constellation 1. A) from EN 474 series:

EN 474 Part 1 (general requirements standard)

Table ZA.1 — Correspondence between this European Standard and Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC*	Clause(s)/subclause(s) of this EN	Remarks/Notes
1.5.9 Vibrations	<mark>4.4.1.4</mark>	

The last row of the table:

*To cover all the relevant Essential requirements for the products(s) in its scope, this standard (providing general/common requirements for a whole machine family) is intended to be applied together with one of those standards as specified in the foreword (providing specific requirements for a particular category of machinery within this family).

Extracts from the main body of EN 474 Part 1

"4.4.1.4 Vibration

The operator's seat shall meet the requirements of EN ISO 7096:2008 with regard to its ability to reduce the vibration transmitted to the operator.

NOTE Comparative data for vibration can be found in ISO/TR 25398:2006"

EN 474 Part 2 Part X (machine specific standard)

Table ZA.1 — Correspondence between this European Standard
and Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes
1.5.9 Vibrations	4.2	

⁴ Examples are taken from EN 474 series of CEN/TC 151

Extract from the main body of EN 474 Part 2

"4.2 Seat

FprEN 474-1:2019, 4.4.1.4 applies with the following modifications:

The seat shall meet the input spectral according to EN ISO 7096:2008:

- EM6 for crawler dozers less than 50 000 kg operating mass according to ISO 6016:2008;
- EM5 for wheel dozers;
- for crawler dozer greater than or equal to 50 000 kg, see EN ISO 7096:2008."

The clauses of the Part 1 should not be indicated in an Annex ZA/ZZ table of the Part X.

Example for constellation 1. b) from EN 474 series:

EN 474 Part 1 (general requirements standard)

Table ZA.1 — Correspondence between this European Standard and Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC*	Clause(s)/subclause(s) of this EN	Remarks/Notes
3.4.3 Roll-over and tip-over	<mark>4.3.3</mark>	

The last row of the table:

*To cover all the relevant Essential requirements for the products(s) in its scope, this standard (providing general/common requirements for a whole machine family) is intended to be applied together with one of those standards as specified in the foreword (providing specific requirements for a particular category of machinery within this family).

Extract from the main body of EN 474 Part 1

"4.3.3 Roll-over protective structures (ROPS)

Earth-moving machinery with a seated ride-on operator shall be fitted with a roll-over protective structure (ROPS), complying with EN ISO 3471:2008.

EN ISO 3164:2013 applies for deflection limiting volume (DLV)."

EN 474 Part 12 Part X (machine specific standard)

Table ZA.1 — Correspondence between this European Standard and Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes
3.4.3 Roll-over and tip-over		Not applicable for this type of machinery in the scope

Extract from the main body of EN 474 Part 12

"4.3.2.1 Roll-over protective structures (ROPS)

FprEN 474-1:2019, 4.3.3 does not apply for cable excavators"

The clauses of the Part 1 should not be indicated in an Annex ZA/ZZ table of the Part X.

Example for constellation 1. c) from EN 474 series:

EN 474 Part 1 (general requirements standard)

Table ZA.1 — Correspondence between this European Standard and Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC*	Clause(s)/subclause(s) of this EN	Remarks/Notes

The last row of the table:

*To cover all the relevant Essential requirements for the products(s) in its scope, this standard (providing general/common requirements for a whole machine family) is intended to be applied together with one of those standards as specified in the foreword (providing specific requirements for a particular category of machinery within this family).

The table of an Annex ZA/ZZ of the Part 1 does not contain any corresponding line in relation to ESHR additionally.

EN 474 Part 12 Part X (machine specific standard)

Table ZA.1 — Correspondence between this European Standard and Directive 2006/42/EC

The Relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes
1.2.5 Selection of control or operating modes.	4.5.2/4.9.3.2/4.9.3.4/4.9.3.5/ 4.12.2	2

Extract from the main body of EN 474 Part 12

"4.5.2 Operating mode

Cable excavators intended for use in different modes shall be fitted with a lockable operating mode selector for at least:

a) excavator operation mode;

NOTE 1 Excavator operation mode can include e.g. excavating, compaction, demolition.

b) lifting operation mode.

The activation of the selected operation mode shall be optically indicated at the operator's station(s).

NOTE 2 A remote control is also considered as an operator's station."

Presentation of detailed Annex ZA for standard series developed in line with Global relevance principles on the example of EN ISO 3691 series and EN 16307 series

a) The concept (interrelation between EN ISO series and the homegrown series)

The EN ISO 3691 series and EN 16307 series were developed in line with **Global Relevance principles** - Route C (see the doc 'Regional requirements in EN ISO standards_Guidance on the implications of the ISO Global Relevance policy'):

- \rightarrow The (EN) ISO 3691 standards contains core requirements applicable to all regions
- → Requirements needed to address market differences are published in separate ISO Technical Specifications (ISO/TSs) which support the core EN (ISO) 3691 standards: ISO/TS 3691-7 for Europe and ISO/TS 8 – for the rest of the world
- \rightarrow One ISO/TS addresses the differences of the European market: ISO/TS 3691-7
- ightarrow The ISO/TS addressing the European difference is adopted as an the EN 16307 series
- → The EN ISO 3691 standard and the corresponding EN 16307 standard together meet the Essential Requirements of the Machinery Directive (and can provide a presumption of conformity).

Both the base standard series EN ISO 3691 and EN 16307 series are cited in the OJEU.

Regional requirements are not normatively referenced in the base (EN) ISO 3691 standard because they contain different regional requirements.

The approach was discussed and agreed at the Machinery Working group meeting of 1/2 June 2010, among others under agenda item 3.10 (<u>https://ec.europa.eu/docsroom/documents/32101</u> In accordance with this arrangement, the information about the relationships between the documents is given in the European Foreword of the EN ISO 3691 standards.

The main conclusions of relevance for "presumption of conformity" and thereby for the development of a detailed informative Annex ZA are the following:

- i. Both documents (EN) ISO 3691 vs. the corresponding EN 16307 have to be used together in order to provide "presumption of conformity"
- ii. Some clauses of (EN) ISO 3691, which contain an informative reference to ISO/TS 3691-7 (taken over at European level as EN 16307), cannot provide "presumption of conformity".

The consequence of the intended interplay of both standards (EN ISO 3691-1 & EN 16307-1), which have to be used together, is that the Annexes ZA have to be used together, too. The same applies to all other parts (EN) ISO 3691-2 to 6 and EN 16307-2 to 6.

Item i. is made clear for the user of both documents by the following measures:

- (EN)ISO 3691-X contains explanations how to use this standard with regard to regional requirements in its introduction and scope (reference to ISO/TS 3691-7). The future

editions of the (EN) ISO 3691 series will reference the relevant part of the EN 16307 series directly without an intermediate reference to ISO/TS 3691-7.

- the European Foreword of EN ISO 3691-X explains that the regional requirements for Europe specified in ISO/TS 3691-7 have been taken over identically as EN 16307-X at European level.
- EN 16307-X when specifying requirements always establishes the link to the corresponding clauses of (EN)ISO 3691-1 via normative references.

With regard to item ii. those clauses which contain an informative reference to ISO/TS 3691-7 should consequently not appear in the detailed Annex ZA for EN ISO 3691-X.

b) Presentation of a detailed Annex ZA

It is proposed to introduce a general note in the third column of a table of an Annex ZA for these Parts of EN ISO 3691 where an equivalent Part of EN 16307 exists¹ explaining that "presumption of conformity" is only provided for a given Part of EN ISO 3691, if it is used in conjunction with the corresponding part of EN 16307.

EN ISO 3692 Part X

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

The relevant Essential Requirements of Directive 2006/42/EC (MD)	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
		To cover all the relevant safety requirements for the products(s) in its scope, this standard (providing global requirements and references to regional requirements for a machine) has to be applied together with one of those standards as specified in the scope (providing European regional requirements for a machine).
[Per row: an essential requirement]	[The relevant normative clauses linked to the individual essential requirement]	

The note should appear only once and should not be repeated in all rows.

¹ The Part 4 of EN ISO 3691 does not contain the divergent requirements for Europe, therefore, there is will be no corresponding Part of EN 16307

i. There are regional requirements but only for the rest of the world. Therefore, a given regional requirement exists only in ISO/TS 3691-8 whereas it is not covered by ISO/TS 3691-7 and as a consequence is not covered by EN 16307-X.

The example of this case are the requirements on brakes in (EN) ISO 3691-2.

The extract from EN ISO 3691-2:

4.3 Brakes

4.3.1 General

All industrial trucks shall be designed with service and parking brakes. Brakes shall comply with ISO 6292.

The parking brake shall be equipped with a system preventing unintentional release. The parking brake force shall be applied by mechanical means.

Braking requirements are subject to regional requirements, additional to the requirements of this part of ISO 3691. See ISO/TS 3691-8.

For sit-down rider trucks, the parking brake system shall be manually operable from the normal operating position or automatically applied by leaving the normal operating position.

Trucks with only non-automatically applied parking brake(s) shall have a warning to the operator to apply brakes before leaving the truck.

The clause 4.3 **shall be** indicated in the Annex ZA of EN ISO 3691-2 in relation to EHSRs 1.2.1 Safety and reliability of control systems, 1.2.4.1. Normal stop and 3.3.3. Travelling function There **is no** clause on brakes in EN 16307-2 so the clause **will not be** referred to in the Annex ZA of EN 16307-2²

ii. There are regional requirements for Europe. Therefore, a given regional requirement exists in ISO/TS 3691-7 (EN 16307-X).

The example of this case are the requirements on brakes in (EN) ISO 3691-1.

The extract from EN ISO 3691-1:

4.3 Brakes

4.3.1 General

All industrial trucks shall be designed with service and parking brakes. Brakes shall comply with ISO 6292.

The parking brake shall be equipped with a system preventing unintentional release. The parking brake force shall be applied by mechanical means.

Braking requirements are subject to regional requirements, additional to the requirements of this part of ISO 3691. See ISO/TS 3691-7:2011 and ISO/TS 3691-8.

Annex ZA for EN ISO 3691-1 **cannot** indicate the clause 4.3.1. because it refers to European regional requirements

² EN 16307-2 does not have a detailed Annex ZA yet

The extract from EN 16307-1:

"4.4 Brakes

The requirements of EN ISO 3691-1:2015+AC:2016, 4.3.1 shall apply, except the reference to ISO/TS 3691-8, with the following addition:

The parking and service brakes of trucks that can travel with an elevated operator position and/or elevated load above 500 mm, and up to and including 1 200 mm, are subject to the following requirements:

— for travel speeds up to and including 9 km/h, parking brakes shall be in accordance with ISO 6292:2008, 6.1.2 a), and service brakes shall comply with the specifications of ISO 6292:2008, Table 2, Group C;

for travel speeds above 9 km/h, parking brakes shall be in accordance with ISO 6292:2008, 6.1.2 b) and service brakes shall comply with the specifications of ISO 6292:2008, Table 2, Group A1."

The Clause 4.4 shall be indicated in Annex ZA of EN 16307-1