

Drafting a detailed Annex ZA/ZZ under the Machinery Directive

- **Frank WOHNSLAND**
Secretary of CEN/TC 153
- **Joanna FRANKOWSKA**
Project Manager for Machinery
CEN-CENELEC

Tag us @Standards4EU
#MachineryDirective

Structure

1. Introduction
2. The European Commission's request for a detailed Annex ZA/ZZ
3. How to draft a detailed Annex ZA/ZZ?
4. Final remarks

Tag us @Standards4EU
#MachineryDirective

1. Introduction

2. The European Commission's request for a detailed Annex ZA/ZZ
3. How to draft a detailed Annex ZA/ZZ?
4. Final remarks

Tag us @Standards4EU
#MachineryDirective

Role of Annex Z as indicated in European Commission's document

Vademecum on European Standardization, Part III 2.8.4

'All information on legal requirements aimed to be covered by a harmonised standard, and only that information, should preferably be set out in an informative annex to the harmonised standard.'

'The information should be drafted in parallel with the provisions given in the harmonized standard and should be available during the public consultation stages (...).'

The link to the Vademecum is [here](#)

Tag us @Standards4EU
#MachineryDirective

Where to find? (1)

- ▶ **Annex ZA (CEN):** CEN BOSS website: Reference Material/Forms and templates/Technical Work (link is [here](#))
- ▶ **Annex ZZ(CENELEC):** CENELEC BOSS ->Reference Material-> Forms and Templates -> Annex ZZ (link is [here](#))

The screenshot shows the CEN BOSS website interface. The top navigation bar includes 'TECHNICAL STRUCTURES', 'STARTING NEW WORK', 'DEVELOPING DELIVERABLES', 'MAINTAINING DELIVERABLES', and 'REFERENCE MATERIAL'. The 'REFERENCE MATERIAL' tab is selected. On the left sidebar, 'Forms and templates' is highlighted. The main content area shows a breadcrumb trail: 'Home > Reference material > Forms and templates'. Below this, there are sections for 'TECHNICAL BODY ORGANIZATION' and 'TECHNICAL WORK'. Under 'TECHNICAL WORK', a list of links is provided, with a red arrow pointing to the first link: '> [Zip file with all forms and templates](#)'.

The screenshot shows the CENELEC BOSS website interface. The top navigation bar includes 'TECHNICAL STRUCTURES', 'HOMEGROWN DELIVERABLES', 'FRANKFURT AGREEMENT DELIVERABLES', and 'REFERENCE MATERIAL'. The 'REFERENCE MATERIAL' tab is selected. On the left sidebar, 'Forms and templates' is highlighted. The main content area shows a breadcrumb trail: 'Home > Reference material > Forms and templates'. Below this, there are sections for 'TECHNICAL BODY ORGANIZATION' and 'TECHNICAL WORK'. Under 'TECHNICAL WORK', there is a section for 'ANNEX ZZ' with a red arrow pointing to it. Below 'ANNEX ZZ', a list of links is provided: '> Generic template ([EN - FR - DE](#))', '> Ecodesign ([EN - FR - DE](#))', '> EMCD ([EN - FR - DE](#))', and '> LVD ([EN - FR - DE](#))'.

Tag us @Standards4EU
#MachineryDirective

Where to find? (2)

CEN Guide 414:2017, p 25, CEN BOSS website: Reference Material/Reference documents/CEN Guides



- > **CEN Guide 16**: Guide for addressing [chemicals in standards](#) for consumer-relevant products (2017).
[Background information](#) on the Guide (2017).
- > **CEN Guide 17**: Safety of pressure equipment - Rules and recommendations for the drafting and presentation of safety standards
- > **CEN Guide 414**: Safety of machinery - Rules for the drafting and presentation of safety standards (2017)
[German version](#)

English version [here](#), the German version [here](#)

Some formal still very important elements

- ✓ Table
- ✓ Reference of the **current** Standardization Request: **M/396**
(or **M/471** only for standards on pesticide application of CEN/TC 144)
- ✓ Reference of the **current** EU legislation to which a standard provides presumption of conformity
- ✓ **Directive 2006/42/EC**
- +
- ✓ Sectoral arrangements of the CEN-CENELEC machinery sector
Consistency across the sector is required!

1. Introduction

2. The European Commission's request for a detailed Annex ZA/ZZ

3. How to draft a detailed Annex ZA/ZZ?

4. Final remarks

Tag us @Standards4EU
#MachineryDirective

EC request for detailed Annex ZA/ZZ (1)

- ▶ The European Commission will **not accept** any longer the previously agreed full set of options for the format of informative Annex ZA/ZZ as specified in CEN Guide 414:2017 (Option A1, A2, B1 and B2)

<p><i>Option A.2:</i> Within the limits of the scope all <u>relevant</u> essential requirements are covered</p>	<p>All normative clauses except clause(s) <i>yyy</i>³⁾</p>	<p>For relation of normative clauses (except clause(s) <i>yyy</i>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).</p>
<p><i>Option B.1:</i> Within the limits of the scope all <u>relevant essential requirements with the exception of essential requirement(s) <i>xxx</i></u> are covered</p>	<p>All normative clauses</p>	<p>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).</p>
<p><i>Option B.2:</i> Within the limits of the scope all <u>relevant essential requirements with the exception of essential requirement(s) <i>xxx</i></u> are covered</p>	<p>All normative clauses except clause(s) <i>yyy</i>³⁾</p>	<p>For relation of normative clauses (except clause(s) <i>yyy</i>¹⁾) of this standard to significant hazards/relevant essential requirements of 2006/42/EC see informative annex XX „List of significant hazards“ of this ...</p>

EC request for detailed Annex ZA/ZZ (2)

- ▶ Instead the European Commission requires that all harmonised standards contain **a detailed format of an Annex ZA/ZZ**, i.e. **the option C** as foreseen in the CEN Guide 414:2017 → **as many rows in the table as many there are Essential Requirements**

		https://boss.cen.eu/ref/CEN_414.pdf
<i>Option C</i> <i>[Per row: an essential requirement]</i>	<i>[The relevant normative clauses linked to the individual essential requirement]</i>	

- ▶ All final drafts which are submitted by TCs to CCMC for Formal Vote have to contain an Annex ZA/ZZ in such **a detailed format**.
- ▶ Amendments should include the necessary adaptation for the format of Annex ZA/ZZ in mother standards.

Granularity of referenced Essential Requirements (ERs)

- ▶ All ERs 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 ERs are covered in so far as they are relevant;
- ▶ In relation to the first indent, reference to subparts of a numbered ER (subclauses starting with a letter, indent or without any marking) is not required
- ▶ It is acceptable to cover all numbered sub-ERs of a main ERs by making reference to the main ER, only (e. g. covering sub-ERs 1.2.1, 1.2.2 and 1.2.3 by reference to ER 1.2 “Control systems”); but, not accepted to make reference to the entire section of ER 1, ER 2, ER 3, ER 4, ER 5 and ER 6.

1. Introduction
2. The European Commission's request for a detailed Annex ZA/ZZ
- 3. How to draft a detailed Annex ZA/ZZ?**
4. Final remarks

Tag us @Standards4EU
#MachineryDirective

Principal challenge

Introduction of a “paradigm shift”

- ▶ Practical standard work:
 - Committee experts identify significant hazards for the respective machine type
 - Formulate requirements and solutions in the standard
- ▶ For many years: Options like A.2 from CEN-Guide 414 largely used in the machinery field (“Within the limits of scope all relevant Essential Requirements are covered by all normative clauses”)
- ▶ European Commission and national authorities, however, rather need a 1:1-relation to Essential Requirements (ERs) of the Machinery Directive (Option C)
- ▶ This constitutes the framework for Annex ZA/ZZ

Principal challenge

Introduction of a “paradigm shift” (2)

- ▶ First experiences: Many experts simply “took” the hazards as named in EN ISO 12100 and listed them as the basis for Annex ZA/ZZ without checking for their correct link to and “completeness” of ERs
- ▶ No exact match of significant hazards in EN-ISO-standard and ERs
⇒ One reason why so many standards have received negative assessments
- ▶ The identification of relevant ERs will, of course, always remain a task that in the first place has to be carried out by the standard writers
- ▶ Practical support urgently needed because
 - Committee experts are viewing the issue from the technical angle
 - Annex ZA/ZZ is for most standard users (manufacturers, operators) only of limited practical value (i.e. its relevance is not always present)

Drafting the Annex ZA/ZZ

Some practical advice

- ▶ As a first step (relatively easy):
 - Take list of significant hazards in the respective standard and match them against the ESRs of the Machinery Directive (this is in fact the “not sufficient” part)
 - Usually gives a first picture of the content of Annex ZA
 - Then, however, it is indispensable to do a cross-check from the “ESR-side”
- ▶ No standard solution available, and discrepancies in interpretation always possible, but what we can offer:
- ▶ VDMA (hosting the German mirror committee on machinery standardization) has developed a “tool” to help setting up an Annex ZA

Drafting the Annex ZA/ZZ: a formal tool

Automatisches Speichern EHRs vs significant hazards_master (en) zum Drucken.xlsx - Excel

Datei **Start** Einfügen Seitenlayout Formeln Daten Überprüfen Ansicht Hilfe Acrobat Suchen

Einfügen Ausschneiden Kopieren Format übertragen

Zwischenablage Schriftart Ausrichtung Zahl Formatvorlagen

Arial 10 A⁺ A⁻ Textumbruch Text Bedingte Formatierung Als Tabelle formatieren Standard Gut Neutral Schlecht

	A	B	C	D	E	F	G	H
	No	EHRs	Group <small>see CEN Guide 414, Annex D</small>		Significant Hazard <small>see CEN Guide 414, Annex D</small>	Clause/Sub-clause of this standard	"x", if applicable	
1								
2	1.	1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS						
3	1.1.2.	1.1.2. Principles of safety integration				4.1.1	x	
4	1.1.3.	1.1.3. Materials and products	1.1	Mechanical hazards	Due to machine parts or workpieces, e.g. — by mechanical strength (break-up)			
5	1.1.3.	1.1.3. Materials and products	7.1	Material/ substance hazards	Hazards from contact with inhalation of harmful fluids, gases, mists, fumes and dusts	4.1.2		x
6	1.1.3.	1.1.3. Materials and products	7.4	Material/ substance hazards	Biological and microbiological (viral or bacterial) agent	4.1.3		x
7	1.1.3.	1.1.3. Materials and products	9.2	Hazards associated with the environment in which the machine is used	Moisture	4.4		x
	1.1.3.	1.1.3. Materials and products	9.3	Hazards associated with the environment in which the machine is	Pollution			

Tag us @Standards4EU
#MachineryDirective

Drafting the Annex ZA/ZZ: a formal tool (2)

Automatisches Speichern EHRs vs significant hazards_master (en) zum Drucken.xlsx

Start Einfügen Seitenlayout Formeln Daten Überprüfen Ansicht Hilfe Acrobat Suchen

Ausschneiden Kopieren Format übertragen Zwischenablage

Schriftart Arial 11

Ausrichtung

Zahl Standard

Formatvorlagen

	A	B	C
	Essential Requirement of Directive	Clause(s)/ subclause(s) of this EN	Remarks/Notes
1			
2	1.1.2. Principles of safety integration	4.1.1	
3	1.1.3. Materials and products	4.1.2	
4	1.1.3. Materials and products	4.1.3	
5	1.1.3. Materials and products	4.4	
6	1.1.4. Lighting	4.6	
7	1.1.5. Design of machinery to facilitate its handling	4.7.2	
8	1.3.2. Risk of break-up during operation	4.3	
9	1.5.5. Extreme temperatures	4.5.1	
10	2.3. Machinery for working wood and material with similar physical characteristics	4.9	
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			

Drafting the Annex ZA/ZZ - Some practical advice

- ▶ Watch out! This Excel-tool serves two purposes
 - To provide standard experts with a simple method to formally check for compliance of their standard with the ERs
 - To produce a tabled list that can be (if necessary complemented and) easily inserted in the pre-formatted Annex-ZA/ZZ-Table
- ▶ It does, of course, NOT relieve the experts from the task to assess their entries in the resulting table for correctness
 - If, for instance, their own list of identified hazards (which often forms the basis for deciding whether an ER applies or not) is wrong then the Annex-ZA/ZZ-Table will of course also be wrong
 - Not all circumstances can be easily pictured on a 1:1-basis between list of hazards and ERs

Drafting the Annex ZA/ZZ - General advice

- ▶ Highly important: Resolving – as far as possible – Annex-ZA-comments during enquiry saves a lot of trouble during FV
⇒ **Drafting a decent Annex ZA/ZZ already for enquiry draft is highly advantageous**
- ▶ Experience shows:
 - Even small inaccuracies in Annex ZA/ZZ lead to negative assessments
 - “Correction” of non-compliance of Annex ZA/ZZ (subsequent communication between TC and consultant) is still considered a general/technical change
 - If such a negative HAS-consultant assessment arrives AFTER the Formal Vote has been started ⇒ 2nd Formal Vote
- ▶ Hence strong appeal to CCMC:
Please always suspend the FV-start until HAS-consultant assessments are available!

are



Drafting the Annex ZA/ZZ - Further remarks

▶ Recent development:

- Additional request to also list in Annex ZA/ZZ those ERs that are relevant for a specific machine type, but are NOT addressed in the standard
- Up to now, however, no clear indication where/how to put this down in Table ZA/ZZ
- Often uncertainty among committee experts how detailed this requirements is to be understood

▶ Message to EU-Commission from our standard committee CEN/TC 153:

- Please keep in mind: Structure of Annex I in Machinery Directive is more complex than in most other Directives; Option C for Annex ZA/ZZ will therefore always bear potential for discussions
- Listing of harmonized standards in the OJ (no complete overview) may be legally correct, but is extremely difficult to understand for standard users

1. Introduction
2. The European Commission's request for a detailed Annex ZA/ZZ
3. How to draft a detailed Annex ZA/ZZ?
- 4. Final remarks**

Tag us @Standards4EU
#MachineryDirective

Don'ts ⁽¹⁾

- ❌ Don't modify the text above the table
- ❌ Don't add any text below the table
- ❌ Don't reverse the order of the three columns of the table

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

Clauses and subclauses of this EN	Essential Requirements (ERs) of Directive 2006/42/EC
1.1.2 Principles of safety	
a) fitted for its function	6, 5.7, 5.8,
b) eliminate or reduce the risks, give measures, inform	Clauses 5, 6, 7, 8
c) intended use and reasonably foreseeable misuse	Clauses 5, 6, 7, 8
d) constraints in use	7.5, 8.3
e) equipment	6.1, 7.8, 8.3
1.1.3 Materials and products	6.2, 6.5, 6.6, 7.3
1.1.4 Lighting	8.3
1.1.5 Design of machinery to facilitate its handling	5.2, 6.6, 7.5
1.1.6 Ergonomics	7.5
1.1.7 Operating position	5.2, 6.6.4, 6.6.8, 8.3
1.2.1 Safety and reliability of control systems	5.1, 5.6, 5.7, 5.9, 7.11, 7.12
1.2.2 Control devices	5.2, 5.3, 5.4, 5.5, 5.6, 6.6, 8.3

Don'ts ⁽²⁾

- ❌ Don't indicate Clause 1 (Scope) or Clause / Annex with List of Significant Hazards in table
- ❌ Don't indicate Essential Requirements 1.1.1 3.1.1 and 4.1.1 about definitions in table
- ❌ Don't indicate other standards or legislation in the table

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		

Coming soon...

- ▶ EC request to indicate in Annex ZA/ZZ these Essential Requirements which are relevant but not-covered
- ▶ Background: this request is made in the current [mandate for machinery M/396](#)
- ▶ Reviewed template for Annex ZA/ZZ is being clarified with the EC
- ▶ Next steps:
 - to receive clarification from the EC regarding the template
 - to submit to CEN and CENELEC BTs for approval

Thank you for your attention!

Questions?

jfrankowska@cencenelec.eu

www.cen.eu

www.cencenelec.eu