

The Annex Z: drafting guidance and best practices

Online – 12 September 2024



The better the question. The better the answer.
The better the world works.



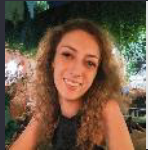
Agenda

1. Introduction
2. Progress of assessment work
3. Best practices for TCs under the HAS system
4. Annex Z
5. Q&A and Closing

EY Core Team



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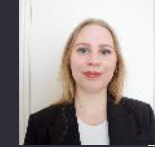
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Technical assistance to the Commission for the assessment of harmonised standards (implementation of Article 10(5) and Article 10(6) of Regulation (EU) No 1025/2012 on European standardisation)

- ▶ **Regulation (EU) 1025/2012** on European Standardisation – Provides frame to standardisation work
- ▶ **Article 10** - Standardisation requests to European standardisation organisations – The Commission may request European standardisation organisations (ESOs) to develop a European standard or a European standardisation deliverable
- ▶ **(Art. 10.5 of Regulation (EU) No 1025/2012)**
“[...] The Commission together with the European standardisation organisations shall assess the compliance of the documents drafted by the European standardisation organisations with its initial request.”
- ▶ **(Art. 10.6 of Regulation (EU) No 1025/2012)**
“Where a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation, the Commission shall publish a reference of such harmonised standard without delay in the Official Journal of the European Union [...]”

The HAS project


is a service to:

- ▶ the European Commission
- ▶ the technical bodies of the European Standardization Organization

Aims to **increase confidence and compliance** of harmonized standards and lead to an **increased publication rate of references** in the OJEU

Main features:

- ▶ Ensure typical compliance concerns are identified to reduce non-compliance
- ▶ Provide targeted training /support to HAS consultants, ESOs, as well as internal EC services
- ▶ ?Support the EC in its efforts to reduce the number of non-cited hENs
- ▶ ?Ensure HAS consultants tasks and resources are focused and limited to the assessments of compliance of candidate hENs



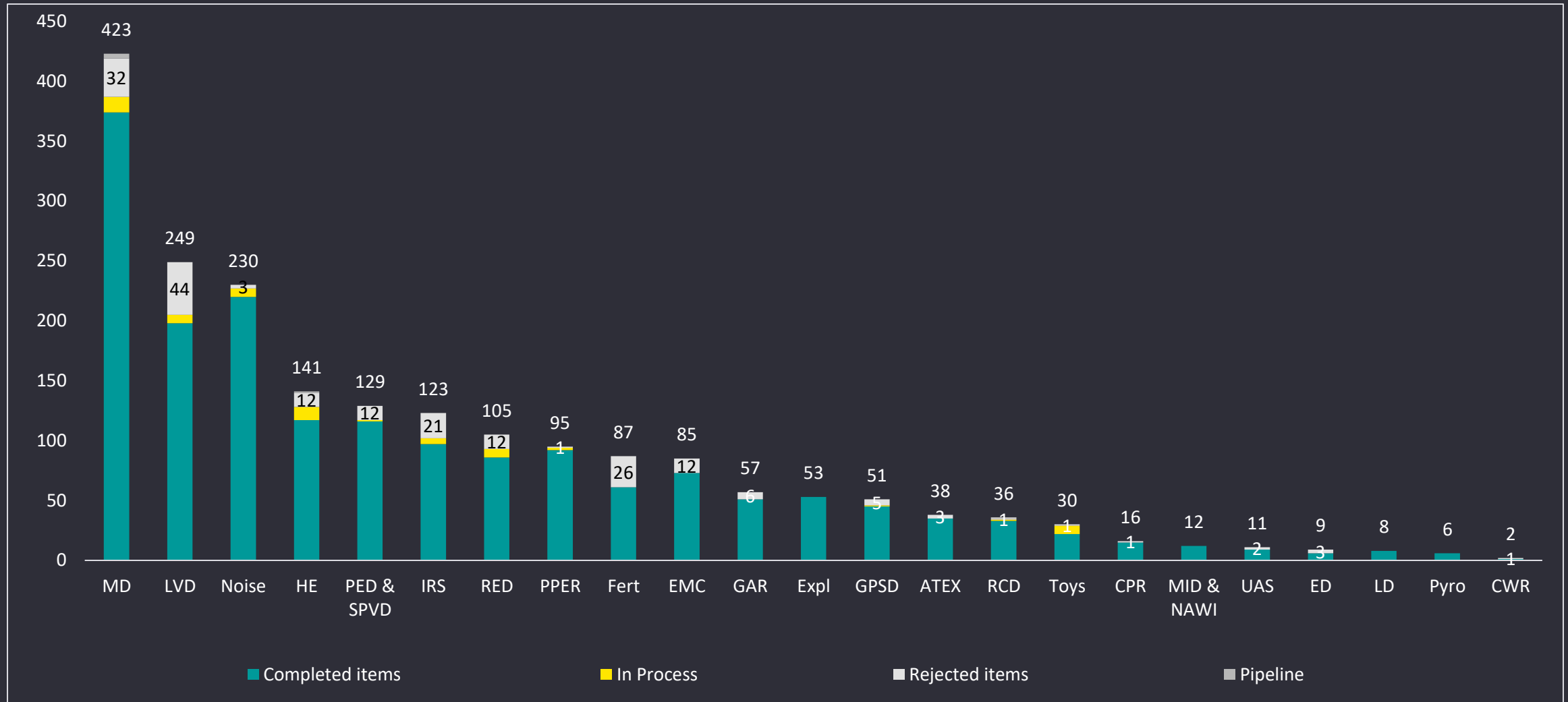
Update on the progress in the
assessment work



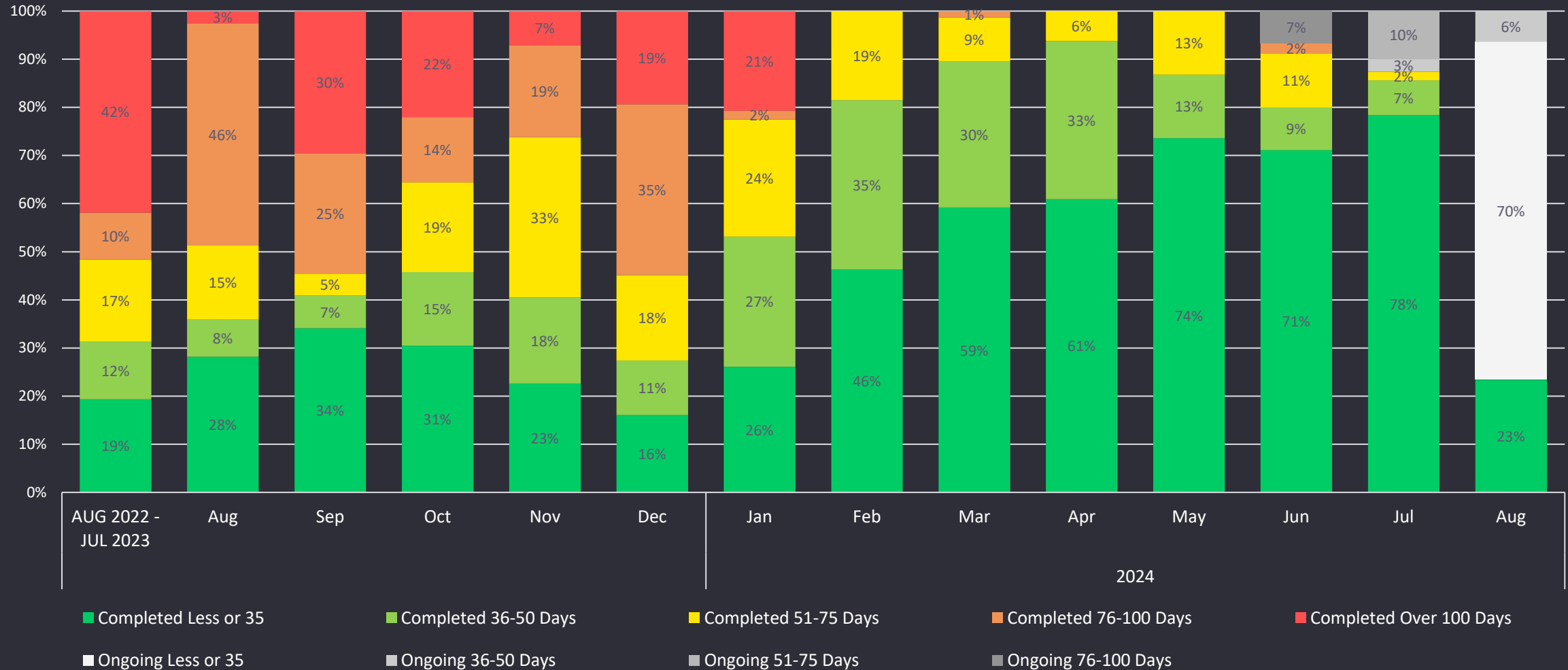
The better the question. The better the answer.
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Total number of requests processed under the HAS project since August 2022 until September 2024



Processing time of AR request since August 2022 until August 2024



Share of outcomes by stage of assessment requests since October 2023

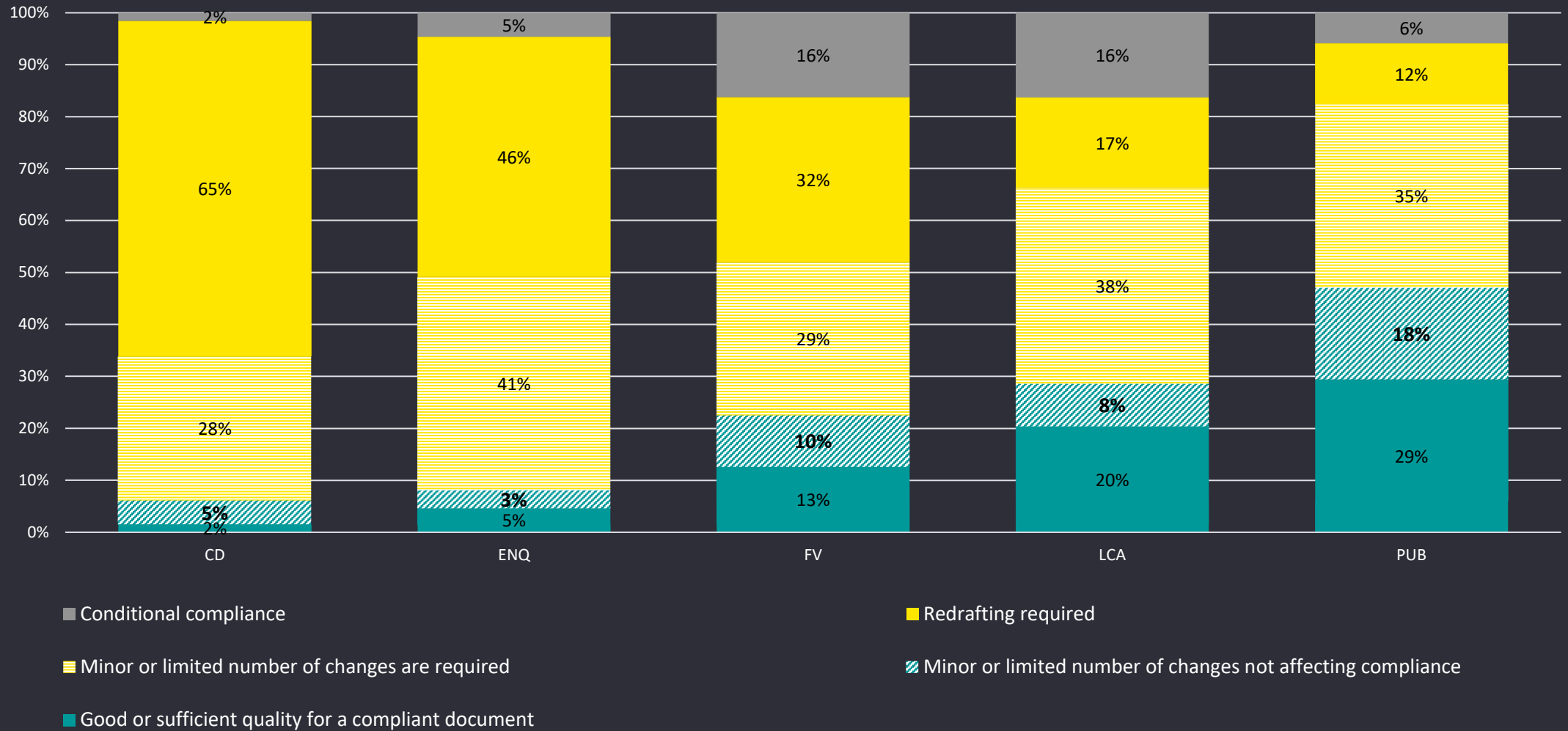
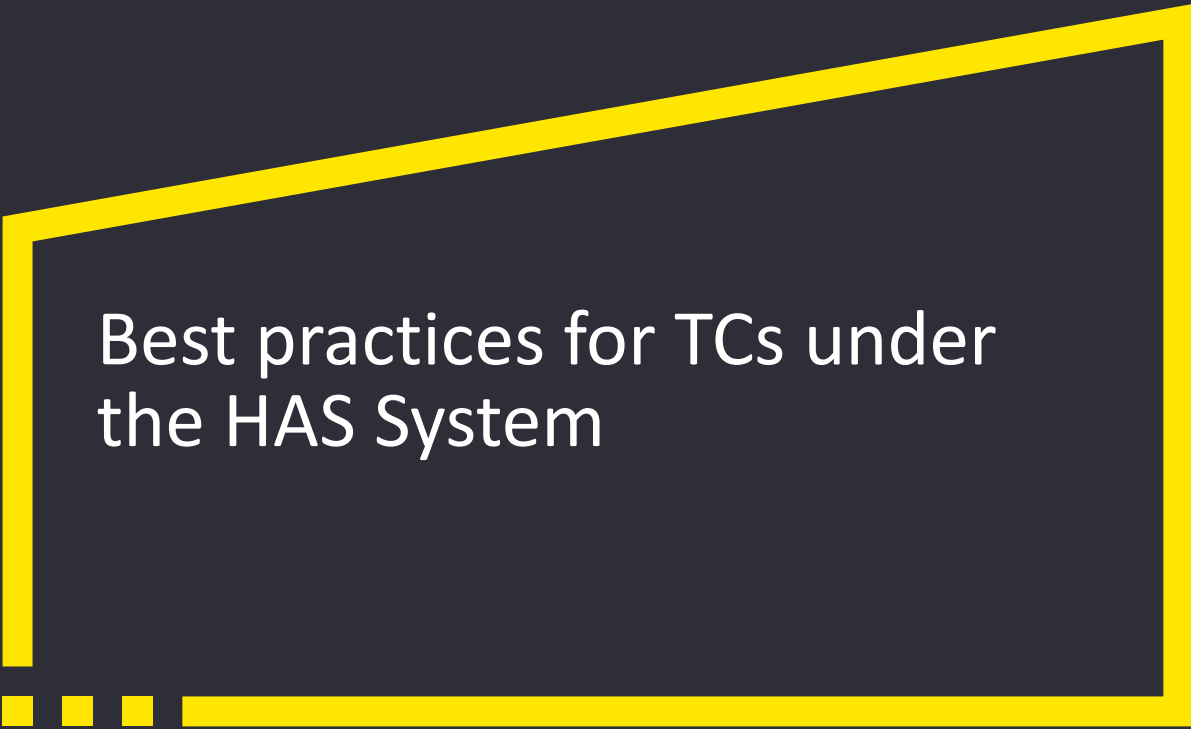


Figure based on 636 analysed reports received between October 2023 and June 2024

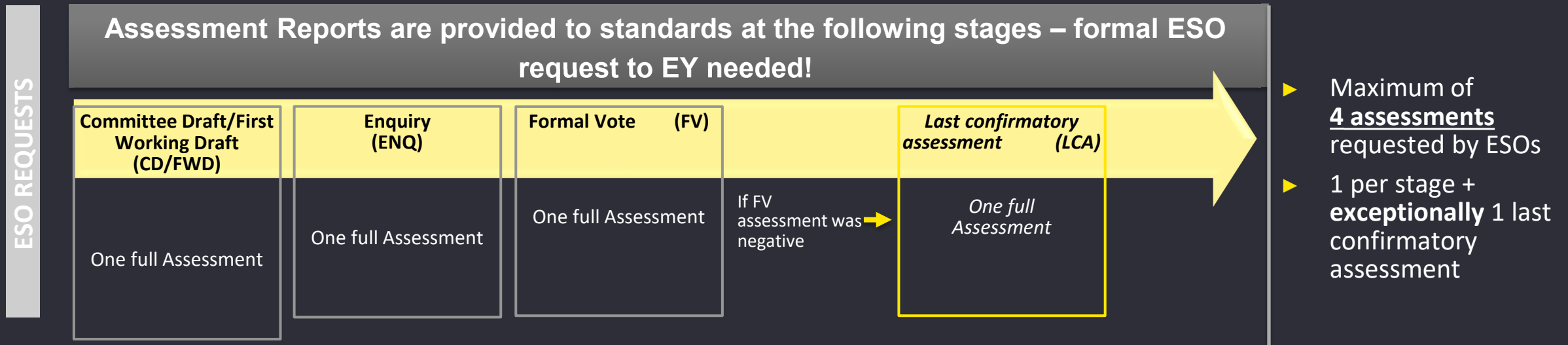


Best practices for TCs under the HAS System



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When to request and assessment and what to expect?



Recap on the role of HAS Consultants:

- ▶ Perform verification and assessment tasks
- ▶ Work in support of but do not represent the Commission
- ▶ Convey the Commission's positions to the ESOs or their technical bodies
- ▶ Are not allowed to modify their report(s) or assess revised documents during meetings with TCs
- ▶ **Do not contribute to the standards development process**
- ▶ The Commission considers but is not bound by the results of the HAS assessment reports

Best practices for TCs when requesting meetings with HAS consultants

- Meeting requests should be submitted about 4 weeks prior to the meeting date
- A full agenda of meeting should be provided to allow the HAS consultants to prepare
- Only meetings linked to a previous assessment are allowed under the HAS project
- Physical meetings are possible but subject to approval by HAS Consultant
- Link to meeting tool: [Link](#)

Reminder on the role of HAS consultants during meetings with TCs

What a HAS Consultant can do

- ▶ Convey the Commission's positions to the ESOs or their technical bodies
- ▶ Participate in meetings to offer clarification on their assessments (but max. 25% of time is spent on meetings)

What a HAS Consultant cannot do

- ▶ Contribute to standards development process
- ▶ Offer guidance to the TCs on how their standards can become compliant
- ▶ Perform assessments on documents received from the TCs/ESOs directly
- ▶ Modify completed assessment reports
- ▶ Participate in meetings without EY approval

Annex Z – non-compliance



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Overview of critical findings leading to lack of compliance

AR ref.	Common Criteria	Fulfilled	Not Fulfilled	% Not Fulfilled
B- 1.2.22	The Annex Z properly relates the relevant legal requirements of EU legislation to the clauses or sub-clauses of the document.	354	268	42.14%
B- 1.2.17	The tests and/or assessment methods are reproducible and appropriate and they can be applied to demonstrate compliance with the legal requirements in an objectively verifiable manner the technical specifications in support of the legal requirement, as indicated in Annex Z.	433	179	28.14%
B- 1.2.21	The Annex Z is sufficiently detailed in describing which clauses or sub-clauses support relevant EU legislation with no ambiguity or need for interpretation. It is granular enough to support the risk assessment and mitigation in a precise manner.	458	156	24.53%
B- 1.2.20	Risk assessment or identification of relevant risks is available or complete and/or there is evidence that all relevant risks were considered. The document clearly specifies in the Annex Z the relevant risks that it does not cover.	434	104	16.35%
B- 1.2.7	The Scope includes products or aspects that are expected to be covered by the standard according to its title or Annex Z in order to support relevant EU legislation and Standardisation Request. This means that there is consistence between the title, the scope and Annex Z.	563	47	7.39%
B- 1.2.5	The Scope covers products, services or aspects not concerned by the relevant legal requirements of EU legislation or the relevant standardisation request, but the organisation/subdivision of technical content and the Annex Z allow to precisely identify the parts in support of the EU legislation.	418	23	3.62%

Figure based on 636 analysed reports received between October 2023 and June 2024

Overview of critical findings leading to lack of compliance by stage

Critical Finding	CD %	ENQ %	FV %	LCA %	PUB %	Overall %
B- 1.2.22 The Annex Z properly relates the relevant legal requirements of EU legislation to the clauses or sub-clauses of the document.	13%	15%	14%	17%	11%	14%
B- 1.2.17 The tests and/or assessment methods are reproducible and appropriate and they can be applied to demonstrate compliance with the legal requirements in an objectively verifiable manner the technical specifications in support of the legal requirements, as indicated in Annex Z.	11%	9%	10%	8%	4%	10%
B- 1.2.21 The Annex Z is sufficiently detailed in describing which clauses or sub-clauses support relevant EU legislation with no ambiguity or need for interpretation. It is granular enough to support the risk assessment and mitigation in a precise manner.	10%	8%	8%	8%	7%	8%
B- 1.2.20 Risk assessment or identification of relevant risks is available or complete and/or there is evidence that all relevant risks were considered. The document clearly specifies in the Annex Z the relevant risks that it does not cover.	6%	6%	4%	10%	4%	6%
B- 1.2.7 The Scope includes products or aspects that are expected to be covered by the standard according to its title or Annex Z in order to support relevant EU legislation and Standardisation Request. This means that there is consistence between the title, the scope and Annex Z.	4%	2%	3%	1%	0%	3%
B- 1.2.5 The Scope covers products, services or aspects not concerned by the relevant legal requirements of EU legislation or the relevant standardisation request, but the organisation/subdivision of technical content and the Annex Z allow to precisely identify the parts in support of the EU legislation.	2%	0%	2%	1%	0%	1%

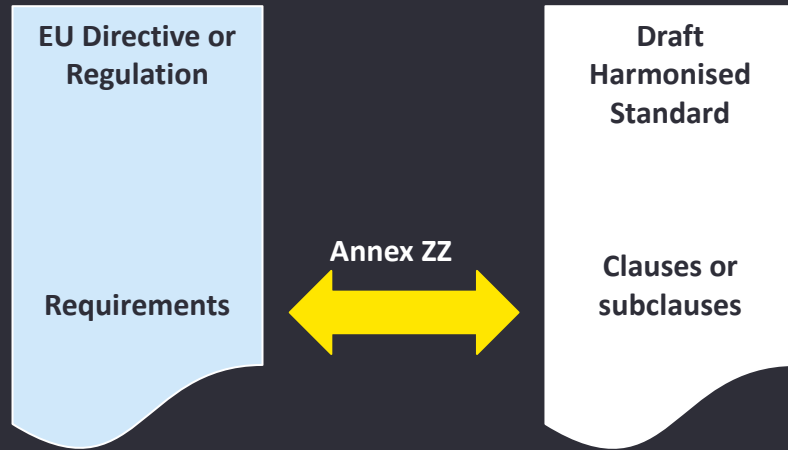
Figure based on 636 analysed reports received between October 2023 and June 2024

An aerial photograph of a large group of triathletes in black wetsuits and white swim caps swimming in clear, turquoise water. A single kayaker in a bright pink kayak is positioned in the center of the group, paddling. The kayaker is wearing a yellow shirt and a white cap. The overall scene is dynamic and captures the intensity of a group swim.

CENELEC specific part

Good practices on Annex ZZ to avoid a lack of compliance assessment

CENELEC: About the Annex ZZ



Annex ZZ

Links:

- Essential Requirements
- Sections of the Standard (relevant clauses or subclauses)

Standardisation perspective:

It is an Informative Annex for the users of the standard

Regulatory perspective:

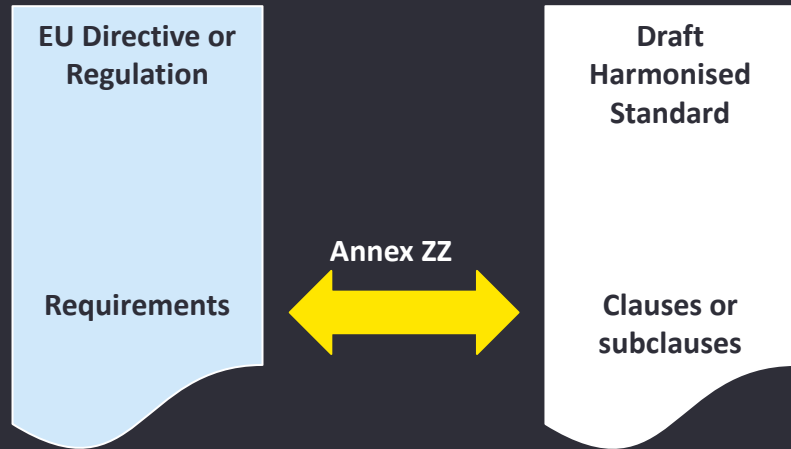
It is important to identify the normative parts of the standards that are necessary to apply to obtain legal effect

It provides transparency on which Clauses or Subclauses apply to obtain presumption of conformity regarding certain requirements of the EU Directive or Regulation

Legal effect (presumption of conformity) only applies if the Standard is cited in the Official Journal under the identified Directive or Regulation

In case of citation in the OJEU with restriction, this will have an impact on the legal effect that could bring applying the standard

CENELEC: About the Annex ZZ



Annex ZZ

Links:

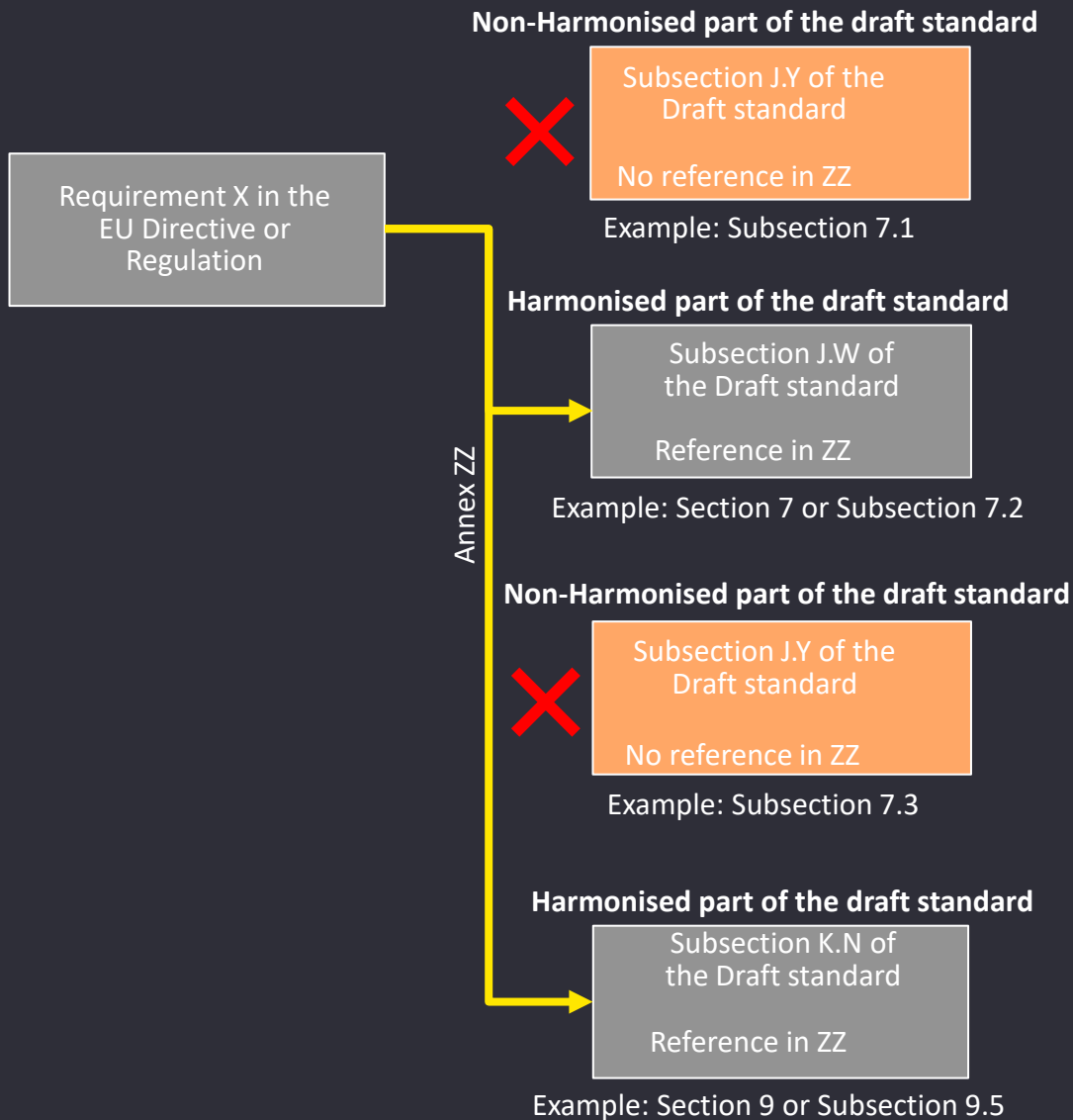
- Essential Requirements
- Sections of the Standard (relevant clauses or subclauses)

- **Mandatory:** Do not refer to Section Scope in Annex ZZ
 - The Scope shall not contain requirements and is not eligible to be cited in Annex ZZ
- **Mandatory:** There shall be consistency between the Title of the Standard, the Scope and the Annex ZZ
- **Mandatory:** Avoid any product or aspect in the Scope that is not covered by the Title of the Standard and/or the Annex ZZ, as this may lead to confusion to the user of the standard
- **Recommendation:** Avoid any reference in Scope on whether the product can be used only by professional or trained staff

Remember: Annex ZZ should not refer to the Scope

- ▶ The scope SHALL NOT contain requirements
- ▶ As a consequence, it can not support the implementation of the Essential Requirements

CENELEC: Harmonised sections or subsections of the draft Standard

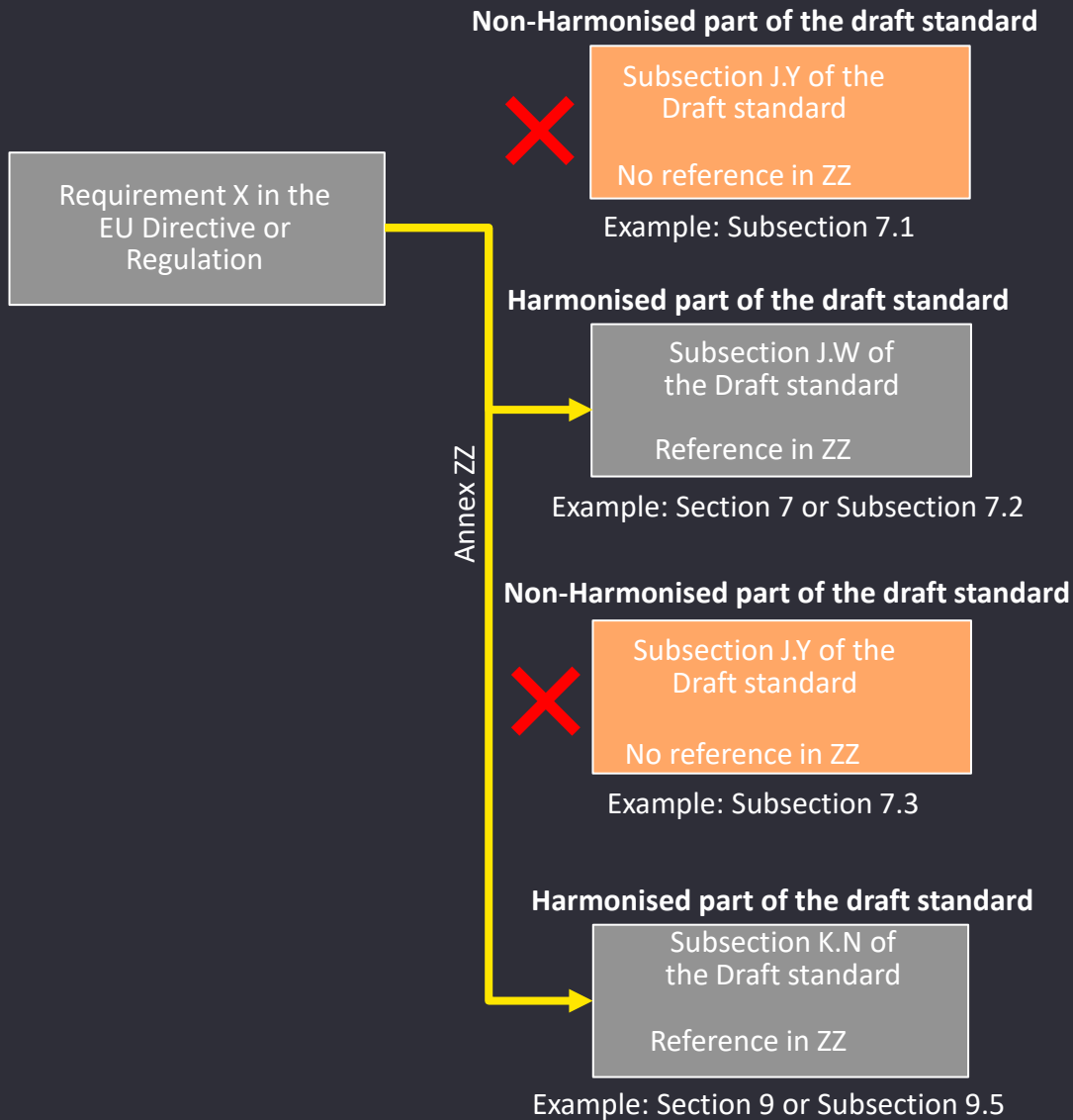


- **Mandatory:**
Put harmonised parts in different sections (clauses or subclauses) of the draft standard than those non-harmonised parts of the draft standard
- **Recommendation:**
It is sufficient that harmonised and non-harmonised parts are in clearly identified and separated subclauses within the same clause.

If they can be placed in different Clauses it is even better.

But this is not mandatory as far as it is clear which section applies or not for each regulatory requirement.

CENELEC: Harmonised sections or subsections of the draft Standard



Mandatory:

- The Annex ZZ is sufficiently detailed in describing which clauses or sub-clauses support relevant EU legislation with no ambiguity or need for interpretation.
- The Annex ZZ is granular enough to support the risk assessment and mitigation in a precise manner.

Proper relation between **Legal Requirements** and **Clauses or Subclauses** of the draft standard

Mandatory:

- ▶ References to informative parts of standard, scope and testing methods **are prohibited** (see next slides)
- ▶ **No reference shall be made to other standards in Annex ZZ**, not even as information or in notes.
 - ▶ Annex ZZ is not the place to refer to other standards
 - ▶ **The right place to refer to other standards** in the context of harmonization **are the sections or subsections that are listed in the Annex ZZ**, but not the Annex ZZ itself
 - ▶ **No reference to Part 1 shall be done in Annex ZZ**, the same as any other standard
 - ▶ **According to CEN and CENELEC Internal Regulations, Part 1 of a standard is to be considered a normative reference** (further analysis in the case of Type A, B and C standards under the Machinery Directive/Regulation)

Proper relation between **Legal Requirements** and **Clauses or Subclauses** of the draft standard

Recommended (but soon to become a general rule):

- ▶ Listing **all applicable and non-applicable essential requirements** in the Annex ZZ could be a good practice
 - ▶ Mandatory: **Check your Standardisation Request, as this is becoming a requirement in many of them**
- ▶ This recommendation should only be considered if this measure does not introduce many unnecessary pages in the standard
 - ▶ A way to measure this is, for instance, if there is a long list of essential requirements and around 80% of them will be shown as “non-applicable”. In this case, it is better not to list all the essential requirements
- ▶ Mandatory: To indicate if each Essential Requirement is:
 - ▶ **Covered** (to indicate in which sections/subsections the ER is covered)
 - ▶ **Partially covered** (in which sections/subsections) or **Not Covered**, or
 - ▶ **Not applicable**

Assessment methods or tests

Mandatory:

- ▶ Assessment methods and Test methods
 - ▶ are indicated in the harmonised section to demonstrate compliance with the relevant Essential Requirements (in the same section, or in other sections of the draft standard, or via normative reference to another standard)
 - ▶ are reproducible and appropriate to the Essential Requirements
- ▶ Annex ZZ shall refer to the section containing the requirements (which will contain or refer to the test/assessment methods), but shall not refer to sections containing assessment or test methods alone.
- ▶ Unless the Essential Requirement refers to Assessment or Test Methods

Examples of this nature can be found in the Essential Requirements of the Machinery Regulation

Recommendations:

- ▶ Taking into account that Assessment methods or Test methods may apply to both harmonised or non harmonised sections of the standard, in this case it may be a good practice that both harmonised and non harmonised sections of the standard refer to the same section or subsection containing the applicable test methods

Do not refer to other standards in the Annex ZZ

Annex ZZ is not the place to refer to another standard, even if it's a part 1 of the same series of standards (some exceptions to be further analysed in the case of Machinery Standards – types A, B and C)

Mandatory:

- ▶ Avoid any reference to another standard

Recommendation:

- ▶ If reference to another standard is needed, then the TC shall introduce it in the harmonised part of the standard and then refer to that part in Annex ZZ

Example for CENELEC: Reference in Annex ZZ to clauses or subclauses of another standard that is not explicitly referred to in the draft standard

- ▶ Annex ZZ of draft prEN 6XXXX-15 refers to sections of EN 6XXXX-1 that are not even referred to in the harmonised sections or subsections of the draft standard

Two issues arise here:

- ▶ Reference to another standard in Annex ZZ
- ▶ The standard that is referred to is not even included in the normative references

Recommendation:

- ▶ The Annex ZZ refers to a section or subsection that contains the reference to sections of EN 6XXXX-1
- ▶ EN 6XXXX-1 is cited in normative references

(some exceptions to be further analysed in the case of Machinery Standards – types A, B and C)

Do not refer to other requirements than the Essential Requirements in Annex ZZ

Sections or Subsections of the draft Standard that address **requirements** that are **not Essential Requirements**

- do not provide legal effect
- shall not be referred to in the Annex ZZ
- and this means sections addressing other requirements **shall not be referred to**
 - directly in the Annex ZZ, or even
 - Indirectly
(by referring in the Annex ZZ to a section that refers to another section containing the requirement)

Example for CENELEC: Referring to informative sections of a draft standard

- ▶ Only sections or subsections containing requirements of the draft Standard shall be referred to in Annex ZZ

HAS8		ANNEX ZZA		<u>Te</u>	Annex ZZ refers to Informative annex F. Informative parts of the standard can not be used as they do not contain any requirements		
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- ▶ If clauses contain elements of other pieces of legislation, please move them to other subsections

HAS7		Annex ZZA		<u>Te</u>	<p>Following the exchanges between TC and consultant (previous assessment):</p> <p>Annex ZZ refers for almost all safety objectives to clause 5,6,8. A granularity to subclause level would be better suited.</p> <p>E.g. (non-exhaustive) –</p> <ul style="list-style-type: none"> - Clause 5 contains mostly definitions, only a couple of subclauses contain requirements that <u>actually matter</u>. - Clause 6 contains subclauses that may be related to other legislation like RoHS (§6.4) - Clause 8 contains subclauses on EMC that are not needed for LVD - Subclause 9 contains non-safety related tests: EMC, power <u>factor,....</u> . 		
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Recap: Recommendations

- ▶ Before drafting the Annex ZZ, the TC should have identified the risks of the product or aspect to be covered by the standard
- ▶ Annex ZZ shall clearly indicate if the risks are [fully] covered, partially covered or not covered

- ▶ Do not mix under the same section or subsection harmonised and non-harmonised parts (sufficient granularity)
- ▶ Do not mix under the same section or subsection requirements from different pieces of legislation if not sufficient granularity is given
- ▶ Do not refer in Annex ZZ to legal requirements that are not the Essential Requirements

- ▶ Do not refer to other standards or part of standards in Annex ZZ
- ▶ Refer to sections or subsections that refer to these standards

- ▶ Do not refer to sections or subsections containing informative parts or parts without requirements
- ▶ Refer to sections or subsections containing requirements (or requirements and test methods)



Thank you for your attention!

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