

TRAINING CEN & CENELEC NEWLY APPOINTED TECHNICAL BODY OFFICERS

Harmonized Standards development (for OJEU citation)

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Agenda

- I. Innovative Process for homegrown harmonized standards
(key principles)

- II. Preparation of harmonized standards in the international context

- III. CCMC Quality Check

- IV. A-deviation in harmonized standards

Glossary

- CCMC: CEN and CENELEC Management Center
- CD: Committee Draft
- EC: European Commission
- EN: European Standard
- HAS: Harmonized Standard
- hEN: Harmonized European Standard
- FV: Formal Vote
- NSB/NC: National Standardization Body (CEN)/National Committee (CENELEC)
- OJ/OJEU: Official Journal / Official Journal of the European Union
- PM: Project Manager
- QC: Quality Check
- SRAHG: Standardization Request Ad-Hoc Group
- SREQ: Standardization Request
- TB: Technical Body
- TBO: Technical Body Officer
- TC: Technical Committee
- WD: Working Draft
- WG: Working Group
- WI/NWI: Work Item / New Work Item

Innovative Process for homegrown harmonized standards (*key principles*)

- ▶ Challenging to get a “compliant” assessment outcome
- ▶ “Innovative process” designed and approved
- ▶ Goal: improve the timely delivery of compliant harmonized Standards



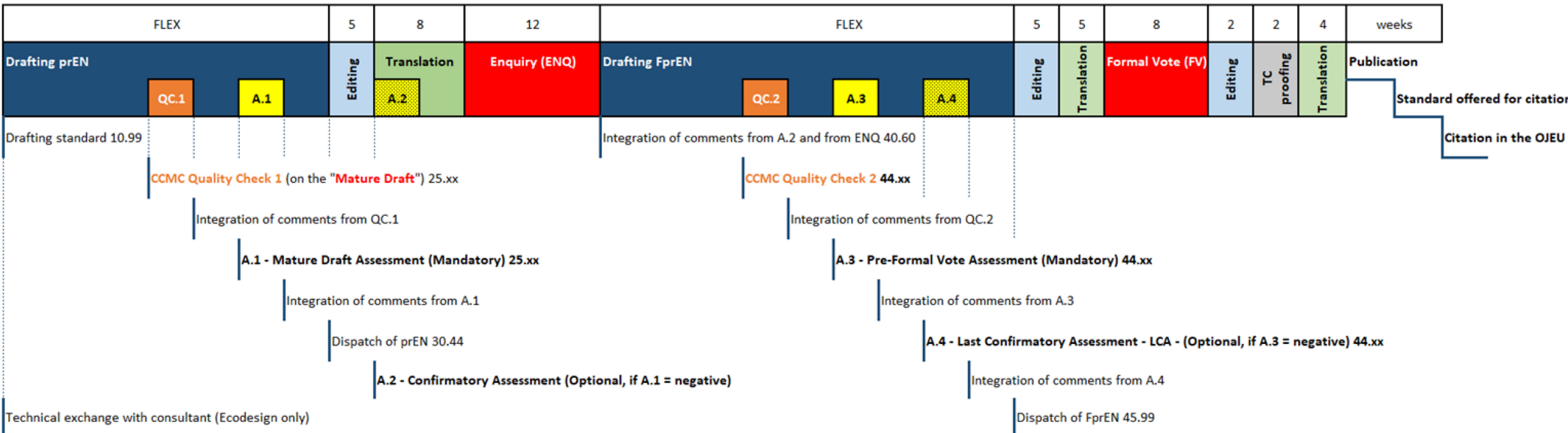
Innovative process based on 2 main pillars:

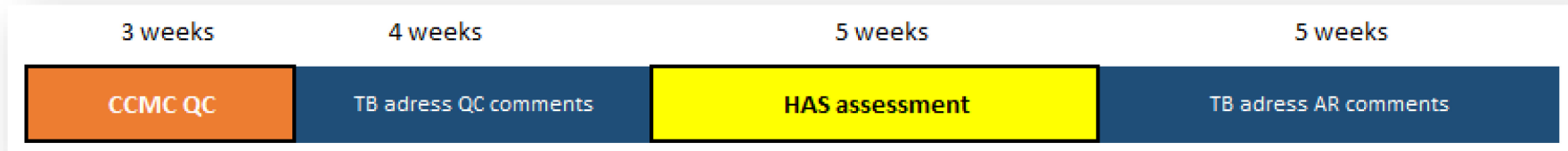
- ▶ Mature draft concept
 - ▶ Draft ready for ENQ
 - ▶ Mature draft assessment **mandatory**
 - ▶ Optional FWD assessment **not possible** anymore (while FWD circulation still possible)

- ▶ CCMC Quality Check
 - ▶ help Technical Bodies identify elements in the draft, or the related Annexes, that could potentially lead to a lack of compliance assessment
 - ▶ Uses Common checklist as support document
 - ▶ Replaces “Harmonized Standards checklist”

Process

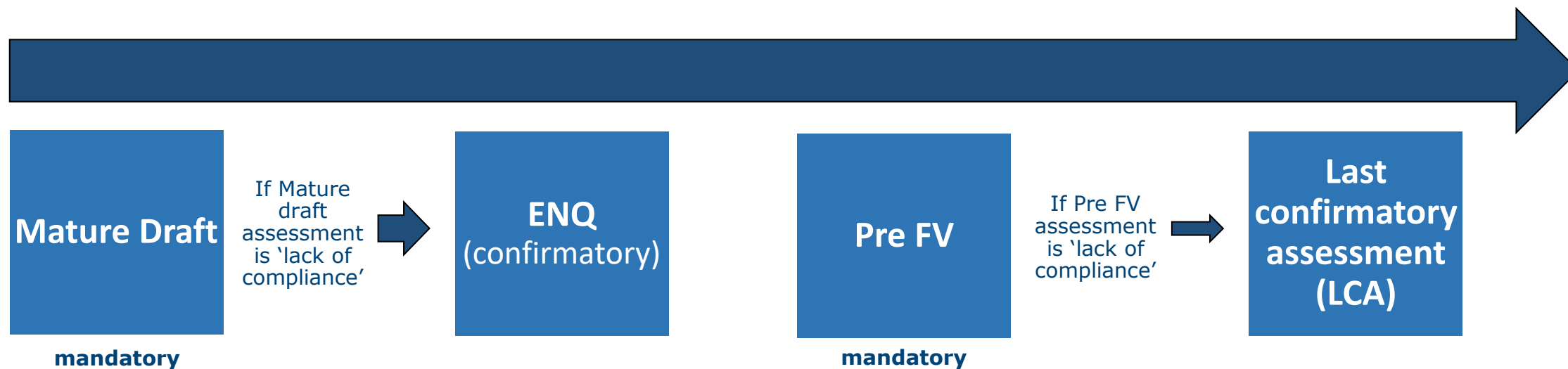
Homegrown candidate hEN for citation





- ▶ Anticipate WG meetings before requesting CCMC QC/HAS assessment
- ▶ TB to prepare Annexes early, in // with draft development
- ▶ TB shall send filled-in Common Checklist, draft and Annexes to CCMC for QC

When to request an assessment



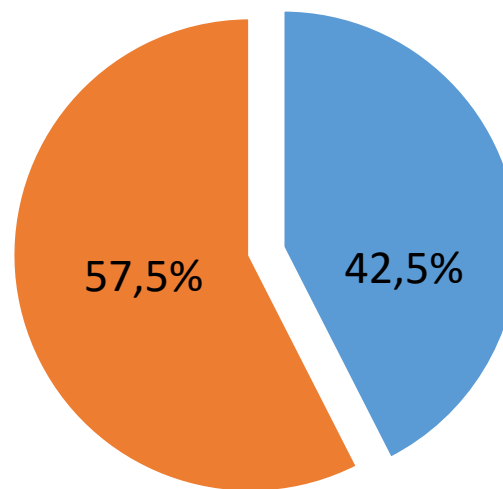
- ▶ Maximum 4 assessments per WI
- ▶ LCA: full assessment, should become exceptional
- ▶ Not possible to request assessments of published standards

Harmonized Standards in the International context

Vienna Agreement

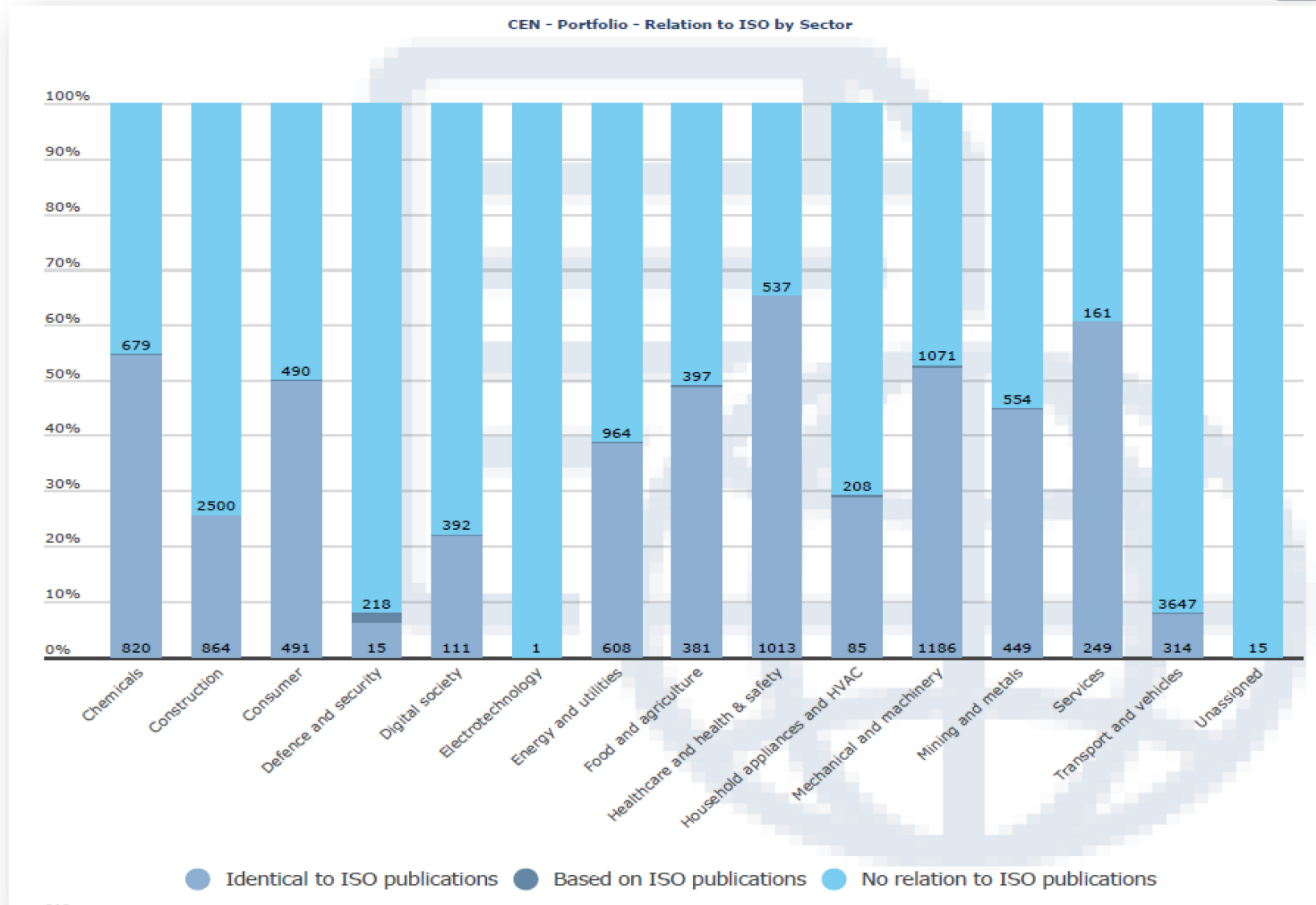
What?	When?	Why?
<ul style="list-style-type: none">• Formal agreement on technical cooperation between ISO and CEN	<ul style="list-style-type: none">• 1991 - Published• 2001 - Revision• 2016 'Guidelines on implementation'	<ul style="list-style-type: none">• Avoid duplication of work at International & European levels• Promote global economy• Ensure rational use of back office resources

CEN – Portfolio – relation to ISO



■ Identical to ISO publications ■ No relation to ISO publications

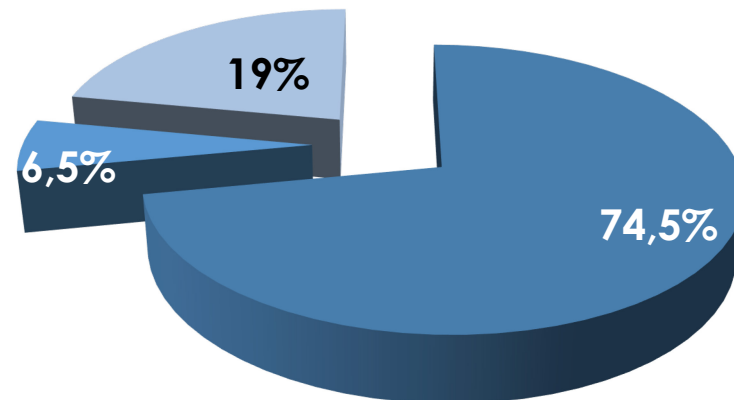
VA facts and figures



Frankfurt Agreement

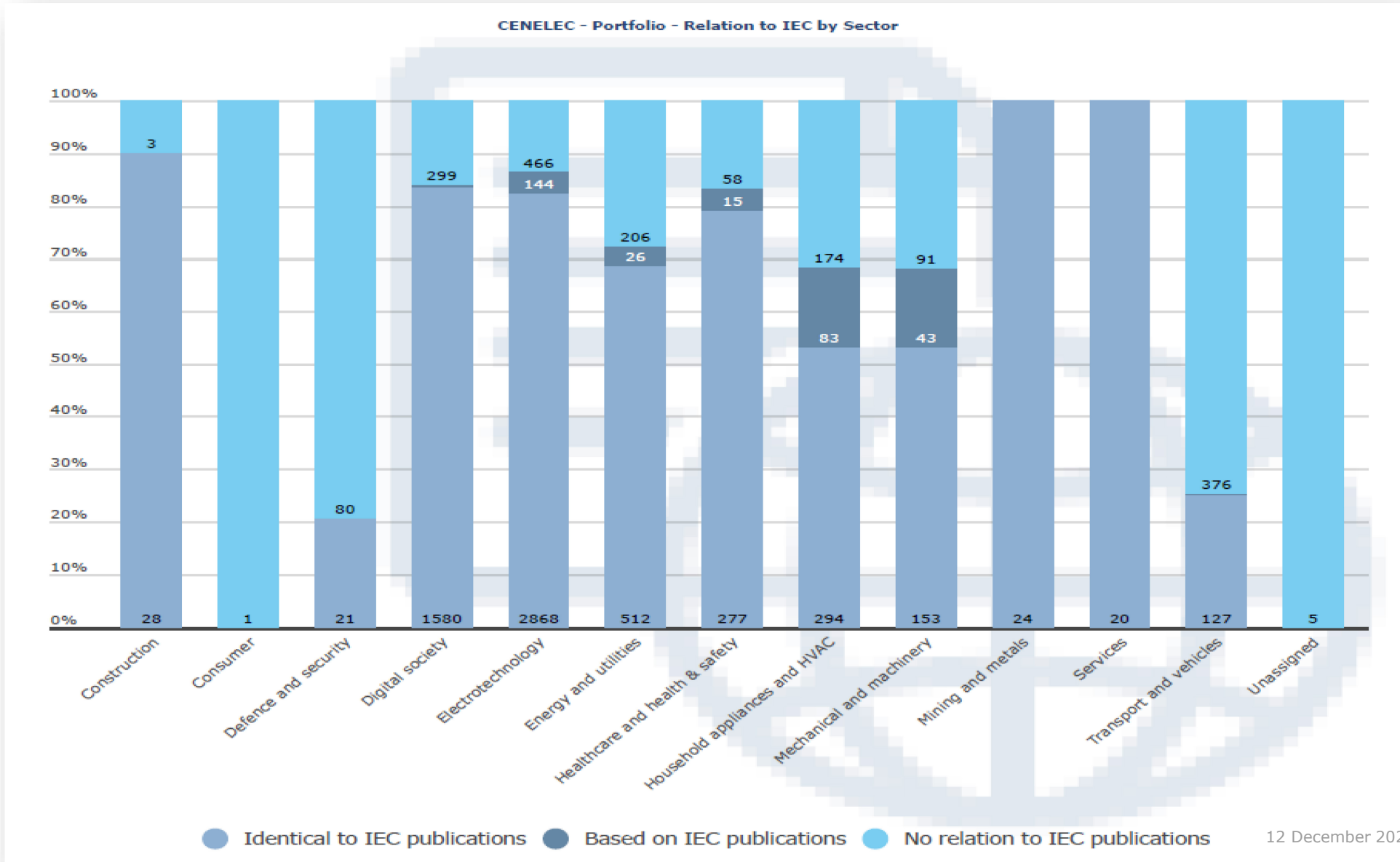
What?	When?	Why?
<ul style="list-style-type: none">• Agreement on common planning of new work and parallel voting between IEC and CENELEC	<ul style="list-style-type: none">• 1996 – Signature Dresden Agreement• 2016 – Signature Frankfurt Agreement	<ul style="list-style-type: none">• Underline commitment of IEC & CLC to undertake work at Intl. level• Promote global economy• Ensure rational use of back office resources

CENELEC – Portfolio – relation to IEC



- Identical to IEC publications
- Based on IEC publications
- No relation to IEC publications

FA facts and figures



Key factors for the International Standardization process:

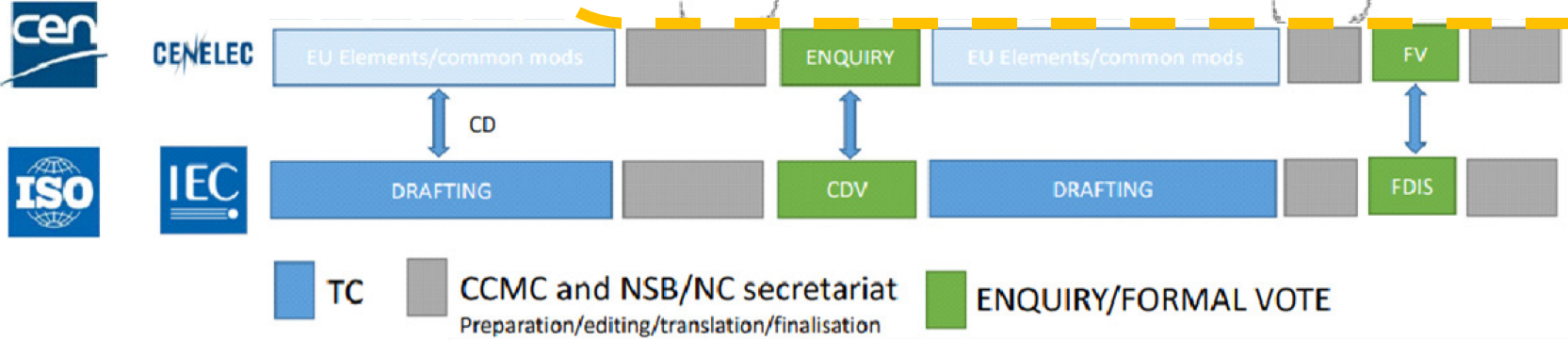
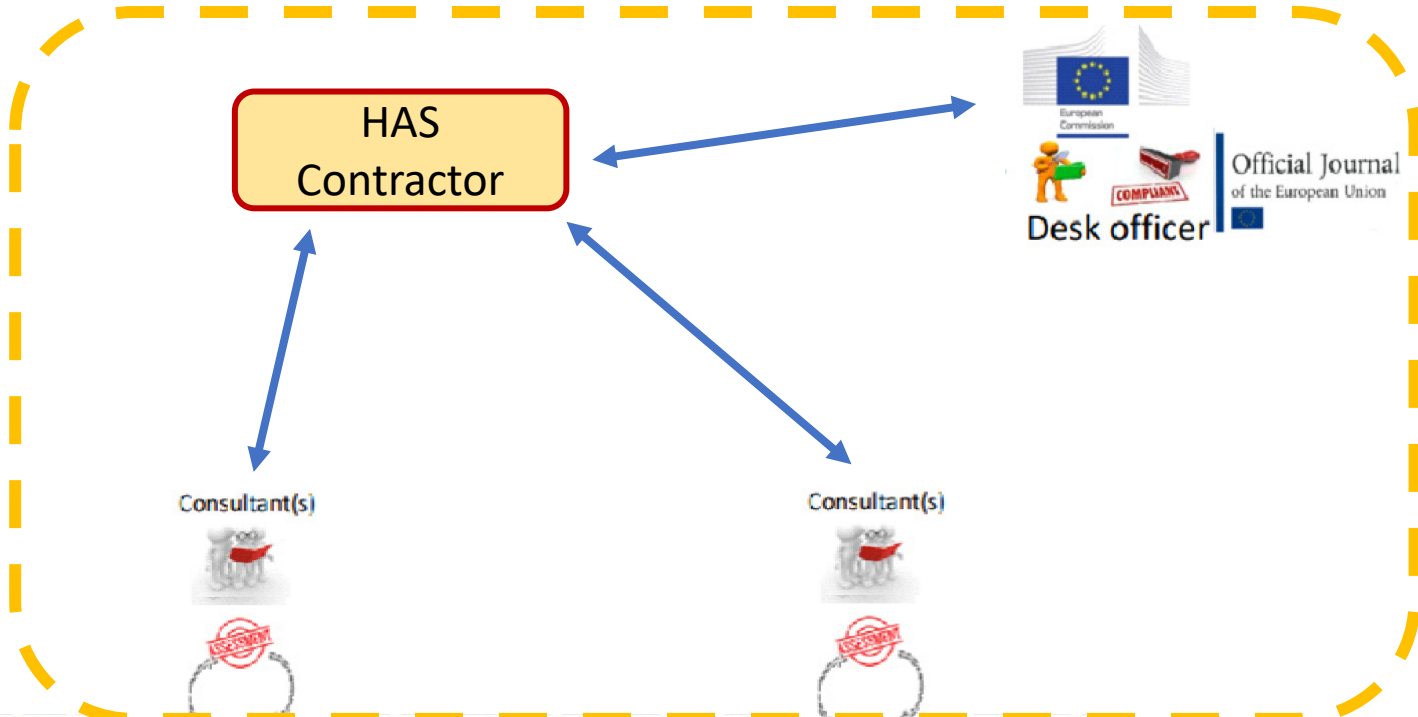
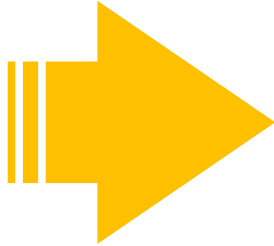
- ▶ **Consensus-Building** at European and International level
- ▶ **Strong Communication and Coordination** between the European TC and the International TC (specific role for secretaries, convenors and TPM)

For Harmonized ENs

The same Standard applies Worldwide and provides presumption of conformity to the European Legislation

Parallel Projects Process

For Harmonized EN



'New' Process for Parallel Projects (hENs)

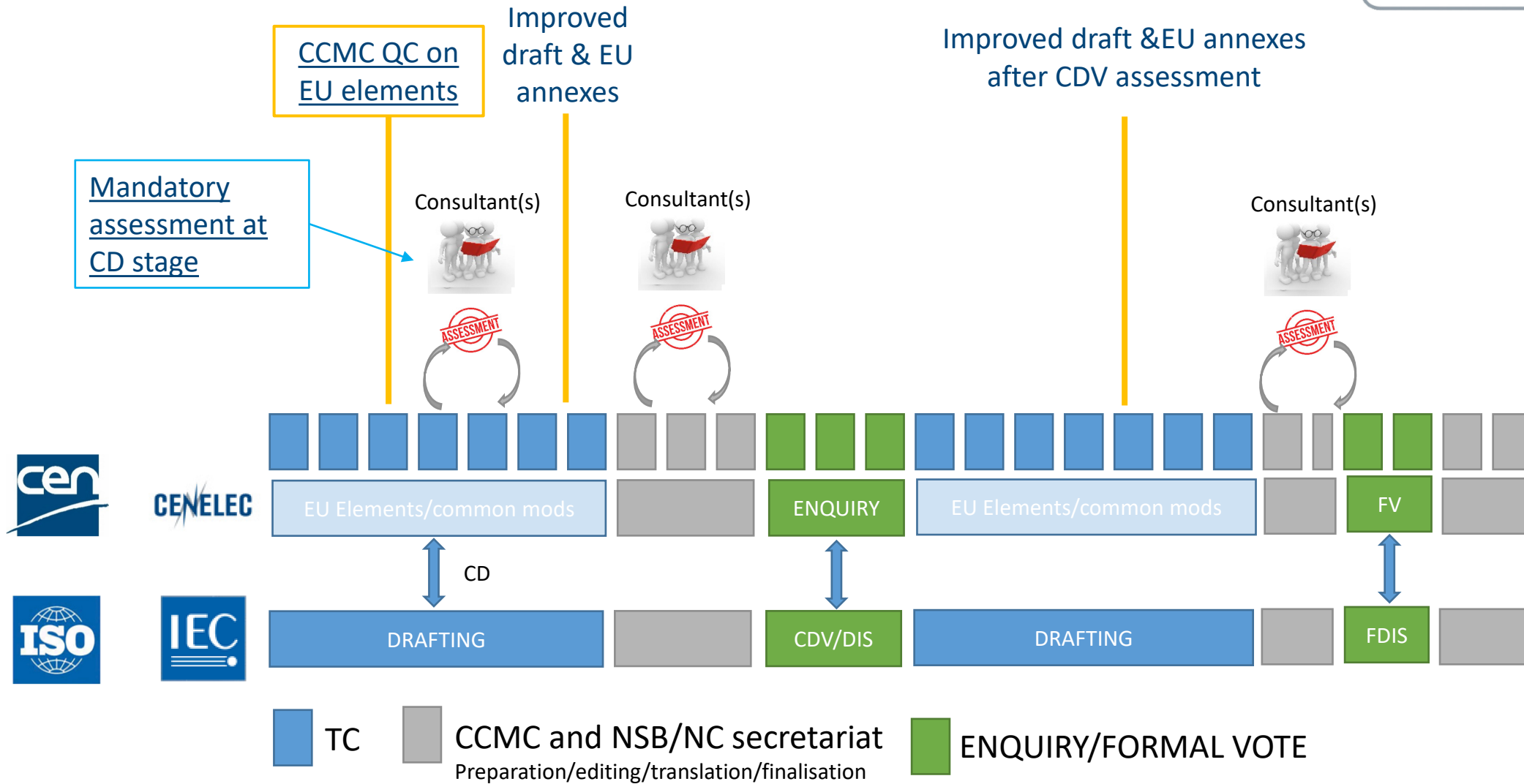
Process intended to:

- ▶ Improve timely delivery for parallel ISO/IEC Harmonized Standards
- ▶ Avoid blocked draft Standards before Publication
- ▶ Minimize interference with International Projects timeframe

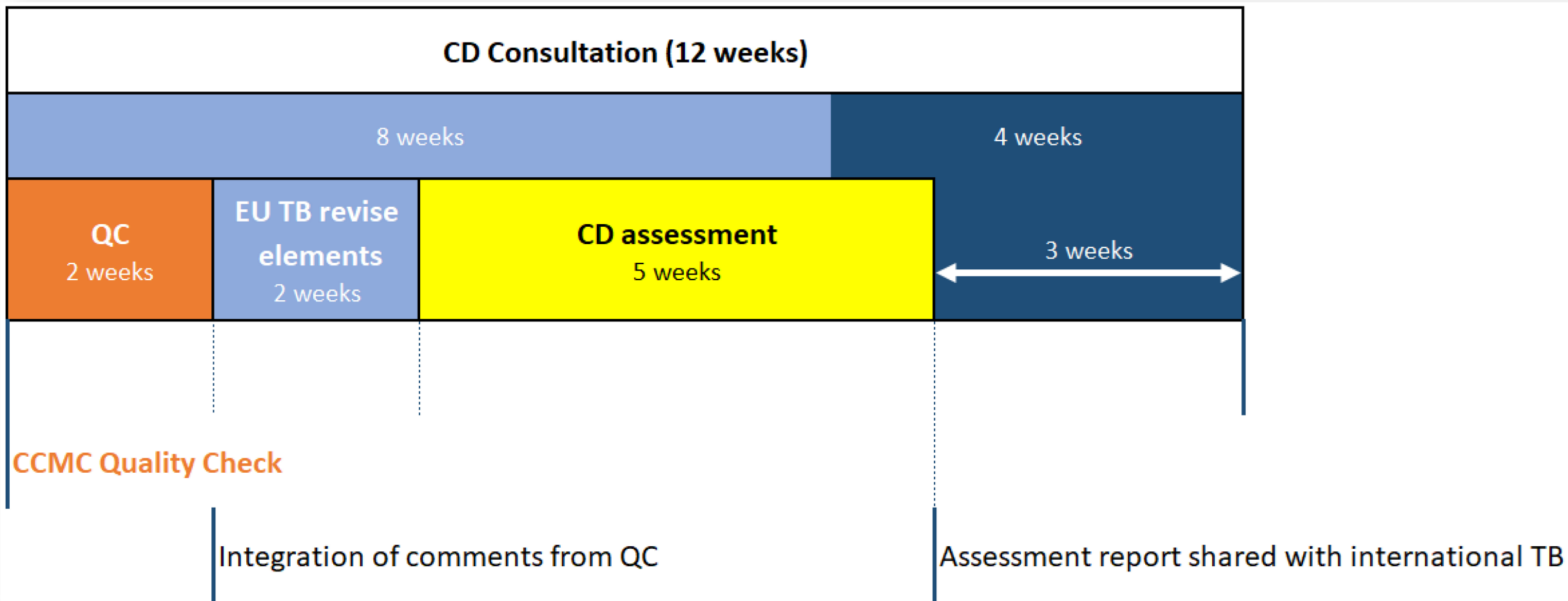
'New' Process for Parallel Projects (hENs)

- ▶ Early awareness of candidate Harmonized Standards at ISO/IEC.
 - ▶ At the start of the CD consultation (if any), ISO and IEC secretariats circulate the Committee Draft (CD) to CCMC.
 - ▶ CD CCMC Quality Check on European Elements, if certain conditions are met.
 - ▶ Mandatory CD HAS Assessment, if certain conditions are met.
 - ▶ HAS Assessment Report officially transmitted to International TCs
- **'New Process' (hENs) only impacts CD stage**

'New' Process for Parallel Projects (hENs)



CD consultation



ISO

CCMC CD Quality Check on EU Elements **only** performed when:

- ✓ Elements are provided by CEN/TC
- ✓ EU Elements are **not** included in ISO CD text
- ✓ CD consultation is above 8 weeks



CCMC CD Quality Check on EU Elements



Summarized process for **ISO**:

	CCMC QC	CD Assessment
No ISO CD	NO	NO
ISO CD with Annex ZA included	NO	YES

ISO CD **without** Annex ZA included:

CD = 8 weeks & Annex ZA delivered by CEN/TC	NO	YES
CD > 8 weeks & Annex ZA delivered by CEN/TC	YES	YES

CEN/TC to provide Annex ZA as soon as CD is available

IEC

CCMC CD Quality Check on EU Elements **only** performed when:

- ✓ Elements are provided by CLC/TC
- ✓ CD consultation is above 8 weeks



CCMC CD Quality Check on EU Elements



Summarized process for **IEC**:

	CCMC QC	CD Assessment
No IEC CD	NO	NO
IEC CD = 8 weeks & EU Annexes delivered by CLC/TC	NO	YES
IEC CD > 8 weeks & EU Annexes delivered by CLC/TC	YES	YES

CLC/TC to provide Annexes ZA and ZZ as soon as CD is available

Key points

- ▶ Start the process as early as possible
 - ▶ European TC invited to closely follow work at international level and to develop Annex Z in parallel with CD draft
- ▶ 'New' Process will only apply if:
 - ▶ CD available
 - ▶ European Elements available
- ▶ Communication is key
 - ▶ Ensure communication flows between CEN/TC, CLC/TC (interaction with the HAS consultants) and ISO/TC, IEC/TC (writing the standard)
- ▶ Common checklist not mandatory, but highly recommended when drafting European Annexes



Useful Links for Parallel Projects

▶ **Vienna Agreement (ISO and CEN)**

- ▶ Vienna Agreement – [here](#)
- ▶ Guidelines for the implementation of the Vienna Agreement - [here](#)
- ▶ Implementation: Day to Day management document - [here](#)

▶ **Frankfurt Agreement (IEC and CENELEC)**

- ▶ CENELEC Guide 13 'IEC - CENELEC Agreement on Common planning of new work and parallel voting' - [here](#)
- ▶ Implementation: Day to Day management document - [here](#)

CCMC Quality Check

Main reasons for Lack of Compliance (status: November 2024)



Non-Compliance Data – Top 10 Reasons for Non-Compliance (status: 12/11/2024)

AR ref.	Critical finding	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.	358	44%
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	221	27%
B- 1.2.14	The normative part of the document is written in a clear way so users will know which specification applies to address EU legal requirements and there is no room for arbitrary choices.	205	25%
B- 1.2.8	All the normative references are available at the time of the assessment.	197	24%
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.	197	24%
B- 1.2.11	All the normative references reflect the state of the art (e.g. not withdrawn standards) and have a relevance for the compliance with EU legislation.	179	22%
B- 1.2.9	The document contains exclusively dated normative references or, if it does not, there is an accompanying acceptable justification for the use of specific undated normative references.	154	19%
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.	140	17%
B- 1.2.13	The normative part of the document only contains requirements that are coherent with EU legislation (e.g. the technical content supports legal requirements, specifies 'technical solutions', or does not conflict with parallel applicable legislation.	72	9%
B- 1.2.10	The document contains limited and coherent chains of publicly available normative references that are needed when applying the harmonised part of the document.	70	9%

*n=814 completed assessments under new assessment template



Quality Check Procedure

- ▶ Quality Check only performed at:
 - Mature Draft stage
 - Pre-Formal Vote stage

- ▶ NEW Common Checklist for Harmonized Standards is the basis of the CCMC Quality Check

- ▶ Only Criteria linked to IR3, Normative References and Annex ZA/ZZ are checked

New EC-ESOs Common Checklist

▶ Goal:

- ▶ support Technical Bodies in drafting hEN
- ▶ Increase HAS assessment 'Compliant'
- ▶ Have a common checklist used by ESOs and EC/HAS
- ▶ TBs will use same document as HAS consultants

▶ **Mandatory for** homegrown draft hEN as of October 2023

▶ Strongly recommended for drafting of hEN under VA and FA (with ISO or IEC lead)

▶ CEN BOSS – CENELEC BOSS

New EC-ESOs Common Checklist

Part A - Criteria for ESOs only		
<p>Introduction</p> <p>This checklist shall be filled in before dispatch for:</p> <ol style="list-style-type: none"> 1. the First Working Draft for optional assessment (if any), 2. the draft for Enquiry, 3. the final draft for Formal vote, 4. In case of lack of compliance assessment at Formal Vote, a Last Confirmatory Assessment. <p>The Technical Committee secretary in CEN and the Technical body secretary / Reporting Secretariat in CENELEC are responsible for ensuring that the checklist below is filled in and submitted to CCMC with the draft candidate harmonised standards and their supporting documents/justifications where relevant. In CEN, the matrix of responsibilities shall be followed (see decision BT C081/2018). In CENELEC, the matrix of responsibilities shall be followed (see decision D169/006).</p> <p>Guidance on the horizontal aspects to be considered when preparing harmonised standards in support of EU legislation can be found on CEN and CENELEC BOSS pages</p> <p>It is strongly recommended to use the checklist for the drafting of harmonised standards in support of EU Legislation under VA and FA (with ISO or IEC lead).</p> <p>If all the questions in the checklist can be positively answered, this increases the likelihood of receiving a compliant assessment and of being accepted by the European Commission.</p> <p>Clarifications or justifications shall be given in the comment section.</p>		
<p>Information on the project (to be filled in by the Technical Body):</p>		
Standard reference		
WI reference		
Stage		
Legislation supported indicate legal act reference(s), its short title (or acronym) and relevant articles and/or annexes supported	Indicate which is the legislation that is being assessed here (e.g. Directive/Regulation xxxx/xxxxx, Short title, Article X/Annex X)	
	If the aspects assessed have a link with another legislation (e.g. electrical safety for LVD and RED) indicate whether a coordination took place or not	
Standardisation request(s) give reference number and relevant point of a request	Indicate the Standardisation Requests/mandate corresponding to the legislation above (i.e. the one that is being considered in this assessment.) [e.g. M/xxx, Annex I point 3 of Table 1]	
ESO technical body	Reference of the Technical Body	
ISO/IEC parallel work	<input type="checkbox"/> No <input type="checkbox"/> Yes	
1.1 Criteria for ESOs only	Compliance check	Comments/Justifications from Technical Body
<p>1.1.1 The draft standard is listed in a Standardisation Request / covered by a Mandate supporting EU legislation.</p> <ul style="list-style-type: none"> • This is reflected in Projex-online database for CEN/CENELEC <p><i>NOTE: This information is normally already provided in the NWI proposal form. If not, contact the TC secretariat. A possible way forward is to propose to the European Commission to add this work item in a (amended/revised) Standardisation Request. This is not applicable if the standard is covered by an old-format "open" Mandate (e.g. M/396 Machinery).</i></p>	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	

New EC-ESOs Common Checklist

Part B.2.: Conclusion of the assessment by the HAS consultant				
1. Consultant's opinion				
1.1 On the document's compliance with the standardisation request(s) and suitability to support relevant EU legislation - <i>i.e.</i> sufficiency and suitability to initiate the intended 'legal effect' in relevant context based on a full verification and assessment as summarised below in 1.2 and 1.3 covering 'Critical findings' and on Part B				
<input type="checkbox"/> Compliance - no 'critical findings' are reported				
<input type="checkbox"/> Good or sufficient quality for a compliant document - no changes required and no critical findings				
<input type="checkbox"/> Minor or limited number of changes not affecting compliance – please indicate those changes in section 2 (other findings)				
<input type="checkbox"/> Conditional compliance - only in case of problems related to the dates of normative references ¹ to other inter-linked standards ²				
<input type="checkbox"/> Lack of compliance - quality not sufficient for a harmonised standard				
<input type="checkbox"/> Minor or limited number of changes are required – <i>e.g.</i> Annex A/Z – please see sections 1.2 and 1.3, Part B and template				
<input type="checkbox"/> Redrafting required - need for substantial changes to the document is reported – please see sections 1.2 and 1.3, Part B and template				
Part B.3: Common criteria for EC/HAS and ESO				
1.2 Common criteria	Compliance check	If not fulfilled: Clause/ Subclause/ § number	Comments/Justifications from HAS consultant	Observations of the secretariat / response from TC/ actions taken by TC
1.2.1 The terminology (including definitions) is consistent with relevant EU legislation.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.2 The Foreword and the Introduction only contains appropriate information (<i>e.g.</i> they shall not contains requirements, legal or technical interpretations or information outside of the scope of the document).	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			

A-deviation in hEN

The A-deviation system

Attention should be paid to those cases where the national regulation in question conflicts with EU harmonization legislation. It is not in the remit of CEN and CENELEC to assess and decide if the national regulation is in conflict or not with the EU/EEA harmonization legislation.

NOTE:

- For EEA countries it is expected that there is no conflict between the National regulation and the EU/EEA harmonisation legislation.
- For non-EEA countries having an agreement with the EU and demonstrating regulatory convergence or compatibility with the essential regulations that support the Single market in areas that are relevant to CEN and CENELEC activities, conflict between their national regulation and EU/EEA harmonisation legislation is expected to be limited given the link between those countries and EU/EEA.

For standards intended to be offered for citation in OJEU, Technical bodies (or SRs) should make every effort to draft the EN/HD in such a way that A-deviations are not needed for those clauses related to the fulfilment of essential requirements of the European legislation

- ▶ [Webinar 'New process for harmonized standards under parallel development'](#)
- ▶ [Webinar 'Presentation of the new EC/HAS ESOs Common checklist'](#)
- ▶ [Webinar 'Innovative process for homegrown harmonised standards \(hENs\)'](#)
- ▶ [Webinar 'CEN Annex ZA - Updates related to the Table ZA.2' - Experts CEN](#)



INFORMATION FOR TECHNICAL BODY OFFICERS

Thank you!

Questions?

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INFORMATION FOR TECHNICAL BODY OFFICERS

COFFEE BREAK – until 3.30



We reconvene in this meeting room (Magellan) after coffee break