



European Standardization Organizations

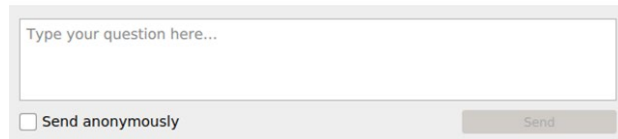
Annex Z: A Key Component of Harmonized Standards

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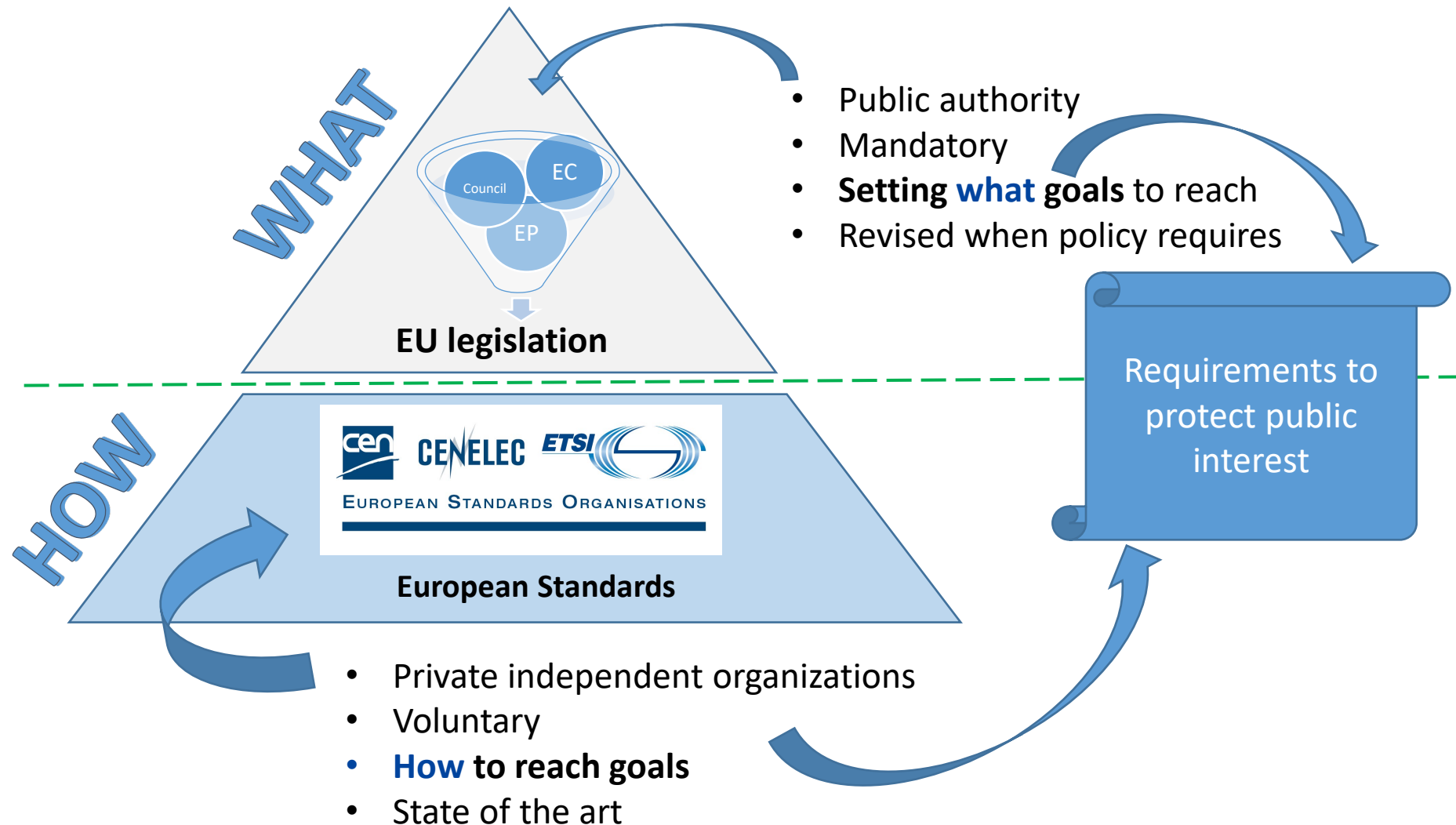
- ▶ You are muted
- ▶ Use the Q&A panel to submit your questions

A screenshot of a 'Question and Answer' panel. At the top, it says 'Question and Answer' in white text on a dark background. Below that, it says 'You 04:36 PM' and 'When is the next session?'. There is a text input field below the question, and a 'Send' button at the bottom right.A screenshot of a question submission form. It has a text input field with the placeholder text 'Type your question here...'. Below the input field, there is a checkbox labeled 'Send anonymously' and a 'Send' button.

- ▶ Talk about us on LinkedIn, Bluesky and Instagram with #training4standards

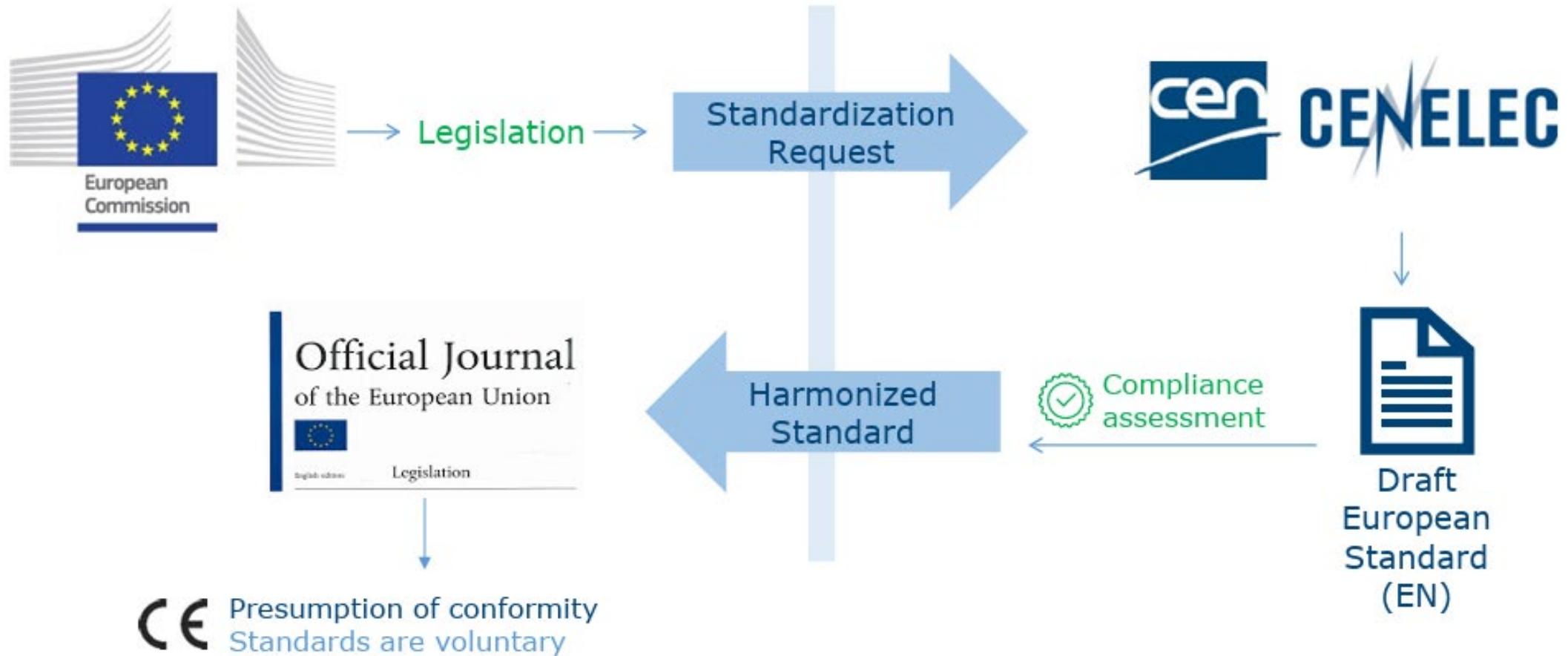
1	Standardization supports Legislation
2	From Request to Presumption of conformity
3	Development processes
4	The Annex Z: what it is, how to fill, where to find
5	Key drafting information
6	The HAS contractor

Standardization supports Legislation



Standardization request

From standardization request to presumption of conformity



What are Essential Requirements?

- *Definition:* Essential requirements are the fundamental criteria specified by EU legislation that products, services, or processes must meet to ensure safety, health, environmental protection, and other important public interests.
- *Legal Framework:* Essential requirements are outlined in various EU directives and regulations, and they form the basis for the development of harmonised standards.
- *Key feature:* Compliance with these essential requirements is mandatory for products to be legally placed on the EU market.
- *Examples:* safety requirements for electrical equipment,
environmental standards for emissions,
health standards for consumer products.

What is the Presumption of Conformity ?

- *Definition:* Presumption of Conformity is a legal concept within the EU legal framework, whereby products, services, or processes that comply with harmonised standards are automatically presumed to meet the essential requirements (i.e. conform to) the relevant EU legislation.
- *Purpose:* Simplifies market access by reducing the need for further conformity assessments.
- *Key feature:* manufacturers may voluntarily comply with harmonised standards to demonstrate conformity of products with essential requirements.
- *Legal Framework:*
 - Regulation (EU) No 1025/2012: on European standardization
 - New Legislative Framework (NLF): includes Decision No 768/2008/EC and Regulation (EC) No 765/2008
 - Harmonised Standards: Developed by European Standardization Organizations (ESOs)

List of references of hENs published in OJEU:

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

Standardization Request is a precondition for citation of harmonized standards in Official Journal of the European Union (OJEU)

Harmonized Standards must be **assessed** and have the following 'European elements'

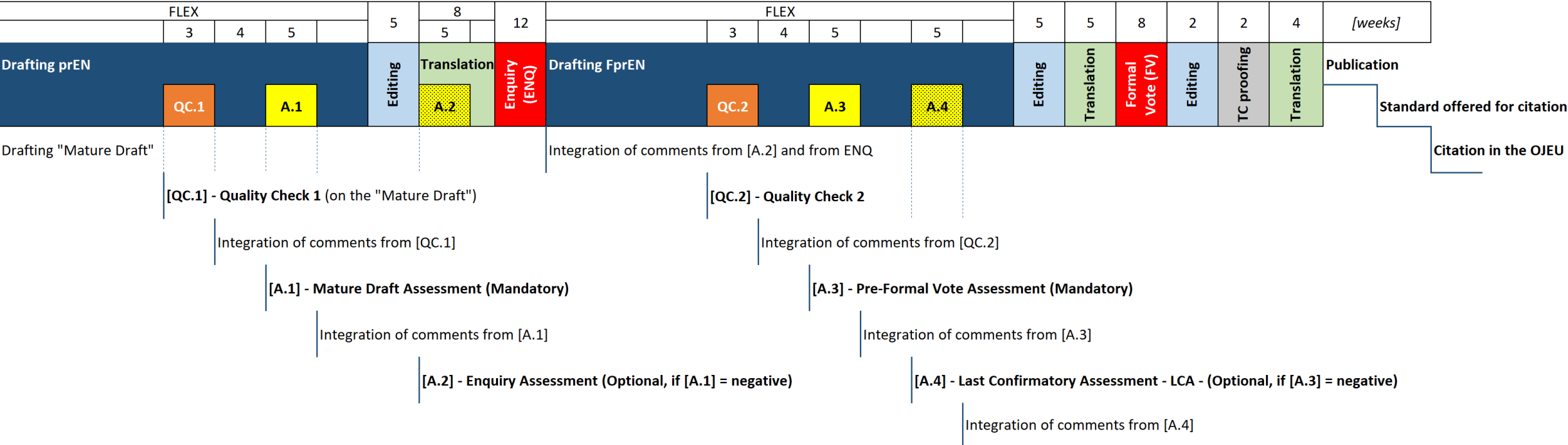
- ▶ Annex ZZ (i.e table establishing the relationship between the clauses of the standard and the regulatory requirements)
- ▶ Other European elements (e.g table establishing the relationship between the international and the European normative references)

→ **To be prepared by the European Technical Committee**

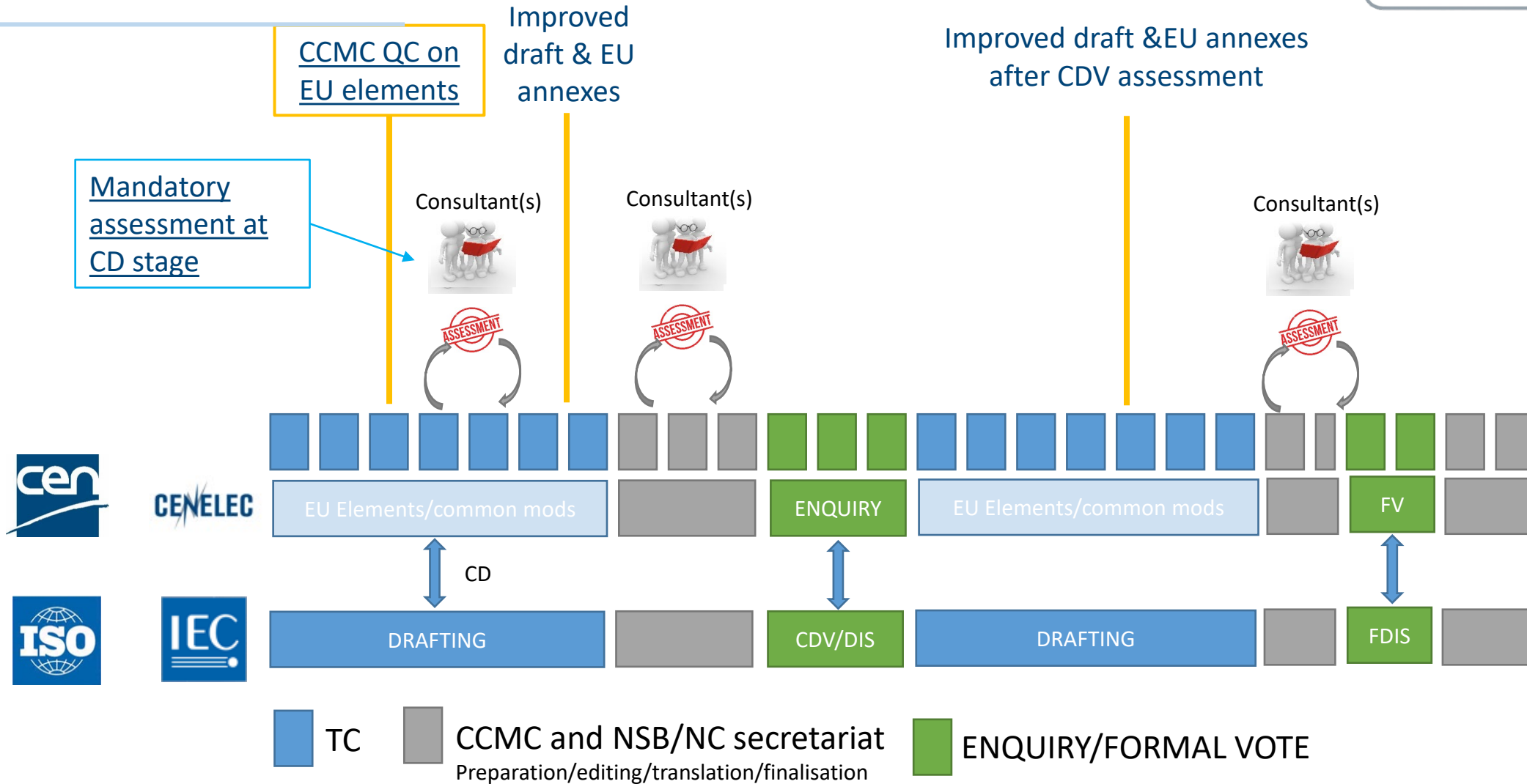
Innovative Process – homegrown hEN



► Workflow



'New' Process for Parallel Projects (hENs)



Key points for // development

- ▶ 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-CLC/TC (interaction with the HAS consultants) and ISO-IEC/TC (writing the standard)
- ▶ Common checklist not mandatory, but highly recommended when drafting European Annexes



What is an Annex Z

- ▶ Annex ZA (CEN) and Annex ZZ (CENELEC)
 - ▶ Informative
 - ▶ Indicates relationship between requirements of a Regulation aimed to be covered and the applicable clauses
 - ▶ As many Annexes ZA/ZZ as Regulations aimed to support
- ▶ CEN: Annex ZA with table ZA.1
- ▶ CENELEC: Annex ZZ with a table ZZ.1
- ▶ Templates available on CEN and CENELEC websites:
 - ▶ [CEN BOSS](#)
 - ▶ [CENELEC BOSS](#)

How to draft Annex ZA/ZZ

- ▶ Table ZA.1/Table ZZ.1 shall indicate the relationship between the Essential Requirements and the specific clause(s) in the standard
- ▶ Harmonized standards does not have to cover all relevant requirements, but Annex ZA/ZZ must always be consistent with the real coverage of the requirements
- ▶ Provide reference(s) to specific clauses/subclauses that provide coverage of requirements, rather than whole sections of standard

Table ZZ.1 – Correspondence between this European Standard and Commission Regulation (EU) 2019/2019 of 1.10.2019 laying down ecodesign requirements for refrigerating appliances pursuant to Directive 2009/125/EC of the European Parliament and of the Council and repealing Commission Regulation (EC) No 643/2009 [OJEU L315/187 of 5.12.2019] and Commission’s standardisation request “Mandate to CEN, CENELEC and ETSI for Standardisation in the field of household refrigerating appliances”, M/459 (2009)

Ecodesign requirements of Regulation No 2019/2019 [OJEU L315/187 of 5.12.2019]	Clause(s) / sub-clause(s) of this EN	Remarks/ Notes
Annex II, 2 c) Marking of compartments	Clause 5.2	Marking for frozen compartments
Annex II, 2 e) 2-star sub-compartments or 2-star sections	Clauses 3.3.16., 3.3.16.2, 3.3.16.4, 3.3.17	
Annex II, 2 f) 4-star compartments	Clause 3.3.16.4	
Article 4.4 Variable temperature compartment	Clause 3.3.4 and Annex B.2.5.2	

Annex Z templates



Where to find?

Annex ZA (CEN): **CEN BOSS**
website: Reference
Material/Forms and
templates/Technical Work (link:
<https://boss.cen.eu/reference-material/formstemplates/pages/>)

Annex Z templates

Reference documents

Guidance documents

Forms and templates

Forms and templates

TECHNICAL BODY ORGANIZATION

TECHNICAL WORK

ANNEX ZZ

- › Generic template (EN - FR - DE)
- › Ecodesign (EN - FR - DE)
- › EMCD (EN - FR - DE)
- › EMCD - generic text for references to EN 5
- › GPSD (EN - FR and DE not available)
- › IVDR (EN - FR - DE)
- › LVD (EN - FR - DE)
- › Medical Devices (EN - FR - DE)
- › Machinery (EN - FR - DE) + Instructions
- › RED - EMC (EN - FR (not available) - DE)

Where to find?

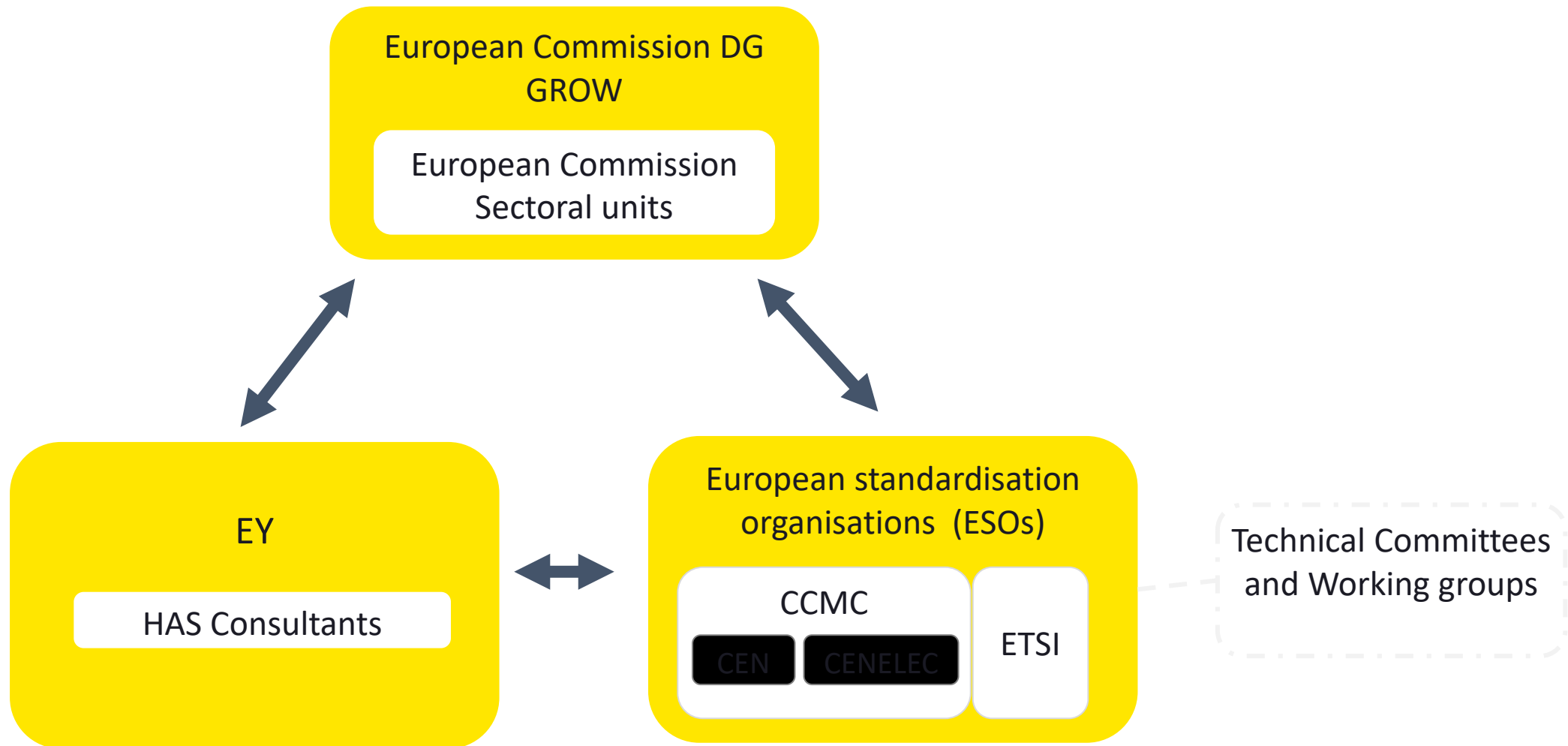
Annex ZZ (CENELEC): [CENELEC BOSS](https://boss.cenelec.eu/reference-material/FormsTemplates/Pages/) → Reference Material → Forms and Templates → Annex ZZ (link: <https://boss.cenelec.eu/reference-material/FormsTemplates/Pages/>)

Key drafting reminders

- ▶ Perform self assessment using [Common checklist](#)
- ▶ Draft **clear** and **verifiable provisions**
- ▶ Normative References :
 - ▶ should be **dated, active, published** when hEN is made available
 - ▶ Recommended to **refer to a specific clause** within the NR (to avoid issues with chains of NRs)
- ▶ Use [CCMC guidance](#) documents: do your homework 😊



The HAS contractor



Role and tasks of HAS Consultants

- The activity of HAS Consultants is described in the Call for Tenders, and it is limited to the “territory” defined in Art. 10(5) and 10(6) of the Standardisation Regulation
- Their main task is to assess (draft) harmonised standards developed on the basis of a Commission standardisation request
- The time allocation of their work is mostly for assessment, with a maximum of 25% for “communication” tasks
- HAS Consultants cannot, under any circumstances, participate to the drafting of standards and to the consensus-building process within ESOs
- Their role is not to compensate possible gaps in the technical, scientific or legal expertise of a technical body

Meeting requests following HAS assessment

- Meetings adhering the below criteria are encouraged
- Meeting requests should be submitted minimum 4 weeks prior to the meeting date
- A full agenda of the 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 Consultants
- 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 clarifications on their previously completed assessments* (but max. 25% of time is spent on meetings)

*Consultants should check if the harmonised standards are compliant with the legislation. Technical comments on elements not linked through Annex Z are considered as recommendations.

What a HAS Consultant cannot do

- ▶ Contribute to standard 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

- CEN webinar '[Drafting harmonized standards - IR3 rules, requirements and normative references](#)'
- Webpage: [Drafting European standards for citation in the OJEU](#)
- Guidance document: [Guidance on normative references in harmonized standards](#)
- [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 \(hENs\)'](#)

Thank you for your attention

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