



INFORMATION FOR TECHNICAL BODY OFFICERS

# CENELEC SESSION

## Understanding the standardization process

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# Historical background



Lugano Agreement  
(1991)

**CENELEC and IEC:  
30 years partnership**



Dresden Agreement  
(1996)

**CENELEC 80%  
aligned on IEC**



Frankfurt Agreement  
(2016)

# Who is CENELEC

## 3 recognized European Standardization Organizations

- ▲ CENELEC – CEN – ETSI

### CENELEC

- ▲ 34 National Committees (NCs)
  - European Economic Area
  - All IEC members
- ▲ Committed to working first at IEC level
- ▲ Implementing IEC Standards as CENELEC Standards (EN IEC)



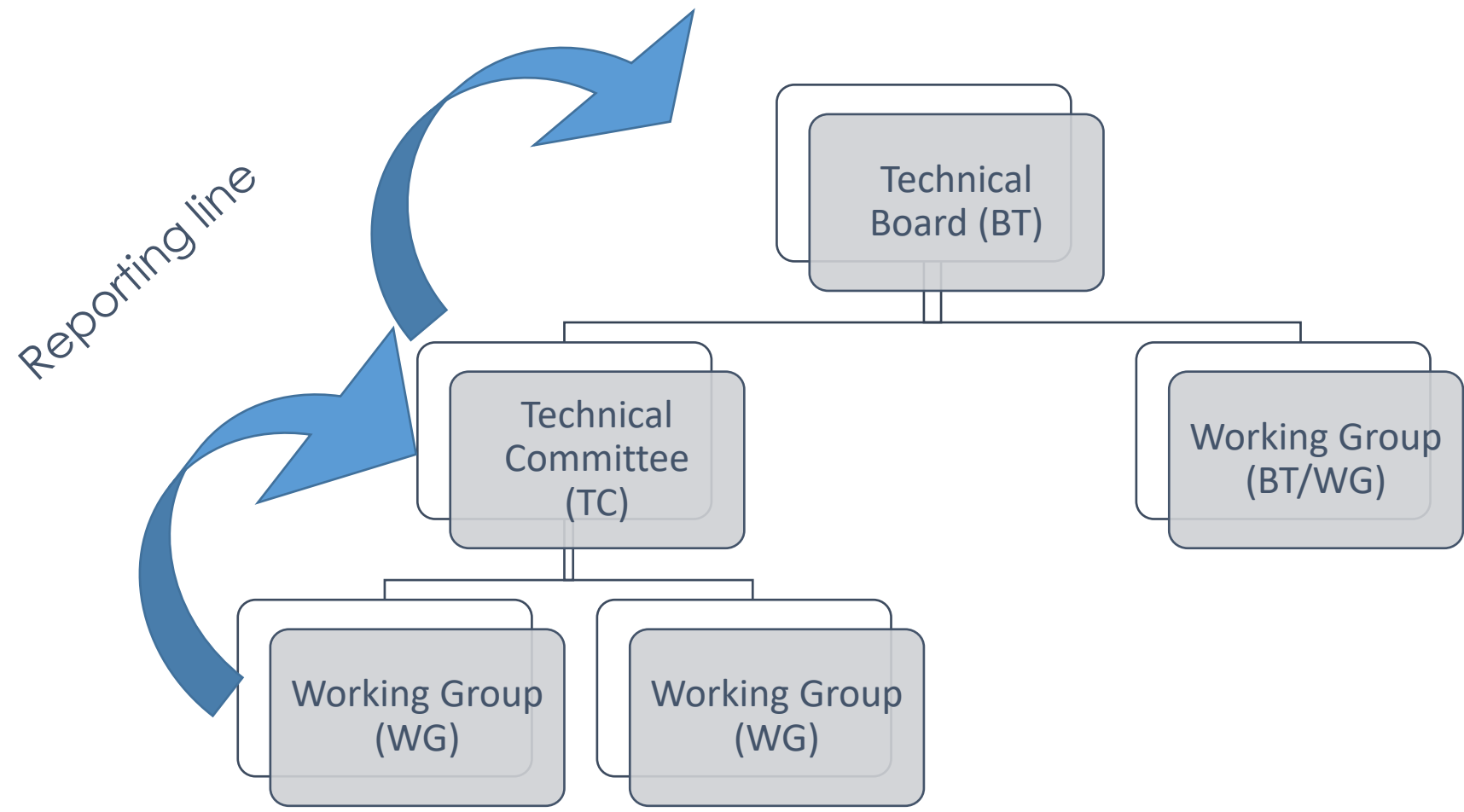
# Understanding the standardization process



1. Roles and Responsibilities of BT, TCs, WGs
2. From New Work Item to Publication
3. Day to day management of Frankfurt Agreement
4. Citations of Harmonized Standards in OJEU
5. CENELEC BOSS and other useful information

# 1. Roles and responsibilities of BT, TCs and WGs

# The three-decision layers at technical level



# Technical Board BT

- ▶ Composition and responsibilities presented in 'The European Standardization System' session

# Technical Committee TC



## Composition:

- ▶ TC Chairperson + TC Secretary + National Delegations (national position, voting right) + European Partners (observers, no voting right)

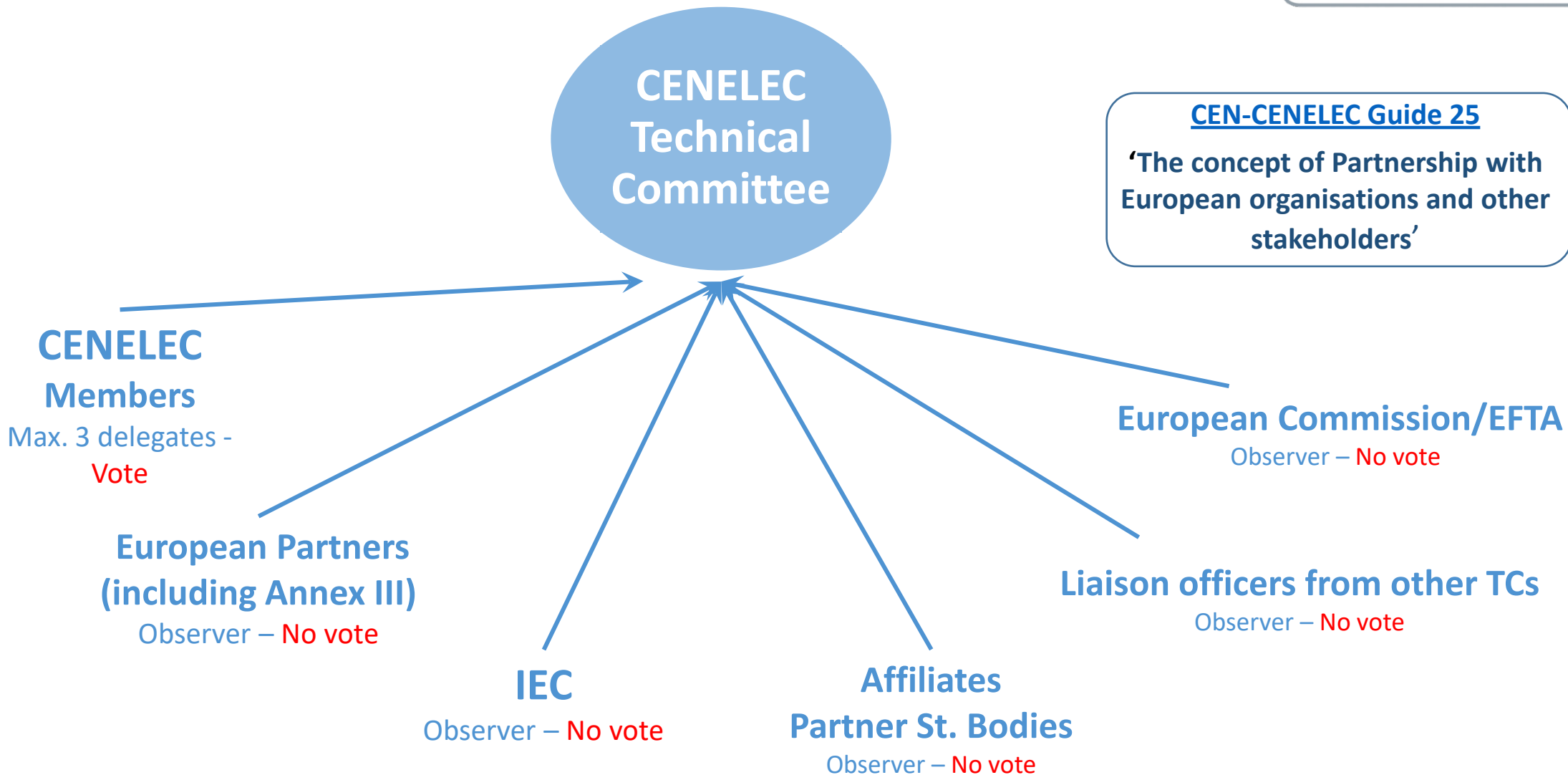
## Role:

- ▶ Responsible for the timely development of deliverables
- ▶ Timely execution of standardization request deliverables (incl. support when Standardization Request development)
- ▶ Always work along the standardization principles: transparency, openness, consensus-building

**Communication** between TC Secretariat and with CCMC (PM) is key!!

→ TC secretariat always on top of the TC's work programme

# Technical Committee composition



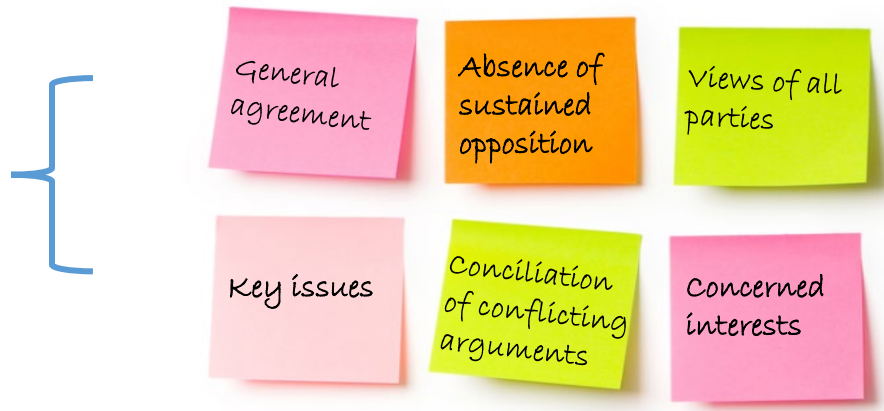
**CEN-CENELEC Guide 25**  
**‘The concept of Partnership with European organisations and other stakeholders’**

# TC Chairperson and Secretary

## TC Chairperson

- ▶ Appointed by CLC/BT
- ▶ Neutral
- ▶ Presides meetings and seeks consensus
- ▶ Interface with CCMC (strategic directions, specific issues,...)
- ▶ Ensures coordination with other TCs

Consensus



## TC Secretary

- ▶ Appointed by NC holding the secretariat
- ▶ On top of CLC/TC work programme
- ▶ Ensures that TC works efficiently & within timelines
- ▶ Prepares and distributes documents (via IT Tool)
- ▶ Aware of relevant CLC/BT decisions and provide inputs when needed
- ▶ Ensures coordination with other TCs
- ▶ In case of Standardization Requests, is responsible for preparing reports

# Technical Committee meetings

## Before plenary

- ▶ Circulates agenda (2 months before) and documents for discussion (4 weeks) - templates available on BOSS
- **New normal:** guidance under development
- ▶ TC Work programme available on Projex-Online
- ▶ 'ERAS' attendance list to be used

## After plenary

- ▶ Prepare report (template on BOSS) to be sent to CCMC ([dataservice@cencenelec.eu](mailto:dataservice@cencenelec.eu)) within 8 weeks → circulated to CLC/BT by correspondence

## Use of CIV

- ▶ The Committee Internal Voting (CIV) is the IT tool, available on CENELEC voting portal, providing the possibility for TC Secretaries to launch ballots by correspondence for any kind of consultations (formal and informal).

# Working Group WG

# Working Group

**Established by the Technical Committee** (short-term task)

**Composition:** Individual experts appointed by the NCs

## **Role:**

- ▶ Responsible for drafting the deliverables + to send to TC for
- ▶ Seeks support from the parent body (if needed)
- ▶ Ensures that WG experts know rules and procedures
- ▶ Actively progresses work and reports regularly to TC

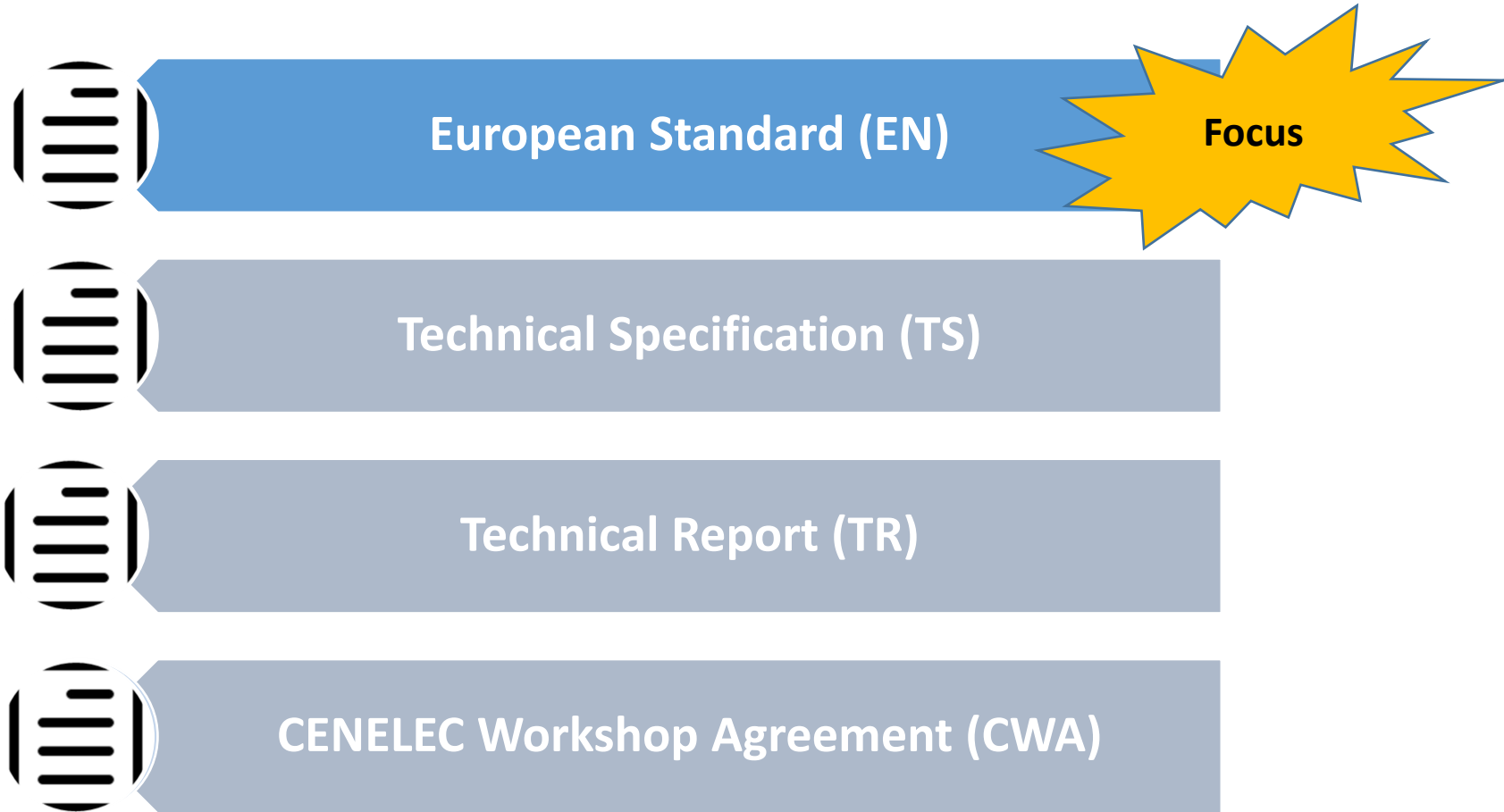
**Efficient and smooth cooperation between TC (WG) experts, delegates and observers contributing to the development of standards is fundamental:**

- ▶ **Code of Conduct for experts participating in CEN and CENELEC (technical work)** – [here](#) → *raises awareness on Internal Regulations and Guides, especially the Policy on Patents and the provisions regarding competition law*
- ▶ **Best practices for improving effectiveness of WG meetings** - [here](#) → *advices and suggestions to WGs convenors on what should be done before, during and after meetings*

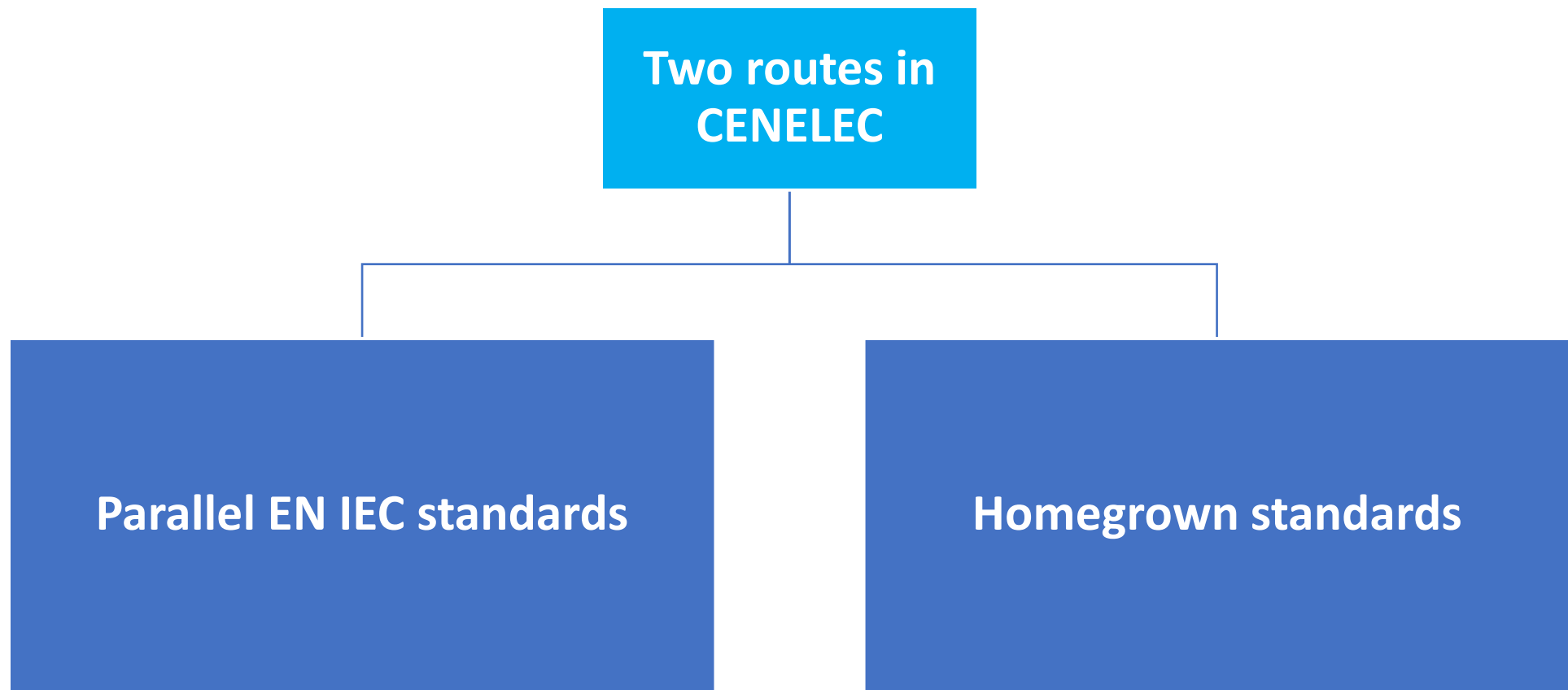
## **2. From New Work Item (NWI) to publication**



# Deliverables



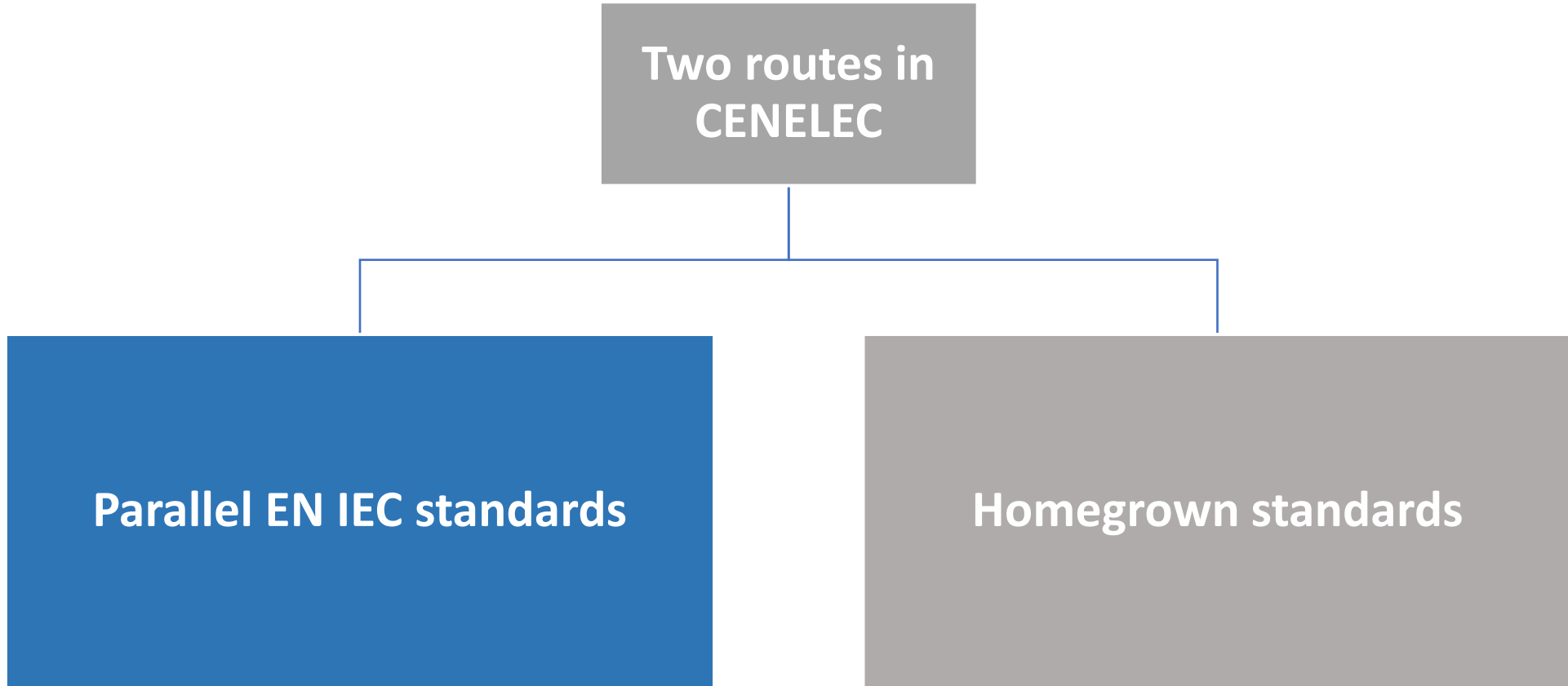
# Standards development



# Standards development



# Standards development

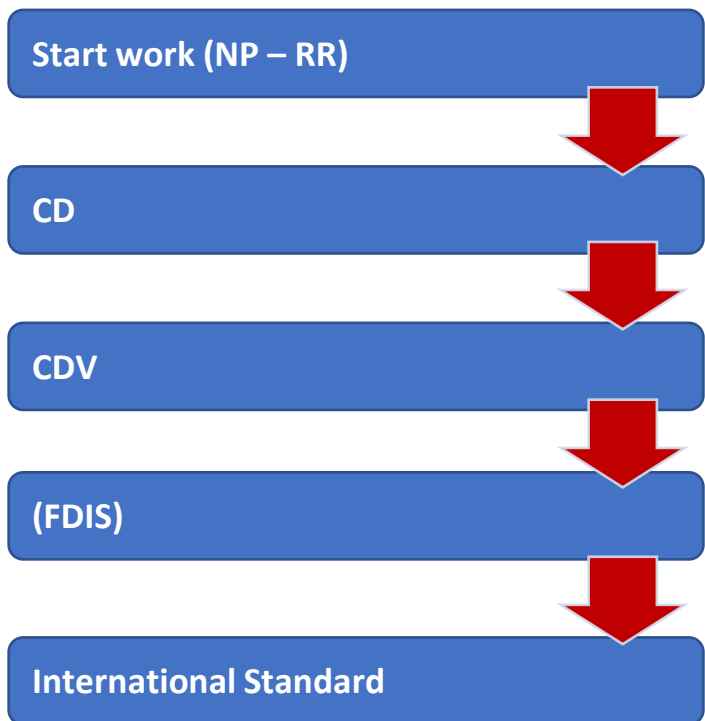


# Standards development

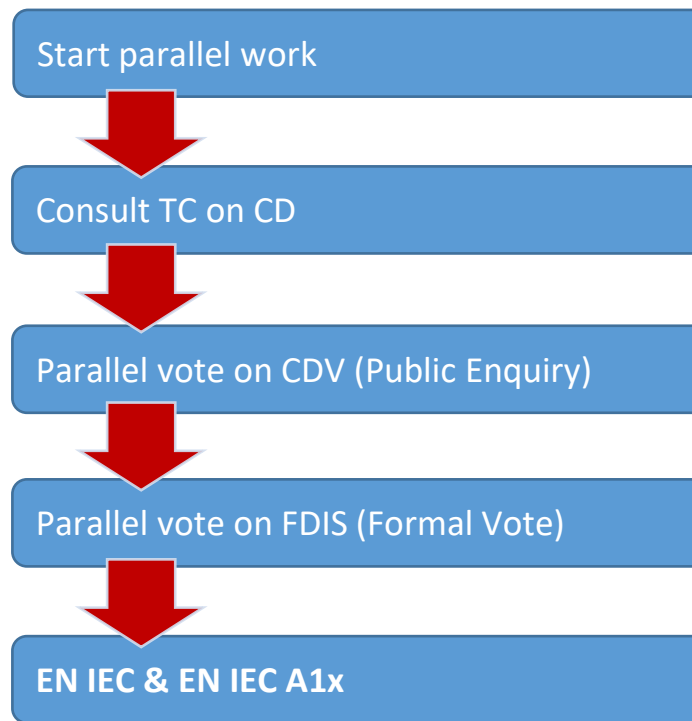


## Parallel work between IEC and CENELEC

IEC



CENELEC



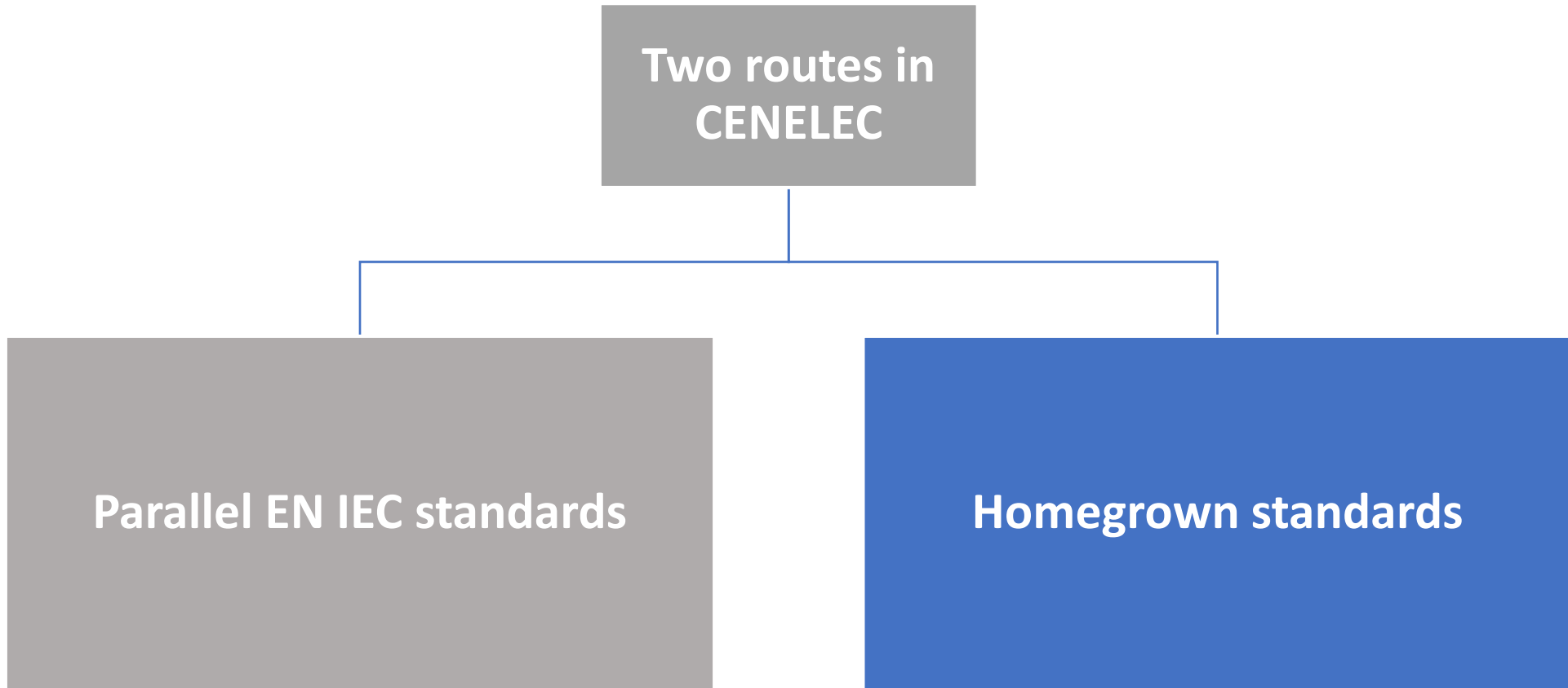
NWI automatically created in the CLC/TC work programme

CLC/TC secretary: monitoring the work programme – proofing before publication

Automatic procedures and collection of European comments and votes

Importance to anticipate future IEC work items for harmonized standards

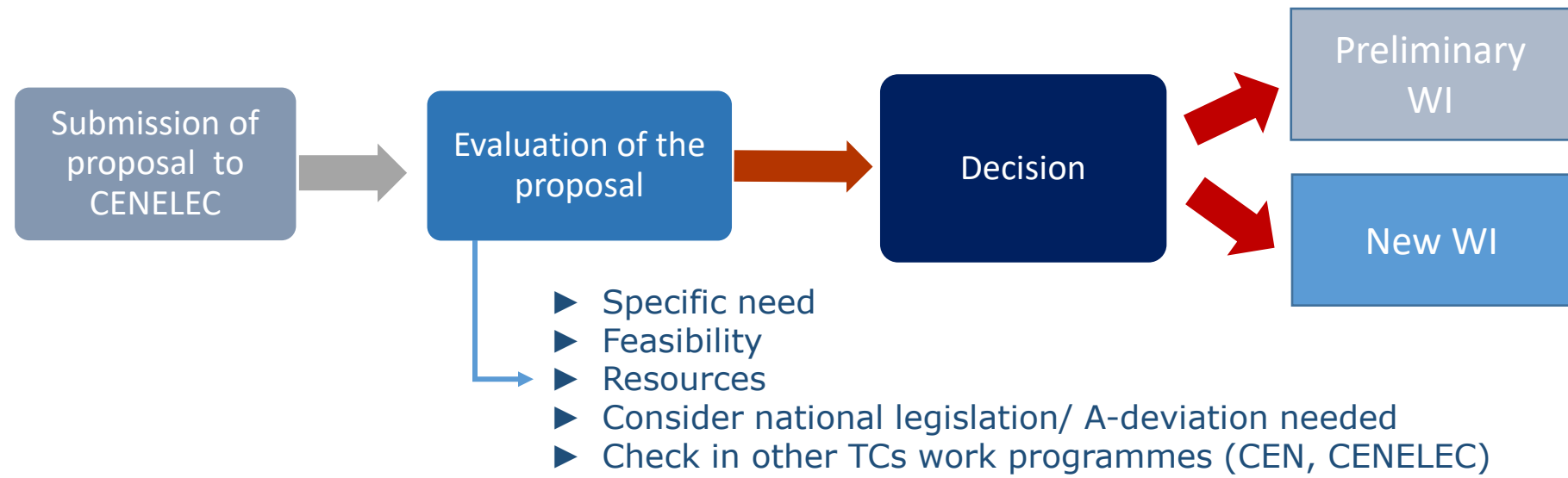
# Standards development



# Proposal – Evaluation and decision

**Proposals may originate from:**

- Existing Technical Committees
- European Commission or Agency
- National Committees (NCs)
- CENELEC Partner Organizations



# New project

Template **mandatory** with a **justification** for not offering it to IEC!

- ▶ Precise information needed (e.g. superseding EN(s), link with IEC, possible a-deviation(s), link with EU regulation, ...)
- ▶ TC decision: 5 members committed to actively participate
- ▶ Target dates are very important
- ▶ Filled in template to be sent to [dataservice@cencenelec.eu](mailto:dataservice@cencenelec.eu)
- ▶ BT decision (by correspondence)
- ▶ If approved → standstill
- ▶ WI in TC work programme → **timeframe to be respected!** → alerts sent by CCMC to TCs



# Creation of New Work Item



- ▶ New Work Item' form: **mandatory**
- ▶ Precise information needed (e.g. superseding EN(s), possible a-deviation(s), link with EU regulation, ...) including the lead
- ▶ Registration of the WI – BT decision and then dataservice activates the NWI
- ▶ If WI is accepted, standstill applies

**CENELEC** New Work Item Proposal

TC Name:	TC_NAME	
TC Title:	TC_TITLE	
Secretariat:	NC	Date of proposal: (YYYY-MM-DD)

**Information on the Work Item**

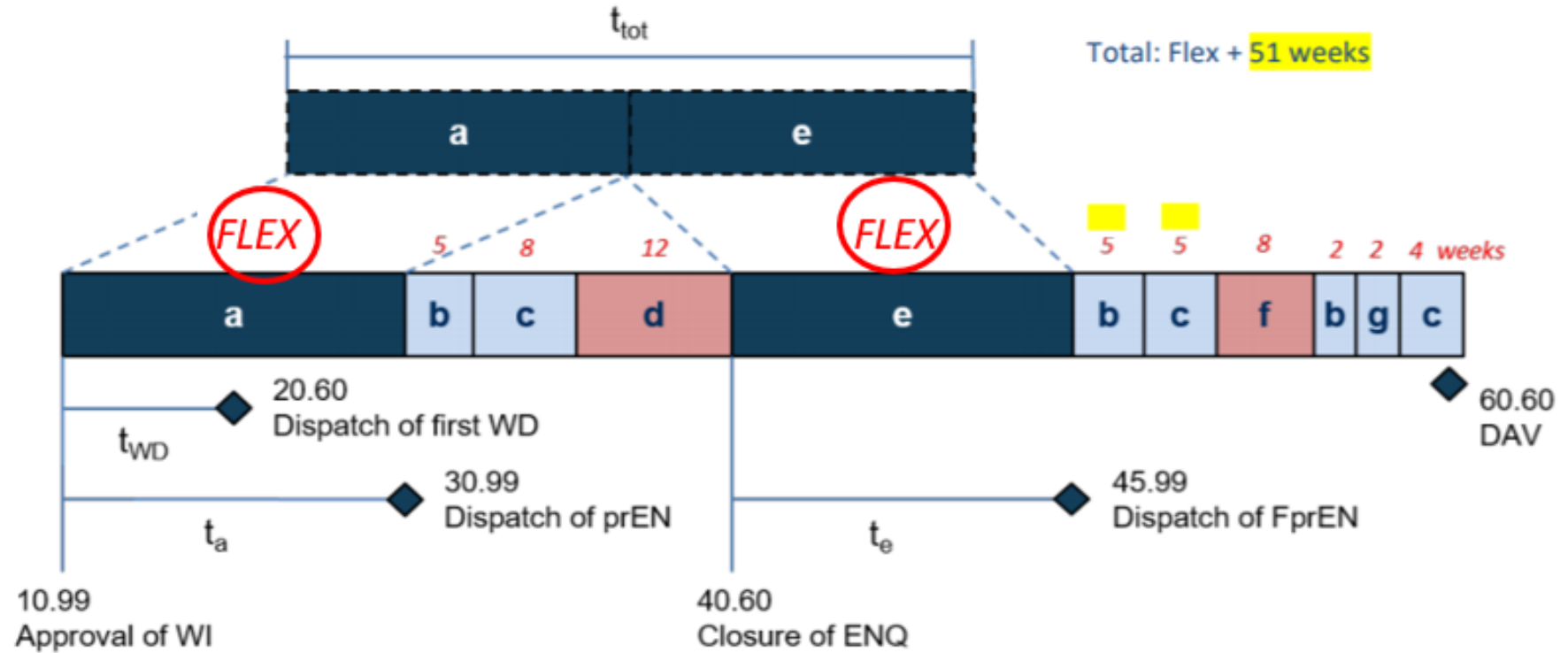
<b>Title:</b>	
English	<b>Title_en</b>
French (optional)	<b>Title_fr</b>
German (optional)	<b>Title_de</b>
<b>Scope:</b>	
Scope	

# Flexible standards development process

- ▶ TCs have 68 weeks to draft standards
- ▶ TC to define the target dates when adopting NWIs:
  - ▶ Target date for dispatch 1st WD
  - ▶ Target date for dispatch ENQ draft to CCMC (min 1 week)
  - ▶ Target date for dispatch FV draft to CCMC (min 6 weeks)

# Flexible standards development process

Fig. 1



- |   |   |  |                  |
|---|---|--|------------------|
| a | Drafting of prEN                                    |  | Internal process |
| b | Editing   |  | Technical work   |
| c | Translation and preparation of national publication |  | Voting           |
| d | Enquiry   |  |                  |
| e | Comments handling / preparation of FprEN            |  |                  |
| f | Formal Vote   |  |                  |
| g | TC proofing   |  |                  |

## BT

- ▶ Flexible standards development process implemented in April 2020
- ▶ Applicable to CENELEC 'homegrown' ENs (not applicable to parallel EN IEC)
- ▶ Some further information:
  - Introduction - [https://youtu.be/JB\\_nX6g6C04](https://youtu.be/JB_nX6g6C04)
  - Module 1: Planning - <https://youtu.be/WGChUW2Tv74>
  - Module 2: Implementing the planning - <https://youtu.be/Gi0ZnuGJ1Bw>
  - Module 3: Monitoring - <https://youtu.be/UJmrbHDNNN4>
  - Module 4: Review of the planning - <https://youtu.be/xZWNE-tQTIs>



## WHAT:

Allocation of time (duration), work item per work item, by indicating the following 3 target dates, in CENELEC NWI form:

- Target date for dispatch of first Working Draft
- Target date for dispatch of ENQ draft
- Target date for dispatch of FV draft

# Timeframe - planning

<u>Project start date (10.99)</u>	1 <sup>st</sup> WD (20.60)	ENQ (30.99)	FV (45.99)
<u>yyyy/mm/dd</u>	Date will be added by CCMC. It is half the number of weeks planned for ENQ (30.99)	yyyy/mm/dd 10.99 + X weeks	yyyy/mm/dd <u>40.60 + X weeks</u>

To indicate the timeframe in # weeks

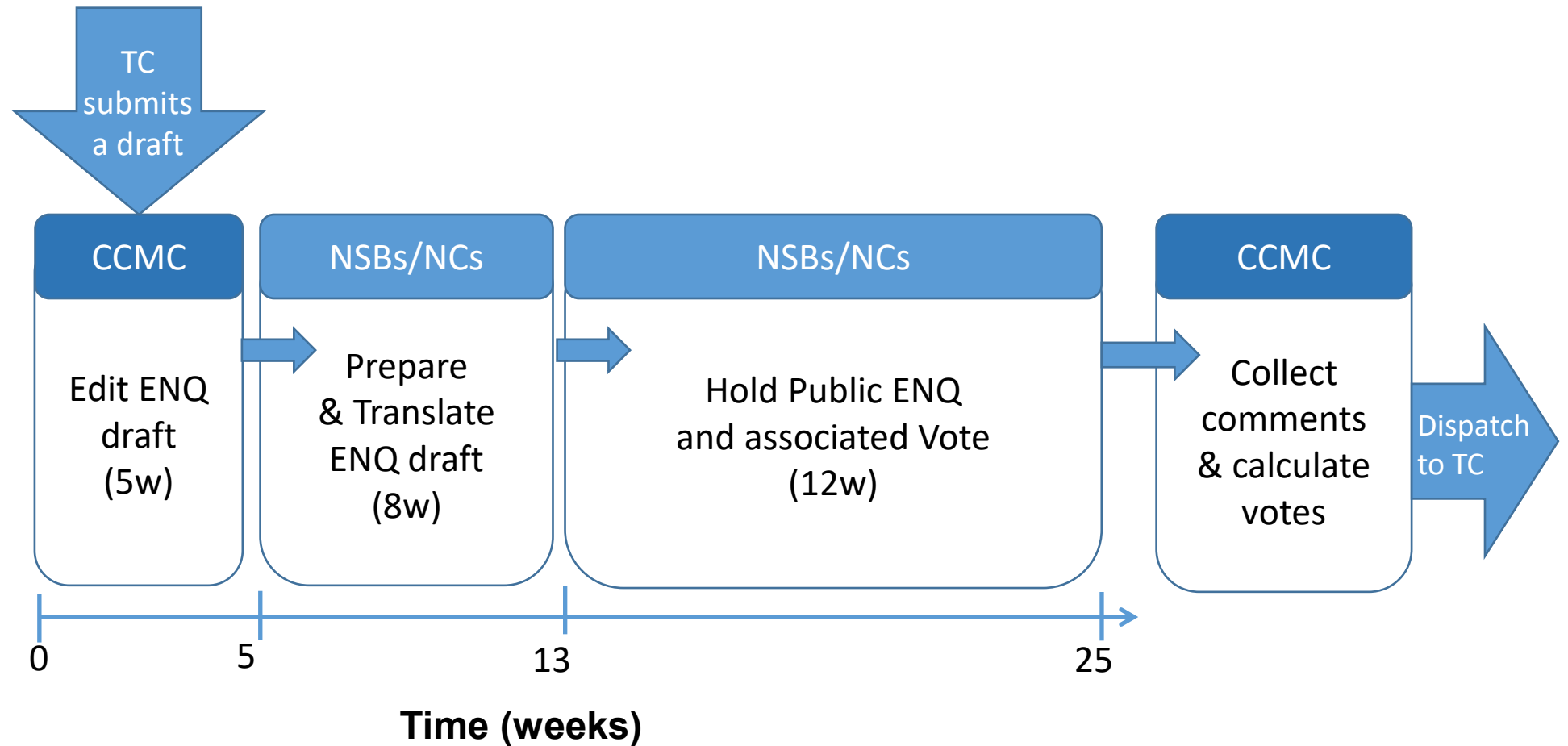


**At any time before the dispatch for Enquiry (i.e. 30.99)** the TC leadership in cooperation with the relevant WG convenor have at their disposal the following options for changing the planning:

- a) To change the planning by using **the 'one change' option**. It requires a TC decision.
- b) To ask for a **tolerance of 9 months**. It requires a TC secretary request. A second tolerance may be granted with a TC decision, approved by CLC/BT.

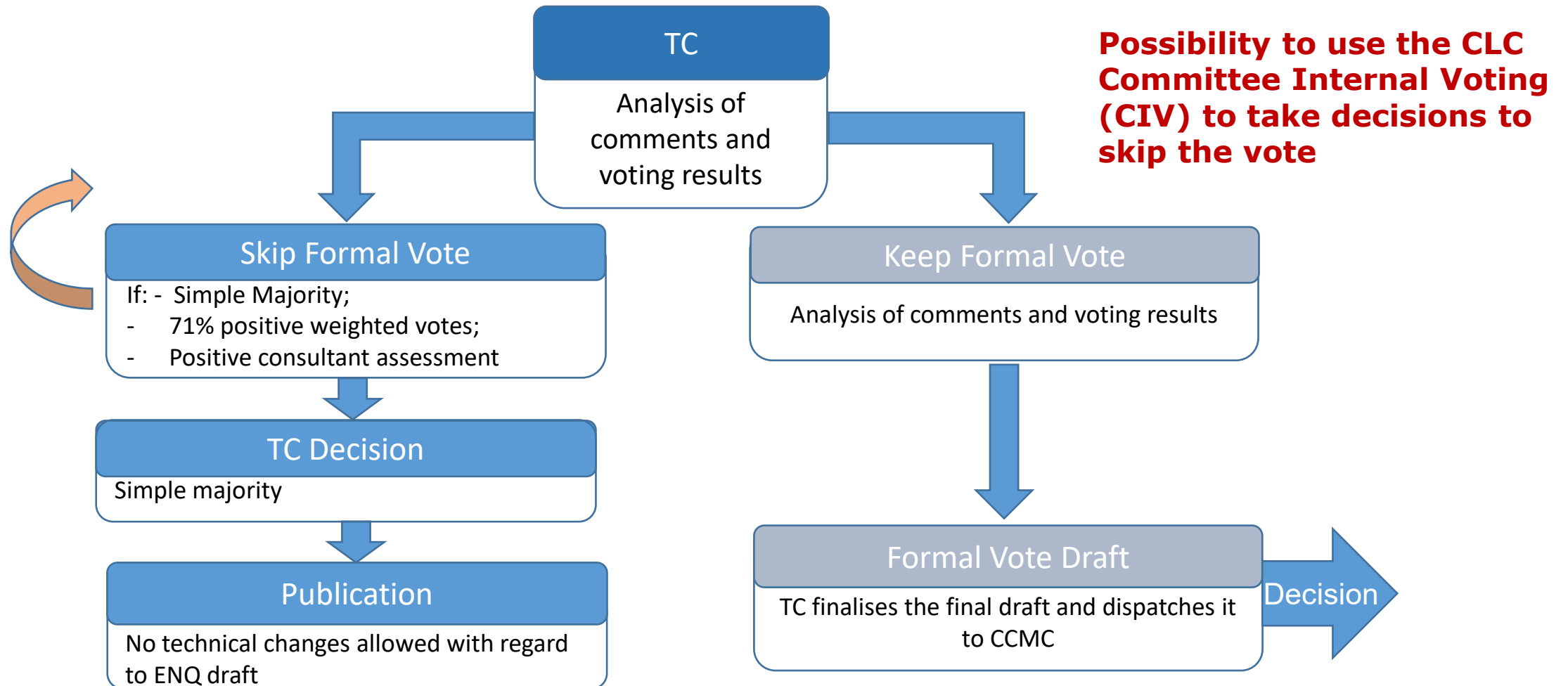


# Public Enquiry

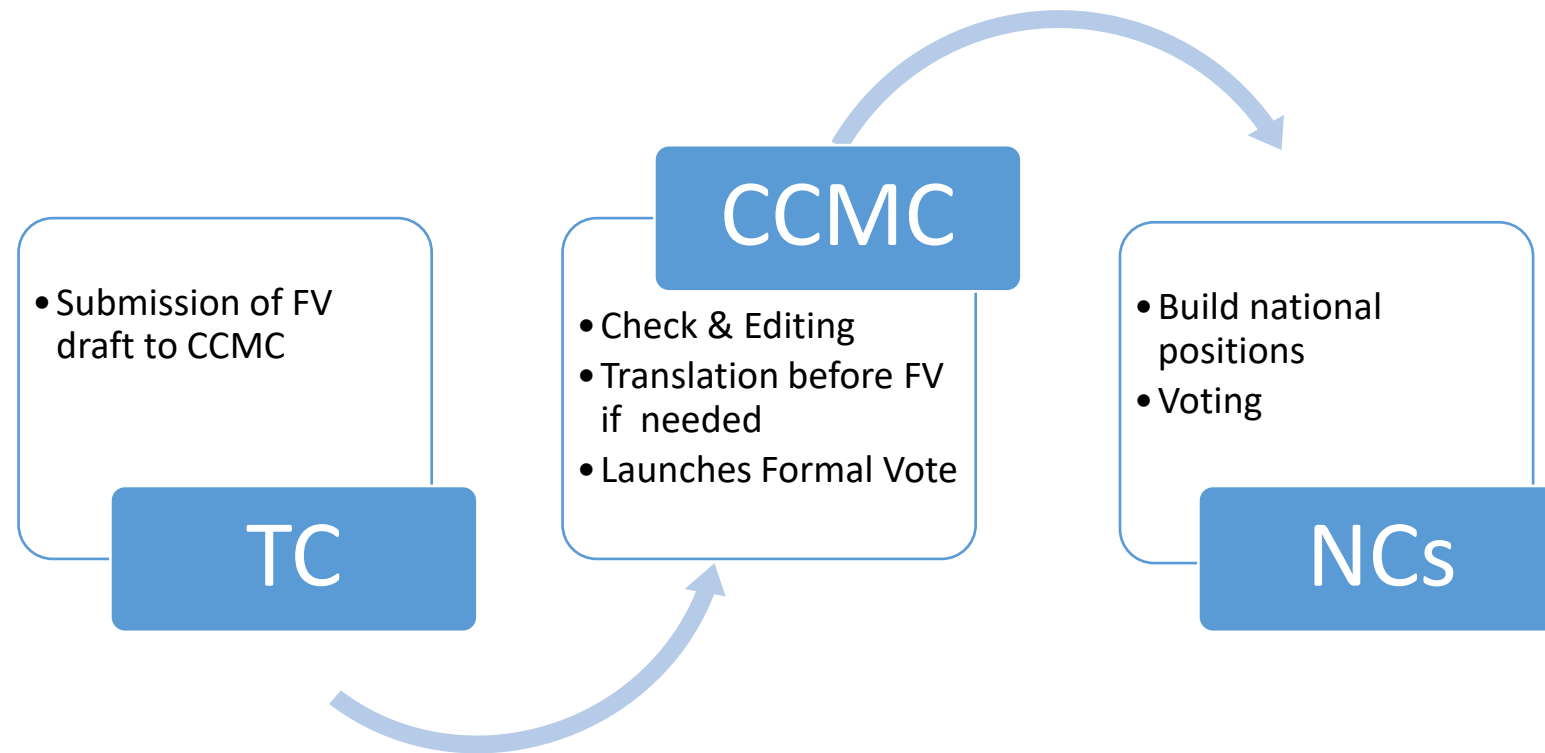




# Consideration of comments



# Approval



**71% positive votes (weighted) → approved European Standard**

# Approval

Member country	Weighting	Member country	Weighting
France	29	Switzerland	10
Germany	29	Serbia	7
Italy	29	Croatia	7
United Kingdom	29	Denmark	7
Turkey	29	Finland	7
Poland	27	Ireland	7
Spain	27	Lithuania	7
Romania	14	Norway	7
Netherlands	13	Slovakia	7
Belgium	12	Cyprus	4
Czech Republic	12	Estonia	4
Greece	12	Latvia	4
Hungary	12	Luxembourg	4
Portugal	12	Slovenia	4
Austria	10	FYROM	4
Bulgaria	10	Iceland	3
Sweden	10	Malta	3
		TOTAL	412

Vote simulation tool available on CENELEC website: [here](#)

**CCMC finalizes** and publishes the EN + provides EN to National Committees for national implementation

- ▶ Members publish ENs as national standards (+ may translate into national language)
- ▶ Withdraw conflicting standard(s)

## Handling comments at Formal Vote – BT decision D163/029

- ▶ Only **obvious editorial errors** and errors introduced by CCMC

*'Obvious editorial error' is an editorial error that is recognized as such immediately and without any doubt, both by the CCMC editor and the TC Secretary'*

### ▶ **TC proofing**

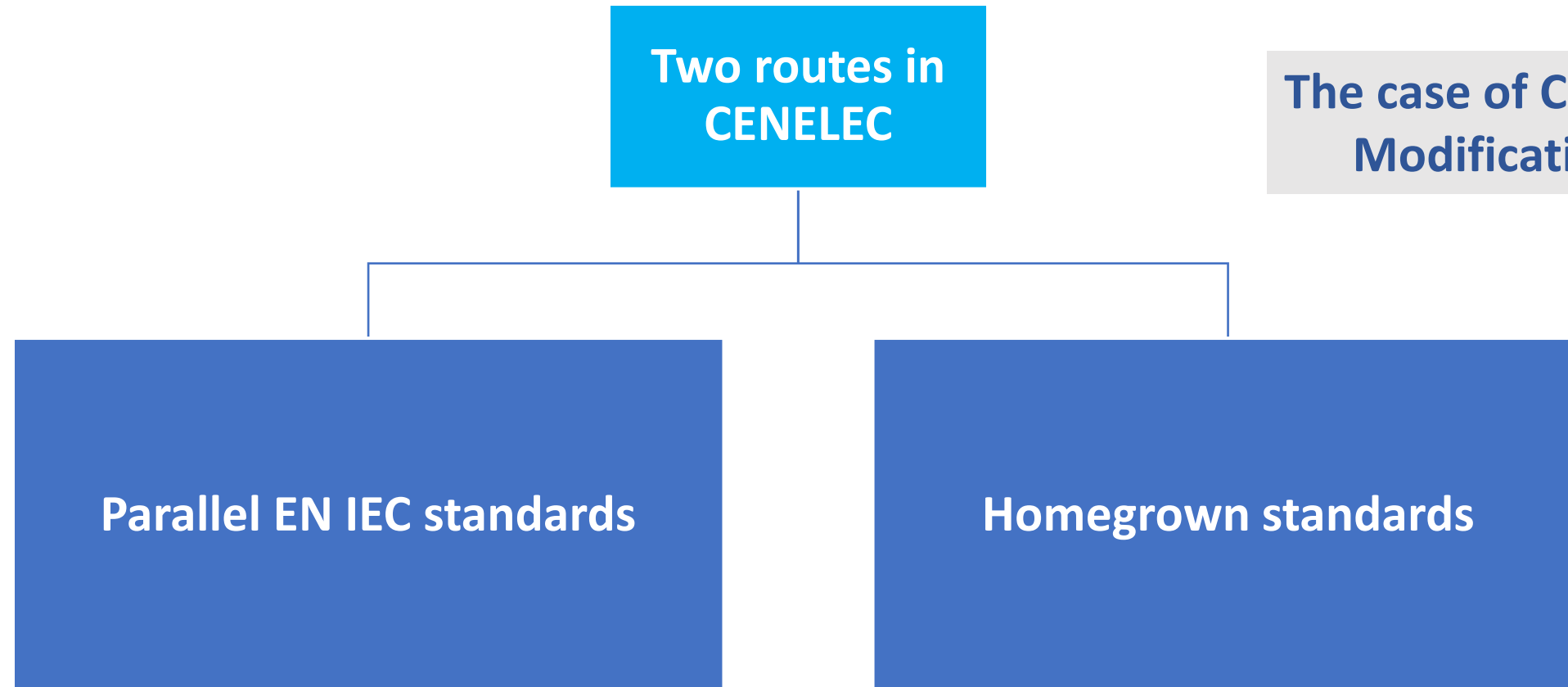
- ▶ 2 weeks → 3 weeks exceptional upon TC request
- ▶ No reply → CCMC proceeds to finalization

**Amendments** = modification/addition to or deletion of specific parts of the text → Only the amended text will be voted upon

▶ If amended → NWI request needed → Track: Enquiry (+ vote)

**Corrigendum** = Corrects mistakes that lead to incorrect/unsafe use of EN (→ TC rationale needed)

**Maintenance** → Process initiated by CCMC (alerts sent) → TC to ensure that EN content is still valid 5 years after publication



**The case of Common Modifications!**

## ▶ CEN-CENELEC Internal Regulations Part 2

### **2.14**

#### **common modification**

alteration of, addition to or deletion from the content of a reference document, approved by CEN/CENELEC and thus forming part of the EN (and HD for CENELEC)

## ▶ CENELEC BOSS:

<https://boss.cenelec.eu/fadel/commonmods/Pages/default.aspx>

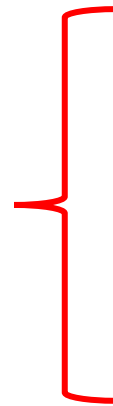
## ▶ [ISO-IEC Guide 21-1](#) 'Regional or national adoption of International Standards and other International Deliverables - Part 1: Adoption of International Standards'

# Common Modifications

## In phase

**Common Modifications through European amendment (A11)**

**2 Work Items in the work programme**



Parallel CDV/ENQ

Parallel FDIS/FV

Publication of EN IEC with

A11 – ENQ  
(CCMC WI)

A11 - FV

A11 publication

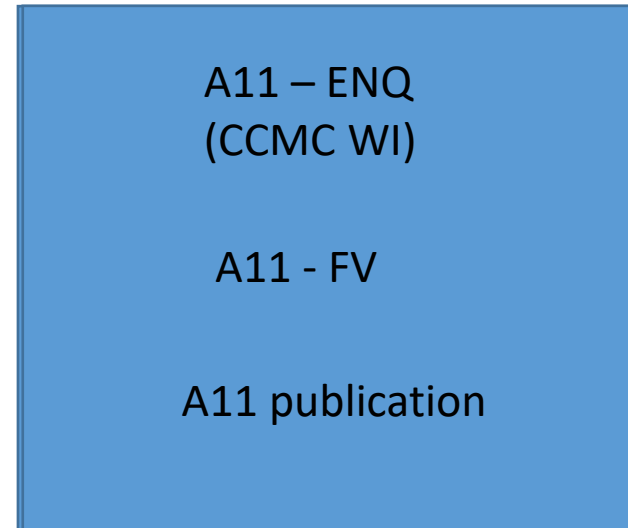
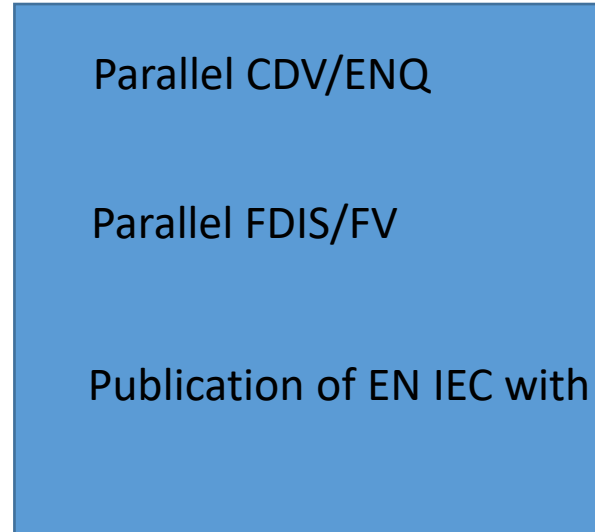
- ▶ TC decision (informs CCMC) - No New Work Item request to BT – Secretary to inform CCMC asap!
- ▶ The two Work Items will progress in parallel (EN IEC and EN IEC A11)
- ▶ European elements → Always in the A11 (common mods as such and European Annexes



# Common Modifications

Not in phase

**EN IEC runs in parallel**



The TC manages the project (start, submission to procedures, subject to the flexible development time process)

- ▶ NWI request to CLC/BT
- ▶ The publication of the EN IEC can be put on hold, pending the finalization of the A11

# Other deliverables

## Adapting to market needs



Technical Specification (TS)



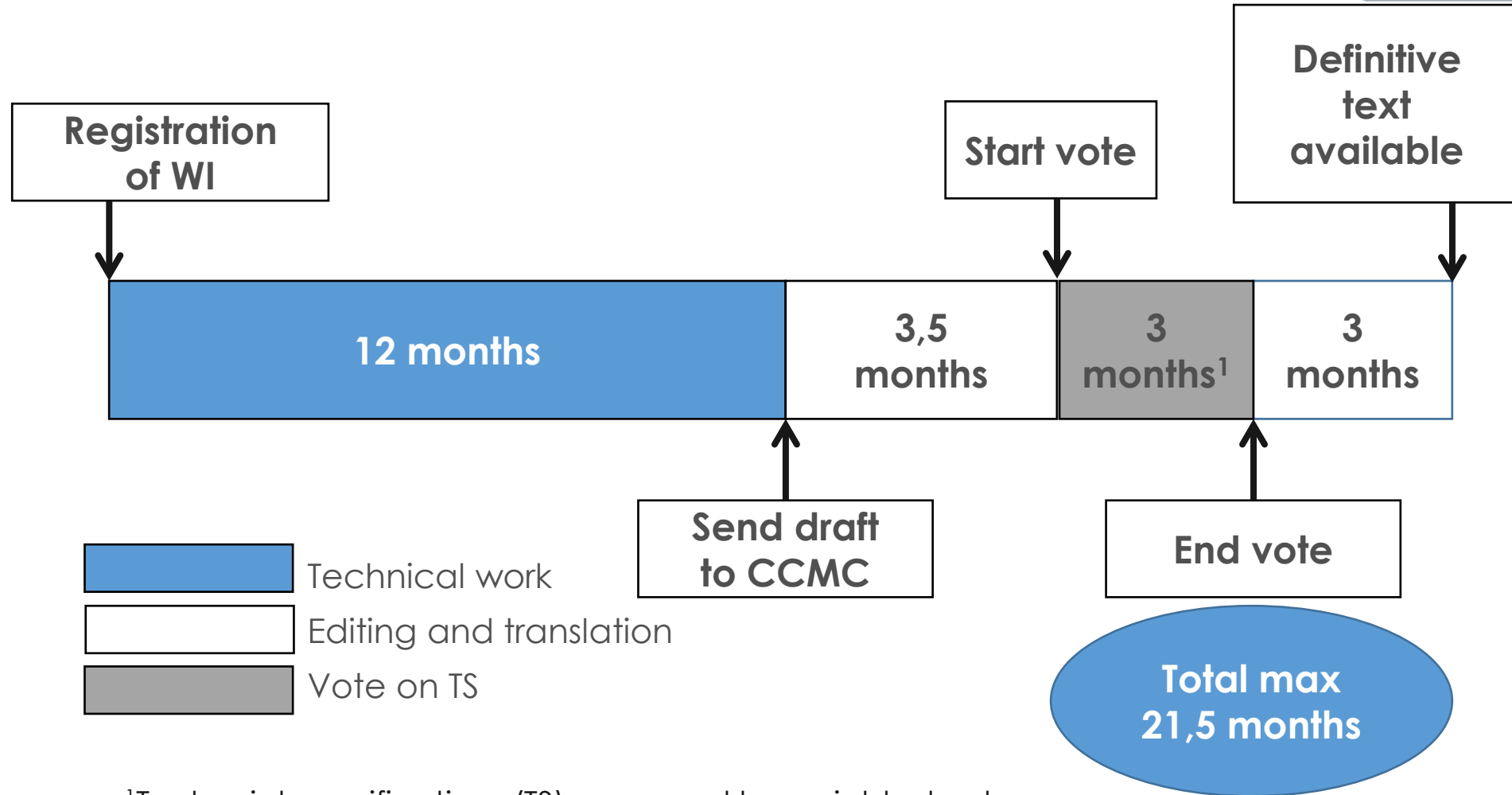
Technical Report (TR)



CEN Workshop Agreement (CWA)

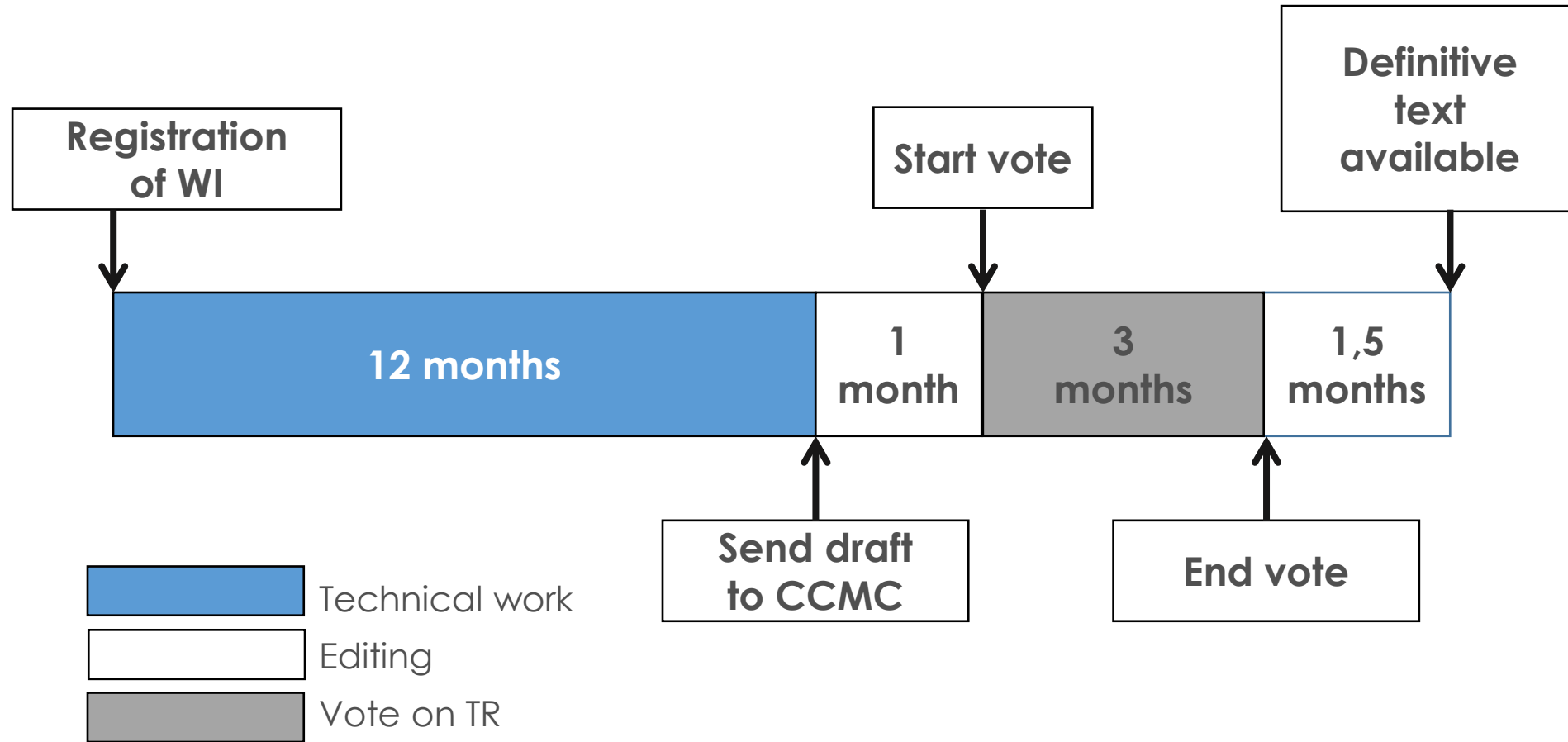
**Outside the Frankfurt Agreement!**

# Technical Specification



<sup>1</sup>Technical specifications (TS) approved by weighted vote

# Technical Report



# Workshop Agreement


## Developed in 'Workshops' (WS):

- Flexible (possibility to join in up until the very end)
- Direct participation
- Open to non-European

## Represent the agreement of the WS participants

### Used for:

- Emerging or rapidly-changing technologies
- Output of Research Projects
- As try-out before the development of ENs

A large blue triangle pointing upwards, containing the text 'Maximum lifetime: 6 years !'.

Maximum  
lifetime:  
6 years !

# Reminder – Drafting, editing and publishing

CEN/TC XXX  
Date: 20XX-XX  
prEN XXXXX: XXXX  
Secretariat: XXX

**Introductory element — Main element — Complementary element**  
Einführendes Element — Haupt-Element — Ergänzendes Element  
Élément introductif — Élément central — Élément complémentaire

ICS:

CCMC will prepare and attach the official title page.

## Useful tools to get you started

- ▶ [Internal Regulations Part 3](#)
- ▶ [STD.dot template](#)

## Simple template

- ▲ Find on [CENELEC BOSS](#)

## Ready-styled

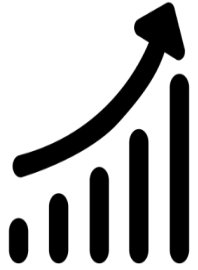
### Contains all elements

- ▲ Styles
- ▲ Headings
- ▲ Content layout

## **3. Frankfurt Agreement & Day-to-day management**



# International dimension



**1 region = one standard instead of 34**

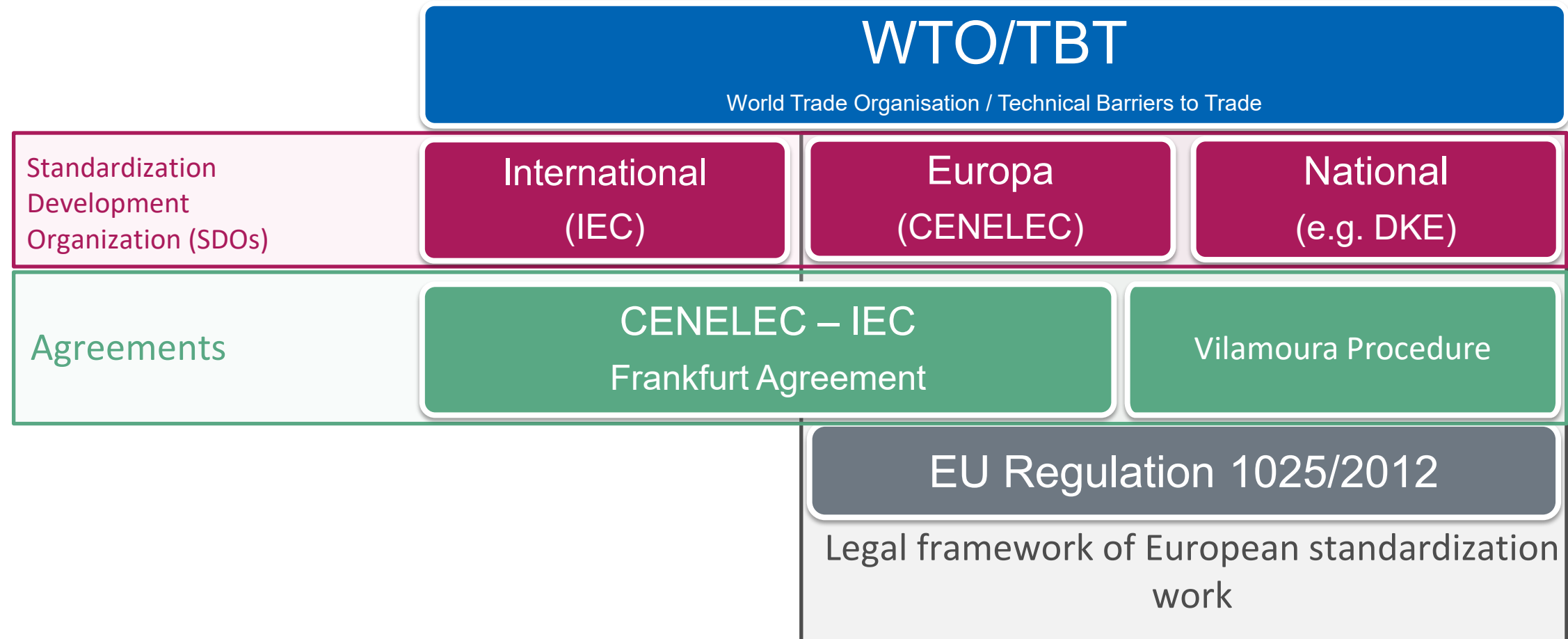
- Status of EN
- Standstill
- Obligation to implement

## Primacy of International standards

- ▶ Commitment to primarily undertake the work at IEC level
- ▶ Expedite publication & common adoption of Int. Standards
- ▶ Rational use of available resources/avoid duplication
- ▶ Accelerate standards preparation process in response to market demands
- ▶ Include mechanisms to cater for particular needs that may arise from European stakeholders



# Cooperation at international and European level

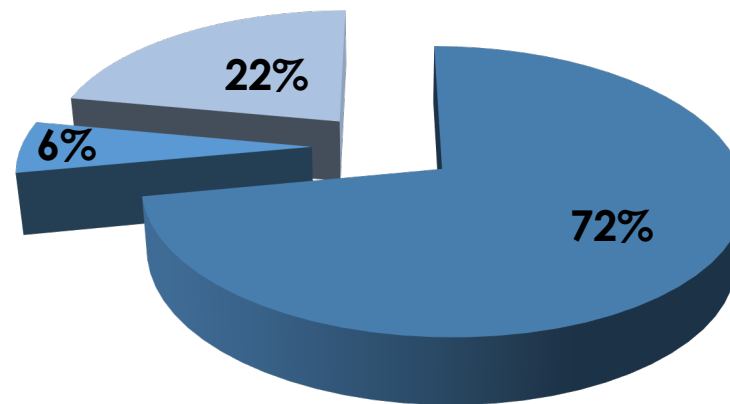


# Facts and figures

What?	When?	Why?
<p>Agreement on common planning of new work and parallel voting between IEC and CENELEC</p>	<p>1996 – Signature Dresden Agreement</p> <p>2016 – Signature Frankfurt Agreement</p>	<p>Underline commitment of IEC &amp; CLC to undertake work at Intl. level</p> <p>Promote global economy</p> <p>Ensure rational use of back office resources</p>

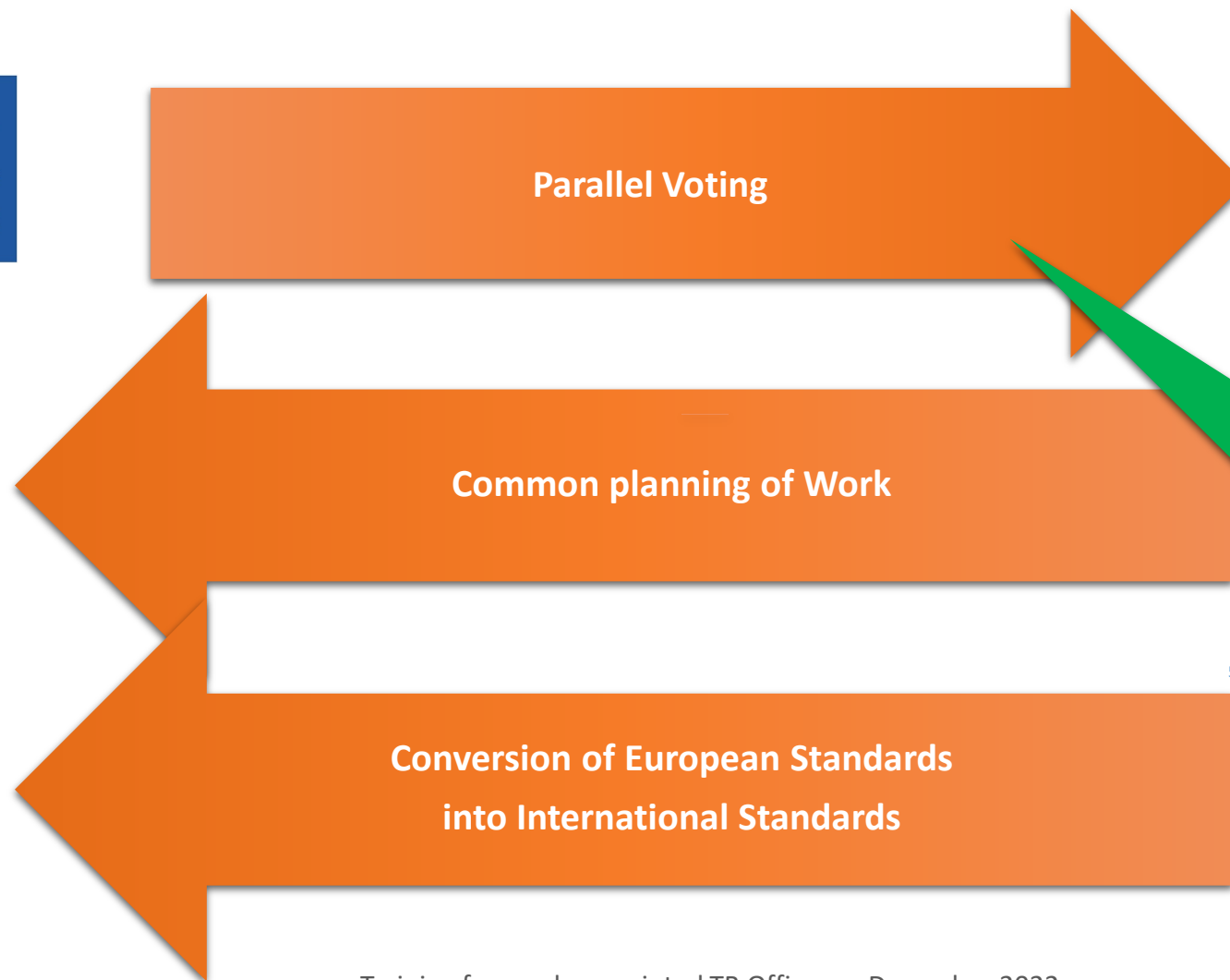
## CENELEC – Portfolio – relation to IEC

Only European Standards (no TS, no TR, no Guides) are covered by the Frankfurt Agreement



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

# Main principles: 3 pillars



Standards that are exempted of the parallel procedure are listed in **Exemption List**. Those exemptions can be temporarily or permanent

## Work initiated in IEC

### When not 'exempted'

- ▶ Assigned to mirroring CLC Technical Committee (CLC/TC) or Reporting Secretariat (CLC/SR)
- ▶ Registered in CLC database with timescales
- ▶ Parallel adoption process starts in CENELEC

### When 'exempted'

- ▶ No 'European adoption' but national adoption possible
- ▶ Standstill may apply → to be **used 'as such'** in Europe, no competing standards

## Work initiated in CENELEC (NWI)

### Before initiating:

- ▶ Assess situation at IEC - possibility the IEC TC timely initiates the work

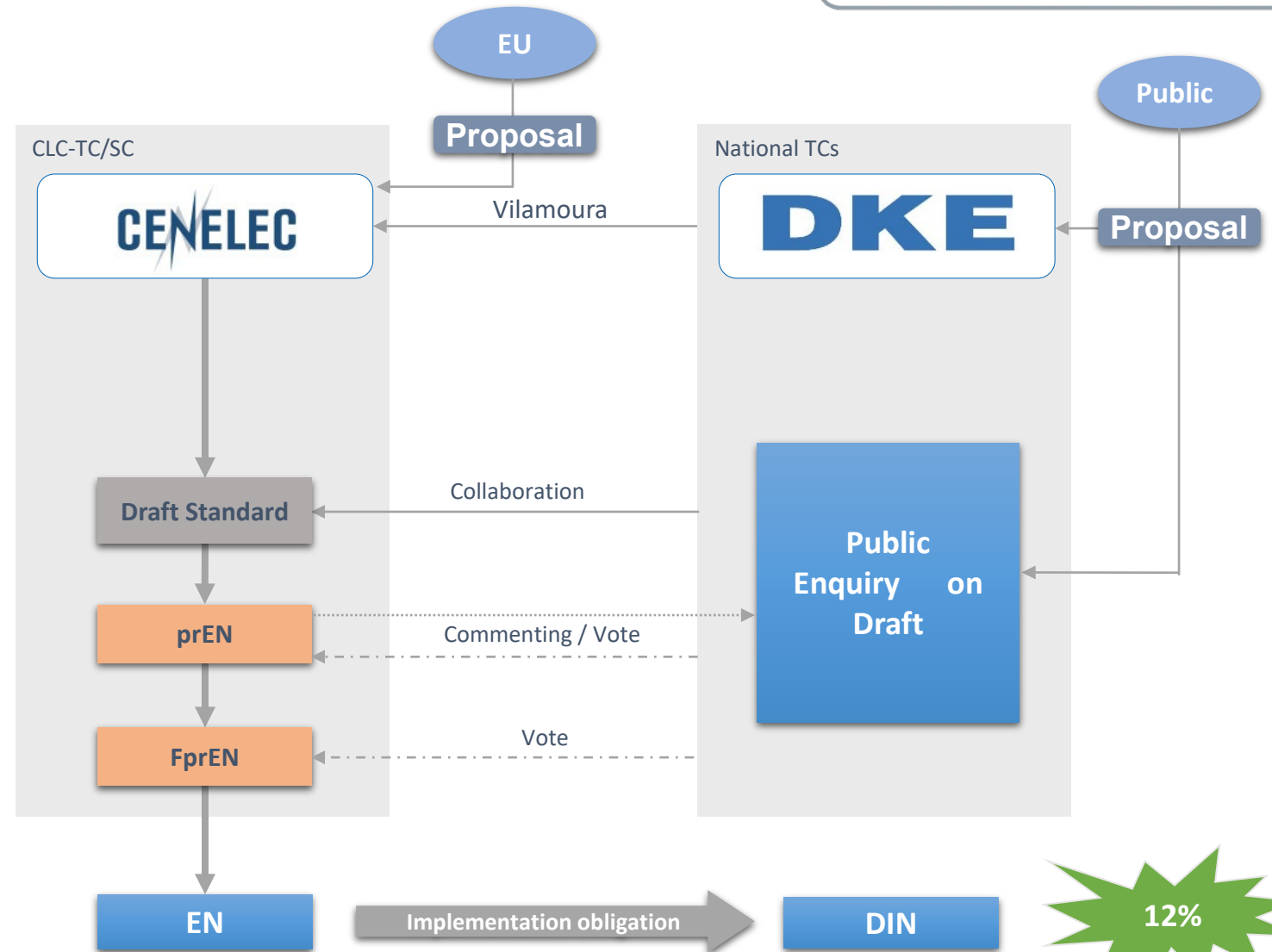
### On approval of a New Work Item for a European standard at CENELEC

- ▶ Default\* -- the New Work Item is offered to IEC
- ▶ The CLC/TC starts the work – IEC starts a NWIP on the WI
- ▶ If IEC NWIP accepted → CLC hands over work

\* For specific reasons, the CLC Technical Board (BT) can decide not to offer

# European standardization procedure

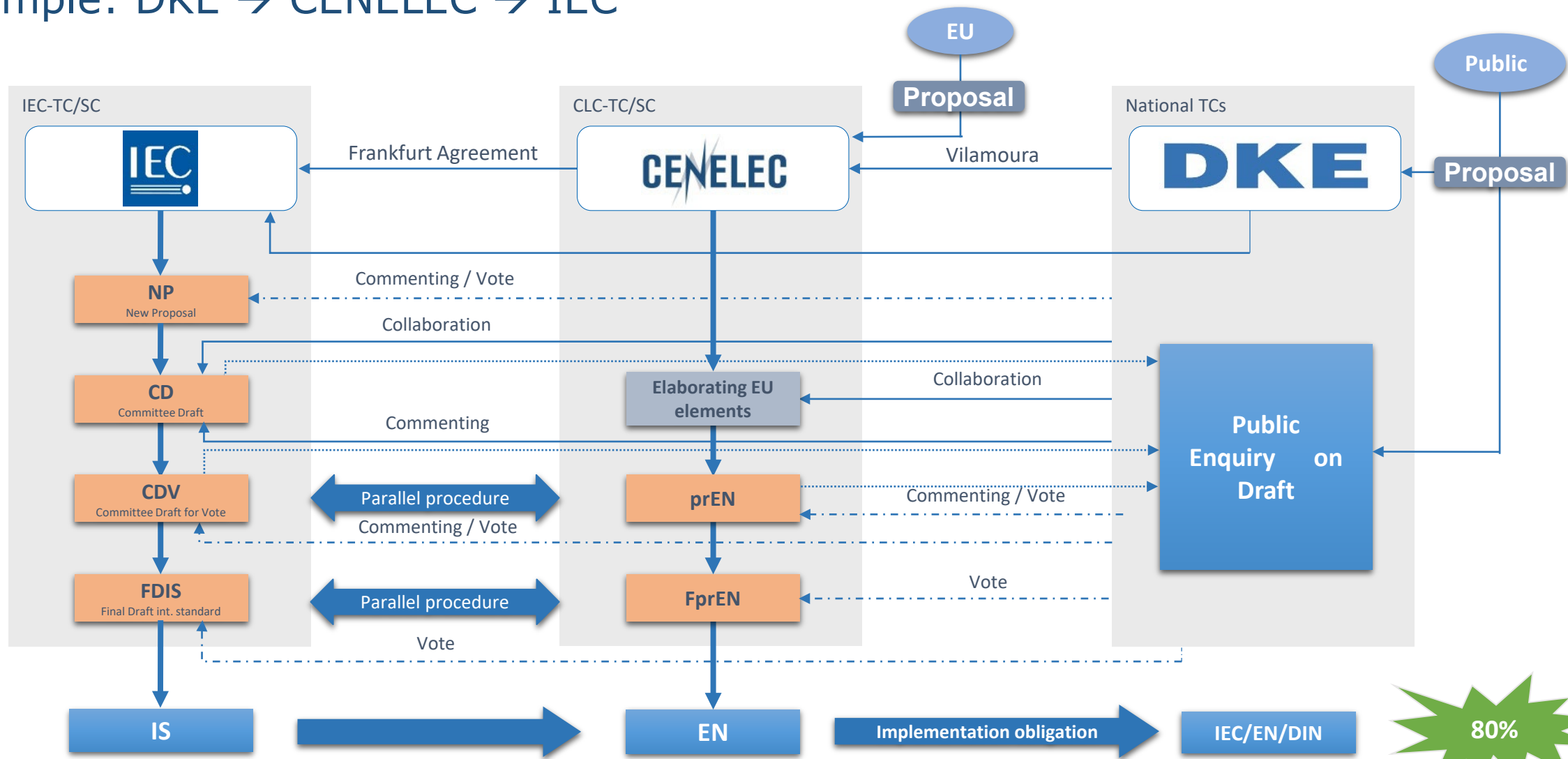
DKE → CENELEC



12%

# Standardization procedure according to Frankfurt Agreement

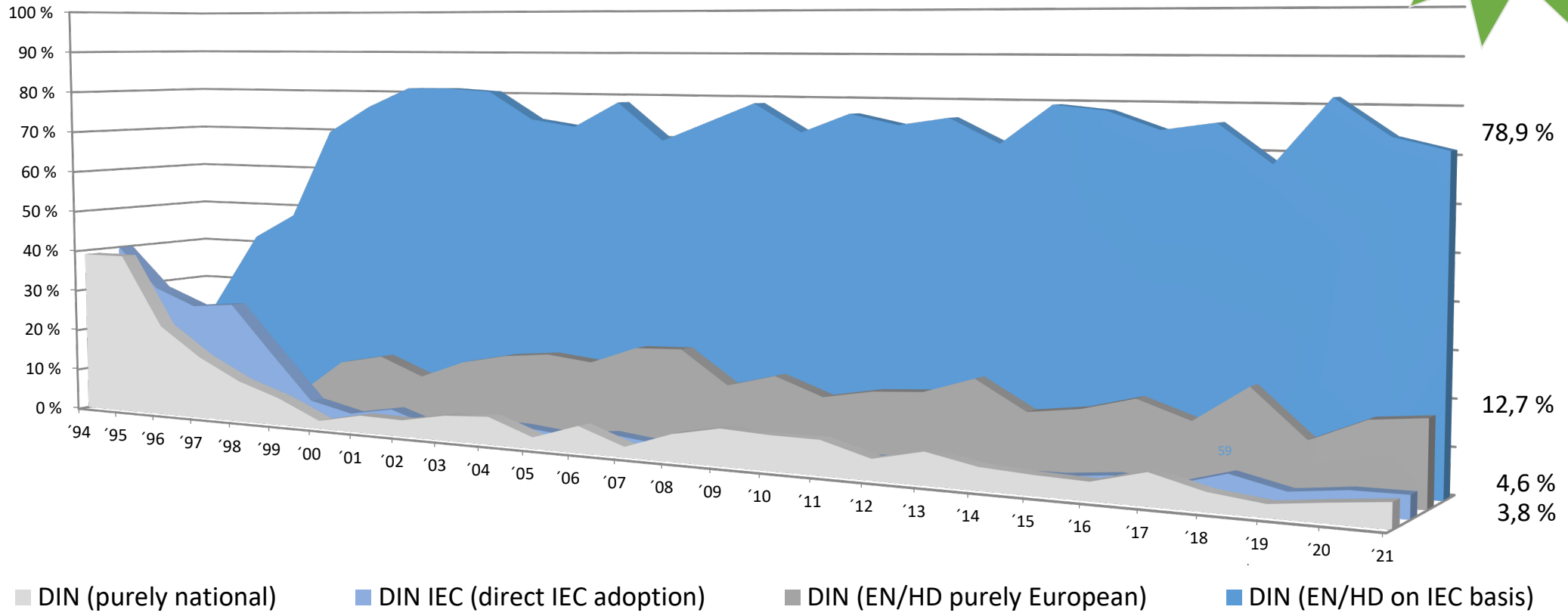
Example: DKE → CENELEC → IEC



# Frankfurt Agreement in practice

## Share of electrotechnical standards in Germany in 2021

84% based on IEC Standards





## **4. Developing ENs intended to be cited in OJEU**

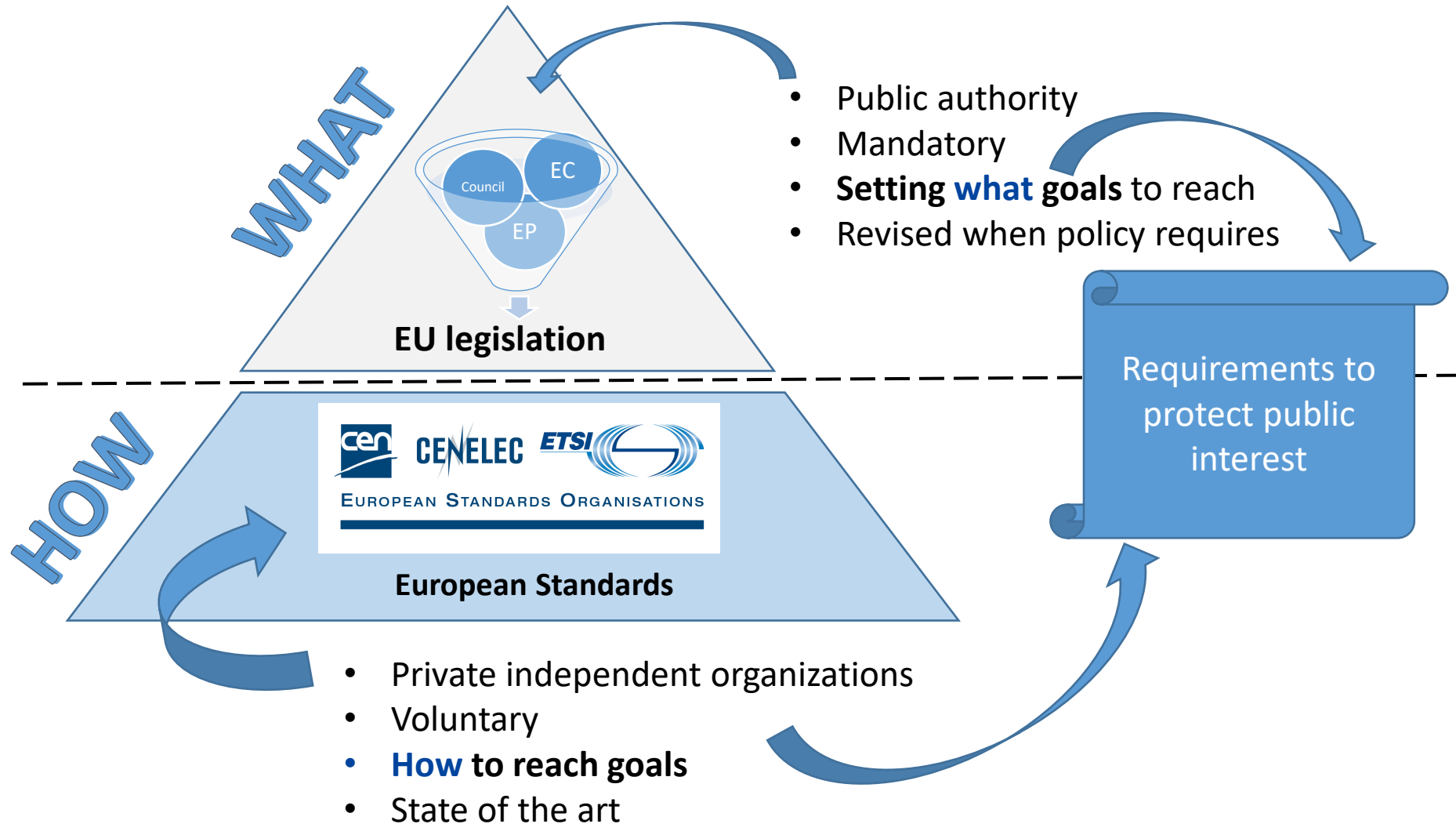
## ▶ **New Approach Directives**

- ▶ Define essential requirements (e.g. health and safety)
- ▶ Indicate WHAT shall be achieved without specifying HOW
- ▶ Transposed in Member States

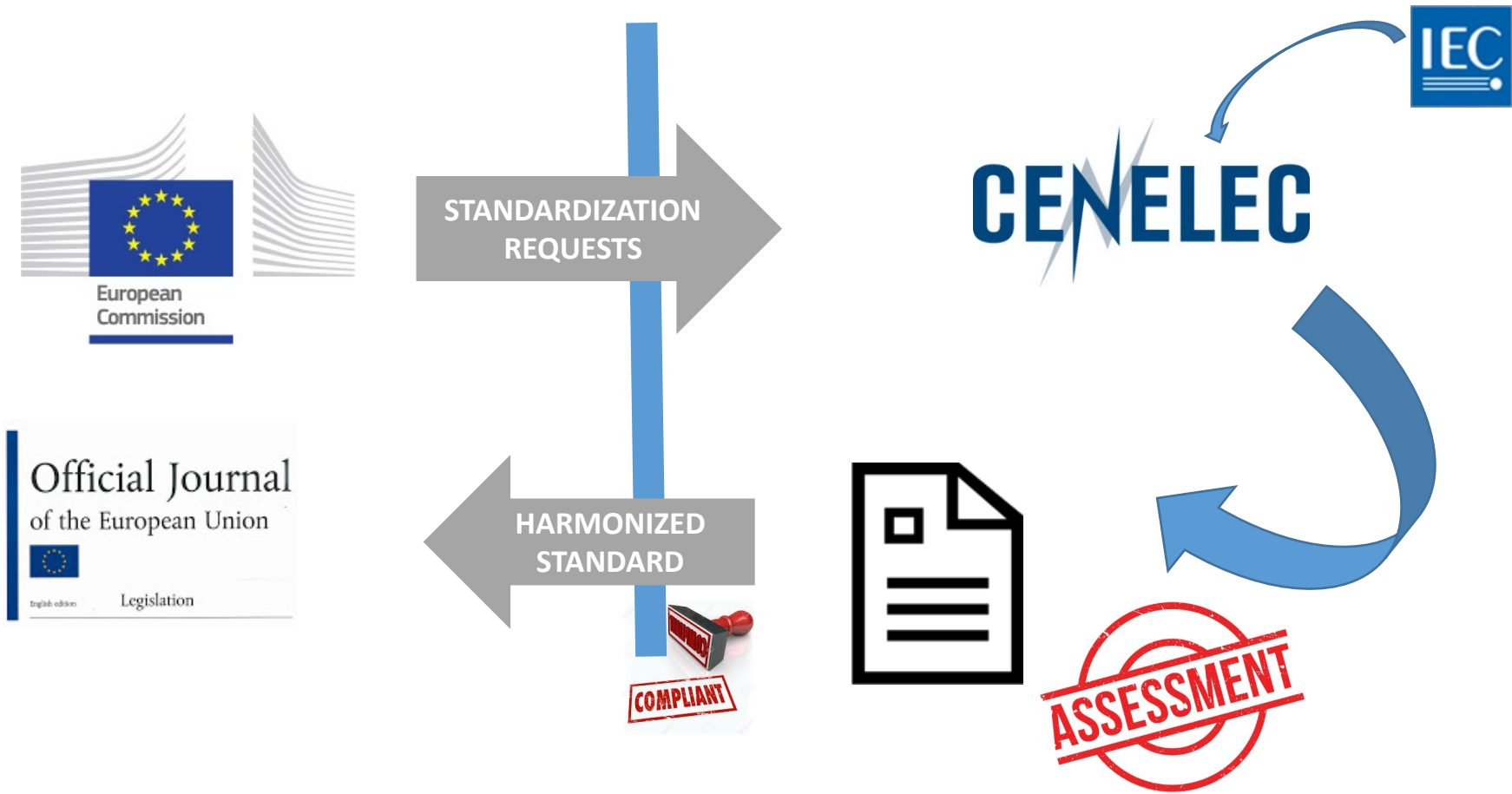
## ▶ **Reference to standards**

- ▶ At EC's request, CEN and CENELEC develop Harmonized Standards (hENs)
- ▶ ENs set out technical specifications to meet Directives' requirements

# How Standardization supports legislation



# Link with EU legislation & Standardization Requests



> **3000 harmonized standards listed in the OJEU**

European law (Directives / Regulations) regulates important industrial sectors:

- ▲ PPE
- ▲ Medical devices
- ▲ Low voltage equipment
- ▲ Machinery
- ▲ EMC
- ▲ Radio Equipment

[Link to EC page on Harmonised standards](#)

- ✓ Standards are a tool to support EU policy and legislation according to the principles of the New Legislative Framework (New Approach)

# New approach

- ▶ **Standardization Request** a precondition for citation of harmonized standards in Official Journal of the European Union (OJEU)
- ▶ **Assessment** of compliance with legal requirements
- ▶ **Annex ZZ** obligatory for candidate harmonized standards (hENs)
- ▶ Citation in the OJEU always **EC responsibility** – CEN and CENELEC offer candidate hENs to EC for citation quarterly
- ▶ The lists of hENs are **published in the OJEU** and continuously updated: [http://ec.europa.eu/growth/index\\_en.htm](http://ec.europa.eu/growth/index_en.htm)
- ▶ **Only when listed in the OJEU → presumption of conformity** for Essential Requirements covered by the hEN

# New approach – Standardization Request

<i>Article 1</i> <b><i>Requested standardisation activities</i></b>	→	Refer to the legislation / policy
<i>Article 2</i> <b><i>Establishment of the work programme</i></b>	→	Work programme of requested deliverables; responsible technical bodies; timeframe.
<i>Article 3</i> <b><i>Agreement on the work programme</i></b>	→	EC to be informed of any changes in the WP
<i>Article 4</i> <b><i>Reporting</i></b>	→	Annual reporting
<i>Article 5</i> <b><i>Harmonised standards</i></b>	→	Clear and precise description of relationship between hEN and EU legislation
<i>Article 6</i> <b><i>Validity</i></b>		
<b>ANNEXES</b>	→	<ol style="list-style-type: none"><li>1. Requirements of the hENs</li><li>2. Harmonised standards and deadlines for adoption</li></ol>

**Annex ZA**  
(informative)

**Relationship between this European Standard and the essential requirements of Directive 2006/42/EC aimed to be covered**

All harmonized standards must include an **Annex ZZ**, demonstrating the relationship between the clauses of the standard and the regulatory requirements

This European Standard has been prepared under a Commission’s standardization request “M/396” to provide one voluntary means of conforming to essential requirements of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast).

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

**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	5.1.1; 5.1.2; 5.3.2	
1.1.4 Lighting	5.7.1; 5.7.2; 5.7.3; 5.7.4; 5.7.5; 5.7.6; 5.8.7	
1.1.5 Design of machinery to facilitate its handling	5.1.1; 5.5.2; 5.5.6; 5.8.1; 5.8.3; 5.8.4; 5.10.1; 5.10.5; 5.10.14.2	
1.1.6 Ergonomics	5.1.1; 5.2.1; 5.2.2; 5.2.3; 5.3.1; 5.3.3; 5.3.4; 5.8.5; 5.10.4; 5.10.8; 5.10.10; 5.10.12; 5.10.14.1	
1.1.7 Operating positions	5.1.1; 5.2.1; 5.2.3	
1.1.8 Seating	5.1.1; 5.3.1; 5.3.3; 5.3.4; 5.3.5	
1.2.1 Safety and reliability of control systems	5.1.9; 5.4.3; 5.5.3; 5.7.3	
1.2.2 Control devices	5.1.9; 5.4.1; 5.4.2; 5.4.3	



# Citation in the Official Journal of the EU (OJEU)



2.4.2020

EN

Official Journal of the European Union

L 102/9

## ANNEX I

Annex I to Implementing Decision (EU) 2019/436 is amended as follows:

(1) row 35 is replaced by the following:

'35.	EN 62841-2-1:2018 Electric motor-operated hand-held tools, transportable tools and lawn and garden machinery – Safety – Part 2-1: Particular requirements for hand-held drills and impact drills (IEC 62841-2-1:2017, Modified) EN 62841-2-1:2018/A11:2019	C
------	--	---

(2) the following rows are added:

'43.	EN ISO 18497:2018 Agricultural machinery and tractors – Safety of highly automated agricultural machines – Principles for design (ISO 18497:2018)	B
44.	EN ISO 19353:2019 Safety of machinery – Fire prevention and fire protection (ISO 19353:2019)	B

[https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards\\_en](https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en)

### Summary list of titles and references of harmonised standards

The summary below consolidates the references of harmonised standards published by the Commission in the Official Journal of the European Union (OJ). It reproduces information already published in the L or C series of the OJ. It contains all references which, when the summary was generated, still provided a presumption of conformity together with references already withdrawn from the OJ.

The Commission services provide this summary for information purposes only. Although they take every possible precaution to ensure that the summary is updated regularly and is correct, errors may occur and the summary may not be complete at a certain point in time. The summary does not as such generate legal effects.

- [Summary list as pdf document](#)
- [Summary list as xls file](#)

# HAS assessment system

- ▶ 2021-12-27: EC launched call for tender '[Technical Assistance to the Commission for the Assessment of Harmonised Standards](#)'
- ▶ HAS budget: 10 800 000 EUR
- ▶ Duration of contract: 2 + 2 years
  
- ▶ [New HAS contract signed in August 2022](#)
- ▶ HAS contractor = **Ernst & Young (EY)**
  
- ▶ **HAS assessments started to be processed: mid-October 2022**
- ▶ Backlog of HAS assessments: 296
- ▶ HAS assessment reports received: 51

# HAS assessment system

- ▶ HAS assessment system is restored and improved:
  - ▶ Increase of budget (from 2200 person-days to 3400)
  - ▶ More communication and meeting participation (from 20% to 25%)
  - ▶ New Last Confirmatory Assessment (LCA)
  - ▶ Introduction of 'conditional compliance' outcome
- ▶ HAS assessment reports are anonymous (at least for now)
- ▶ All meetings shall be requested via the **HAS meeting request tool**:  
[https://globaleysurvey.ey.com/jfe/form/SV\\_b71bSqkXAtAqqTs](https://globaleysurvey.ey.com/jfe/form/SV_b71bSqkXAtAqqTs)
- ▶ Assessment duration: **normally 5 weeks after notification to EY**

# HAS Consultants

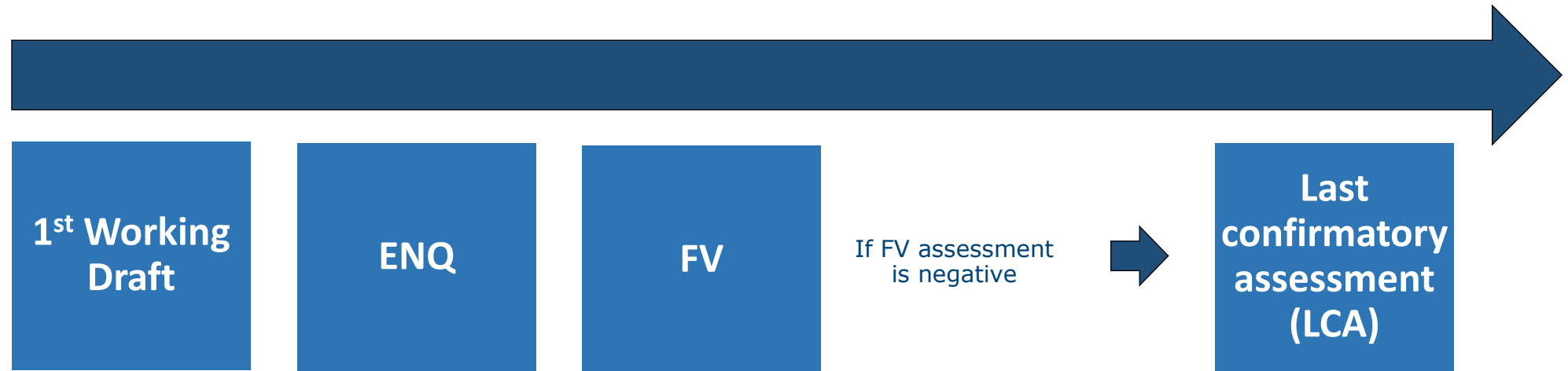
## HAS consultants can:

- ▶ Perform assessment tasks (75% of their time)
- ▶ Participate in meetings to offer clarification on their assessments (max. 25% of time spent on meetings)
- ▶ Convey EC positions to Technical Bodies

## HAS consultants cannot:

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

## When can assessments be requested?

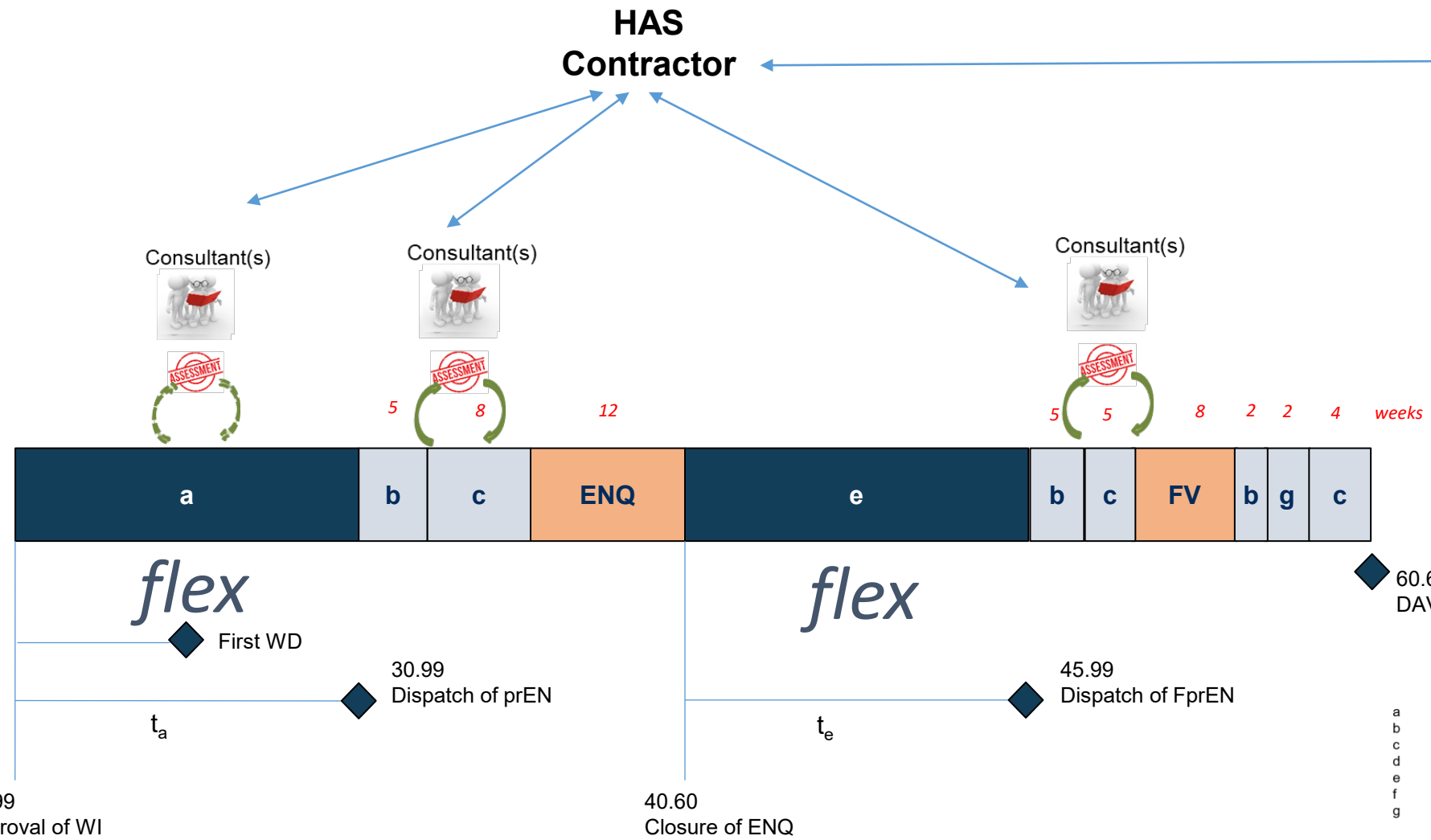


- ▶ ESOs can request maximum 4 assessments per WI
- ▶ 1 assessment per stage + LCA
- ▶ LCA: full assessment
- ▶ Not possible to request assessments of published standards

# Assessment of standards



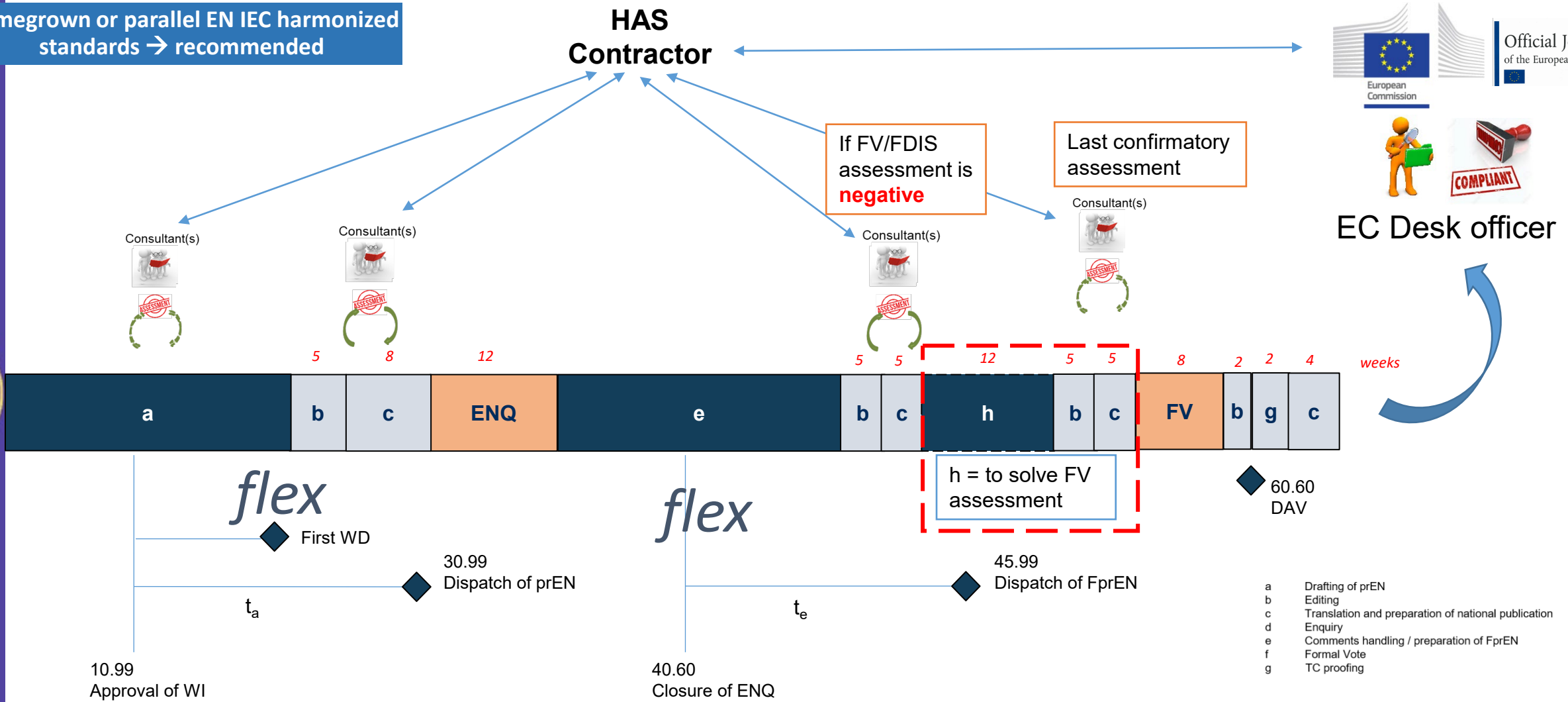
EC Desk officer



# Assessment of standards: LCA before FV

Homegrown or parallel EN IEC harmonized standards → recommended

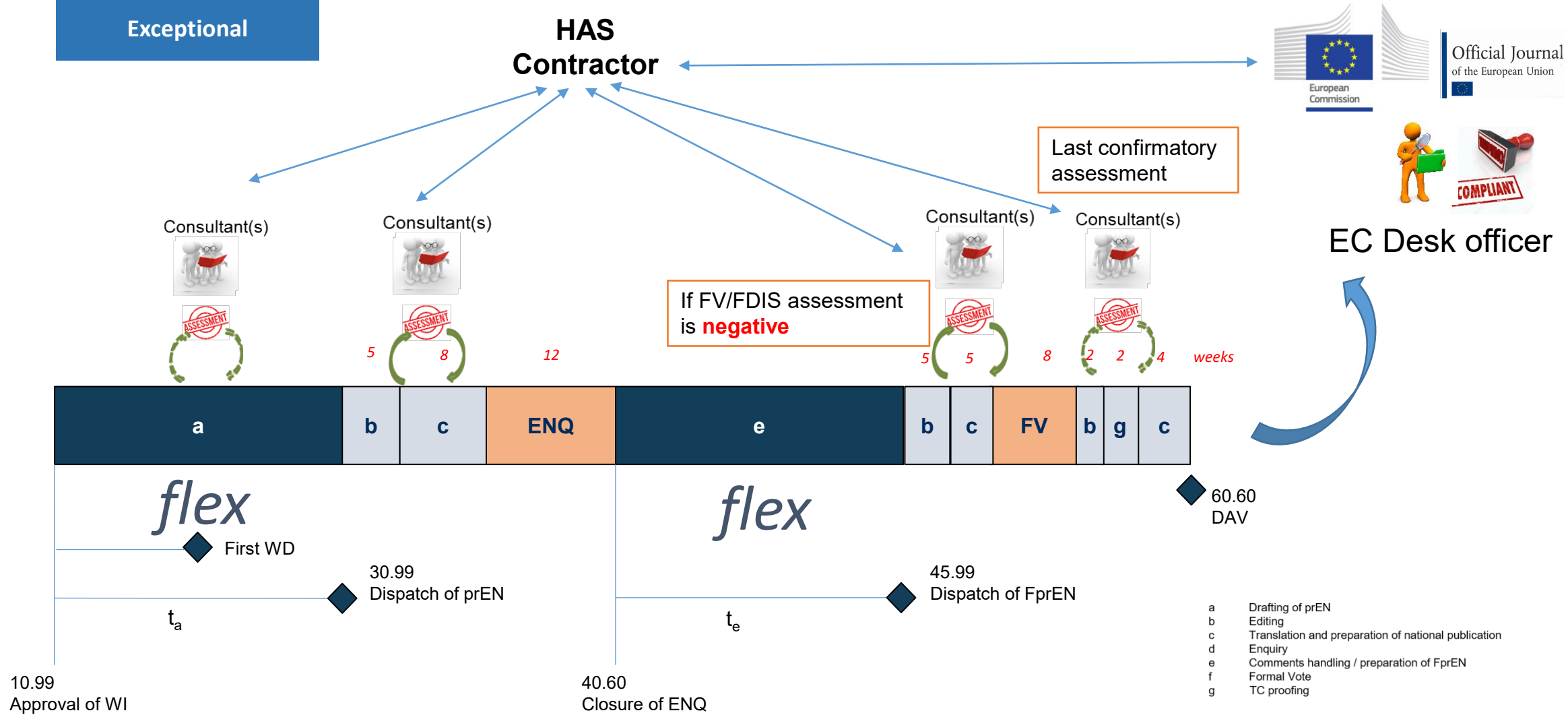
HAS Contractor



- a Drafting of prEN
- b Editing
- c Translation and preparation of national publication
- d Enquiry
- e Comments handling / preparation of FprEN
- f Formal Vote
- g TC proofing

# Assessment of standards: LCA after FV

Exceptional



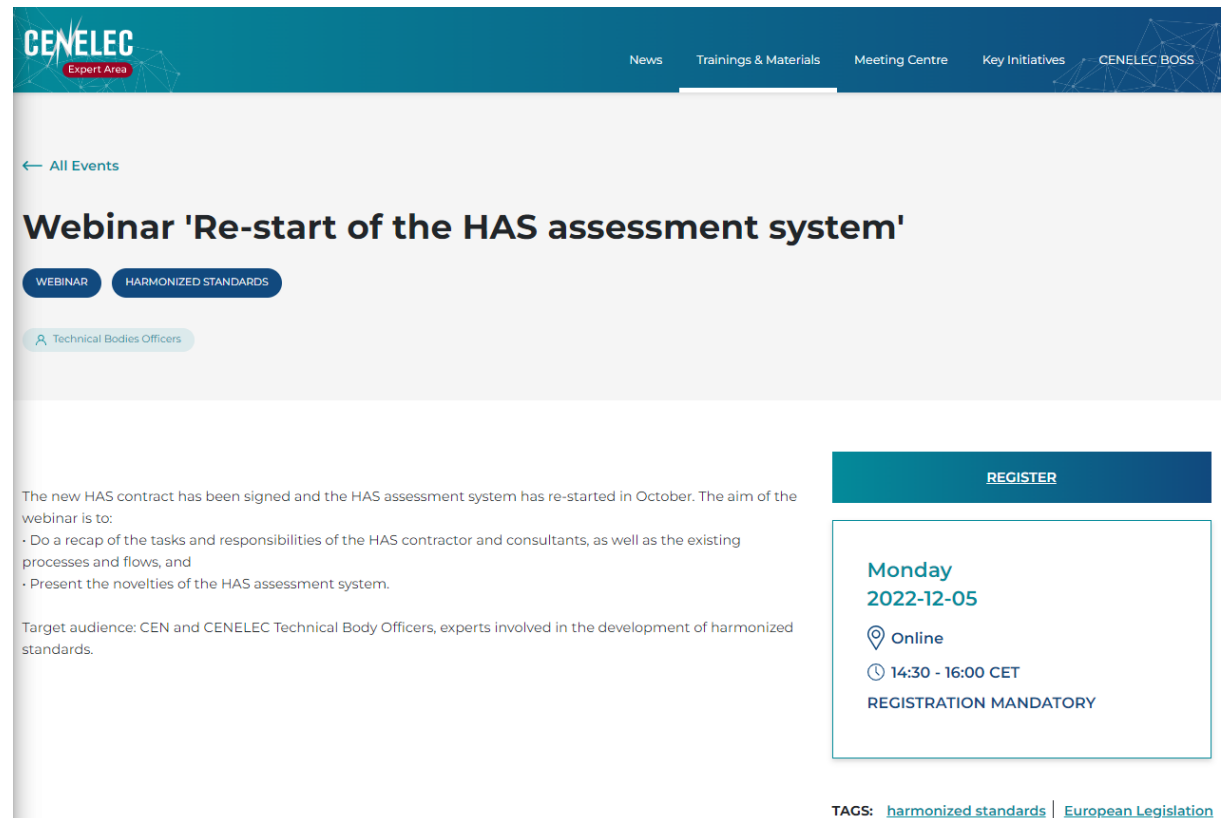


## Outcome

<b>'Compliant'</b>	If the same conclusion is done reached by EC, the publication of the reference in the OJ is normally possible without any specific notice
<b>'Conditional compliance'</b>	To be used only in case of problems related to the dates of normative references to other inter-linked standards and meaning that, if the identified issue(s) is positively addressed by the ESO after the assessment, and if the same conclusion is reached done by EC the publication of the reference in the OJ is normally possible without any specific notice
<b>'Lack of compliance'</b>	If the same conclusion is reached done by the Commission, the publication of the reference in the OJ is likely not possible without adaption of the document

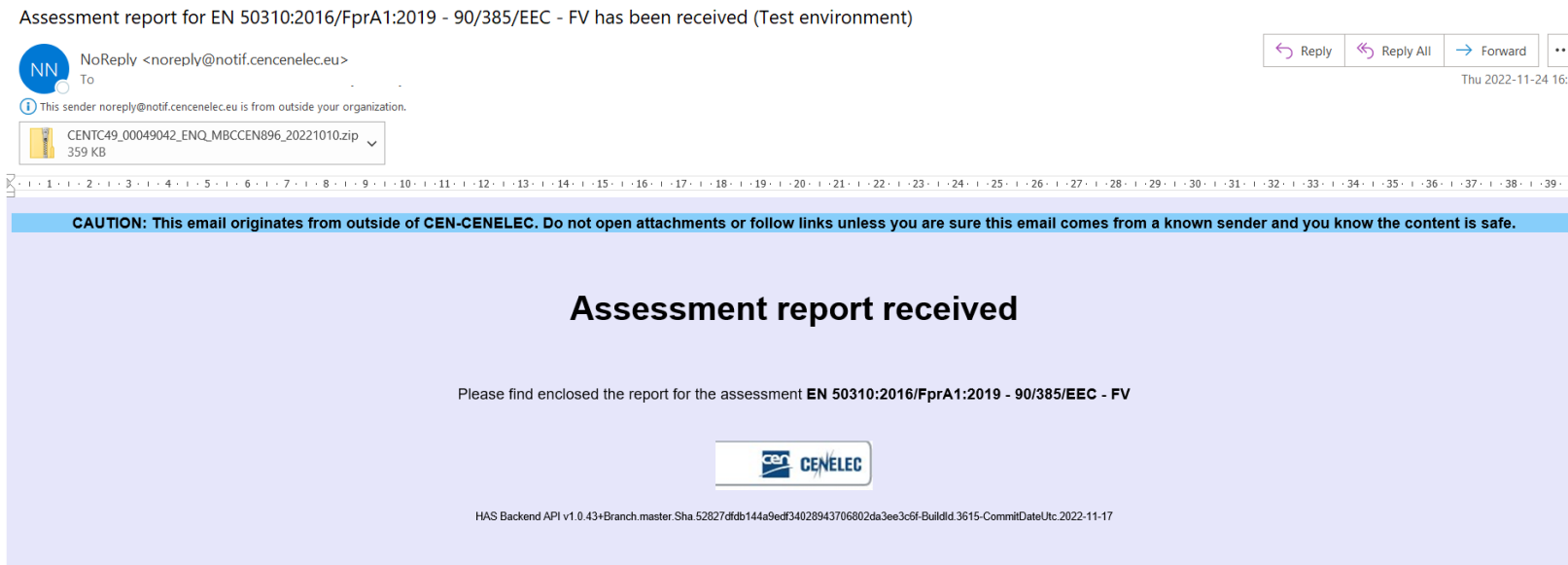
# Interaction with standards development

- ▶ 2022-12-05: [CEN webinar](#) and [CENELEC Webinar](#)  
'Re-start of HAS assessment system'



The screenshot shows the CENELEC website interface for a webinar event. The header includes the CENELEC logo and navigation links for News, Trainings & Materials, Meeting Centre, Key Initiatives, and CENELEC BOSS. The main content area features a breadcrumb trail '← All Events', the event title 'Webinar 'Re-start of the HAS assessment system'', and category tags 'WEBINAR' and 'HARMONIZED STANDARDS'. A search filter 'Technical Bodies Officers' is also present. The event description states: 'The new HAS contract has been signed and the HAS assessment system has re-started in October. The aim of the webinar is to: · Do a recap of the tasks and responsibilities of the HAS contractor and consultants, as well as the existing processes and flows, and · Present the novelties of the HAS assessment system.' The target audience is identified as 'CEN and CENELEC Technical Body Officers, experts involved in the development of harmonized standards.' A 'REGISTER' button is prominently displayed. The event details box specifies the date as 'Monday 2022-12-05', the location as 'Online', and the time as '14:30 - 16:00 CET', with a note that 'REGISTRATION MANDATORY'. The page concludes with tags for 'harmonized standards' and 'European Legislation'.

- ▶ New HAS Platform tool → **Consultant Assessment interface**
  - ▶ CCMC requests draft hENs for assessment
  - ▶ EY uploads HAS assessment report
- ▶ Technical Body secretary will get a notification (via email) when HAS assessment report is available



Harmonized standards (hEN) are developed in the same way as any other EN in CENELEC – **but with additional considerations:**

## ❑ Mandatory for hEN:

All harmonized standards shall include an informative Annex ZZ, demonstrating the relationship between the clauses of the standard and the regulatory requirements.

→ For standards developed under the Frankfurt Agreement, a normative Annex ZZ 'normative references' shall be included as well.

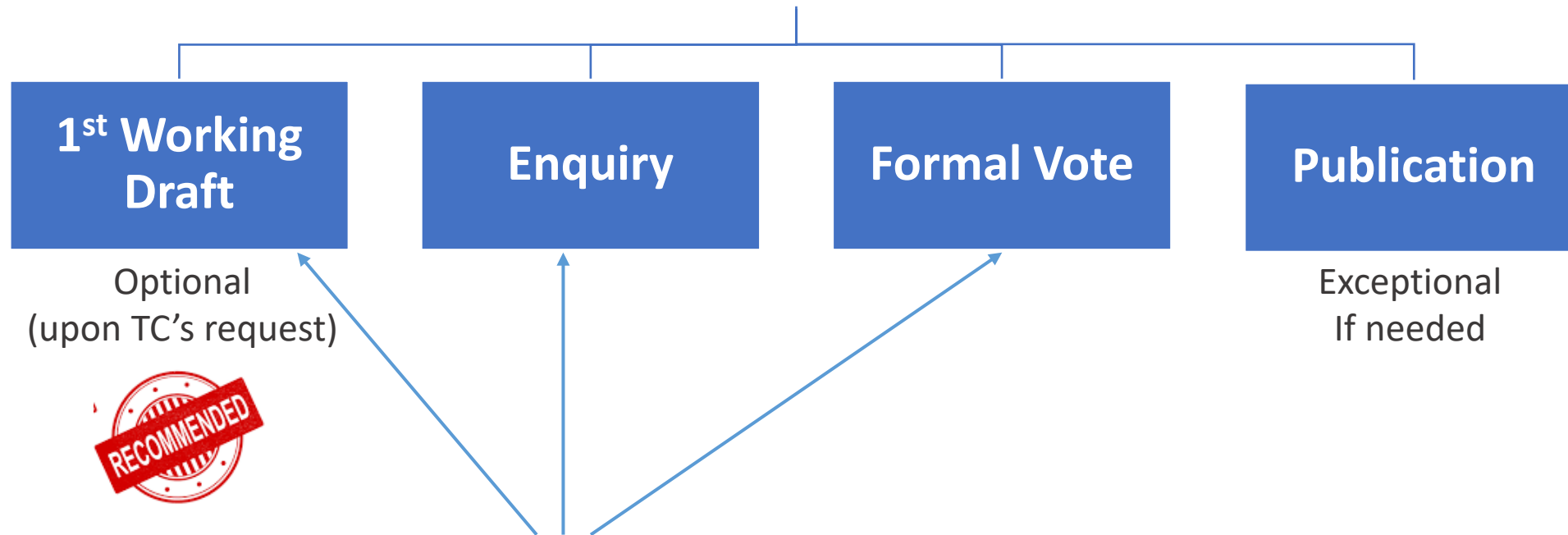
## ❑ Consultant assessments:

The HAS consultants assess the compliance of a standard with directive's (and standardization request) requirements, via communicating with and delivering assessments to the TCs - they work on behalf of the EC.



**'Compliant assessment' on EN is needed to have the EN "offered" (by CEN & CENELEC) to the European Commission and then cited in the OJEU (European Commission decision)!**

## When can assessment be requested?



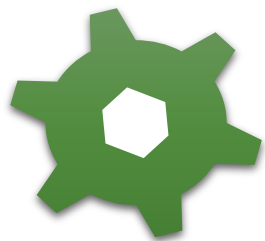
**At any of above stages assessment can be requested.  
However, only 1 assessment per stage !**

## What TC needs to deliver to CCMC?

Optional assessment	<b>1<sup>st</sup> Working Draft</b>	<ul style="list-style-type: none"><li>✓ Draft standard (e.g. IEC CD - not in CCMC possession: TC to provide it)</li><li>✓ Risk assessment</li><li>✓ Informative Annex ZZ (however not mandatory at this stage)</li></ul>
Formal assessment	<b>Enquiry</b>	<ul style="list-style-type: none"><li>✓ Informative Annex ZZ</li><li>✓ Normative Annex ZA (CCMC can deliver a draft – but formally under TC responsibility)</li><li>✓ Risk Assessment</li><li>✓ Recommendation to include responses to the Consultant's comments at 1<sup>st</sup> Working Draft</li></ul>
Formal assessment	<b>Formal Vote</b>	<ul style="list-style-type: none"><li>✓ Informative Annex ZZ (send the Annex again to CCMC, even if unchanged!)</li><li>✓ Normative Annex ZA (send the Annex again to CCMC, even if unchanged!)</li><li>✓ Risk Assessment (send the Annex again to CCMC, even if unchanged!)</li><li>✓ Responses to the Consultants' comments received at Enquiry</li></ul>
Exceptional, only when needed	<b>Publication</b>	<ul style="list-style-type: none"><li>✓ Informative Annex ZZ</li><li>✓ Normative Annex ZA</li><li>✓ Risk Assessment</li><li>✓ Responses to the Consultants' comments received at Formal Vote</li></ul>

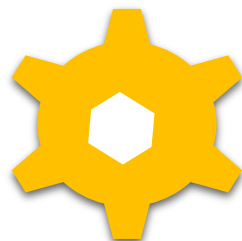
# Citation of a harmonized Standard in OJEU

**hEN standard developed in the support of legislation**



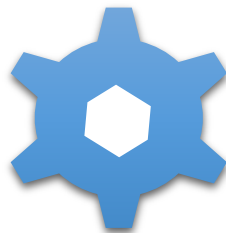
## **Annexes:**

TC to provide additional European elements



## **HAS Assessment:**

Ensuring the standard complies to the Safety Objectives of the Directive(s)



## **Offering to EC:**

Only if positively assessed, CCMC offers the standard to EC for citation



## **Final decision:**

EC's decision to cite the standard in the OJEU

**Standard cited in the OJEU**



## Principles for a successful assessment

- ▶ **Start the process as early as possible!**  
i.e. with the assessment request of the first working draft: the consultant would flag compliance issues early in the process
- ▶ **Systematically provide feedback!**  
TC shall provide feedback by responding, in writing, to the HAS consultant's comments  
(column: observations from the secretariat)
- ▶ **Communication is the key!**
  - Ensure communication flows between CLC/TC (interaction with the HAS consultants) and IEC/TC (writing the standard)
  - Ensure communication flows with HAS Consultant: After the submission of the assessment by CCMC, TCs are encouraged to engage with HAS consultants





## **5. CENELEC BOSS and other useful information**

# CENELEC Expert Area

- ▶ Link: <https://experts.cenelec.eu/>
- ▶ Your platform to:
  - ▶ Applications & services
  - ▶ Expert news (with 'subscribe to news' option)
  - ▶ Trainings & materials
  - ▶ Key initiatives
    - ▶  Digital Transformation
    - ▶  Online Collaborative Authoring
    - ▶  Standards of the Future
    - ▶  Open Source Solutions
- ▶ CENELEC BOSS

# Business Operation Support System

- ▶ Source of stable information to CENELEC/TC secretaries, chairpersons and experts
- ▶ Quick and easy access to navigate-internet tool with public access from main CENELEC website
- ▶ CEN-CENELEC Internal Regulations are on the BOSS
  - Part 2: Common Rules for Standardization Work
  - Part 3: Rules for the structure and drafting of CEN & CENELEC Publications



**CENELEC**

TECHNICAL STRUCTURES HOMEGROWN DELIVERABLES FRANKFURT AGREEMENT DELIVERABLES REFERENCE MATERIAL

## Business Operations Support System

The Business Operations Support System (BOSS) aims at providing practical information to those actively contributing to the development of deliverables within the CENELEC system. It clearly describes processes and gives access to instructions and guidance for their day-to-day work.

Enter key words or phrase

# Business Operation Support System

## Forms and templates

### TECHNICAL BODY ORGANIZATION

- › Meeting agenda (NEW!)
- › Terms of Reference
- › TC Business Plan
- › TC report to BT (NEW!)
- › JTC report to BTs
- › SC report to TC
- › BTTF report to BT
- › Registration form TC meeting
- › Registration form BTTF meeting
- › Registration form (BT)WG meeting
- › Workshop - Registration Form
- › Workshop - Proposal Form
- › Workshop - Project plan
- › Application form to become member in a Joint advisory or coordination g

### TECHNICAL WORK

- › Commenting template
- › Checklist – Items to be considered when drafting standards to be offered
- › IPR- Exploitation Rights License Agreement
- › IPR - Attendance list
- › IPR - Patents declaration
- › IPR - WS exploitation
- › NWI form
- › New Field of Technical Activity

### ANNEX ZZ

- › Generic template (EN - FR - DE)
- › Ecodesign (EN - FR - DE)
- › EMCD (EN - FR - DE)
- › EMCD - generic text for references to EN 55011, EN55014-1, EN 55015,
- › GPSD (EN - FR and DE not available)
- › IVDR (EN - FR and DE not available)
- › LVD (EN - FR - DE)
- › Medical Devices (EN - FR and DE not available)
- › Machinery (EN - FR and DE not available)
- › RED - EMC (EN - FR (not available) - DE)
- › RED - Safety (EN - FR (not available) - DE)
- › Railway (EN - FR and DE not available) + Explanatory note

### TECHNICAL BOARD

- › NC template for BT documents
- › Reply to BT consultation (NCs) - general NEW!
- › Reply to BT vote on Standardization Requests (NCs)
- › Reply to BT consultation - Partners
- › Comments on draft Standardization Requests
- › Candidature for (re)allocation of TC/SC/JTC secretariat
- › Candidature for (re)allocation of SR secretariat

TECHNICAL STRUCTURES   HOMEOWN DELIVERABLES   FRANKFURT AGREEMENT DELIVERABLES   REFERENCE MATERIAL

## Operations System

stem (BOSS) aims at  
lose actively contributing  
within the CENELEC  
s and gives access to  
ice for their day-to-day work.



# BT newsletter

## Sent after each BT meeting

- ▲ Report on the main outcomes of crosscutting nature discussed in the BT meetings as well as on the latest decisions of transversal nature taken by correspondence
- ▲ Sent by email to all TC Officers





# More information

- ▶ Webinar: [The Frankfurt Agreement: Principles and day-to-day management](#)
- ▶ Webinar: [Standardization Requests – State of Play](#)
- ▶ Webinar: [Use and justification of normative references for harmonised standards](#)
- ▶ Webinar: [Risk assessment in standards tool for harmonisation](#)
- ▶ Webinar: [Harmonized European standards: Drafting standards compliant with EU legislation](#)
- ▶ Webinar: [Webinar on EMC matters in relation to harmonized standards](#)
- ▶ Webinar: [Harmonized European standards under the Low Voltage Directive \(LVD\)](#)

# Contact points



TC reports to BT, NWI requests: [dataservice@cencenelec.eu](mailto:dataservice@cencenelec.eu)

Texts for procedures: [production@cencenelec.eu](mailto:production@cencenelec.eu)

Liaisons with European federations: [partners@cencenelec.eu](mailto:partners@cencenelec.eu)

Support on research projects: [research@cencenelec.eu](mailto:research@cencenelec.eu)

For anything else, contact your project manager! 😊



# Questions ?

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