



European Standardization Organizations

# Webinar: restart of the HAS assessment system

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# Your speakers today



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## Background

- ▶ HAS contractor = EY
  - ▶ 1 April 2018 – 31 March 2022
- ▶ Issues with HAS budget (old contract):
  - ▶ March 2021: meetings between HAS consultants and TCs interrupted
  - ▶ October 2021: EC started prioritize FV and PUB assessments → many requests put on hold
- ▶ Causes for budget issues: new sectors (e.g. fertilizers, explosives), consultant management, etc

# HAS contract: backlog

- ▶ HAS assessment requests under the HAS contract not received

	FWD	ENQ	FV	PUB	Total
CEN	4	28	2	1	35
CENELEC	10	25	0	0	35

- ▶ Documents received in CCMC where HAS assessments is due: 296

	ENQ	FV	LCA	Total
CEN total	117	72	3	192
CEN-parallel	32	32		64
CENELEC total	52	52		104
CENELEC-parallel	14	10		24

# New HAS contract

- ▶ 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**
- ▶ HAS assessment reports received: 51

# New HAS contract

- ▶ HAS assessment reports will be **anonymous** for **new assessments** received due to GDPR
- ▶ Small adjustments in database/tools needed
- ▶ Projex-online will not display Consultant's name



## Consultant Assessments:

Consultant name and function:	HAS PED - Consultant PED		
Phase	Event	Realized	CAss Result
Consultant assessment ENQ 111	Start of CAss		
	Completion of CAss (receipt)		Accepted
Consultant assessment FV2 111	Start of CAss	2022-09-01	
	Completion of CAss (receipt)	2022-11-16	Compliant

- ▶ **HAS contractor = EY**
- ▶ EY manages pool of HAS consultants

Formal contact point towards EC and ESO's:

- ▶ **Task 1:** Administrative & logistical tasks
- ▶ **Task 2:** Horizontal verifications and checks of non-technical nature
- ▶ **Task 3:** Evaluation of the assessment results and the effectiveness of the assessment concept
- ▶ **Task 4:** Communication and information to Technical Bodies and EC 

## 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

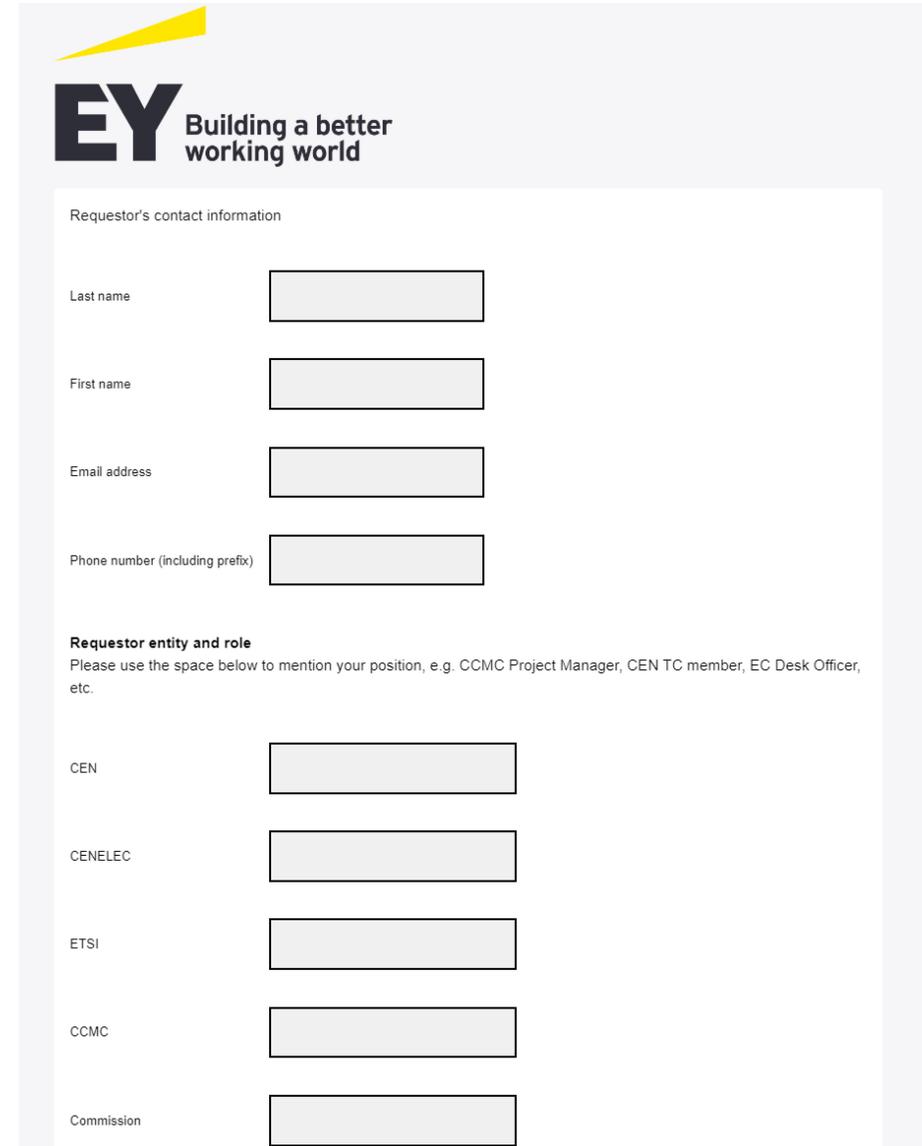
## HAS consultants cannot:

- ▶ 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 

- ▶ EY launched call for consultants:
  - ▶ CPR
  - ▶ Machinery (MD) & Lifts (LD) & Cableway installations designed to carry persons (CWR)
  - ▶ Medical devices & Active implantable medical devices & In vitro diagnostic medical devices
  - ▶ Eco-design (Several Regulations)
  - ▶ Rail

# HAS Consultants

- ▶ New **HAS meeting request tool**:
  - ▶ [https://globaleysurvey.ey.com/jfe/form/SV\\_b71bSqkXAtAqqTs](https://globaleysurvey.ey.com/jfe/form/SV_b71bSqkXAtAqqTs)
  - ▶ **General rule**: HAS consultants to meet TCs to discuss assessments under the new contract
  - ▶ **Case by case**: some meetings with HAS consultants under the previous contract might be possible
  - ▶ Technical Body secretary to make request



**EY** Building a better working world

Requestor's contact information

Last name

First name

Email address

Phone number (including prefix)

**Requestor entity and role**  
Please use the space below to mention your position, e.g. CCMC Project Manager, CEN TC member, EC Desk Officer, etc.

CEN

CENELEC

ETSI

CCMC

Commission

# Sectors covered by HAS system

## DG GROW

**Unit H.2  
Machinery & Equipment**

- Equipment for potentially Explosive Atmospheres (ATEX)
- Machinery (MD)
- Measuring Instruments (MID&NAWI)
- Gas Appliances (GAR)
- Recreational Craft (RCD)
- Electro-magnetic Compatibility (EMC)
- Radio Equipment (RED)
- Lifts (LD)
- Protective Equipment (PPE)
- Cableway installations (CWR)
- Low Voltage Equipment (LVD)
- Pressure equipment and Simple Pressure Vessels (PED&SPVD)

**Unit F.2  
Bioeconomy, Chemicals & Cosmetics**

- Explosives for Civil Use (Expl)
- Pyrotechnic Articles (Pyro)
- Toys
- Fertilisers (Fert.)

**Unit H.1  
Construction**

- Construction Products (CPR)

**Unit I.3  
Green and Circular Economy**

- Eco Design (ED)

**NEW UNDER THIS CONTRACT**

## DG SANTE

**Unit B.6 -Medical devices, Health Technology Assessment**

- Medical Devices (HE)

## DG DEFIS

**Unit A.1- Defence Industry and Market Policy**

- Unmanned Aircraft Systems (UAS)

## DG JUST

**Unit E.4- Product safety and Rapid Alert System**

- General Product Safety (GPSD)

## DG MOVE

**Unit C.4- Rail Safety and Interoperability**

- Interoperability of Rail Systems (IRS)

# Interaction with standards development

- ▶ When creating NWI, important to link with relevant legislation and standardization request/mandate:



New Work Item Proposal	
* to be attached to the CIB	
TC name – TC title	
Secretariat:	Proposal documented in N xx
Date of circulation:	Closing date for voting:
Decision reference:	Decision date:



## New Work Item Proposal

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

### Proposal

<p><b>0. This proposal relates to</b></p> <p><input type="checkbox"/> the adoption of a New Work Item in the committee's work programme (stage 10.99)</p> <p><input type="checkbox"/> the adoption of a Preliminary Work Item in the committee's work programme (stage 00.60)</p> <p><input type="checkbox"/> the activation of a Preliminary Work Item in the committee's work programme (stage 10.99): PWI XXXXX</p>
<p><b>1. Deliverable</b></p> <p><input type="checkbox"/> European Standard (EN)</p> <p><input type="checkbox"/> Technical Specification (TS)</p> <p><input type="checkbox"/> Technical Report (TR)</p>

<p><b>20. Related standardization request(s) (formerly mandate):</b></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes (please specify):</p>						
<p><b>21. Related directive(s)/regulation(s)</b></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes</p> <table border="1"> <thead> <tr> <th>Directive/ Regulation reference</th> <th>Candidate for citation in Official Journal?</th> </tr> </thead> <tbody> <tr> <td></td> <td><input type="checkbox"/> No <input type="checkbox"/> Yes</td> </tr> <tr> <td></td> <td><input type="checkbox"/> No <input type="checkbox"/> Yes</td> </tr> </tbody> </table>	Directive/ Regulation reference	Candidate for citation in Official Journal?		<input type="checkbox"/> No <input type="checkbox"/> Yes		<input type="checkbox"/> No <input type="checkbox"/> Yes
Directive/ Regulation reference	Candidate for citation in Official Journal?					
	<input type="checkbox"/> No <input type="checkbox"/> Yes					
	<input type="checkbox"/> No <input type="checkbox"/> Yes					

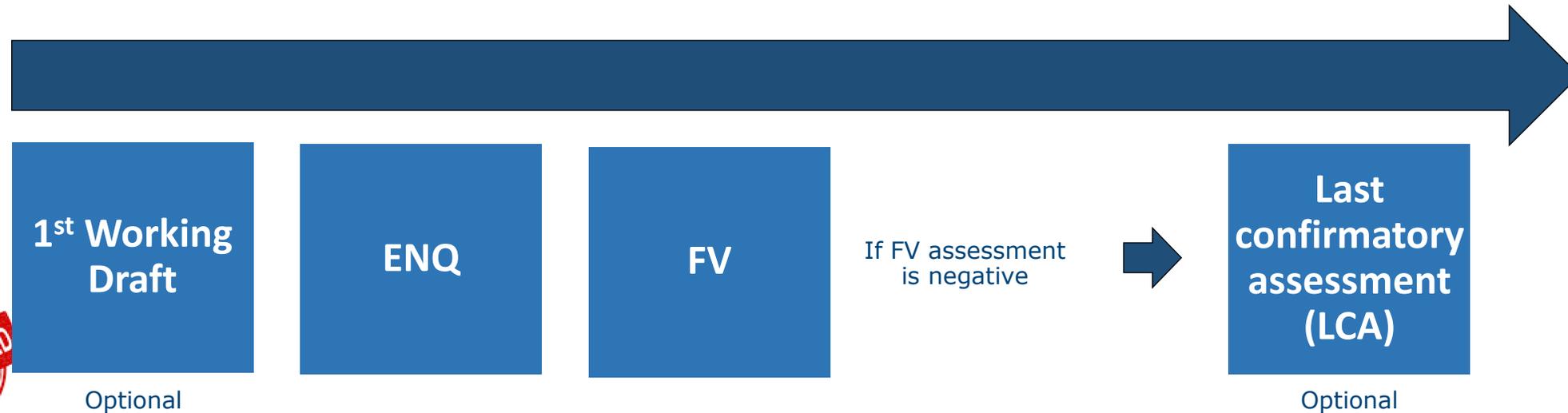
### Information on the Work Item

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

### Relation to European legislation and policies

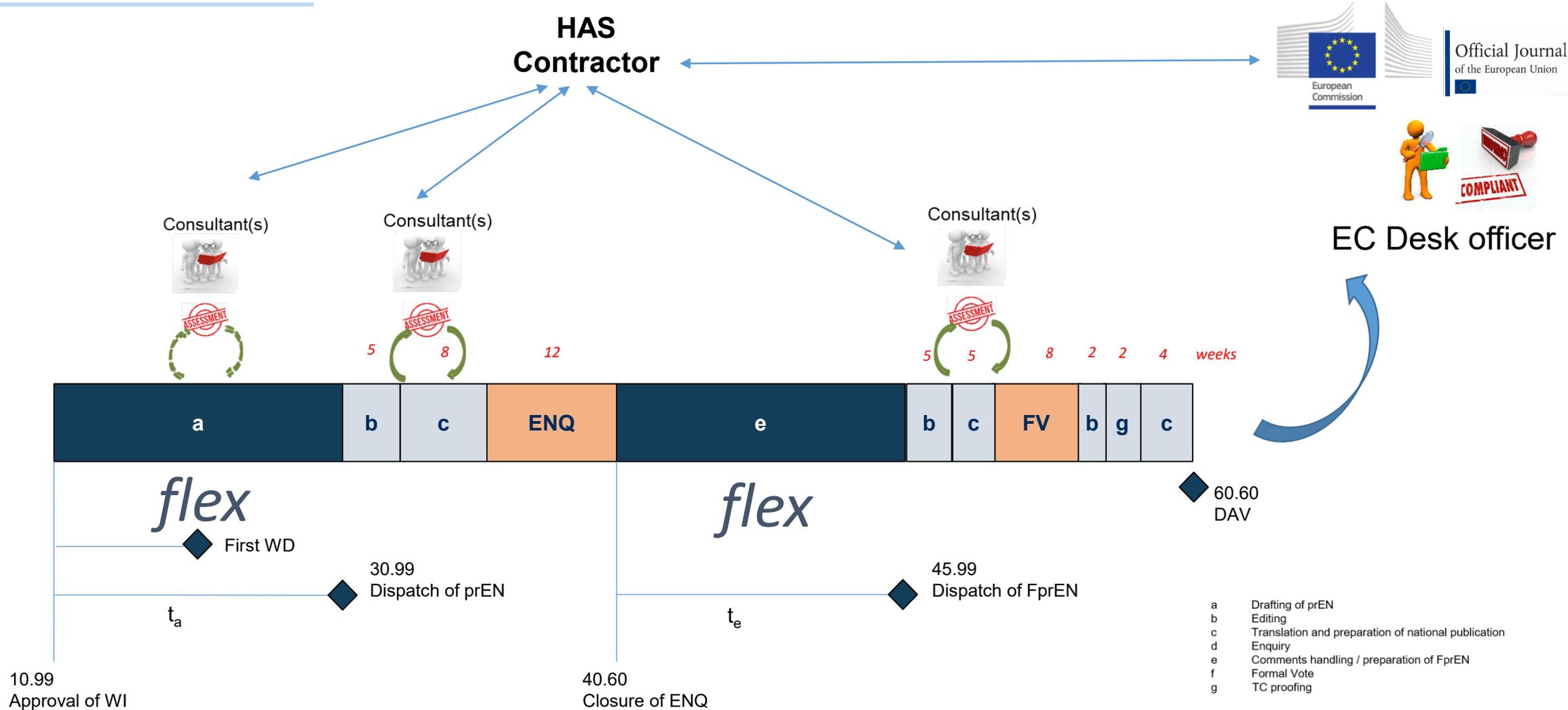
Identification of Standardization request, legislation and policies:					
<input type="checkbox"/> Work supporting legislation or policies					
Standardization request	Legislation/policy	OJEU	Assessment Method		
			HAS	EC	Other (specify)
SREQ_1	LEG_1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> method
SREQ_2	LEG_2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> method
SREQ_x	LEG_x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> method
<b>Additional information/Other legislation:</b>					
<u>Legislation_policy_info</u>					

## When can assessments be requested?



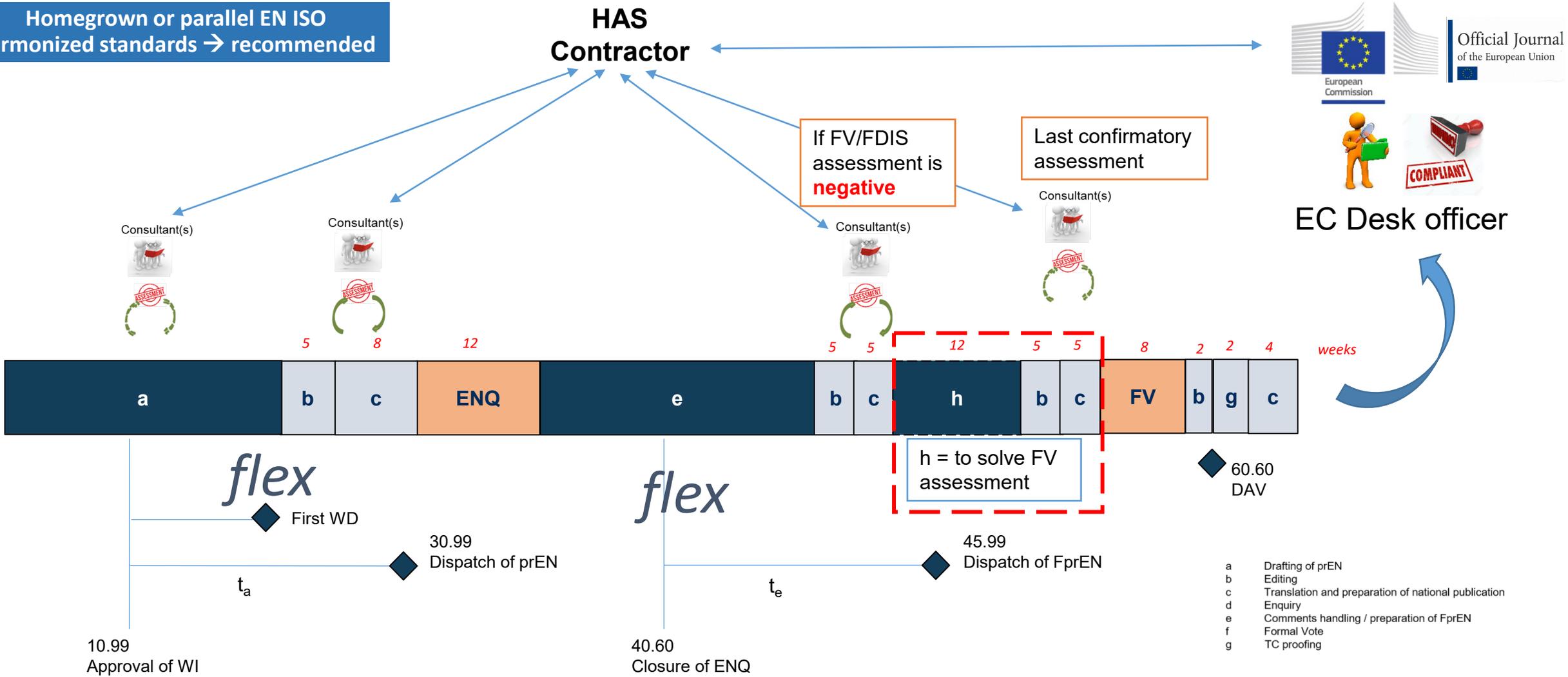
- ▶ ESOs can request maximum 4 assessments per WI
- ▶ 1 assessment per stage + LCA
- ▶ LCA: full assessment
- ▶ Not possible to request assessments of published standards

# Assessment of standards



# Assessment of standards: LCA before FV

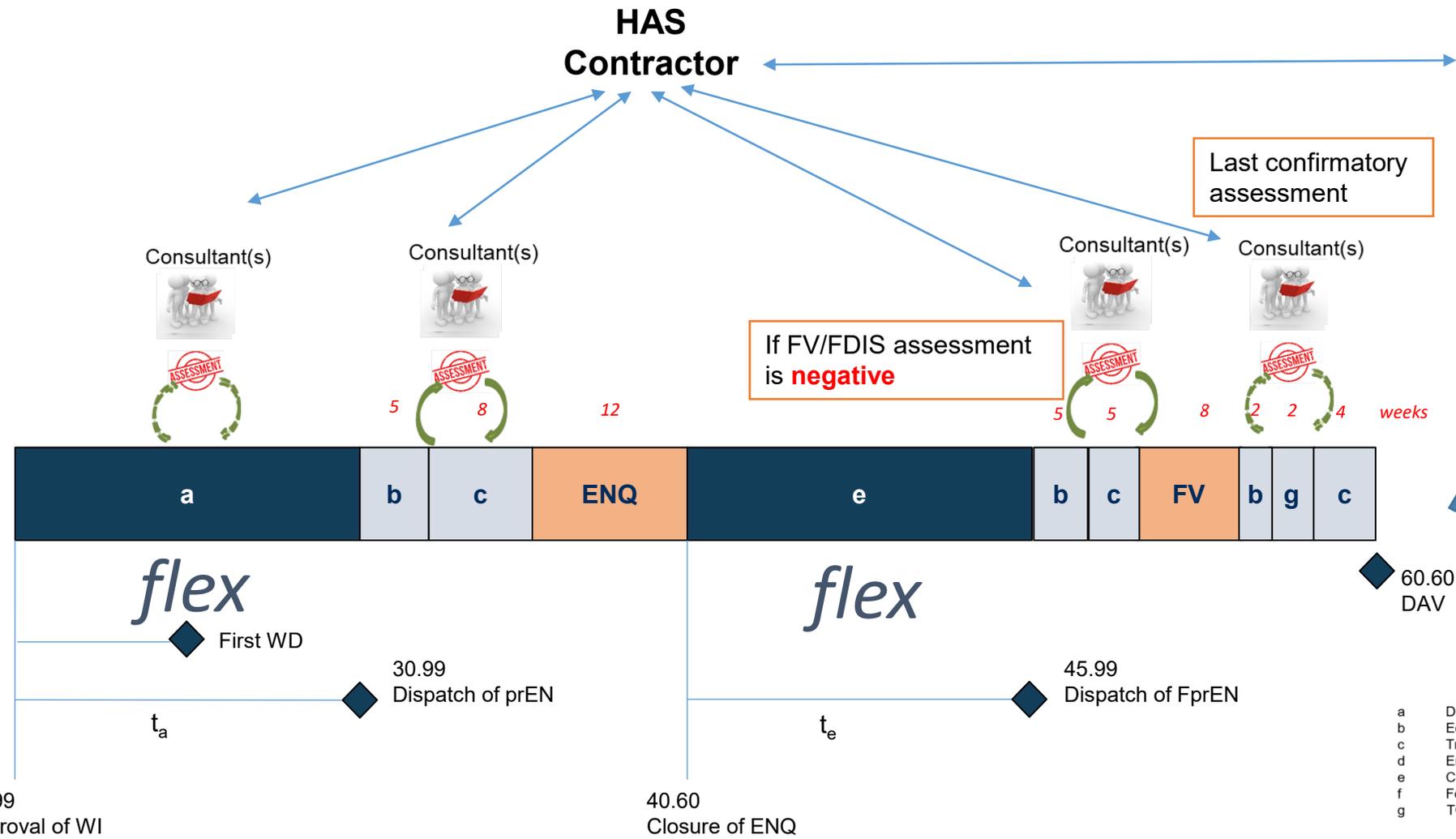
Homegrown or parallel EN ISO harmonized standards → recommended



# Assessment of standards: LCA after FV



EC Desk officer



## Outcome

<b>'Compliant'</b>	If the same conclusion is 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 by the Commission, the publication of the reference in the OJ is likely not possible without adaption of the document

- ▶ **HAS assessment report:** [CEN](#) and [CENELEC](#) BOSS pages

## Part A: Summary of the assessment

### 1. Consultant's opinion

**1.1 On the document's compliance with the standardisation request(s) and suitability to support relevant EU legislation -** i.e. 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

- Compliance** - no 'critical findings' are reported
  - Good or sufficient quality for a compliant document** - no changes required and no critical findings
  - Minor or limited number of changes not affecting compliance** – please indicate those changes in section 2 (other findings)
- Conditional compliance** - only in case of problems related to the dates of normative references to other inter-linked standards
- Lack of compliance** - quality not sufficient for a harmonised standard
  - Minor or limited number of changes are required** – e.g. **Annex Z** – please see sections 1.2 and 1.3, Part B and template
  - Redrafting required** - need for substantial changes to the document are reported – please see sections 1.2 and 1.3, Part B and template

- ▶ **Assessment duration: normally 5 weeks after notification to EY**

# HAS assessment platform

- ▶ 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 

Assessment report for EN 50310:2016/FprA1:2019 - 90/385/EEC - FV has been received (Test environment)

 NoReply <noreply@notif.cenelec.eu>  
To

 This sender noreply@notif.cenelec.eu is from outside your organization.

 CENTC49\_00049042\_ENQ\_MBCCEN896\_20221010.zip  
359 KB

 Reply  Reply All  Forward 

Thu 2022-11-24 16:21

**CAUTION: This email originates from outside of CEN-CENELEC. Do not open attachments or follow links unless you are sure this email comes from a known sender and you know the content is safe.**

## Assessment report received

Please find enclosed the report for the assessment **EN 50310:2016/FprA1:2019 - 90/385/EEC - FV**



HAS Backend API v1.0.43+Branch.master.Sha.52827dfdb144a9edf34028943706802da3ee3c6f-BuildId.3615-CommitDateUtc.2022-11-17

# HAS and legislation information



- ▶ Projex-online will include HAS assessment and legislation information: NEW
- ▶ **HAS assessment reports** will be available in Projex-online for download
- ▶ New fields related to legislation (e.g. referencing method, assessment method)
- ▶ Citation monitoring information
- ▶ New fields in Projex-online expected in Q1/2023

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 Last update: 2022-11-01 [Nuno Pargana](#) [Sign Out](#)

You are here: [Home](#) > [Simple Search](#) > 73514 
[My Projex-Online](#) [Simple Search](#) [Complex Search](#) [Working Area](#) [Image Quality Check](#)

★ 73514 - EN IEC 62052-11:2021/A11:2022  
 Electricity metering equipment - General requirements, tests and test conditions - Part 11: Metering equipment

[Access to current document\(s\)](#)  
(authorised users only)

<i>Responsible:</i>	CLC/TC 13	<i>Drafting:</i>	CLC/TC 13/WG 01	<i>Project Leader:</i>	Mr R. Bauknecht
<i>WI/Standard status:</i>	Active/Published	<i>Track:</i>	EN/ENQ+FV	<i>Contact point:</i>	Ms M. De Coninck
<i>Category:</i>	Amendment	<i>Parallel:</i>	No	<a href="mailto:mdeconinck@cencenelec.eu">mdeconinck@cencenelec.eu</a>	

EC/EFTA relations
Consultants
WI relations
Standstill & Deviation
Decisions
Classifications

**Standardization request (formerly mandate):**

Reference	Mandate Title (Full)	Status
<a href="#">M/552 (EMC)</a>	[C(2016) 7641 final] Standardisation request as regards harmonised standards in support of Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility	Confirmed
<a href="#">M/541 (Measuring Instruments)</a>	[C(2015)8558] Standardization request in support of the implementation of Directive 2014/32/EU on measuring instruments	Confirmed

**Directive:**

Reference	Directive Title	Harmonised	Supporting	Citation Candidate	Official Journal Ref. (Date)
<a href="#">2014/30/EU (EMC_2014)</a>	Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)	Yes	No	Yes	-
<a href="#">2014/32/EU (MID_2014)</a>	Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments	Yes	No	Yes	-

**Specific agreement (formerly order voucher):**

-

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"Webinar: restart of the HAS assessment system"

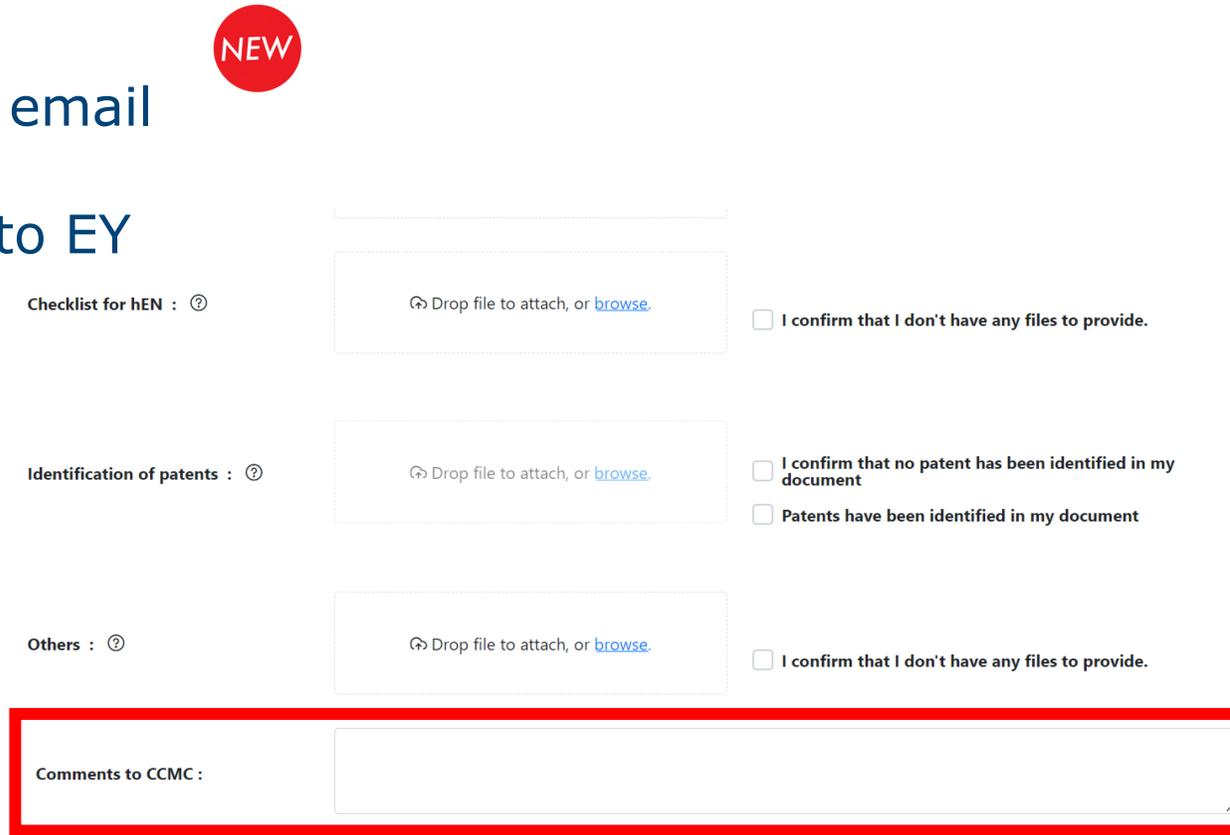
2022-12-05

20

# FWD HAS assessment request

- ▶ First working draft (FWD) is optional but **strongly recommended**
- ▶ Technical Body secretary submits to CCMC FWD
  - ▶ In CEN via Submission Interface
  - ▶ In CENELEC via Submission Interface or email (until Feb 2023)
  - ▶ CCMC Project Manager submits request to EY
  - ▶ First draft Annex Z 
  - ▶ For parallel work: CD-text
- ▶ Technical Body secretary will receive notification via email when report is ready
- ▶ **Lack of compliance** → possible mtg

NEW



Checklist for hEN : ⓘ

Drop file to attach, or [browse](#).

I confirm that I don't have any files to provide.

Identification of patents : ⓘ

Drop file to attach, or [browse](#).

I confirm that no patent has been identified in my document

Patents have been identified in my document

Others : ⓘ

Drop file to attach, or [browse](#).

I confirm that I don't have any files to provide.

Comments to CCMC :

Submit Cancel

# ENQ HAS assessment - Homegrown

- ▶ Homegrown: Technical Body secretary submits prEN for ENQ
  - ▶ Annex Z
  - ▶ Checklist for hENs
  - ▶ CCMC editor requests assessment at start translation
  - ▶ Technical Body secretary will receive notification via email when report is ready
  
- ▶ Dealing with the outcome:
  - ▶ **Compliant** → if all criteria are met: possibility to skip FV
  - ▶ **Lack of compliance:**
    - ▶ Launch of ENQ is not delayed
    - ▶ TC meeting with HAS consultant to solve the issues (recommended)

# ENQ HAS assessment - Parallel

- ▶ Parallel ISO notification to CCMC when DIS is available
  - ▶ Annex ZA – included in the text
  - ▶ CCMC requests assessment prior to start of ENQ
  - ▶ Technical Body secretary will receive notification via email when report is ready and ISO receive them from CCMC
  
- ▶ Parallel IEC – notification to CCMC when CDV is available
  - ▶ TC provides Annex ZZ and Annex ZA
  - ▶ CCMC requests assessment prior to start of CDV
  - ▶ Technical Body secretary will receive notification via email when report is ready
  - ▶ If common mods are needed → ad-hoc procedure to be followed
  
- ▶ Dealing with the outcome:
  - ▶ **Compliant** → if all criteria are met: possibility to skip FV in line with international process
  - ▶ **Lack of compliance:**
    - ▶ Launch of ENQ is not delayed
    - ▶ TC meeting with HAS consultant to solve the issues (recommended)

# FV HAS assessment - Homegrown



- ▶ Homegrown: Technical Body secretary submits FprEN for FV
  - ▶ Annex Z
  - ▶ Checklist for hENs
  - ▶ ENQ HAS assessment report → last column 'observations of the secretariat' filled to show how consultant comments have been addressed

MB/NC <sup>1</sup>	Line-number <sup>2</sup> (e.g. 17)	Clause/-Subclause <sup>3</sup> (e.g. 3.1)	Paragraph/-Figure/-Table/ <sup>4</sup> (e.g. Table-1)	Type-of-comment <sup>5</sup>	Comments <sup>6</sup>	Proposed-change <sup>7</sup>	Observations-of-the-secretariat <sup>8</sup>
JJ1		7.2.2		Te	The technical text in the DIS made rightly reference to Annex A of ISO 7960 for the operating conditions of building site saws during noise emission measurement. Unfortunately, in the FDIS this text has been replaced by a mere reference to clause 7.2.2 of Part 1. Consequently, a manufacturer using Part 10 is not going to know which operating conditions he has to use.	Re-integrate in 7.2.2 the DIS text relating to Annex A of ISO 7960 i.e. replace the current text of 7.2.2 by: "This sub-clause of ISO 19085-1:2017 applies with the following additions: - → Operating conditions shall comply with A.2.b) in Annex A of ISO 7960:1995 - → Measurement surface, number of microphone positions and measuring distance shall comply with	We fully agree with this comment. It was not the intention during DIS/CRM to delete so much of 7.2.2 – but it happened. We had no technical reason. It was a mistake, as you can see also in the fact, that Annex E (for machines not in ISO 7960) is marked as "does not apply". We will change 7.2.2 to: <b>7.2.2 Noise emission measurement</b> This subclause of ISO 19085-1:2017 applies with the following additions.

- ▶ CCMC editor requests assessment at start translation
- ▶ Technical Body secretary will receive notification via email when report is ready

# FV/FDIS HAS assessment – Parallel ISO



- ▶ Parallel ISO: ISO provides the document for HAS assessment
  - ▶ Annex ZA is included
  - ▶ ENQ HAS assessment report → last column 'observations of the secretariat' filled to show how consultant comments have been addressed

MB/NC <sup>1</sup>	Line number <sup>2</sup> (e.g. 17)	Clause/Subclause <sup>3</sup> (e.g. 3.1)	Paragraph/Figure/Table <sup>4</sup> (e.g. Table 1)	Type of comment <sup>5</sup>	Comments <sup>6</sup>	Proposed change <sup>7</sup>	Observations of the secretariat <sup>8</sup>
JJ1		7.2.2		Text	The technical text in the DIS made rightly reference to Annex A of ISO 7960 for the operating conditions of building site saws during noise emission measurement. Unfortunately, in the FDIS this text has been replaced by a mere reference to clause 7.2.2 of Part 1. Consequently, a manufacturer using Part 10 is not going to know which operating conditions he has to use.	Reintegrate in 7.2.2 the DIS text relating to Annex A of ISO 7960 i.e. replace the current text of 7.2.2 by: "This sub-clause of ISO 19085-1:2017 applies with the following additions: - → Operating conditions shall comply with A.2.b) in Annex A of ISO 7960:1995 - → Measurement surface, number of microphone positions and measuring distance shall comply with	We fully agree with this comment. It was not the intention during DIS/CRM to delete so much of 7.2.2 – but it happened. We had no technical reason. It was a mistake, as you can see also in the fact that Annex E (for machines not in ISO 7960) is marked as "does not apply". We will change 7.2.2 to: <b>7.2.2 Noise emission measurement</b> This sub-clause of ISO 19085-1:2017 applies with the following additions.

- ▶ CCMC requests assessment
- ▶ Technical Body secretary will receive notification via email when report is ready

# FV/FDIS HAS assessment – Parallel IEC



- ▶ Parallel EN IEC: IEC notification to CCMC when FDIS is available
  - ▶ CENELEC Technical Body secretary submits EU elements for FV (Annex ZA and Annex ZZ)
  - ▶ If common mods are needed → ad-hoc procedure to be followed
  - ▶ ENQ HAS assessment report → last column 'observations of the secretariat' filled to show how consultant comments have been addressed

MB/NC <sup>1</sup>	Line number <sup>2</sup> (e.g. 17)	Clause/Subclause <sup>3</sup> (e.g. 3.1)	Paragraph/Figure/Table/ <sup>4</sup> (e.g. Table 1)	Type of comment <sup>5</sup>	Comments <sup>6</sup>	Proposed change <sup>7</sup>	Observations of the secretariat <sup>8</sup>
JJ1		7.2.2		Text	The technical text in the DIS made rightly reference to Annex A of ISO 7960 for the operating conditions of building site saws during noise emission measurement. Unfortunately, in the FDIS this text has been replaced by a mere reference to clause 7.2.2 of Part 1. Consequently, a manufacturer using Part 10 is not going to know which operating conditions he has to use.	Reintegrate in 7.2.2 the DIS text relating to Annex A of ISO 7960, i.e. replace the current text of 7.2.2 by: "This sub-clause of ISO 19085-1:2017 applies with the following additions: - → Operating conditions shall comply with A.2.b) in Annex A of ISO 7960:1995 - → Measurement surface, number of microphone positions and measuring distance shall comply with	We fully agree with this comment. It was not the intention during DIS/CRM to delete so much of 7.2.2 – but it happened. We had no technical reason. It was a mistake, as you can see also in the fact, that Annex E (for machines not in ISO 7960) is marked as "does not apply". We will change 7.2.2 to: <b>7.2.2.Noise emission measurement</b> This subclause of ISO 19085-1:2017 applies with the following additions.

- ▶ CCMC requests assessment
- ▶ Technical Body secretary will receive notification via email when report is ready

## Homegrown and parallel under Vienna Agreement:

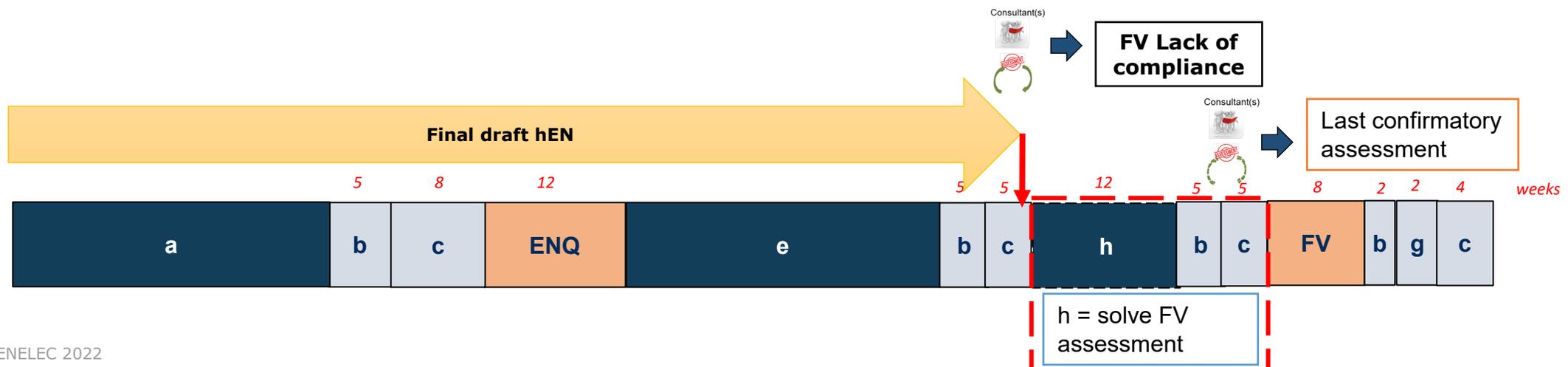
Decision BT C161/2022 and D172/C108, in case of a '**Lack of Compliance**' at FV stage:

- ▶ **FV is suspended** after the reception of assessment
- ▶ **Within 7 weeks**, Technical Body secretariat informs CCMC on the way forward

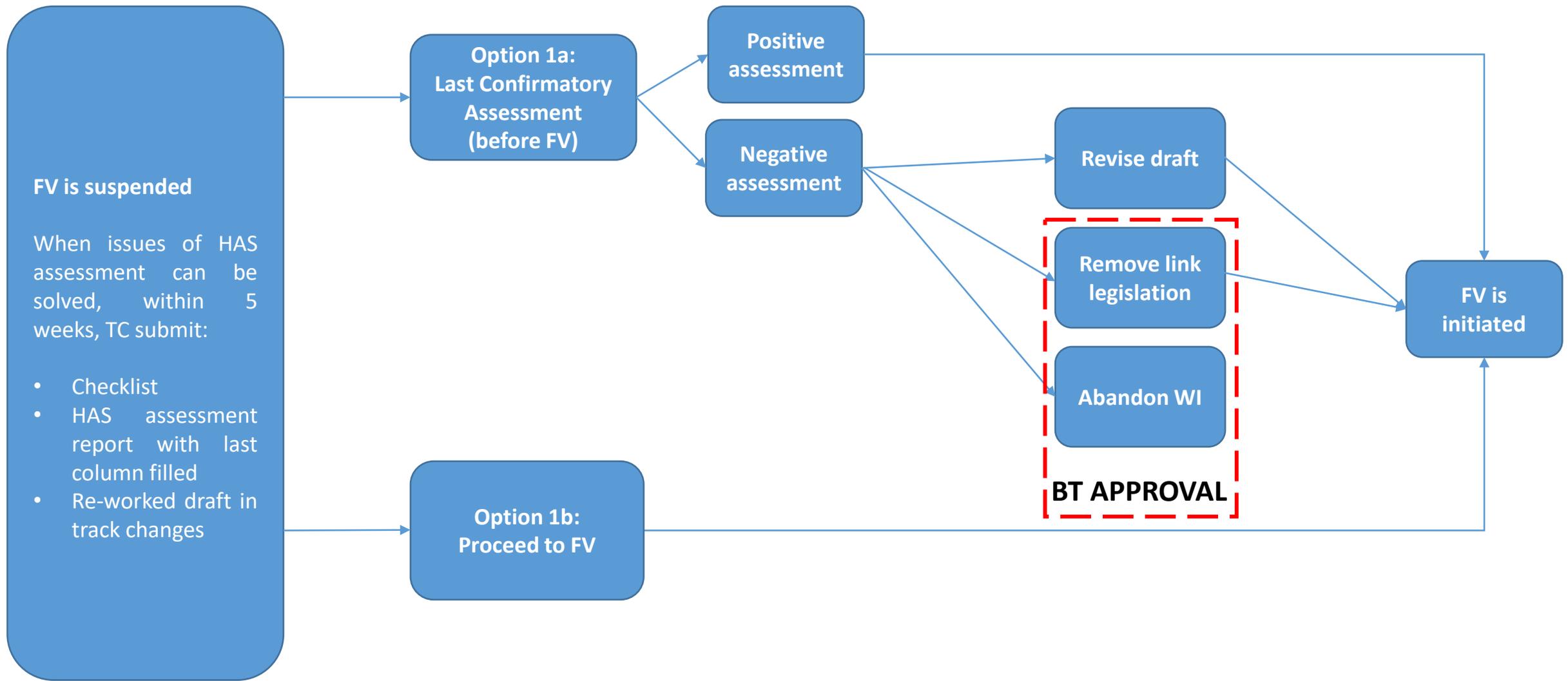
# FV Lack of compliance: moving forward

## Option 1a (recommended)

- ▶ When issues of assessment can be solved, within 5 additional weeks, TC secretary submits revised draft to CCMC + the following documents:
  - ▶ Checklist for hENs
  - ▶ HAS Assessment report with the last column 'Observations of the secretariat' filled to indicate how the Technical Body addressed the comments from the HAS Consultant
  - ▶ Re-worked draft in track changes
- ▶ Upon TC request, CCMC will request Last Confirmatory Assessment **before launch of FV**



# FV Lack of compliance: Option 1a



## FV is suspended

When issues of HAS assessment can be solved, within 5 weeks, TC submit:

- Checklist
- HAS assessment report with last column filled
- Re-worked draft in track changes

# FV Lack of compliance: moving forward

## Option 1b (not recommended)

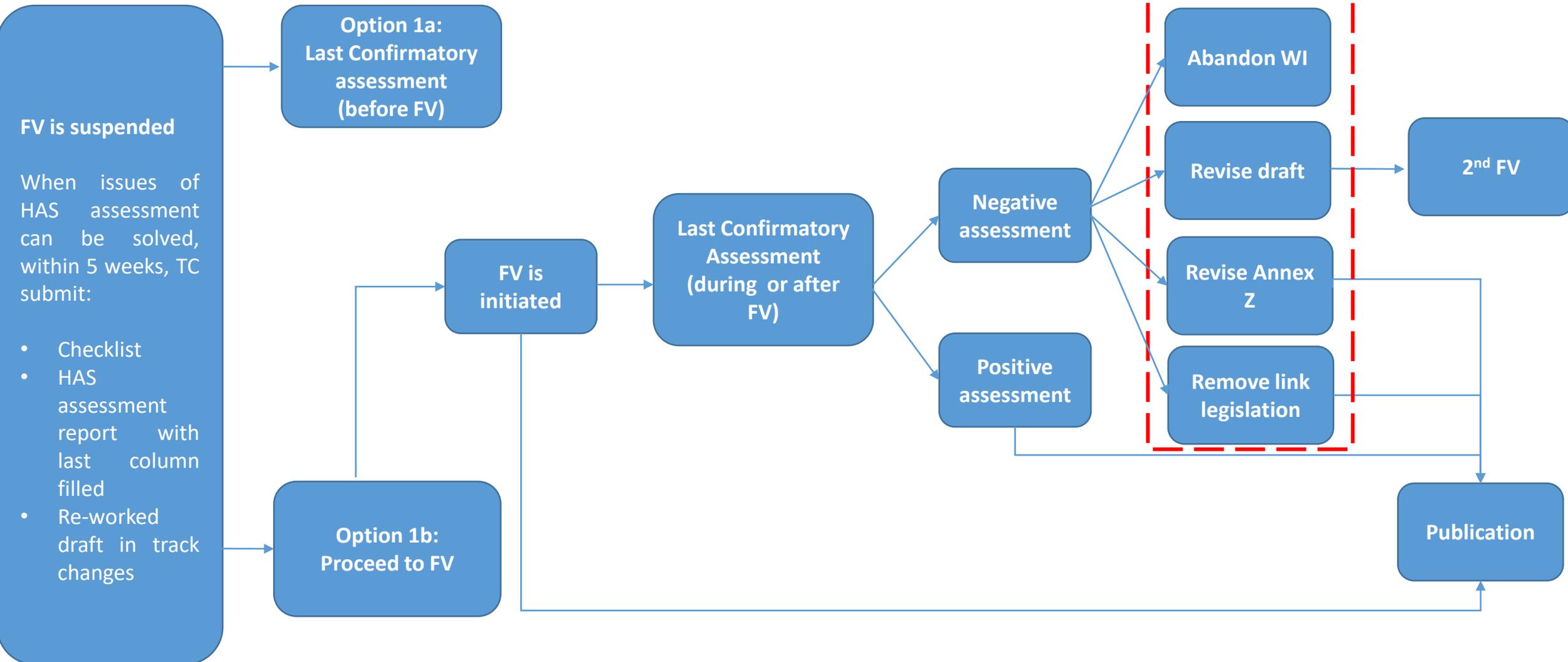
- ▶ When issues of assessment can be solved, within 5 additional weeks, TC secretary submits revised draft to CCMC + the following documents:
  - ▶ Checklist for hENs
  - ▶ HAS Assessment report with the last column 'Observations of the secretariat' filled to indicate how the Technical Body addressed the comments from the HAS Consultant
  - ▶ Re-worked draft in track changes

### Upon TC request (exceptional):

- ▶ Final draft proceeds to FV and publication or
- ▶ CCMC will request Last Confirmatory Assessment **during or after FV**



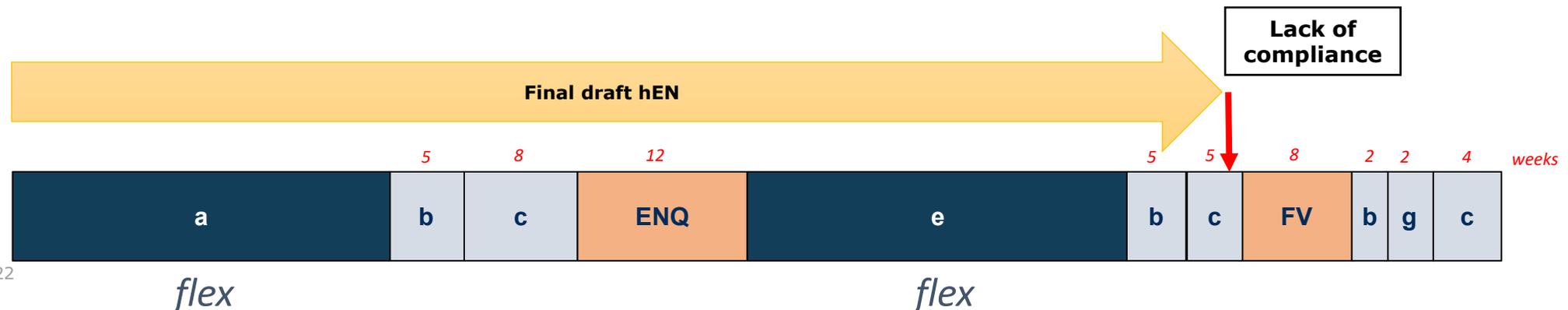
# FV Lack of compliance: Option 1b



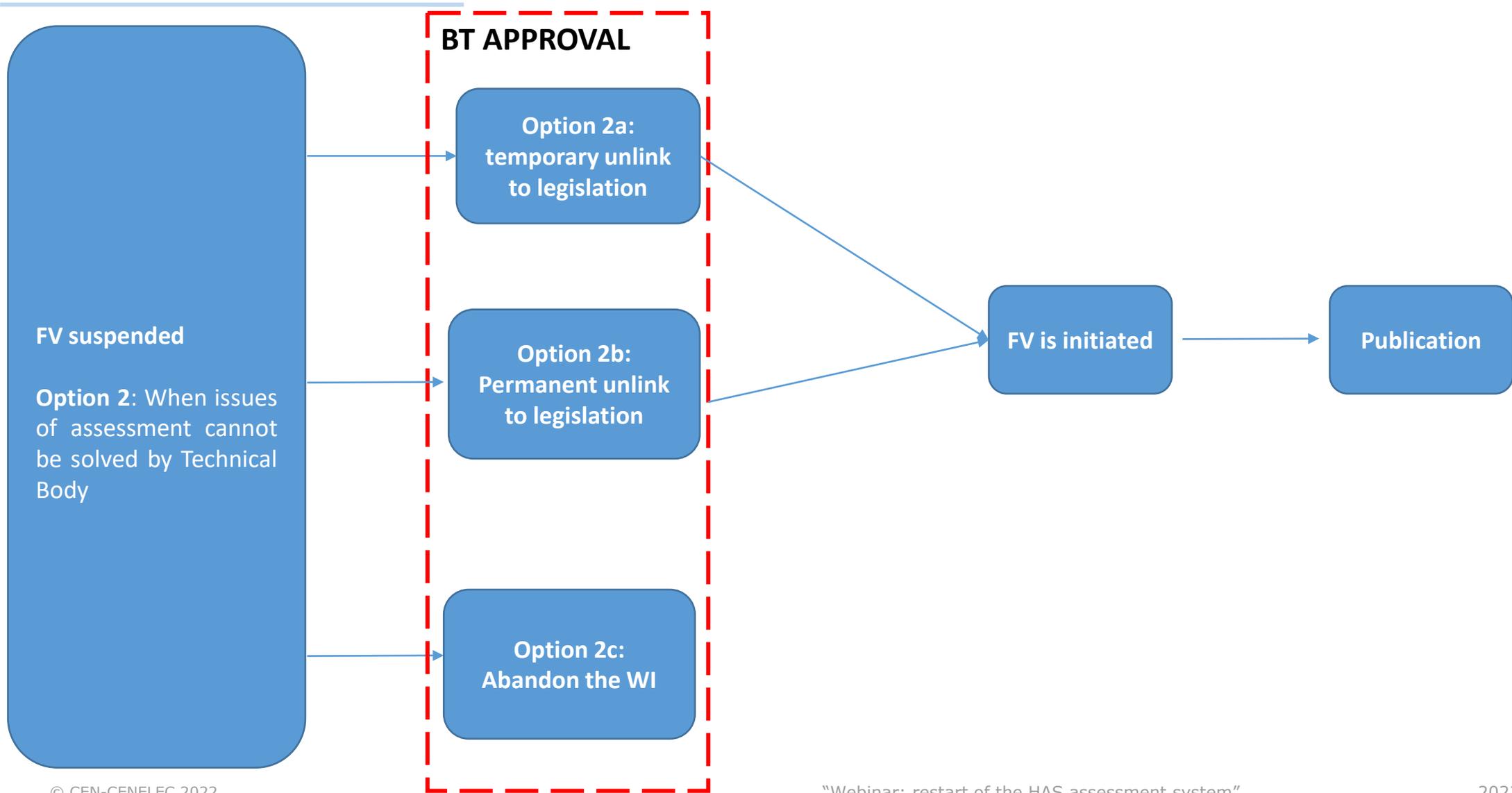
# FV Lack of compliance: moving forward

## Option 2

- ▶ When issues of assessment cannot be solved by TC, a proposal is circulated to BT:
  - ▶ **Option 2a:** Unlink the EN temporarily from legislation and initiate an amendment/revision to resolve the lack of compliance assessment.
  - ▶ **Option 2b:** Unlink the EN permanently from legislation
  - ▶ **Option 2c:** Abandon the project



# FV HAS assessment 'LoC' – Option 2



## EN IEC under Frankfurt Agreement:

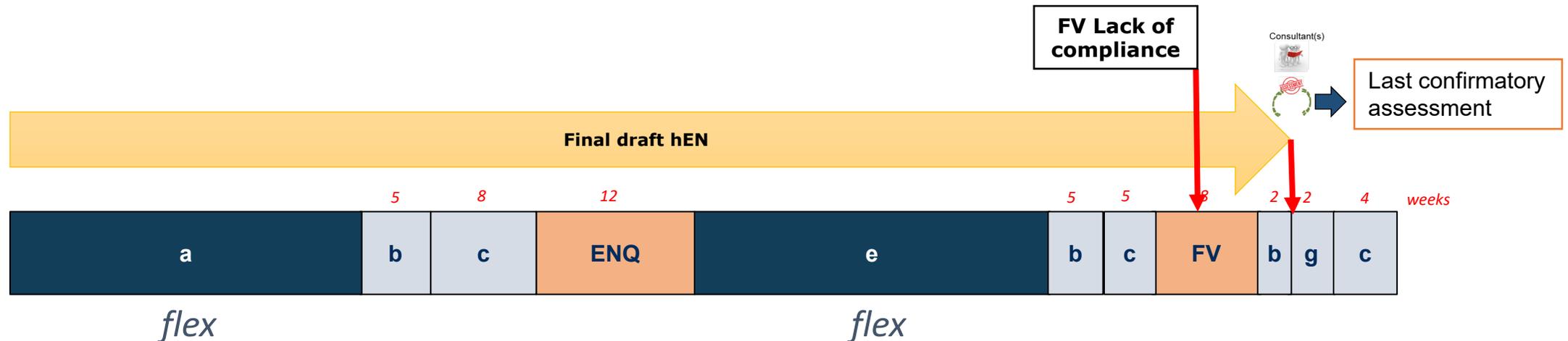
Decision BT C161/2022 and D172/C108, in case of a '**Lack of Compliance**' at FV stage:

- ▶ **FV is not suspended** after the reception of assessment
- ▶ EN IEC harmonized standard is blocked after FV

# FV Lack of compliance: moving forward

## Parallel EN IEC

- ▶ Upon TC request, CCMC can request Last Confirmatory Assessment **after FV**
- ▶ To be used only to fix the Annex ZA and Annex ZZ
- ▶ TC secretary submits the following documents:
  - ▶ Revised Annex ZA and Annex ZZ
  - ▶ HAS Assessment report with the last column 'Observations of the secretariat' filled to indicate how the Technical Body addressed the comments from the HAS Consultant;
- ▶ If technical changes are needed → common modifications are an option



On justified disagreement of Technical Body:

- ▶ Technical Body Secretary send a request for a review of assessment to CCMC Project Manager
- ▶ CCMC will submit request to HAS Contractor
- ▶ HAS Contractor has 3 weeks to reply with a reviewed assessment
  
- ▶ Technical Body can request to review FV HAS assessment 'Lack of compliance' within 4 weeks of reception of assessment (if justified)

# Key learning points (1/2)

- ▶ HAS assessment system is re-stored 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
- ▶ Backlog will imply delays in delivering assessment reports
- ▶ 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)

# Key learning points (2/2)

- ▶ First working draft assessment optional, but strongly recommended
- ▶ New HAS Platform tool: Technical Body secretary will get a notification (via email) when HAS assessment report is available
- ▶ New LCA can be requested if FV assessment is lack of compliance
  - ▶ For homegrown and EN ISO harmonized standards → recommended before FV
  - ▶ Exceptional: after FV, but before publication
  - ▶ No assessments are possible when hEN is published



European Standardization Organizations

# Thank you! Any questions?

Next webinars

2022-12-06 – Training [“Training - Use of Submission Interface + Image Quality Check”](#)

2022-12-12 – [Training for newly appointed CEN & CENELEC Technical Body Officers](#) – fully booked

2023-01-24 - Webinar ['Harmonized Healthcare Standards'](#)