



European Standardization Organizations

Webinar 'The functioning of the HAS system, interactions with HAS consultants and best practices'

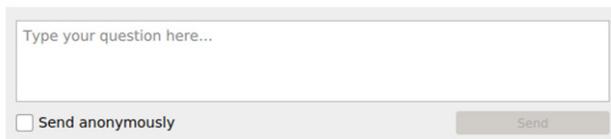
A webinar in cooperation with the European Commission and Ernst & Young



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Project Manager
Policy & Partnerships
CEN-CENELEC
esomers@cencenelec.eu

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Speakers



- ▶ For CEN and CENELEC:
 - Mauro Soares - Project Manager Harmonized Standards Compliance
 - Frédéric Mlanao - Account Manager Harmonized Standards Compliance

- ▶ For the European Commission:
 - Federico Musso - EC/ GROW.H3

- ▶ For Ernst & Young:
 - Daan Bijwaard - EY HAS Support
 - Emmanuelle Potar - EY HAS Support
 - Francisco Verdera - EY Quality Review coordinator



EY Core Team



Daan Bijwaard
Core Team Leader



Emmanuelle Potar
HAS Operations Coordinator



Francisco Verdera
Senior Adviser Standardisation



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1. Introduction – European Commission (Federico Musso)
2. Harmonised Standards development process recap – CCMC (Mauro Soares & Frédéric Mlanao)
3. Updates from Ernst & Young
 1. Progress in assessment work under the new contract
 2. Best practices for Technical Bodies under the HAS system
 3. Acceptable use of Normative References in Harmonised Standards
4. Q&A and closing



Webinar

“The functioning of the HAS system, interactions with HAS consultants and best practices”

The new HAS Consultants contract

16 May 2023

Main new elements of the second HAS Consultants system

- **Increase of budget:** from 2200 man-days per year for HAS Consultants services to 3400 (ca. 55% more) – pre-defined allocation among sectors.
- **More communication and meeting participation:** from 20% to 25% (maximum).
- Introduction of feedback mechanism (in case of negative assessments at FV).
- Introduction of a **new task for the contractor:** Communication and information to the Technical Bodies of the ESOs and to the Commission services, in order to train and explain the beneficiaries of the system on its functioning.
- Introduction of “**conditional compliance**” assessment result option.

The technical specifications for the new contract

- The Technical Specifications of the call for tenders describe the system and how it will work (<https://etendering.ted.europa.eu/cft/cft-documents.html?cftId=9845>).
- The specifications provide a full description of the scope of the system, of all related tasks and contain clarifications on the relevant aspects.
- The new elements of the system have been introduced to improve its working, based on the experience gained during the implementation of the previous contract and on the feedback received from the ESOs and from the desk officers of the Commission.
- The overall intention of the new contract is to ensure a high degree of continuity of the HAS Consultants system, improving it where possible but keeping its main principles

Increase of resources

- From 2200 man-days per year to 3400 (Task 10 + Task 20), with a fixed pre-allocation per sector – this is a limit to the amount of work to be carried out each year for a specific sector.
- Pre-allocation to be reviewed each year by Commission in cooperation with EY to decide distribution of man-days per sector for the successive 12 months period(s) on the basis of practical experience during the first 12 months and on the basis of the evolution of actual work programmes of the ESOs and related deadlines.
- From 20% to 25% maximum of each consultant's man-days for Task 20 (Communication) – hard limit, no flexibility.
- Consultants can attend (on an ad-hoc basis and upon justified invitation) meetings of ESOs/TCs and of Commission expert groups – but no AdCo groups nor coordination groups of notified bodies.

Introduction of “feedback mechanism”

- CD, ENQ and FV assessments remain as before.
- In addition, in case of a negative assessment at FV stage, possibility for the ESOs to revise the draft standard and then to request a second FV assessment, called Last Confirmatory Assessment (LCA) – this is a right that ESOs now have.
- This way, the exceptional PUB limited-scope assessment no longer needed => abolished.
- Possibility for Commission services to request an assessment of a final standard (Final Verification), formally proposed for OJ-citation, for the purpose of deciding whether to cite it in the OJ or not.

New possible assessment outcome

- Previously, only binary outcome possible: compliance vs. non-compliance.
- Now, third possible outcome: conditional compliance.
- This option is meant exclusively for those standards, being part of a series developed in parallel and to be adopted and then submitted to the Commission for OJ-citation at the same time, containing normative references to each other.
- In case the only reason for a non-compliance outcome would be the fact that the normative references are to draft standards (prENs) being developed in parallel, then conditional compliance outcome must be used now.

New task for contractor

- EY must provide systematic communication and information to the Technical Bodies of the ESOs and to the Commission services (i.e., to the main users and beneficiaries of the system) to increase knowledge and understanding of the HAS Consultants scope of work, how the system is designed and how it functions in practice.
- Events will be organised to this purpose, also jointly with the ESOs. The present webinar falls under this task.
- This task includes the elaboration by EY of data, statistics and qualitative analyses to be used during the communication and training activities, and the obligation to maintain this set of information continuously updated.

Main principles unchanged but clarified where necessary

- HAS Consultants assess only and exclusively harmonised standards (and GPSD standards, which a legislative proposal in the pipeline will make equivalent to harmonised standards).
- HAS Consultants work for the Commission, supporting the legal obligations to carry out the assessment/evaluation tasks pursuant to Articles 10(5) and 10(6) of the Standardisation Reg.
- The HAS Consultants will not participate in the drafting and consensus building processes of the ESOs and will not have any drafting responsibilities for harmonised standards. They are not responsible for providing scientific, legal or technical advice which would go beyond normal assessment tasks defined in this Contract.
- The role of the HAS Consultants is not to compensate possible gaps in the technical, scientific or legal expertise of a technical body.

Many thanks for your attention!

Questions?

Federico Musso

European Commission

DG GROW – Unit H.3 “Standards Policy”

Federico.MUSSO@ec.europa.eu

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

0. This proposal relates to

the adoption of a New Work Item in the committee's work programme (stage 10.99)

the adoption of a Preliminary Work Item in the committee's work programme (stage 00.60)

the activation of a Preliminary Work Item in the committee's work programme (stage 10.99): PWI XXXXX

1. Deliverable

European Standard (EN)

Technical Specification (TS)

Technical Report (TR)

Information on the Work Item

Title:	
English	Title_en
French (optional)	Title_fr
German (optional)	Title_de
Scope:	
Scope	

20. Related standardization request(s) (formerly mandate):

No

Yes (please specify):

21. Related directive(s)/regulation(s)

No

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

Relation to European legislation and policies

Identification of Standardization request, legislation and policies:

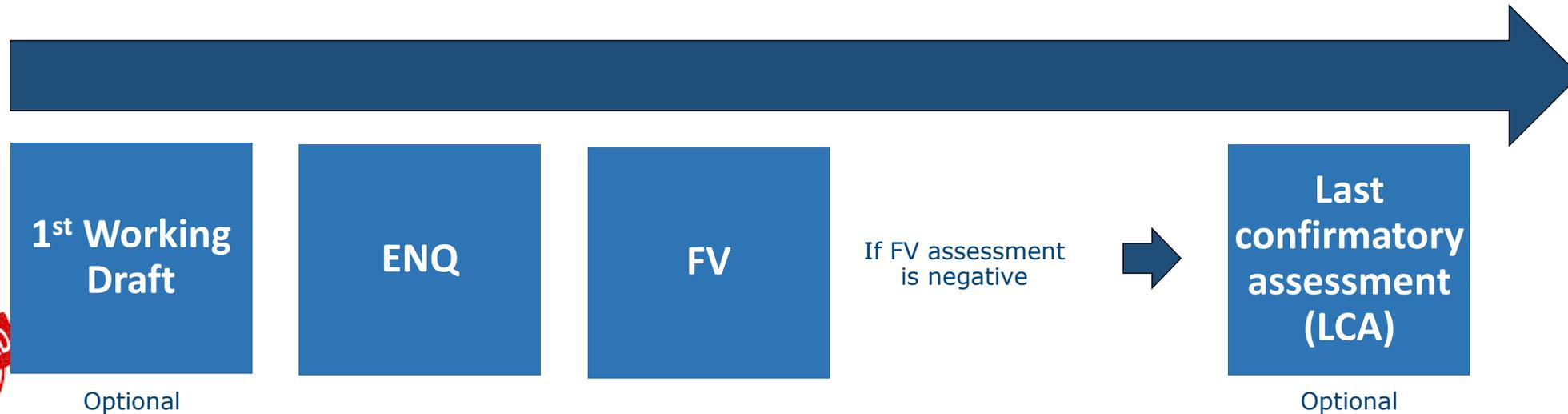
Work supporting legislation or policies

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

Additional information/Other legislation:

Legislation_policy_info

When can assessments be requested?



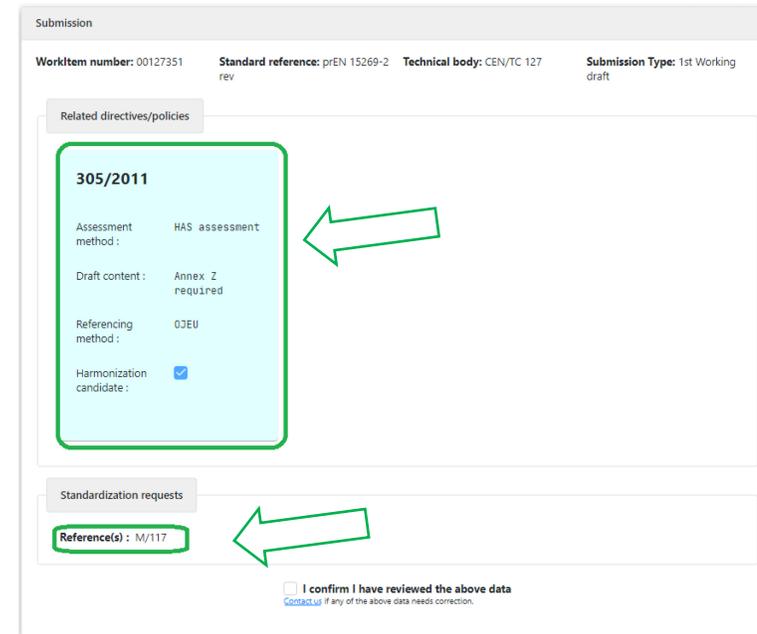
- ▶ ESOs can request maximum 4 assessments per WI
- ▶ 1 assessment per stage + LCA
- ▶ LCA: full assessment
- ▶ Not possible to request assessments of published standards

FWD HAS assessment request

- ▶ First working draft (FWD) is optional but **strongly recommended**
- ▶ Technical Body secretary submits to CCMC FWD
 - ▶ via Submission Interface
 - ▶ 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

FWD HAS assessment request

- ▶ Submission Interface
- ▶ Ensure that any relations/links to directive are directly registered upon the creation of NWIs.



Submission

Workitem number: 00127351 Standard reference: prEN 15269-2 rev Technical body: CEN/TC 127 Submission Type: 1st Working draft

Related directives/policies

305/2011
Assessment method : HAS assessment
Draft content : Annex Z required
Referencing method : 03EU
Harmonization candidate : <input checked="" type="checkbox"/>

Standardization requests

Reference(s) : M/117

I confirm I have reviewed the above data
[Contact us](#) if any of the above data needs correction.



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 : ⓘ

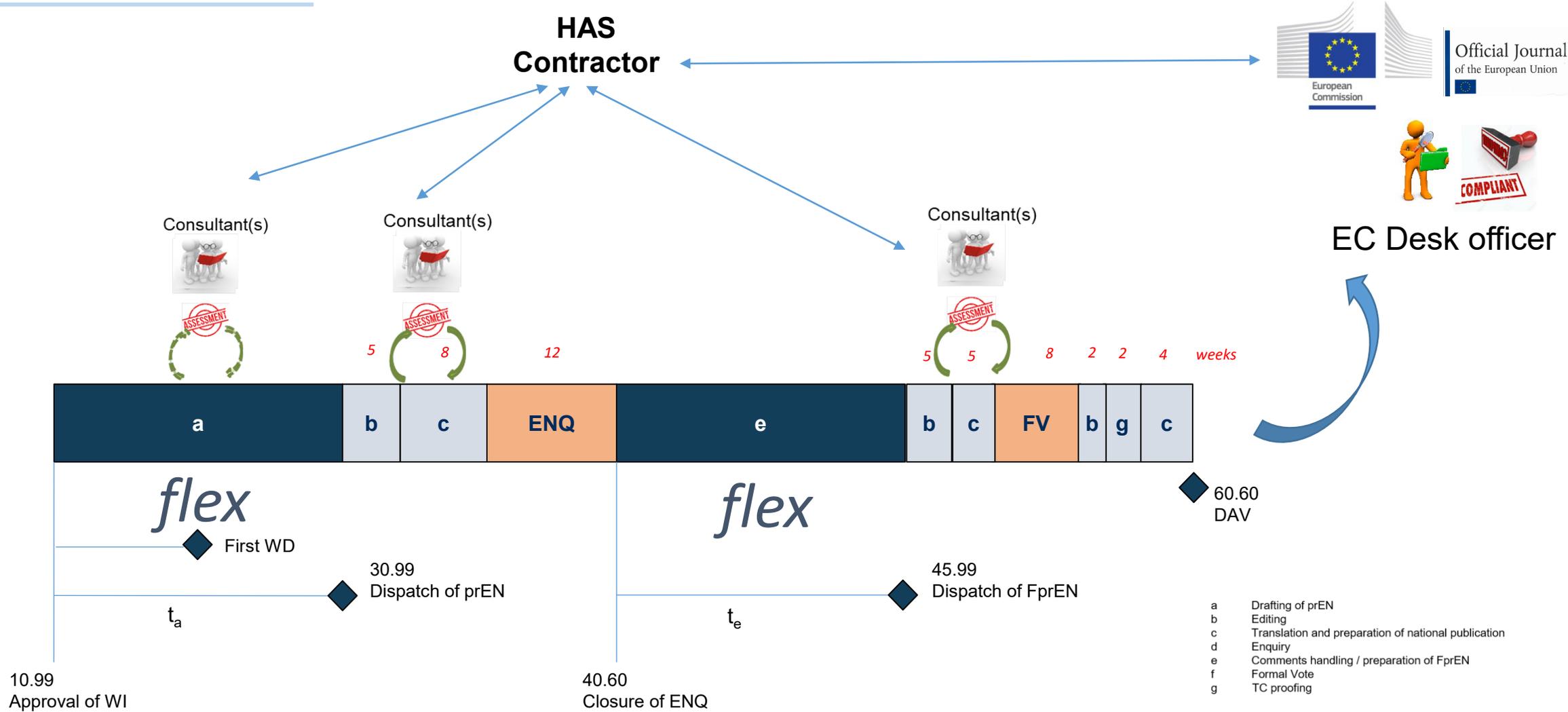
Drop file to attach, or [browse](#).

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

Comments to CCMC :

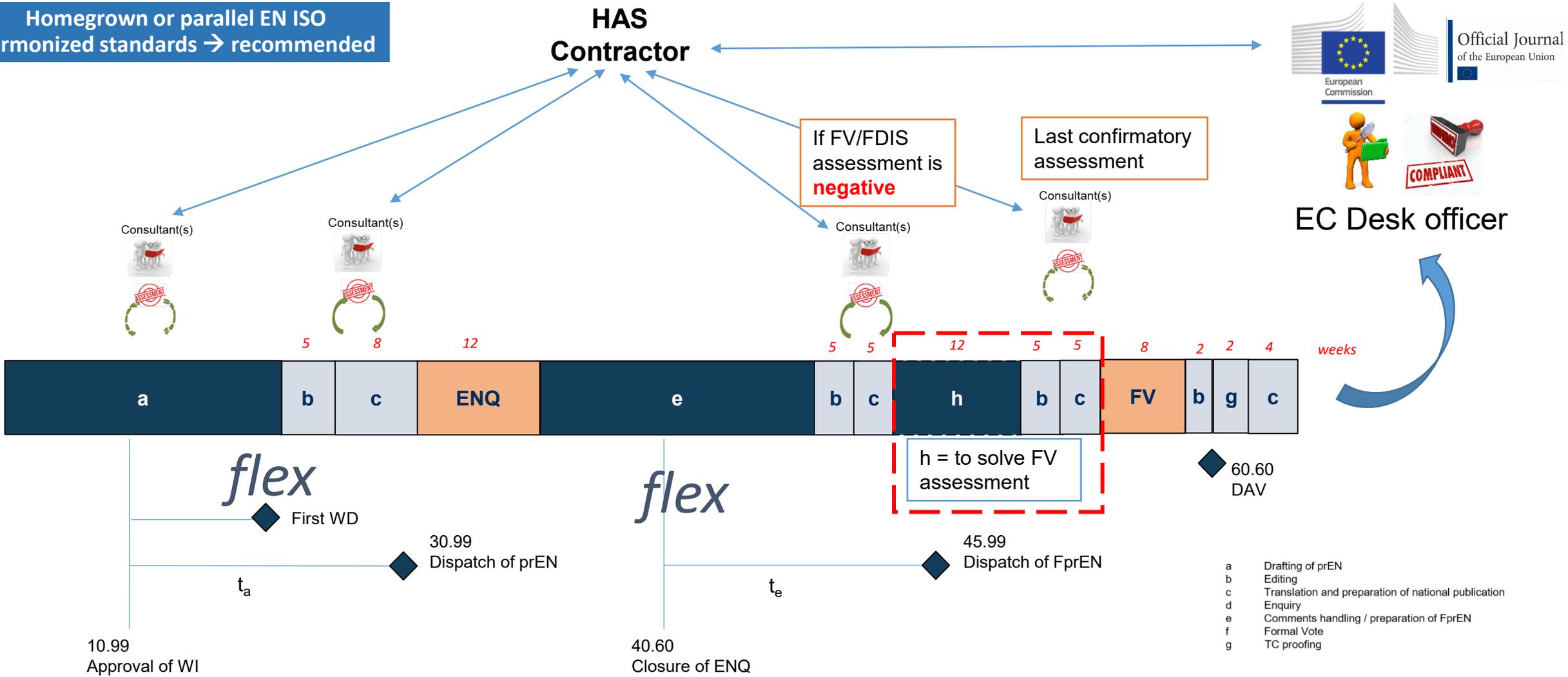
- ▶ Insert “HAS assessment required” in the “Comments to CCMC” field, when applicable.

Assessment of standards

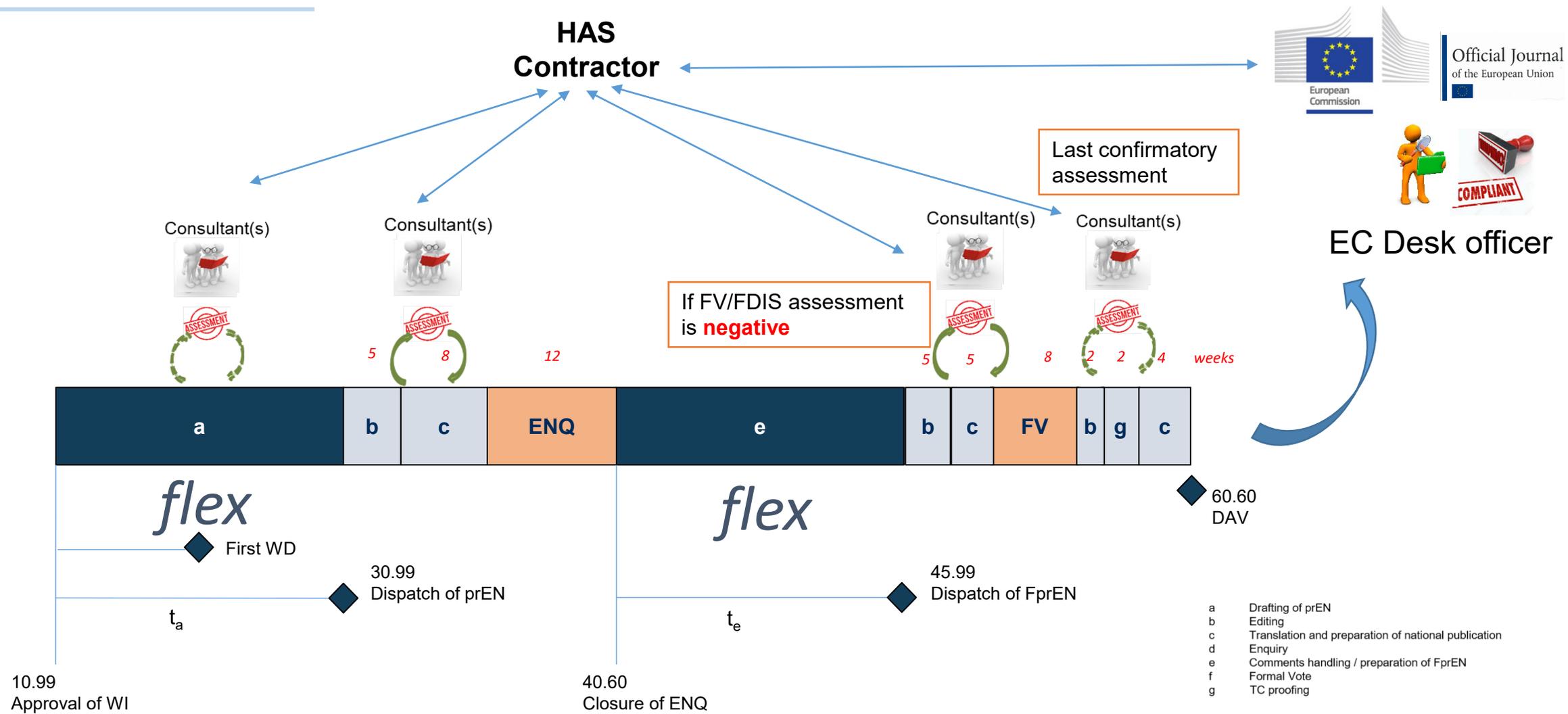


Assessment of standards: LCA before FV

Homegrown or parallel EN ISO harmonized standards → recommended



Assessment of standards: LCA after FV



Outcome

'Compliant'	If the same conclusion is reached by EC, the publication of the reference in the OJ is normally possible without any specific notice
'Conditional compliance' 	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
'Lack of compliance'	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**

Checklist for hEN

- ▶ Designed to assist Technical Bodies in drafting harmonized standards
- ▶ Covers horizontal aspects
- ▶ Mandatory as of end 2021
- ▶ Checklist shall be completed before dispatching draft standard for all stages
- ▶ Checklist strongly recommended when drafting hEN under VA (with ISO lead) and FA

Checklist for hEN

v2021-04-14

Checklist – Items to be considered when drafting standards answering a Standardisation Request and to be offered for citation in the OJEU

This checklist was prepared following the format of Internal Regulations CEN/CENELEC Part 3 – Annex A “Checklist for writers and editors of document”. All CEN/CENELEC standards and deliverables shall follow the provisions of IR 3.

This checklist is applicable for all sectors, except construction.

This checklist shall be fulfilled before dispatch for:

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, a new optional assessment after Formal vote (PUB assessment).

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 out and submitted to CCMC with the draft candidate harmonized standards and their supporting documents/justifications where relevant. In CEN, the matrix of responsibilities shall be followed (see decision BT C081/2018).

It is strongly recommended to use of the checklist for the drafting of harmonized standards in support of EU Legislation under VA and FA (with ISO or IEC lead).

	Check the following questions – if you answer yes to all the questions, the draft is probably ready for submission to CCMC (and HAS Consultant assessment).	Check
General	<p>Is this draft standard listed in a Standardisation Request / covered by a Mandate? Is this reflected in Projex-online database? <i>NB: This information is normally already provided in the NWIP form.</i> <i>NB: If not, contact the TC secretariat. A possible way forward is to propose to the European Commission to add this work item in a (revised) Standardisation Request. This is not applicable if the standard is covered by an open Mandate (e.g. M/396 Machinery)</i></p>	<input type="checkbox"/> <input type="checkbox"/>
	<p>If the HAS assessment was performed (i.e. optional assessment at First Working Draft (FWD) stage or assessment at Enquiry stage), has the WG answered all comments from the HAS Consultant(s)? <i>NB: The last column of the HAS Assessment Report ('Observations of the secretariat') at previous stage shall be filled in with the information on how the comments have been addressed.</i></p>	<input type="checkbox"/>
	<p>If the text deals with requirements that are not linked to essential requirements of EU legislation, are these requirements in separate clauses, so that in Annex Z only the clauses covering essential requirements are identified?</p>	<input type="checkbox"/>
European foreword	<p>If the standard is a revision, are the significant changes with respect to the previous edition precisely defined? <i>NB: The list of the significant changes with respect to the previous edition is an important element of the useful information to the standard users. It should not be too vague.</i> <i>NB: When the list of significant technical changes is extensive, it may be included in an informative annex. A reference to that annex shall be included in the foreword, preferably after the generic sentence that refers to the superseded document.</i></p>	<input type="checkbox"/>
	<p>Does it include the following sentences “The standard has been prepared under a standardisation request given to CEN/CENELEC by the European Commission and the European Free Trade Association and support essential requirements of EU Directive / Regulation. For relationship with EU Directive / Regulation, see informative Annex Z, which is an integral part of this document.”? <i>NB: Annex ZA in CEN and Annex ZZ in CENELEC.</i></p>	<input type="checkbox"/>
Scope	<p>Is the scope concise and clear? Is it worded as a series of statements of fact? Are the title, <u>scope</u> and annex Z consistent regarding exclusion / content covered by the standard? <i>NB: The scope of the standard could be broader than the relationship between this standard and the requirements of the EU legislation.</i> <i>NB: The scope shall not include requirements, <u>permission</u> or recommendation (in line with IR 3).</i></p>	<input type="checkbox"/> <input type="checkbox"/>
Normative reference	<p>Are the standards listed in the Normative references Clause 2 normatively referenced within the text (i.e. are they cited in the text in such a way that some or all of their content constitutes requirements of the document, for instance with a “shall”). <i>NB: See IR 3 with the preferred verbal form to be used to express a requirement.</i></p>	<input type="checkbox"/>
	<p>Are the normative references dated in Clause 2 and in all clauses of the draft standard?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

- ▶ New Checklist developed, common to EC, ESOs and HAS consultants
- ▶ Common Checklist divided in 3 parts:
 - ▶ Part A: It includes criteria for ESOs only
 - ▶ Part B.3: It includes common criteria for EC/HAS and ESOs
 - ▶ Part C: Administrative requirements for the HAS consultants
- ▶ Under final stage of approval
- ▶ Will replace previous Checklist in the coming months
- ▶ Communication will follow

New ESOs-EC Common Checklist for hEN



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: <ul style="list-style-type: none"> ○ → Projex online database for CEN/CENELEC ○ → Work Programme for ETSI <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 <u>old-format</u> "open" Mandate (e.g. M/396 Machinery).</i></p>	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	☐
<p>1.1.2 The TC/WG has answered to all the comments from the previous stage assessment of the HAS consultant(s).</p> <p><i>NOTE: The last column of the HAS Assessment Report ('Observations of the secretariat' at previous stage shall be filled in with the information on how the comments have been addressed.</i></p> <p><i>NOTE: The last column of the HAS Assessment Report ('Observations' for ETSI) at previous stage shall be filled in with the information on how the comments have been addressed.</i></p>	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	☐

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 (e.g. they shall not contain 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	☐	☐	☐
1.2.3 The Scope covers products, services or aspects concerned, at least in part, by the relevant legal requirements of EU legislation and the relevant standardisation request.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	☐	☐	☐
1.2.4 The Scope does not set requirements.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	☐	☐	☐

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.

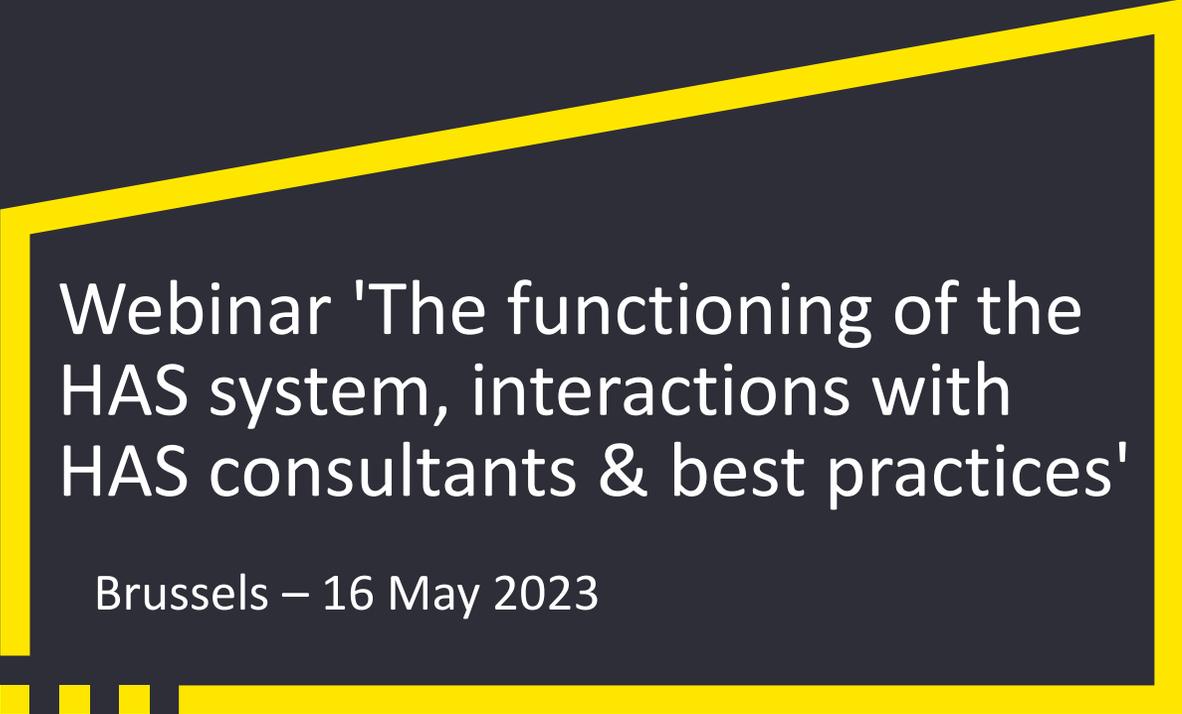
Assessment report received

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

Webinar 'The functioning of the HAS system, interactions with HAS consultants and best practices'



Webinar 'The functioning of the
HAS system, interactions with
HAS consultants & best practices'

Brussels – 16 May 2023



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



Building a better
working world

Agenda

1. Introduction
2. Progress in assessment work under the new contract
3. Best practices for TCs under the HAS system
4. Acceptable use of Normative References in Harmonised Standards
 - Dated or undated Normative References?
 - References to European or International Standards
 - Where to place Normative References in the standards?
5. Q&A and Closing

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

- ▶ **Regulation (EU) 1025/2012** on European Standardisation – Provides frame to standardisation work
- ▶ **Article 10** - Standardisation requests to European standardisation organisations – The Commission may request European standardisation organisations (ESOs) to develop a European standard or a European standardisation deliverable
- ▶ **(Art. 10.5 of Regulation (EU) No 1025/2012)**

“[...] The Commission together with the European standardisation organisations shall assess the compliance of the documents drafted by the European standardisation organisations with its initial request.”

The HAS project

is a service to:

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

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

Main features:

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



Update on the progress in the
assessment work

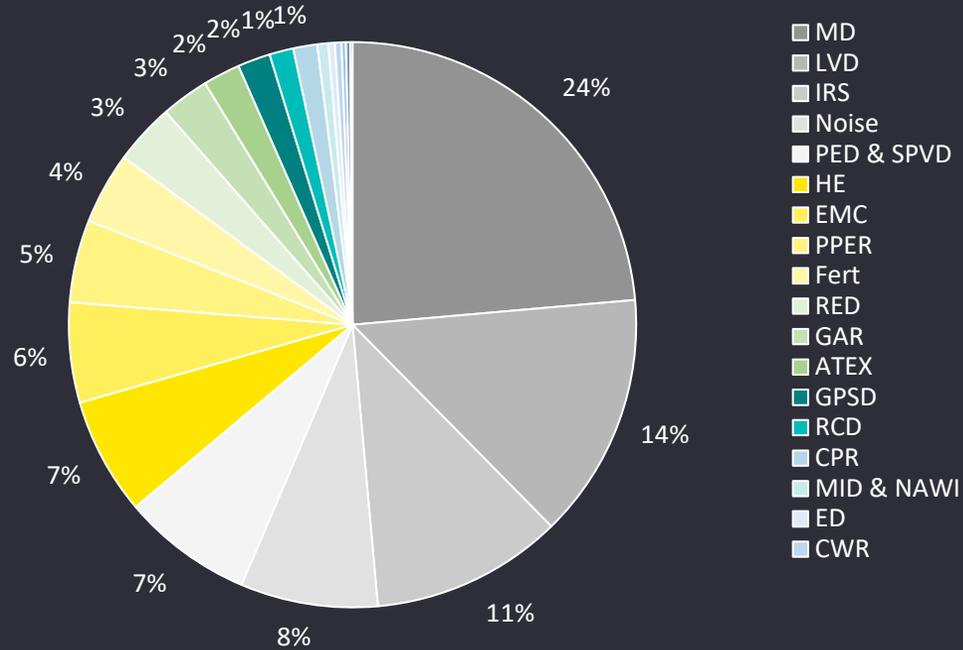


The better the question. The better the answer.
The better the world works.

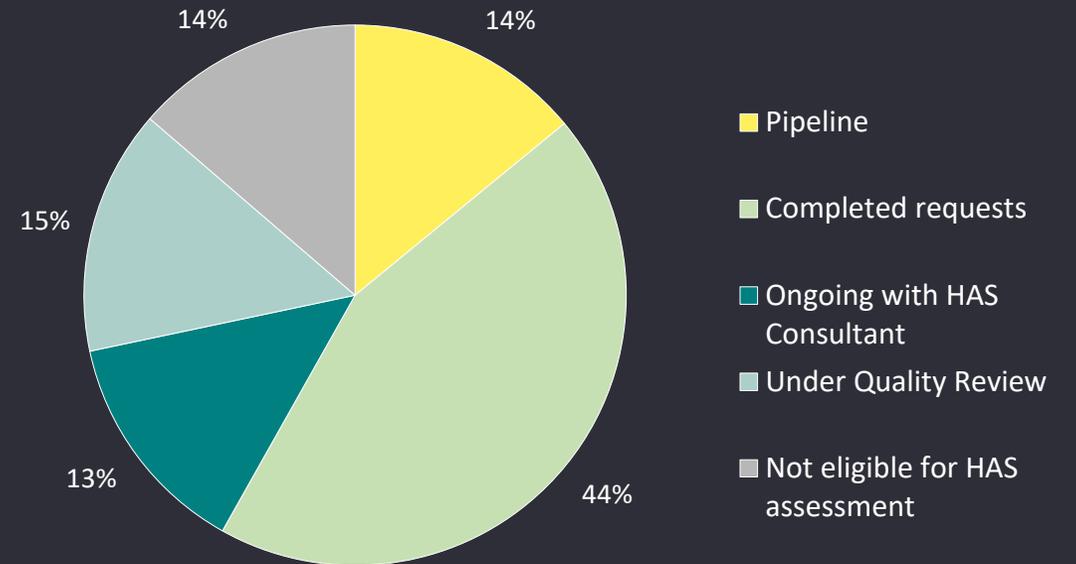


Structure of requests received from the ESOs since August 2022

Requests from ESOs per sector since August 2022

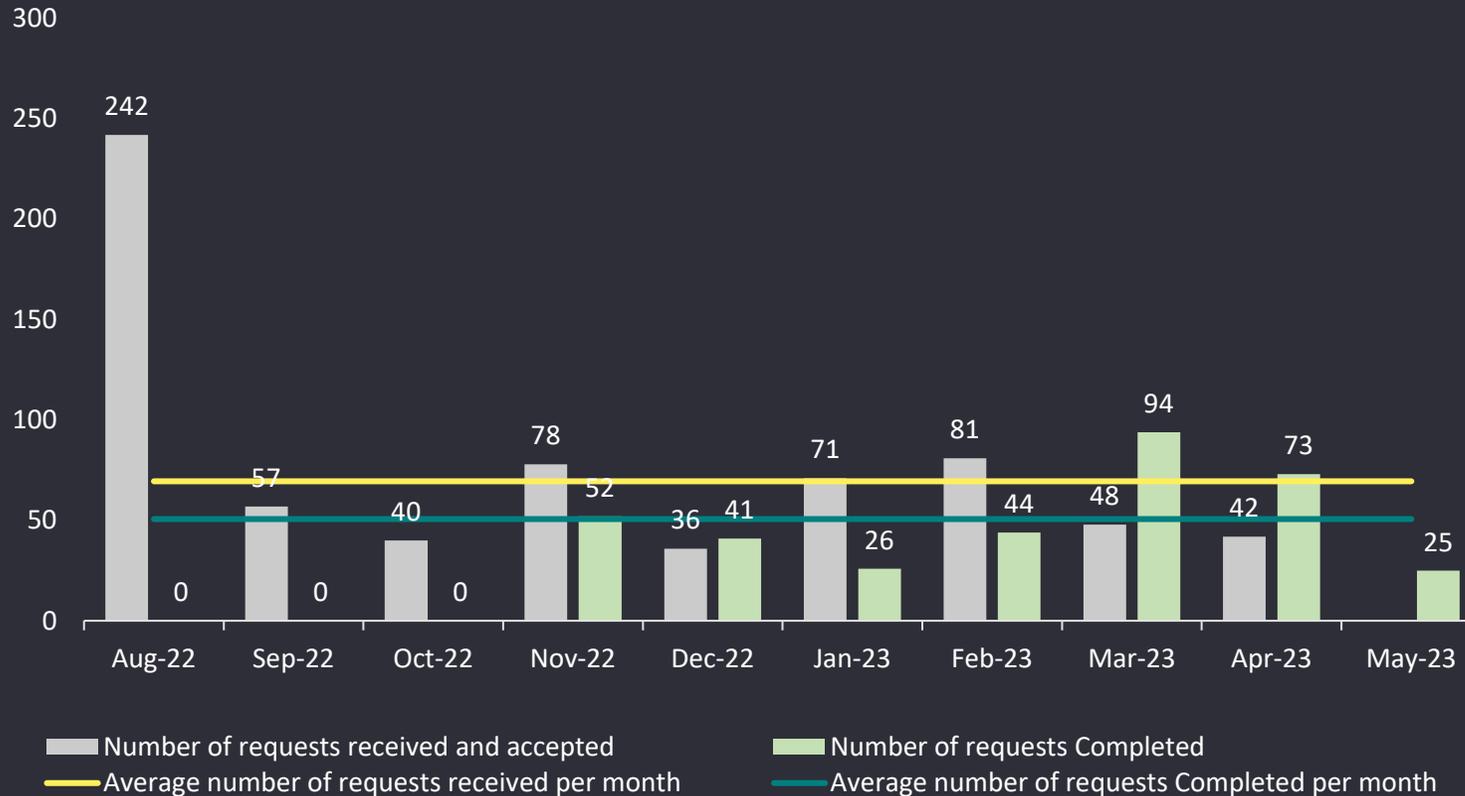


Status of Requests from ESOs (05.05.2023)



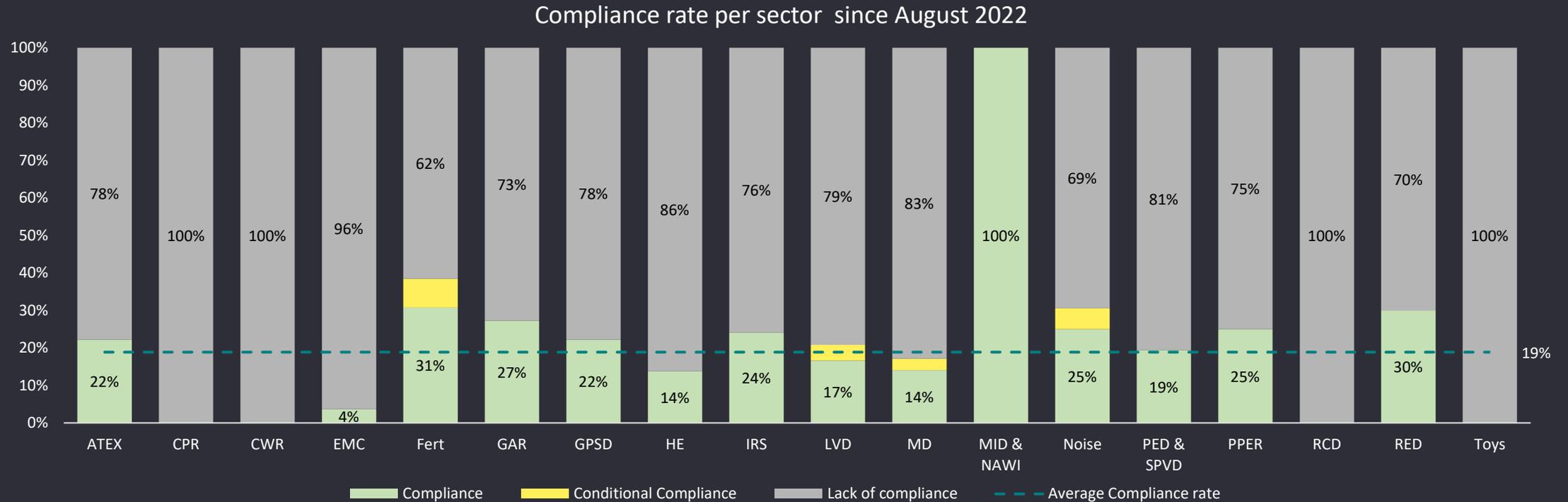
Number of requests received vs. Number of reports provided to ESOs per month since August 2022

Number of requests received and accepted vs. Number of completed reports sent to ESOs per month since August 2022 (until 05.05.2023)

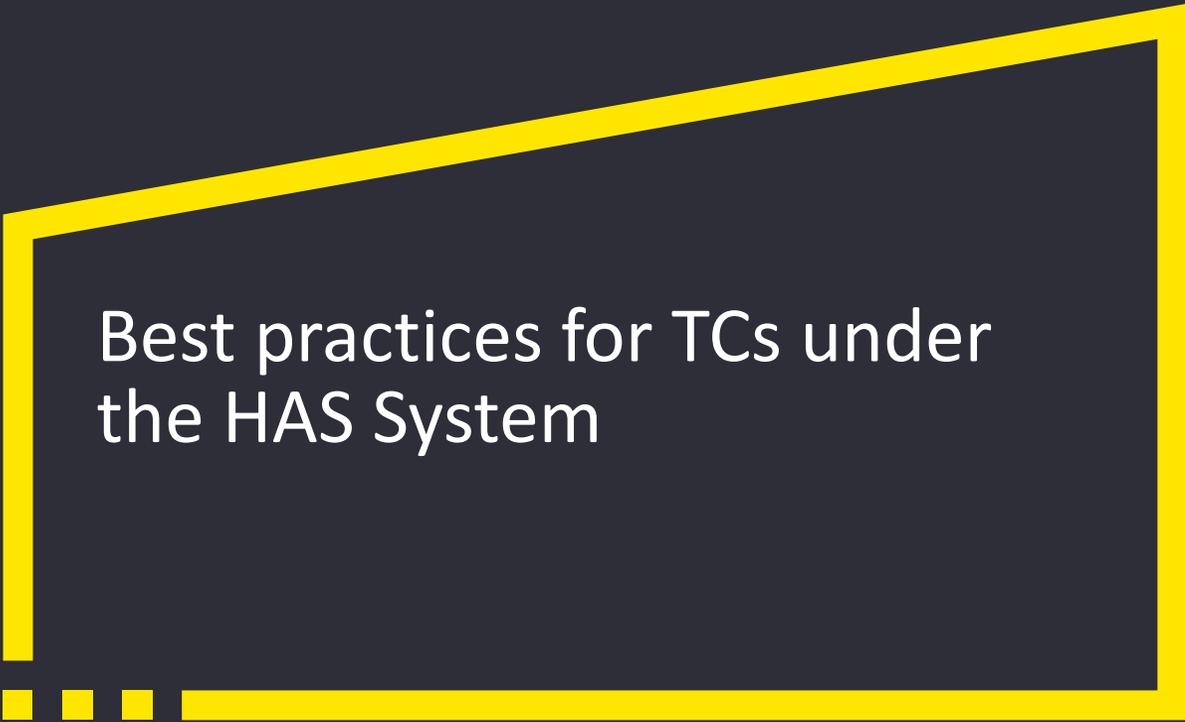


- ▶ Very high number of requests received in the first 6 months of the HAS project
- ▶ Increase in the number of requests completed as of Q1 2023
- ▶ Higher number of requests completed in Q1 and Q2 2023 than number of requests received

Outcome of assessment reports per sector since August 2022



- 19% average compliance rate across all sectors of the HAS project
- Many reasons leading to non compliance and non citation in the OJEU

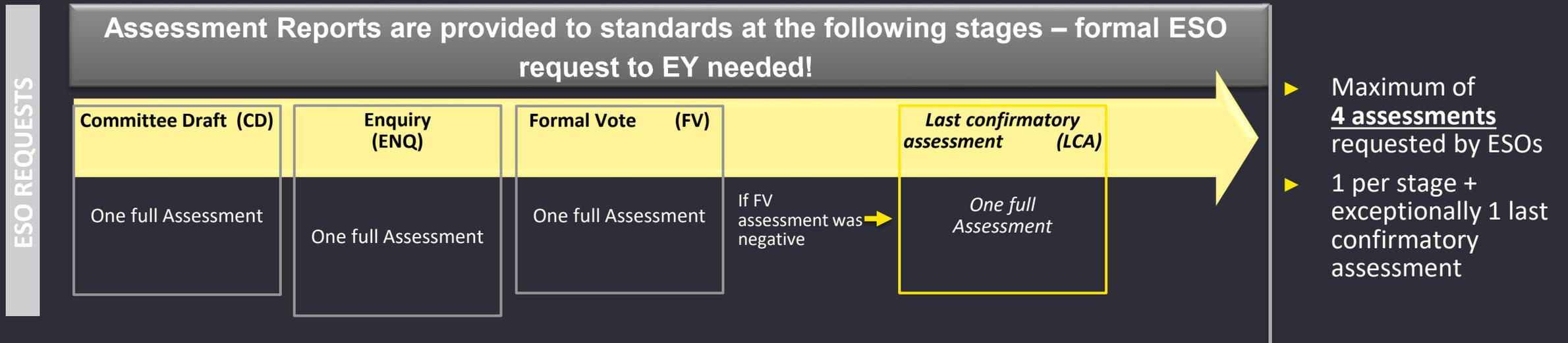


Best practices for TCs under the HAS System



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

When to request and assessment and what to expect?



Recap on the role of HAS Consultants:

- ▶ Perform verification and assessment tasks
- ▶ Work in support of but do not represent the Commission
- ▶ Convey the Commission's positions to the ESOs or their technical bodies
- ▶ **Do not contribute to the standards development process**

The EC considers but is not bound by the results of the assessments performed by the HAS consultants

Technical verifications of candidate harmonised standards

1. Ascertain whether the standard qualifies as a harmonised standard as foreseen in Regulation 1025/2012
2. Verify which legal requirements the standard is intended to cover
3. Assess whether the standard sufficiently satisfies those requirements
4. Check whether the scope of the standard goes beyond the scope of the relevant standardisation request and legal requirements aimed to be supported
5. Establish that the 'non-harmonised content', which goes beyond the scope of relevant legal requirements, is not incorrectly or inappropriately associated with any legal requirements

Technical verifications of candidate harmonised standards – Recap on EC Procedure before deciding to publish references of a harmonised standard in the OJ

Step 1: Verification of procedural formalities:

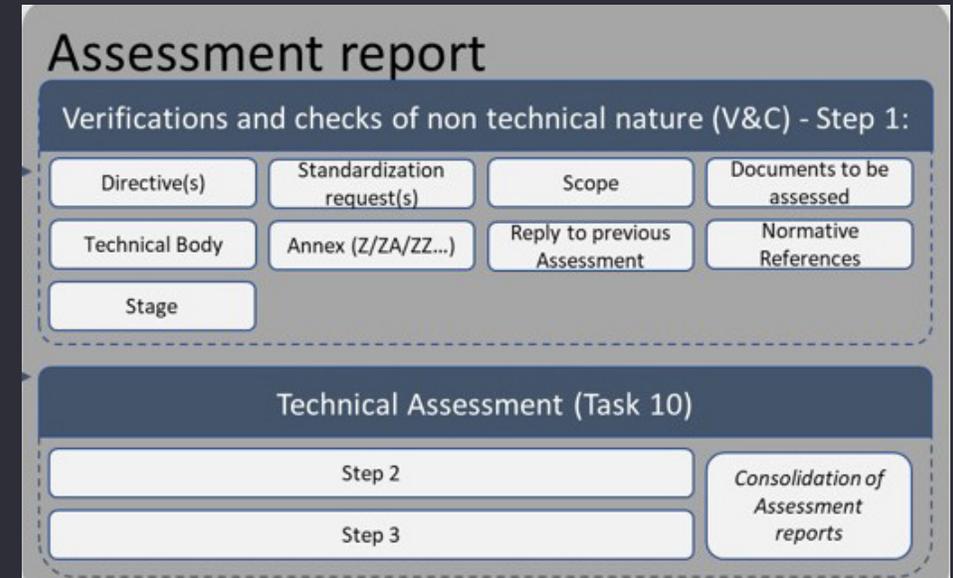
- ✓ standardisation request and Union harmonisation legislation
- ✓ Absence of a formal objection
- ✓ Annex Z or equivalent informative element is available
- ✓ Normative references are made available

Step 2: verification as regards the legal requirements aimed to be covered on the basis of the standardisation request:

- ✓ Clarity and transparency of normative parts of the standard aiming to support legal requirements
- ✓ The standard does not contain normative elements outside the scope of the relevant request(s)

Step 3: assessment as regards the legal requirements aimed to be covered :

- ✓ To assess whether a standard sufficiently satisfies the relevant legal requirements aimed to be covered
- ✓ non-harmonised content' is drafted in an acceptable way and not incorrectly associated with any supported legal requirements



OJEU_CITATION_EC_CHECKLIST.pdf

Best practices for TCs when requesting a HAS assessment

TCs should ensure the following elements are included before submitting a request for assessment by HAS Consultant(s):

- ▶ All European elements must be present in the documents submitted for HAS assessment
- ▶ TCs are encouraged to request a first assessment as early as possible to increase compliance rate of standards submitted to the EC for citation
- ▶ Ensure complete Annex(es) Z are provided (for all applicable directives)
- ▶ Most recent version of the standard is provided for assessment
- ▶ When possible, providing a track changes version of the standards will facilitate the work of HAS consultants after a previous assessment
- ▶ Response from TC to the comments of the HAS consultant (Template for comments)

TCs are encouraged to perform a self-verification of these elements when drafting standards and before submitting a request for a formal assessment

Best practices for TCs when requesting meetings with HAS consultants

- Meeting requests should be submitted about 4 weeks prior to the meeting date
- A full agenda of meeting should be provided to allow the HAS consultants to prepare accordingly
- Only meetings linked to a previous assessment are allowed under the HAS project
- Link to meeting tool: [Online Survey Software | Qualtrics Survey Solutions](#)

Reminder on the role of HAS consultants during meetings with TCs

What a HAS Consultant can do

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

What a HAS Consultant cannot do

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



Rules for Normative References



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

Normative references remain an important cause of Non Compliance

- ▶ **Normative references** (NRs) relating to clauses that support the legislation's essential requirements

Must comply with certain rules...

The standards listed in the Normative References Clause 2 are normatively referenced within the text, i.e. they are cited in the text in such a way that some or all of their content constitutes requirements of the document, for instance with a “shall”.

Certain and clear references

Acceptable
references
to
standards

- Dated
- To European or International standards
- In relevant Sections and Subsections of the Harmonised Standards

Ensure **legal certainty** and **clarity** for the users of the standards

Dated or undated normative references?

► Clauses or Subclauses referred to in the Annex Z (having legal effect)

Homegrown European standards

Dated in the specific clauses/subclauses of the text of the draft **and** dated in 'Normative References'

Undated in the specific clauses/subclauses of the text of the draft **but dated** in 'Normative References'

European standards adopting ISO standards

The ISO text is undated but the European part contains an Annex **referring to dated versions**

European standards adopting IEC standards

The IEC text is undated but the European part contains an Annex ZA **referring to dated versions**

'Zero tolerance' for undated Normative References related to clauses that support essential requirements

Accepted undated references must be agreed upon with the relevant EC desk Officer

NRs must be dated and published

- ▶ Dated references
 - ▶ Clauses or Subclauses referred to in the Annex Z
- ▶ Published standards
 - ▶ Published: Legal certainty and clarity on which version applies
- ▶ **No reference to draft standards**
 - ▶ No continuous availability in time
 - ▶ Difficulty to keep track of changes
 - ▶ **If blocks of draft standards developed in parallel: conditional compliance MAY apply**

Unaccepted examples of normative references include*:

- a reference to a standard removed from OJ due to formal objection
- reference(s) to non-publicly available documents (e.g. draft standards)
- reference(s) to standards containing no clearly defined specifications allowing to satisfy the requirements of the referencing hEN
- non-specific normative references to 'series of standards'
- reference(s) to legal acts
- references which create contradictory normative reference chains (e.g. implying that different versions of the same standards should be applied in parallel)

(*EC presentation on Normative References–HAS project -16.06.2020)

Possible undated references not leading to a Lack of Compliance

Limited number of cases could be acceptable (**subject to EC acceptance**)

- ▶ Standardised consumables or sizes that do not change over time
- ▶ Terminology standards / databases
- ▶ Graphical symbol standards / databases
- ▶ Plugs and socket outlets dimensions (catalogue standards - if not standardised in Europe, such as in the case of Europlug)
- ▶ Electrical installation standards if not in sections supporting Annex Z
- ▶ Undated references in clauses not supporting legal requirements

Allowed and nonallowed normative references

Allowed references:

- ▶ **European Standards:** EN, EN ISO, EN IEC
- ▶ **International Standards:** ISO, IEC, ISO/IEC, ITU R
- ▶ **Some international benchmarks:**
 - ▶ IMO or ICAO
 - ▶ CIE
 - ▶ UIC Specs
 - ▶ ETSI Partnerships (such as 3GPP, OneM2M, ...)
 - ▶ Some well known consortiums applying FRAND principles (Bluetooth, USB C,...)

Allowed and nonallowed normative references

▶ Not allowed :

Reference to National adoptions of ENs (BS EN, DIN EN)

Reference to National standards from NSBs (NF, UNI, UNE...)

References to other national standards (ANSI, Canadian, AU/NZ standards,...) or

to other US SDOs (ASTM, UL, ASME, SAE, ASHRAE, IEEE,...)

Examples of acceptable references

▶ EN, EN ISO, EN IEC:

- EN XXXX:202X
- EN ISO YYYY:202X
- EN 6XXX:202X
- EN 55XXX:202X
- EN IEC ZZZZ:202X

- EN/ASTM XXXX:202X
- EN ISO/ASTM YYYY:202X
- EN IEC/IEEE UUUU:202U

References to **draft** European or **draft** international standards

- ▶ Not accepted in general
- ▶ See criteria on “Conditional Compliance”
- ▶ **Need to ensure availability and traceability in time (future)**
 - Some drafts ISO/DIS or ISO/FDIS are publicly available and can be purchased today but maybe not tomorrow
 - New versions of the draft will be made available instead of the version that is being referred to in the draft under assessment
 - Once the new version of the standard is approved as a published ISO standard, this published version will replace the draft versions
 - Old draft versions will no longer be available, not even for purchase

Where to date Normative References?

NRs should be dated in:

- ▶ Section normative references (or European annex if ISO or IEC)
- ▶ Clauses or Subclauses referred to in Annex Z

NOTE: Attention to “State of the Art”:

- The most recent standard (if compliant) should be used - No references to outdated standards (no longer state-of-the-art) or to superseded/withdrawn standards
- Unless there is an objective and justified reason for using an older version

References to Standards in Annex Z are NOT allowed

- ▶ Annex Z is NOT the place to include references to other standards
- ▶ In some cases, references to Part 1 of the same standard can be included
(if the Part 1 has exceptions to be applied in conjunction with the assessed standard)

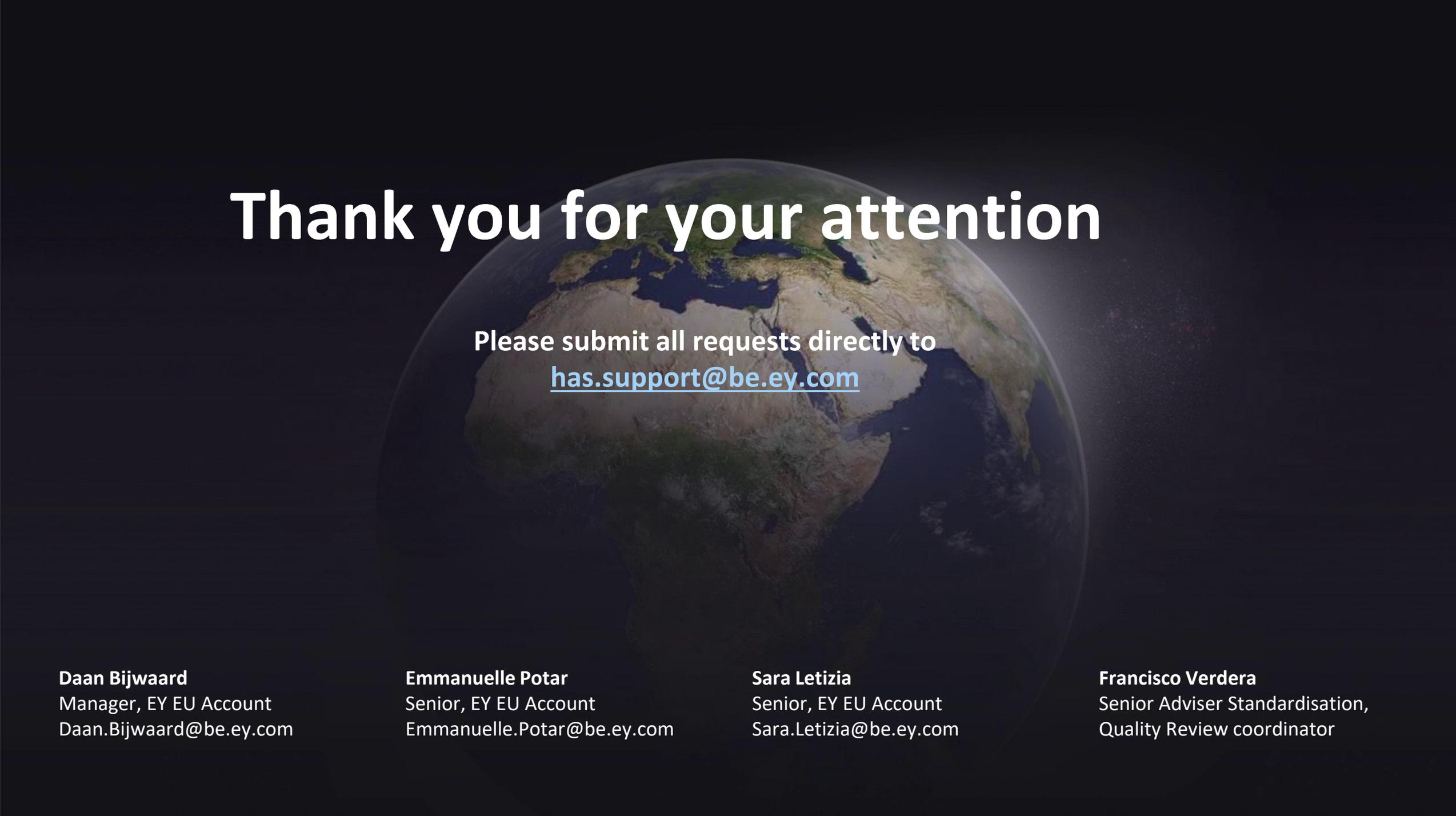
-> in these cases, confirmation with the EC Services is needed
[examples: Part 2-x of EN 60335 and Part 1]

Conclusion

Normative references (NRs) play an **essential role** in providing presumption of conformity

NRs shall:

- respect applicable drafting rules of the ESOs
- provide legal certainty and clarity for the user
- be dated and published
- be fully compliant in case they support essential requirements
- remain available over time for the user of the standard



Thank you for your attention

Please submit all requests directly to
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- ▶ Webinar drafting guidance: [CEN](#) – [CENELEC](#)
- ▶ Guidance document on normative references:
 - ▶ [CEN BOSS](#) – [CENELEC BOSS](#)
- ▶ [Webinar restart of the HAS system](#)

Your feedback





CENELEC

Thank you for your participation!

Next webinars

2023-05-26 – [Webinar 'Standardization Request for the Machinery Regulation, a smooth transition from the Directive to the Regulation'](#)

2023-06-08 – [Stakeholder Workshop 'Standards: Driving the future of CleanTech in Europe'](#)